Evaluation of the Post-WTO Sustainability of the Pharmaceutical Industry in Iran

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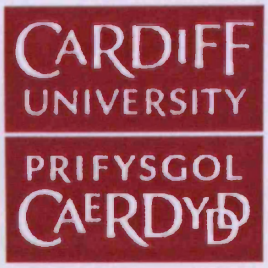

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Abstract

The outcome of joining the WTO and implementing TRIPS agreement has caused a never-ending dispute in terms of both positive and negative perspectives. Patient's access to essential medicines and sustainability of the domestic pharmaceutical industry are two important relevant topics in the developing countries. Two major consequences are trade liberalisation and enforcing an international intellectual property rights. The immediate impact will be free flow of medicines from the developed countries in the case of innovative drugs and more recently from India and China for cheap commodity medicines that are supported by the internationally enforceable intellectual property protections. The aim of the study was therefore to evaluate sustainability of the pharmaceutical industry in Iran post WTO agreement using the readiness index.

In the absence of previously developed instruments, two study tools were developed and validated in the course of this study namely WTO pharmaceutical Industry (PI) Impact Rating Scale and Pharmaceutical Industry Transition Instrument (PITI). Using the Delphi technique, an expert panel consisting of academics, industry senior managers and regulators identified 29 parameters that the study should focus on generating consensus for the industry in preparation of joining the WTO. The top 6 parameters included importation tariff, management knowledge, training, R&D, customer satisfaction and patent review.

The study was then carried out throughout the industry to evaluate the current situation and future importance of the identified parameters that were restructured in 66 statements of the PITI. The outcomes of the studies reported in this thesis suggest that with the current situation in the pharmaceutical industry in Iran, it is unlikely that the industry will be able to cope with the post-WTO challenges to deliver the growth needed to underpin its long term sustainability. The compliance of the industry with the requirements of the WTO at the current situation was concluded to be "unsatisfactory" for the majority of the PITI statements using binomial test ($p<0.05$). The future

importance of all of the 15 PITI categories e.g. patient review, licence technology, transfer agreement, sales and marketing, GMP & QA, R&D, product packaging, manufacturing technology, pricing policy, training, customer satisfaction and qualified personnel were considered to be significant ($p<0.05$). The results based on the gap analysis and measuring the Pharmaceutical Industry Readiness (PIR) index yielded an overall value of 57% with a range of 37 to 67% for the PITI categories and 30 to 70% for the 22 companies. The priorities attached to individual activities by participating companies were identified by calculating the gap rank of 1 for 'studying the financial impact of enforcing patent protection' which showed the poorest readiness index of 24%. This was followed by 'having dedicated personnel for reviewing intellectual property rights to prevent patient infringements', 'comparability of marketing expenditure to that of international rivals' and 'to have GMP approval of international inspectors' with PIR indices of 27%, 31% and 39% respectively.

The findings indicate that the pharmaceutical industry in Iran is not suitably equipped to meet the challenges of post WTO agreement, posing a threat to its sustainability. It is therefore hoped that the recommendations arising from this work are considered carefully by the individual pharmaceutical companies and the results synthesised in relation to their respective infrastructure in order to help them with their preparation for embracing the challenges of post WTO.

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List of Abbreviations

AD: Anno Domini, Years are designated as after the Christ's birth

AIDS: Acquired Immune Deficiency Syndrome

ANOVA: Analysis of Variance

BC: Before Christ

BMS: Bio-Medical Sciences

BS: Bachelor of Science

BSC: Balanced Scorecards

CAPI: Computer Assisted Personal Interviewing

CATI: Computer Assisted Telephone Interviewing

CE: Christian Era, Current Era

CMR International: Centre for Medicines Research International

DDA: Doha Development Agenda

DEA: Data Envelopment Analysis

EFQM: European Foundation for Quality Management

EU: European Union

EUR: Euro

FDA: Food and Drug Administration

FDI: Foreign Direct Investment

GATT: General Agreement on Trade and Tariff

GDP: Gross Domestic Production

GMP: Good Manufacturing Practice

HIV: Human Immune Deficiency Virus

ICC: Intra Class Correlation

IT: Information Technology

IMF: International Monetary Found

IMS: Infrastructure Managed Services

IP: Intellectual Property

ITO: International Trade Organisation

KRNW: knowledge Resource Nomination Worksheet

LDC(s): Least Developed Countries

MBA: Master of Business Administration

MD: Doctor of Medicine

MFN: Most Favoured Nation

MSc: Master of Science

NDDS: Novel Drug Delivery System

NGO: Non-Governmental Organisation

OECD: Organisation for Economic Co-operation and Development

OTC: Over the Counter

PCT: Patent Cooperation Treaty

PDAs: Personal Digital Assistants

PEPFAR: the President's Emergency Plan for AIDS Relief

PESTEL: Political, Economic, Social, Technological, Environmental and Legal

Pharm. D: Doctor of Pharmacy

PhRMA: Pharmaceutical Research and Manufacturers of America

pictf: Pharmaceutical Industry Competiveness Task Force

PIR Index: Pharmaceutical Industry Readiness Index

PITI: Pharmaceutical Industry Transition Instrument

QA: Quality Assurance

R&D: Research and development

SDB: Social Desirability Bias

SPSS: Statistical Package for the Social Sciences

SWOT: Strengths, Weaknesses, Opportunities and Threats

TNCs: Trans-National Corporations

TRIPS: Trade Related Aspects of Intellectual Property Rights

UK: United Kingdom

USA: United States of America

USD: United States Dollar

WHO: World Health Organisation

WIPO: World Intellectual Property Organisation

WTO, PI Impact Rating Scale: WTO Pharmaceutical Industry Impact Rating Scale

WTO: World Trade Organisation

Glossary of Terms

Biotechnology: is a field of applied biology that involves the use of living organisms and bioprocesses in engineering, technology, medicine and other fields requiring bio-products. Modern use includes genetic engineering as well as cell and tissue culture technologies.

Copyright: is a set of exclusive rights granted by the law of a jurisdiction to the author or creator of an original work, including the right to copy, distribute and adapt the work. Exceptions and limitations to these rights strive to balance the public interest in the wide distribution of the material produced and to encourage creativity.

Creativity: refers to the phenomenon whereby a person creates something new (a product, a solution, a work of art etc.) that has some kind of value. What counts as "new" may be in reference to the individual creator, or to the society or domain within which the novelty occurs. What counts as "valuable" is similarly defined in a variety of ways.

Foreign Direct Investment: refers to long term participation by country A in country B. It usually involves participation in management, joint-venture, transfer of technology and expertise.

Generic drug: is a drug which is produced and distributed without patent protection. The generic drug may still have a patent on the formulation but not on the active ingredient. A generic must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are considered (by the FDA) to be identical in dose, strength, route of administration, safety, efficacy, and intended use.

Good Manufacturing Practice (GMP): is part of a quality system covering the manufacture and testing of active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs are guidelines that outline the aspects of production and testing that can impact the quality of a product. Many countries have legislated that pharmaceutical and medical device companies must

follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation.

Health Technology Assessment: is the term used for the assessments made by government and insurance reimbursement agencies, hospital formulary committees and other bodies representing the payers for healthcare and medicines.

Hi-tech product: is technology that is at the cutting edge, the most advanced technology currently available. The adjective form is hyphenated: high-tech or high-technology (There is also an architectural style known as high tech.). There is no specific class of technology that is high tech — the definition shifts over time — so products hyped as high tech in the 1960s would now be considered, if not exactly low tech, then at least somewhat obsolete. This fuzzy definition has led to marketing departments describing nearly all new products as high tech.

Holding Company: is a company or firm that owns other companies' outstanding stock. It usually refers to a company which does not produce goods or services itself and its only purpose is that it owns shares of other companies. Holding companies allow the reduction of risk for the owners and can allow the ownership and control of a number of different companies. The degree of control the holding companies have over their companies depends on their parenting strategies.

Importation Tariff: a tariff on goods coming into a country from abroad, often used by governments as a way of reducing imports and protecting local industries.

Innovation: the process that renews something that exists, the introduction of something new.

Intellectual Property: is a term referring to a number of distinct types of creations of the mind for which property rights are recognised. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; discoveries and inventions; and words, phrases, symbols, and designs. Common types of intellectual property include copyrights, trademarks, patents, industrial design rights and trade secrets in some jurisdictions.

Joint Venture (JV): the JV parties agree to develop, for a finite time, a new entity and new assets by contributing equity. They both exercise control over the enterprise and consequently share revenues, expenses and assets.

Licence Agreement: granting the permission by the licensor to the other party (licensee) to use the brand name, technology or design of a product.

Mergers and Acquisitions: refers to the aspect of corporate strategy, corporate finance and management dealing with the buying, selling and combining of different companies that can aid, finance, or help a growing company in a given industry grow rapidly without having to create another business entity.

Nanotechnology: is the study of manipulating matter on an atomic and molecular scale. Generally, nanotechnology deals with structures between 1 and 100 nanometres and involves developing materials or devices within that size.

OTC products: pharmaceutical products that do not require a prescription.

Patent Protection: is a set of legislations to enforce the exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention.

Patent Review: to review that the international filing date of a registered patent is expired or valid and examine the details of registered process or product in order to prevent patent infringement.

Pharmaceutical Industry transition Instrument (PITI): a study instrument specifically developed for evaluating the pharmaceutical industry during the transition state towards the implementation of the WTO/TRIPS regulations. The instrument consists of 66 statements categorised in fifteen groups, namely "Research and Development", "GMP and QA", Sales and Marketing", etc.

PIR Index: an index to measure the readiness of the pharmaceutical industry to face the challenges of the post-WTO/TRIPS situation. The scores given by the respondents to the performance of the industry in the current situation will be divided by the future importance of that parameter to measure PIR Index.

Privatisation: is the process of divesting the government stake both in terms of money and control from public companies.

Productivity: is a measure of output from a production process, per unit of input.

Quality Assurance: planned and systematic activities implemented in a quality system that provide confidence that quality requirements are fulfilled.

Quality audit: involves the assessment of any designated process or plant to obtain objective evidence that the existing requirements have been met (for example, effective and efficient implementation of processes and resources). Quality audits can be internal or external.

Quality Control: is operational techniques and activities that are used to fulfil requirements for quality. It involves techniques that monitor a process and eliminate causes of unsatisfactory performance at all stages of the quality cycle.

Quality system: the organisational structure, responsibilities, procedures, processes and resources for implementing quality management

R&D Expenditure: the total expenditure on all research and development activities relating to ethical pharmaceuticals. This includes salaries and all other personnel-related costs, costs related to consumable materials and supplies, and an appropriate share of overheads to cover administration, depreciation, space charges, rent, etc. The cost of R&D conducted by means of grants or contracts to other companies or institutions, and proportional costs for joint ventures should be included.

Regulatory Authority: a regulatory authority (also regulatory agency, regulatory body or regulator) is a public authority or government agency responsible for exercising autonomous authority over some area of human activity in a regulatory or supervisory capacity.

Research and Development: creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

Sales: The income from sales of products. This includes finished products, bulk sales and royalties from licensed-out pharmaceuticals.

Strategic Alliance: is a formal relationship between two or more parties to pursue a set of agreed upon goals or to meet a critical business need while remaining independent organisations. Partners may provide the strategic alliance with resources such as products, distribution channels, manufacturing capability, project funding, capital equipment, knowledge, expertise, or intellectual property.

Sustainability: is the capacity to endure. It is meeting the requirements for present activities without compromising future obligations.

Technology Transfer: is the process of sharing skills, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities to ensure that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology into new products, processes, applications, materials or services.

Total Quality Management (TQM): this is a philosophy and style of management that gives all staff in an organisation responsibility for delivering quality to the customer. Total quality management views each task in the organisation as a process. The objective at each stage is to define and meet the customer's requirements in order to maximize the satisfaction of the final consumer at the lowest possible cost.

Trade Liberalisation: is a system of trade policy that allows traders to act and or transact without interference from government. According to the law of comparative advantage the policy permits trading partners mutual gains from trade of goods and services. Under a free trade policy, prices are a reflection of true supply and demand, and are the sole determinant of resource allocation

Validation System: the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment. It is a requirement for Good Manufacturing Practices and other regulatory requirements. Since a wide variety of procedures, processes, and activities need to be validated, the field of validation is divided into a number of subsections including: Cleaning Validation, Process Validation, Analytical Method Validation, and Computer System Validation. Similarly, the activity of qualifying systems and equipment is divided into a number of subsections including: Design qualification (DQ), Component qualification (CQ), Installation qualification (IQ), Operational qualification (OQ) and Performance qualification (PQ).

WTO, PI, Impact Rating Scale: the instrument developed to identify the influencing parameters in the post-WTO situation. The instrument includes 29 statements under three headings of "Structure", "Content", and "Context" sections.

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Chapter 1

General Introduction

Background

The global pharmaceutical market value was more than US$800bn in 2009 and has had a growth rate of 6.7% for the past five years. The market value is distributed with 40% in US, 30% in Europe, 12% in Asia, Africa and Australia, 11% in Japan and 5% in Latin America (IMS, 2010). From a company perspective, Pfizer with US$57bn was at the top of the list followed by Merck & Co. with US$38bn, Novartis; US$38bn, Sanofi-Aventis; US$ 36bn and GlaxoSmithKline; US$35bn. The top five global products were Lipitor (Atorvastatin from Pfizer), Plavix (Clopidogrel from Sanofi and BristolMyersSquibb), Nexium (Astrazeneca's Esomeprazole), Seretide (Fluticazone plus Salmetrol from GlaxoSmithKline) and Seroquel (Quetiamine from AstraZeneca) (IMS, 2009). The data indicate the best sellers are original brands as a result of intensive R&D investment by multinational companies.

The Pharmaceutical Industry in Iran

History

Iran (formerly *Persia*) is located in southwest Asia with a territory of 1,648,195 square kilometres and a population of more than 70 million people. This country, also, played an important role in the history of medicine and pharmacy in the world. A history of pharmacy in Iran goes back several centuries. R Campbell Thomson examined hundreds of clay tablets obtained from the library of *King Assurbanipal* and found valuable materia medica. He identified 250 vegetable drugs, 120 mineral drugs, alcoholic beverages, and parts of animals being used as drugs (Kremers and Sonnedecker, 1976). From the oldest documents of medicine and pharmacy of ancient Persia, the holy book of *Avesta* should be mentioned. The term "drug" is probably derived from the Avestan ancient term "*darav*" meaning the stem of a plant as the origin of medicinal herbs, (*Dar* in Current Farsi language stands for tree). This word later changed into "darug" in the median Farsi language, and then changed to "droga" in Latin, "*drogue*" in French" *drug*" in English and "*daru*" in Farsi language (Farsam, 2009). The *Jundishapur* academic centre was established during *Sassanid Dynasty in* 530 AD (Figure 1.1).

Figure1.1 The Persian Empire about 500 B.C. (thejournal.org, 2010)

This scientific centre, due to its cosmopolitan characteristics, can be considered as one of the earliest universities (IPM, 2003; Söylemez, 2005; University of Tehran, 2010). One of the famous pharmacists in this school was *Shapur Sahl who* composed his *Aqrabadin Kabir* (great formulary) in 869 CE, which became the first formulary that was used in hospitals and pharmacies (Farsam, 2009). According to Edward Brown; the most convincing evidence for ancient Iranian interest in pharmacy is the Iranian origin of many drug names in medieval medicine (Brown, 1921).

A group of medico-pharmaceutical scientists came into practice with considerable medical and pharmaceutical knowledge to commence a brilliant period of scientific knowledge, which later distributed into Europe. *Ali ibn Sahl Rabban Tabari (839 A.D), Mohammad ibn Zakariya Razi (Rhazes in Latin) (864-930 CE)* also, well known as 'The Galen of East', *Abu Mansur Muwaffaq Heravi and Abu Ali Al-Husain ibn Abdullah ibn Sina (Avicenna in Latin) (980-1037 CE)* was also called "The prince of physicians" by the Europeans are some of the most reputable ones (Al-Ghazal et al, 2007; Farsam, 200; Iran Chamber Society, 2010 and Ghomi, 2010).

The Modern Pharmaceutical Industry

The approval of the 1920 Medicine Law and foundation of the school of pharmacy in Tehran University in 1934 as well as the establishment of the first pharmaceutical

factory in 1955 are the first steps towards a modern pharmaceutical industry in Iran (Lotfi, 2000). In 1979, a number of domestic and foreign companies were operating in a market with a $300 million annual cash flow. There were nearly 4,000 kinds of pharmaceutical products available in Iran; 70% of which was provided by imports (Siamak Nejad, 1989). The foundation of Generic Scheme in 1981 can be considered as a new era which is characterised by using the generic name of the medicines (Vaziri, 1991 and Foroughi, 1994).

Centralised policymaking was deployed to face the challenges resulted from the Iran-Iraq war (1980 – 1988) mainly by categorising pharmaceuticals as basic and strategic commodities and accordingly, supporting the local production of inexpensive medicines available to the entire nation (Azarnoosh, 1991). The Ministry of Health was put in charge of the nomenclature framework, pricing policies and also profit margins on producers, importers, distributors, and pharmacies. As a result of these tough controls, the average drug price index increased by only 118.2% at the fixed prices of 1982, while the other goods reached a 706% growth in their price index during the same period (Basmanji, 1995).

Later on, in 1992 the government's inexpensive foreign exchange allocations to the sector was removed and in 1994, the entire sector had to import all the finished pharmaceuticals as well as ingredients and equipment necessary for local production at the floating foreign exchange (Dinarvand, 1996). To prevent the negative consequences resulting from this decision on people's purchasing power, the government allocated a direct subsidy to producers and importers (Montaseri, 1997). Due to the large investments by public sector during the 1980s, many new companies were operating in the sector in 1999 (Vasefi, 1997).

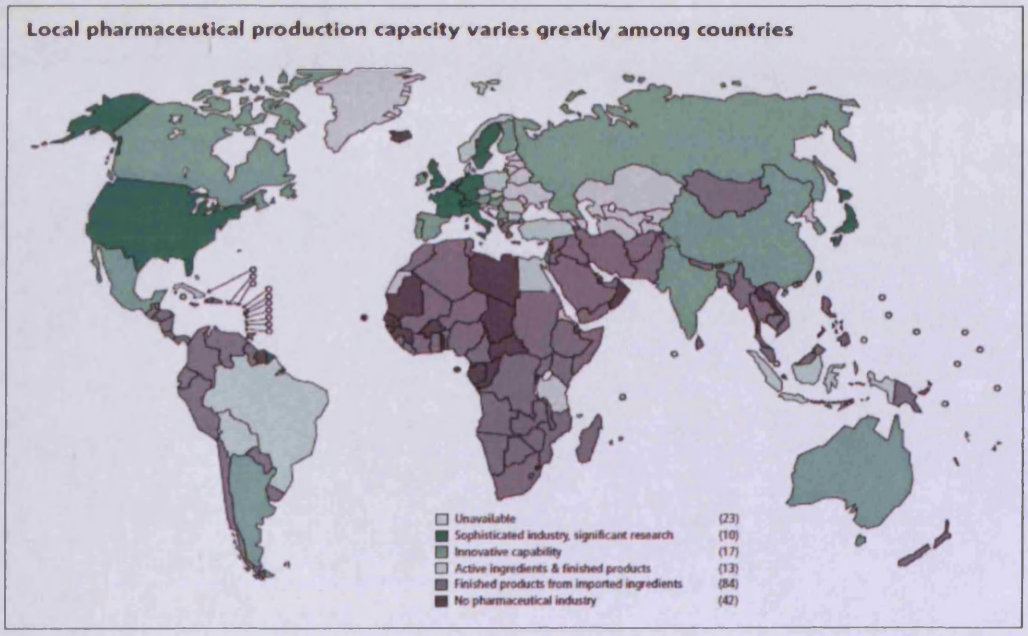
During the Second Plan, per capita expenditure on pharmaceutical products increased from US$12 to US$25 showing an annual growth of 14%. Local companies produced 85% of the country's pharmaceutical needs in terms of value and 97% in terms of quantity. However, 43% of the total foreign exchange spent on the pharmaceutical products was used for importation of the finished drugs (Ministry of Health and Medical Education, 1998).

Due to the fact that the government is the owner of a major part of healthcare facilities and therefore is the main purchaser of medicines, the government is a direct beneficiary of keeping pharmaceutical prices low (Zomorrodian, 1989). Due to the low price policy, local companies procure materials and equipment from the cheapest sources. They were also unable to invest in upgrading their production facilities or developing innovative products. This was also the main reason for medicine smuggling from Iran into the neighbouring countries and over-consumption of medicines in the country itself. The Third Plan defined two different categories for medicines: Essential Drugs (very vital and necessary drugs) and Nonessential Drugs. For the second category, the producers could provide higher quality goods, since they can price their products free from the governmental pricing policies and also under their own trade labels (Planning and Budget Organisation, 2000 and Basmenji, 2004). There are several important socio-economic advantages in Iran's pharmaceutical industry: good industrial infrastructure, an inexpensive and highly educated workforce, a large and growing domestic market and access to other regional markets.

Iran Pharmaceutical Market

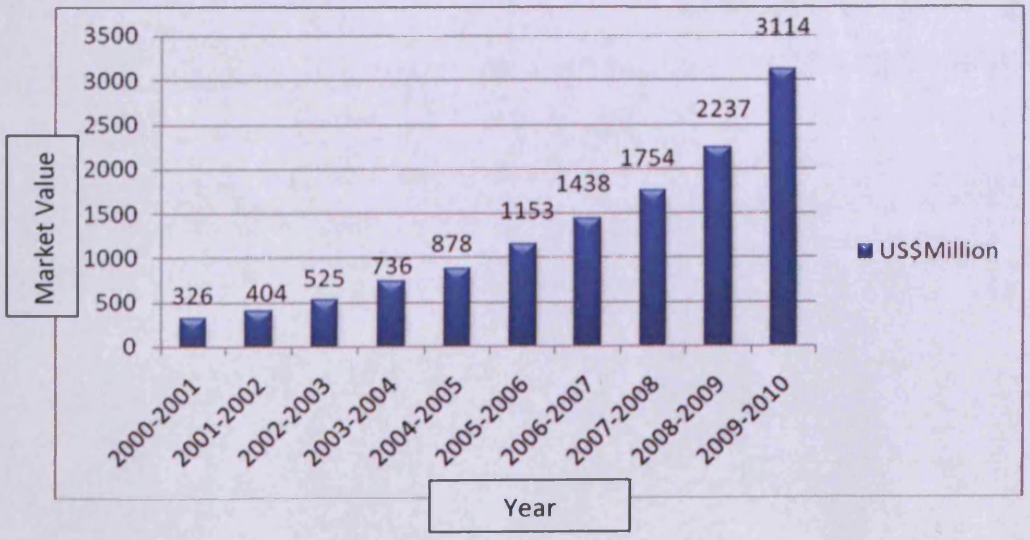
Countries are classified by WHO into five levels according to the evaluation of their pharmaceutical production: 1, sophisticated pharmaceutical industry and research base; 2, innovative capabilities; 3, reproductive capabilities—active ingredients and finished products; 4, reproductive capabilities—finished products from imported ingredients only; 5, no pharmaceutical industry (Semin and Güldal, 2008). Iran is categorised as a level 4 country indicating the capacities for production of the finished products with the imported material (Figure 1.2) (WHO, 2004). However in the recent years many plants are producing Pharmaceutical raw materials for local and international market.

Figure 1.2 The situation of the countries from the view of their pharmaceutical industry



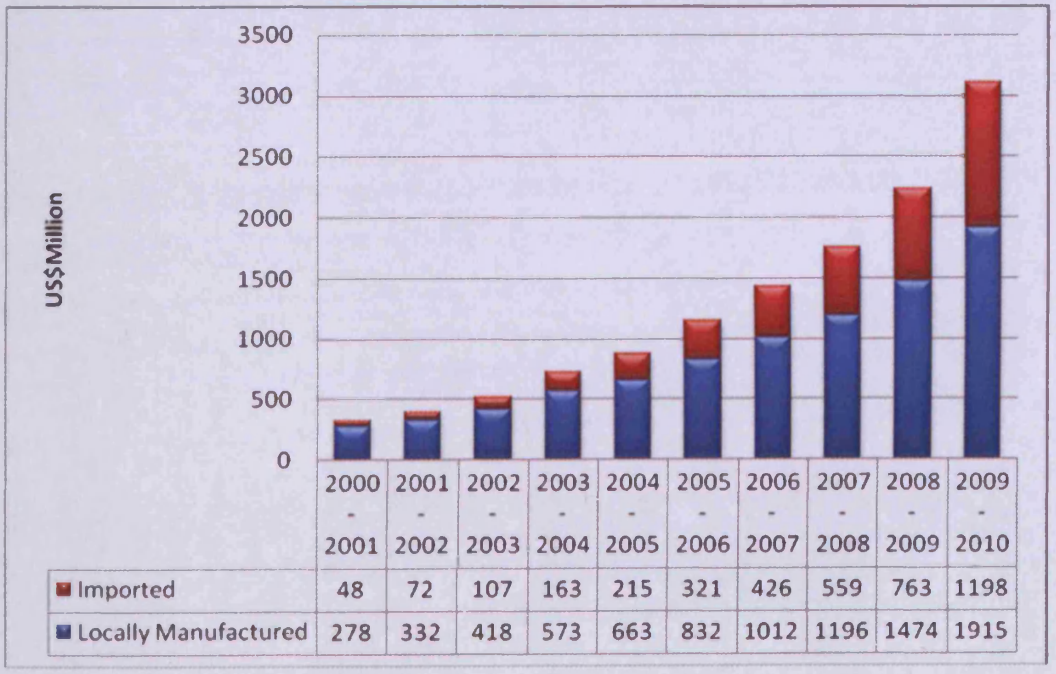
The value of the Iranian pharmaceutical market in 2009-2010 (the Iranian year begins in March 22nd) was US$3.1bn showing 24% growth comparing with the previous year (Drug and Narcotics Monitoring Directorete, 2009). The market growth rate has been more than 20% in the past 10 years (Figure 1.3).

Figure 1.3 The Pharmaceutical Market value in Iran



In terms of other comparable markets, although Iran scores well for its opportunities such as large and growing population and plans developed to improve healthcare services. It is believed that low intellectual property (IP) protection and other regulatory criteria are major weaknesses especially in the pharmaceutical environment. Iran has a highly educated workforce in the field of industry and science and its pharmaceutical manufacturing capabilities are in place to meet the bulk of local demand. The local pharmaceutical industry is expected to boost domestic pharmaceutical spending through increased diversification and new products, including biological drugs. The plan to export products to international markets is limited to less-regulated regional markets (business Monitor International, 2010). The needs of the improving healthcare system cannot be met by relying merely on the local production and a considerable part is imported. The data published by the Drugs and Narcotics Monitoring Directorate (2009) shows that the ratio of the imported medicines has been increased from 15% in 2000 to 38% in 2009 (Figure 1.4). The imported products are mainly expensive new medicines for treating multiple sclerosis, cancers and severe infections but there are also a few less sensitive products such as supplements and multivitamins.

Figure 1.4 Imported and locally manufactured pharmaceuticals in Iran



	2000 - 2001	2001 - 2002	2002 - 2003	2003 - 2004	2004 - 2005	2005 - 2006	2006 - 2007	2007 - 2008	2008 - 2009	2009 - 2010
Imported	48	72	107	163	215	321	426	559	763	1198
Locally Manufactured	278	332	418	573	663	832	1012	1196	1474	1915

The list of the top imported drugs according to the data published by the Drugs and Narcotics Monitoring Directorate (2009) is presented in the Table 1.1.

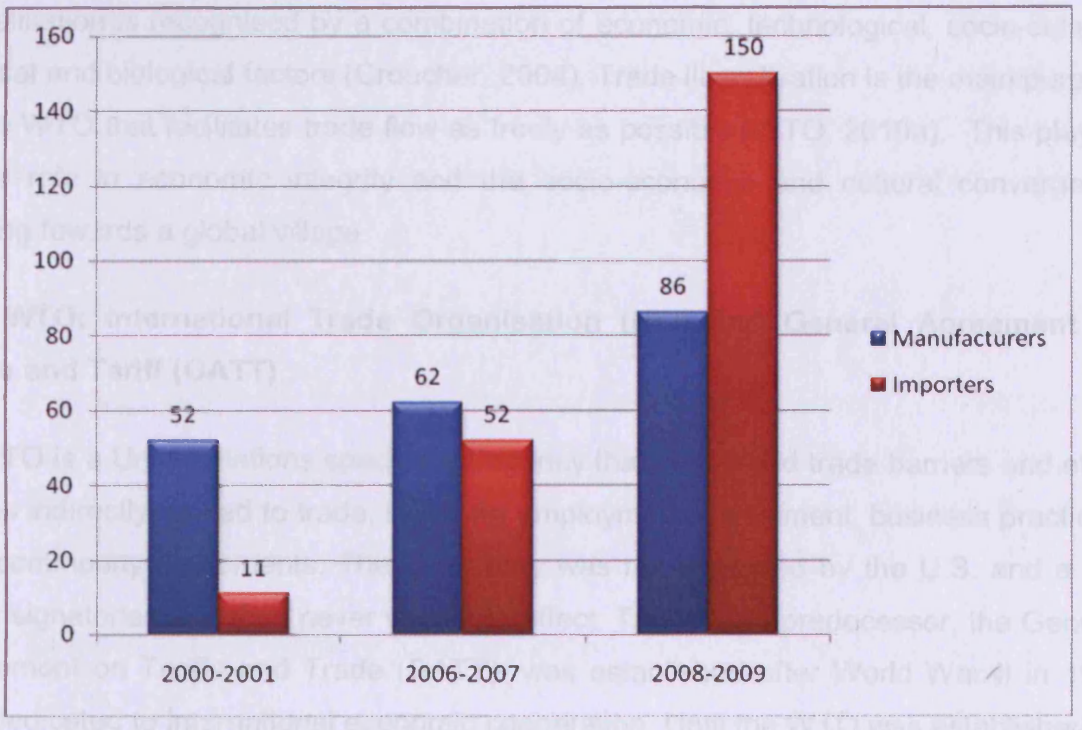
Table 1.1 The characteristics of the top imported drugs in 2009

Generic Name	Brand Name(s)	Number of Units	Sales value Million (USD)
1. ALBUMIN (HUMAN) 20% 50ML VIAL	Different brands	833,581	43.50
2. INTERFERON B 1B 8MIU VIAL	Betaferon, Extavia	596,917	32.83
3. CLOPIDOGREL 75MG TAB	Plavix	11,606,088	28.21
4. DOCETAXEL 80MG VIAL	Taxotere, Docetax	30,468	26.25
5. IMIPENEM+CILASTATIN(500+500)MG VIAL	Tienem,	791,893	21.70
6. RITUXIMAB 500MG/50ML VIAL	Mabthera	9,322	19.80
7. SALMETEROL+FLUTICASON 25/250MIC EVOHALER	Seretide	368,726	18.02
8. IMMUNE GLOBULIN 5G INJECTION POWDER (IV) VIAL	Different brands	41,094	17.57
9. GLUCOSAMINE+CHONDROITIN+MSM	Tripleflex	30,931,550	17.29
10. TRIPTORELIN 3.75MG VIAL	Decapeptyl, Dipherline	167,285	17.09
11. TRASTUZUMAB 440MG VIAL		5,501	16.93
12. INTERFERON B 1A 44MCG/0.5ML AMP	Avonex, Rebif	285,286	15.69
13. PANTOPRAZOLE 40MG FOR INFUSION	Pantozol	972,120	15.01
14. MENOTROPINS 75 IU FSH+75IU LH AMP	Menopur, Menogon, IVF	1,057,298	14.98
15. VACCINE-INFLUENZA VIRUS KILLED SYRINGE	Influvac, Inflexal V, Vaxigrip,	465,010	13.98
16. ISOTRETINOIN 20MG CAP	Roacutan, Decutan, Oratane	13,738,022	13.28
17. GEMCITABINE HCl 1 G VIAL	Gemzar	56,606	11.74
18. OXALIPLATINE 100MG VIAL	Eloxatin	25,322	11.51
19. SOMATROPIN 4U AMP	Nordilet	689,154	10.99
20. MULTIVITAMINE CAP	Geriatric Pharmaton	27,282,520	10.44

These data reveal that the ratio of the imported medicines is steadily increasing in the recent years. It can be also concluded that the majority of the imported products are high value innovative brands that have not been produced by the local companies.

The number of companies involved in the pharmaceutical market is another criterion to illustrate the pharmaceutical environment in Iran. The number of the companies is increasing for both importers and manufacturers; manufacturing companies increased from 52 to 86 companies between 2000 and 2009 while importer companies increased ever faster from 11 to 150 over the same period (Figure 1.5).

Figure1.5 The number of the companies involving in the pharmaceutical market in Iran (2000-2009)



An increasing number of importer companies show that there is a significant unmet need in the Iran pharmaceutical market and this gap is increasingly filled by importation. The local industry also has the opportunity to invest on developing new products or produce the original brands under the licence of the patent holders. In 2009, the first,

second and third local manufacturing companies had a total sales of 130, 100 and 96 million US dollars which was comparable with the largest importer companies (Drug and Narcotics Monitoring Directorete, 2009).

The World Trade Organisation, WTO

The era of globalisation is characterised by the process by which regional economies, societies, and cultures have become integrated through a global network of communication, transportation and trade. This phenomenon is closely associated with economic globalisation which explains the integration of national economies into the international economy through trade, foreign direct investment, capital flow, migration, the spread of technology and military presence (Bhagwati, 2004). However, globalisation is recognised by a combination of economic, technological, socio-cultural, political and biological factors (Croucher, 2004). Trade liberalisation is the main purpose of the WTO that facilitates trade flow as freely as possible (WTO, 2010a). This plays a major role in economic integrity and the socio-economic and cultural convergence leading towards a global village.

The WTO; International Trade Organisation (ITO) and General Agreement on Trade and Tariff (GATT)

The ITO is a United Nations specialised agency that addressed trade barriers and other issues indirectly related to trade, including employment, investment, business practices, and commodity agreements. The ITO treaty was not approved by the U.S. and a few other signatories and thus never went into effect. The WTO's predecessor, the General Agreement on Tariffs and Trade (GATT), was established after World War II in 1948 and dedicated to international economic cooperation. Until the WTO was established on 1 January 1995, seven rounds of negotiations occurred under the GATT. The first rounds concentrated on reducing tariffs. Then, the Kennedy Round in the mid-sixties, created GATT anti-dumping Agreement. The Tokyo Round during the seventies was to deal with non–tariff trade barriers. Several of the GATT agreements were amended in the Uruguay Round, and accepted by all WTO members.

The Uruguay Round. The eighth GATT round, known as the Uruguay Round, launched in September 1986, in Uruguay extended the trading system into several new areas, particularly trade in services and intellectual property (WTO, 2010c).

The Doha Round. The current round of negotiations, Doha Round, was launched at the fourth ministerial conference in Doha, Qatar in November 2001. The Doha round was an effort to involve more countries and help poor nations, particularly by removing barriers and subsidies in farming. The initial agenda included both trade liberalisation and new regulations, highlighting the need and commitment to help developing countries (Fergusson, 2008). On the 10th December 2002, the General Council agreed a new range of measures enabling the world's poorest countries, the least-developed countries (LDCs), to join more quickly and easily. Member governments agreed to apply "special and differential treatment" to those countries as soon as they become members, and to grant transitional periods in specific WTO agreements. Levels of the countries' development, financial, trade and technical needs were taken into consideration (the accession procedure for Nepal and Cambodia completed in the light of these measures) (WTO, 2010b).

Functions

WTO is an organisation for liberalising trade, a forum for governments to negotiate trade agreements and a place to settle trade disputes (WTO, 2010a). The WTO purpose is to help trade flow as freely as possible, so long as there are no undesirable side effects (WTO, 2010a). The main functions of the WTO (WTO, 2010) are to:

- Oversee implementation, administration and operation of the relevant agreements.
- Provide a forum for negotiations and for settling disputes.
- Review and publish the national trade policies, and to ensure their consistency and transparency.
- Assist developing, least-developed and low-income countries in transition to adjust to WTO rules and disciplines through technical cooperation and training.

- Conduct economic research and analysis with regular assessments of the global trade situation in its annual publications.
- Cooperate with the International Monetary Fund (IMF) and the World Bank.

Principles of the Trading System

The five important principals are (WTO, 2010i):

1. **Non-Discrimination**. There are two major components related to this topic: the Most Favoured Nation (MFN) rule, and the national treatment policy. The MFN requires that a WTO member must apply the same conditions on all trade with other WTO members. In other words, if a country grants a special favour to a country, it has to do the same for all other WTO members. National treatment means that imported goods should be treated equally in comparison to the local products and was introduced to tackle non-tariff barriers to trade (e.g. technical standards, security standards as discriminations against imported goods).
2. **Reciprocity**. This reflects that trade relationships under WTO should secure mutual benefits of the involved countries.
3. **Binding and enforceable commitments**. The tariff commitments made by WTO members in a multilateral trade negotiation and on accession are listed to establish "ceiling bindings": A country can change its bindings, but only after negotiating with its trading partners, which could mean compensating them for loss of trade. If satisfaction is not obtained, the complaining country may appeal to the WTO dispute settlement procedure.
4. **Transparency**. The WTO members are required to publish their trade regulations, review the administrative decisions affecting trade, respond to requests for information by other members, and report changes in trade policies to the WTO.
5. **Managing Special Cases**. Governments can restrict trade in three specific circumstances: to attain noneconomic objectives; to ensure "fair competition"; and intervention in trade for economic reason. Exceptions to the MFN principle

also allow for preferential treatment of developing countries, regional free trade areas and customs unions.

Organisational structure

The General Council meets either as the Trade Policy Review Body or Dispute Settlement Body. It has multiple groups which monitor committees in different areas; Council for Trade in Goods, Council for Trade-Related Aspects of Intellectual Property Rights, Council for Trade in Services and Trade Negotiations Committee (WTO, 2010d).

Voting System

The WTO operates on a *one country, one vote* system. In fact, votes have never been taken and decision-making is based on consensus generating to find the most widely acceptable decision. It should be taken into consideration that relative market size is the primary source of bargaining power. In reality, WTO negotiations proceed by a process of informal negotiations between small groups of countries that is criticised by many of the developing countries which are often excluded from these negotiations. Some analysts argue that the WTO's consensus governance model favours Europe and the U.S (Steinberg, 2002) (WTO, 2010j).

Accession and Membership

The process of becoming a WTO member depends on the situation in each country, its economic development and current trade regime. The process takes about five years, on average, but it can last longer due to political and economical issues. The accession procedure will be completed once consensus is reached among the interested parties (The Centre for International Development at Harvard University, 2010).

Members and Observers

The WTO has 153 members with 30 countries nominated as observers including Iran that are currently negotiating their membership. Russia is the biggest economy outside WTO but after the completion of Russia's accession; Iran would be the biggest economy

outside the WTO. Having become observers, accession negotiations must start within five years. There are 14 states and 2 territories currently with no official interaction with the WTO (WTO, 2010b).

WTO Agreements

The WTO covers about 60 different agreements as international legal texts. Member countries must sign and ratify all WTO agreements on accession. Some of the most important agreements are; The Agreement on Trade-Related Aspects of Intellectual Property Rights, The Agreement on Technical Barriers to Trade (ensures that technical negotiations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade) and The Agreement on Customs Valuation, formally known as the Agreement on Implementation of Article VII of GATT (WTO, 2010c).

Iran Trade Regulations

Iran is gradually modifying its trade regulations in accordance with the WTO requirements. Here are the most important aspects:

Customs Tariff Structure

The average of import duties in Iran's National Tariff System (NTS) is currently 25.5%. There are 2278 tariff lines (that is 33.8% of the total tariff lines) that have the minimum tariff rate of 4 percent (which has the highest frequency among tariff groups) and about 44% of the tariff lines have tariff rates less than or equal to 10 percent. Goods having tariffs more than 100% constitute less than 0.5% of the tariff lines in the NTS. The highest tariff rate is 200%. The statistics for the Iranian year 1385 (2006-2007) indicates that an average import duty of 11.6 percent was actually collected for the total imported goods in that year (Ministry of Commerce, 2009). The importation tariff for finished pharmaceutical products that have local production is around 60% which plays a major role in protecting the local pharmaceutical industry.

Application of Most Favoured Nation, Tariff Rates and Tariff Preferences

Iran applies tariff rates on a non-discriminatory basis for all countries. However, a limited number of goods have been subject to the exchange of concessions in the framework of the Preferential Trade Agreement between Iran and Pakistan (Ministry of Commerce, 2009).

Tariff Quotas, Tariff Exemptions

No tariff quota is applied to Iran's trade regime. In addition, since March 2003, all tariff exemptions enjoyed by some government agencies have been removed by virtue of the "Act on Consolidation of Duties" (Ministry of Commerce, 2009).

Other Duties and Charges

There are no taxes, fees or charges, other than "import duties". The last version of import duties is annually published as an attachment to "the Act on Export-Import Regulations Book" by the Ministry of Commerce. (Ministry of Commerce, 2009).

Quantitative Import Restrictions

There are no quantitative restrictions on imports in Iran's trade regime. Import prohibitions are only applied on items whose sales, purchases and consumption is prohibited by the Islamic principles or according to laws as dictated by the specific agencies of the country (Ministry of Commerce, 2009).

TRIPS Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organisation (WTO). It defines minimum standards for intellectual property (IP) regulation and is applicable to all WTO members. TRIPS agreement was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. This agreement contains requirements for copyright; industrial design; patents; trademarks; and undisclosed or confidential information. TRIPS agreement also determines enforcement procedures, compensations, and dispute settlement procedures. The philosophy behind the protection and enforcement of intellectual property rights is to contribute to the promotion of technological innovation and to the transfer and distribution of technology, in a manner to secure the rights of its producers.

The concerns of the developing countries about the strict interpretation of TRIPS by developed countries initiated a round of talks in 2001 that resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, stating for example that TRIPS can and should be interpreted in the light of the goal to promote access to medicines for all. The ministerial conference held in Doha issued a declaration on the TRIPS agreement and public health to recognise the importance of the public health problems affecting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics (WTO, 2001). TRIPS has been criticised by the social movements due to its consequences with regard to the AIDS pandemic in Africa.

Background and History

Modern patent legislation has its roots back in three or four centuries ago. At that time, a pharmaceutical product was called "nostrum" and were mainly made in some monasteries in Italy, France, and Germany. In some cases the rulers paid their investors for the valuable nostrums and published them to the public. A famous story for such a deal is selling the formula of decoction of cinchona bark by an Englishman to Luis XIV of France in 1680 for an undisclosed high price. Similarly in 1775, the inventor of a nostrum for the treatment of tapeworm received immunity and a noble title from Fredrick, the great of Prussia. England was the first country to establish governmental regulations in this regard (Agrawal and Takkar, 1997).

The recent development to strengthening intellectual property rights has happened since the formation of the WTO as a result of a intense lobbying by the United States, supported by the European Union, Japan and other developed countries (Braithwaite and Drahos, 2000).

Ratification of TRIPS is a compulsory requirement of WTO membership, in order to obtain easy access to the numerous international markets. Furthermore, unlike other agreements on intellectual property, TRIPS has a powerful enforcement through the

WTO's dispute settlement mechanism (Braithwaite and Drahos, 2000 and WTO, 2010e).

The Requirements of TRIPS

The central part of the TRIPS agreement is article 27, which states that all signatories are obliged to grant protection to any invention including products and processes in all technology sectors. The TRIPS agreement requires member countries to grant strong protection for intellectual property rights, for example, under TRIPS (John and Masterson, (2002); WTO, 2010k and WTO, 2010m):

- Copyright must be granted automatically, and not based on any "formality", such as registrations or systems of renewal.
- National exceptions to copyright (such as "fair use" in the United States) are constrained by the Berne Convention.
- Patents must be granted in all "fields of technology," although exceptions for certain public interests are allowed (Art. 27.2 and 27.3) and must be enforceable for at least 20 years (Art 33).
- Exceptions to the exclusive rights must be limited, provided that a normal exploitation of the work (Art. 13) and normal exploitation of the patent (Art 30) is not in conflict.
- Legitimate interests of third parties have to be taken into account by patent rights (Art 30).
- In each country, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPs signatories.

Compulsory Licensing; Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner (WTO, 2010g). Compulsory licensing as explained by the WTO (2003) is an important flexibility resulted from the Doha Declaration in 2002. This is also known as 'use without authorisation of the rights holder'. There are some preconditions for compulsory licensing such as: being unsuccessful in voluntary licensing from the patent holder and

the presence of a national emergency for public non-commercial use (Dhar and Gopakumar, 2006).

Parallel Importation; 'Parallel imports' or 'grey imports' are considered where a country can legally import a patented drug from another country (with lower prices) without the permission of the patent owner (WTO , 2003).

Burden of Proof; This means that the party claiming a violation of a provision of the WTO Agreement, the complainant, must prove its claim. In turn, the party appealing in defence of a provision that is an exception to an obligation (i.e. the respondent) bears the burden of proof that the conditions set out in the exception are met (WTO, 2010h). Burden of proof is an important legal issue especially while a country or a company intends to take advantage of the exceptions to the WTO/TRIPS provisions.

Mailbox System; Article 70.8 considers the establishment of a "mailbox system" for receiving and filing patent applications upon entry into force of TRIPS. The files in a mailbox are to be retrieved after a specific period of time and reviewed by the authorities for patentability (Chulalongkorn University, Feb 2001). If the products obtained marketing approval in any WTO Member country, then exclusive marketing rights for five years had to be granted before the patent on the product was either granted or rejected (Dhar and Gopakumar, 2006).

The TRIPS agreement has forced many countries to adapt their national legislation in a way to comply with its provisions mainly 20 years of patent protection from the date of filing (Ganguli, 2003). Some of the legislative modifications in different countries are summarised in Table 1.2.

Access to Essential Medicines

An interpretive statement in the Doha Declaration was issued in November 2001 which indicated that TRIPS should not prevent states from dealing with public health crises (WTO, 2001). Despite the role that patents have played in maintaining higher costs of drugs that were necessary for public health programmes across Africa, no revision of TRIPS has occurred. After Doha, Pharmaceutical Research and Manufacturers of

America (PhRMA) and other developed nations began working to minimise the effect of the declaration. The agreement that allowed developing countries to export to other countries where there is a national health problem without a commercial or industrial interest is no longer enforceable (WTO, 2003).

Table 1.2 Modifications of the legislations to comply with TRIPS agreement in different countries

Country	Year	Modified Regulation
USA	1995	The Term of Patent was extended from 17 to 20 years.
EU	July 8, 1998	Legal protection was granted to biotechnology products and processes.
Japan	December 14, 1994	Patent law was extended and classification was changed.
India	March 10, 1999	Transitory mailbox provision was approved.
Spain	January 1998	Obtaining interim injunctions against patent infringers was facilitated.
Argentina	1995	20 years protection from the date of filing instead of 15 years from the date of granting was approved.
Australia	August 10, 1988	Patents effective term increased to 20 years.
New Zealand		Rules on parallel importation were relaxed.
Estonia	June 16, 1998	Protection granted to process patent.
Mexico	1994	Patentability to practically all types of inventions was allowed.
Brazil	April 1966	Included a shortened year transition period before WTO intellectual property rules come into force.
Kuwait		Patents are granted to all industrial products, methods or new applications.
South Africa	December 12, 1997	Parallel importation and patent protection were approved.

In 2003, the Bush administration announced a new policy concluding that generic treatments might be a component of an effective strategy to combat HIV. Bush created "the President's Emergency Plan for AIDS Relief" (PEPFAR) programme, which received $15 billion from 2003-2007, and was re-authorised in 2007 for $30 billion for the next five years. Despite wavering on the issue of compulsory licensing, PEPFAR began to distribute generic drugs in 2004-5 (Office of the Global AIDS Coordinator, 2008).

Implementation in Developing Countries

The obligations under TRIPS, apply equally to all member states, however developing countries were given more time to implement the changes to their national laws, in two protocols of transition according to their development level. The transition period for developing countries expired in 2005. The transition period for least developed countries to implement TRIPS was extended to 2013, and until 1 January 2016 for pharmaceutical patents, with the possibility of further extension (WTO, 2010f).

Developed countries are major exporters of copyright, patent and trademark-related royalties. It has therefore been argued that the TRIPS standard will be harmful to poorer countries' development (WIPO, 2005). A report in 2005 by the WHO stated that many developing countries have not incorporated TRIPS flexibilities (compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability, etc.) into their legal system that were permitted under the Doha declaration (Braithwaite and Drahos, 2000; Musungu and Oh, 2005). This is probably caused by the lack of legal and technical expertise needed to draft legislation that implements flexibilities. This often resulted in directly copying developed countries' IP legislation (Finger, 2000), or relying on technical assistance from the World Intellectual Property Organisation (WIPO), which encourages them to implement stronger intellectual property monopolies.

Post-TRIPS Expansionism

The requirements of TRIPS are extremely strict. Despite this, some of the developed countries tried to strengthen existing forms of intellectual property rights such as; restricting the possibility of compulsory licences, aggressive enforcement demands in bilateral agreements and extension of the patent system by using the wording of TRIPS 27 on non-discrimination (Braithwaite and Drahos, 2000). It is recommended that developing countries should be cautious about enacting legislation that is stricter than the TRIPS requirements ("TRIPS-plus") (Chulalongkorn University, Feb 2001).

Controversies, the supporters and opponents of Intellectual Property Rights

Since TRIPS came into force, it has received a growing level of criticism from developing countries, academics, and non-governmental organisations. Some of this criticism is against the WTO as a whole, but many supporters of trade liberalisation also consider negative consequences for TRIPS. They believe TRIPS facilitates moving money from people in developing countries to copyright and patent owners in developed countries (Drahos and Braithwaite, 2003).

It is obvious that TRIPS has a legal base for protecting innovation and rewarding investors in high risk areas of research and development. This will result in the development of novelty products that are necessary for a healthier society in the future. On the other hand, we have patients which need the best available medicines right now. The only way to ensure their efficient accessibility to medicines and make a balance to reach intergeneration equity is to carefully define the strength and the period of patent protection. The supporters of TRIPS underline the necessity of strong protection for patent holders and innovators to ensure sustainable innovation. They consider it as a challenging trade-off between inexpensive drugs today and novel drugs for the future (Agrawal and Takkar, 1997).

Multinational companies generally prefer higher standards of intellectual property protection due to their investment in R&D. The need for more income is also influenced by shorter product cycles due to technological changes and market forces. This also causes an opportunity for developing countries to host some R&D and production facilities for the multinational companies. (Vogel, 2006). Some researchers believe these solutions create a midway approach emphasising the intellectual property rights of the patent holders and at the same time, sharing their benefits with developing societies (Ganguli, 2003). Some opponents investigate more deeply the financial structure of reported R&D expenditures and conclude some parts of it, phase IV clinical trial expenses for instance are arguably a marketing cost (Moerman and Laan, 2006)

The Impact of the WTO/TRIPS Agreement on developing countries

Jordan is a successful example of joining the WTO. According to some local pharmaceutical executives, enacting the new patent law could "run their business into the ground". The current patent law offered pharmaceuticals protection for "process" but not for the end product. At that time, Jordan had 17 pharmaceutical companies with 3500 employees and 2% under licence products. The Pharmaceutical industry was the second largest exporting industry after mining in Jordan. The US industry claimed their losses for unauthorised copies in Jordan to be $20-25 million/year. The American Pharmaceutical Industry Association reported only 10% of the market value would be affected but, would bring foreign investment to the country and create jobs. At the same time, the head of the Arab Union for Drug Security indicated that the $400 million pharmaceutical industry's turnover in Jordan would suffer (Maayeh, 1999). By 2006 this country's pharmaceutical industry exported $250 million to 60 countries and the industry was a major contributor to the national economy (Sboul, 2006). This experience was also repeated in some other Arabian countries in the Persian Gulf such as Saudi Arabia (Taher, 1999).

In India, industry analysts believed that most of the new medicines would be priced out of reach of the great majority of people by joining the country to WTO in 2005. Until that time, India had allowed only manufacturing process patents for pharmaceuticals but not for the end products. In India, 60,000 generic brands in 60 therapeutic areas were available which accounted for 1% of the value and 8% of the volume of the pharmaceuticals sold in the world. A governmental report stated only in antibiotics; new patent law would cost Indians $700 million each year against a gain of $57million in profits of multinationals. Others believed that only 10% of people could pay for costly medicines and the new law would cost the lives of millions for the greater profit of rich multinationals (James, 2004). Some researchers tried to quantify the impact of this monopoly under patent. They concluded that in the case of a linear demand function the price of pharmaceuticals would increase by 26% but if the demand function was considered with constant elasticity, the price rise would be as high as 242%. They

suggested that compulsory licensing could be a solution to prevent welfare loses (Watal, 2000).

The final impact on the pharmaceutical industry in India was not so negative. Companies like Ranbaxy were more optimistic to adapt to a research based strategy or offer low cost production for high income multinationals (James, 2004). The main reason for this optimism was the strong bases of the generic pharmaceutical companies in India that emerged as a result of the implementation of the Patents Act in 1970. Two key provisions facilitated this process. The first was the introduction of a process patent regime for chemicals and the second, a shortening the validity period of the patents granted for pharmaceuticals. The proper use of TRIPS flexibilities played a major role in the future prospect of the industry. Analysis of the generic pharmaceutical industry shows that they developed strategies to meet the challenges posed by the post-TRIPS patent regime. These strategies include the consolidation of the Indian firms and the increase in the R&D spending of some of the leading firms. This resulted in them receiving market approvals in both the US and the UK and playing the role of a hub for contract research and manufacturing. A number of major pharmaceutical companies are establishing joint ventures with the Indian generic producers. Indian firms have also increased their focus on the more profitable regulated markets and received the FDA approvals for 60 manufacturing plants that are more than any other country. There is also an increased focus on product innovation; one-third of all FDA applications came from India in 2003. Multinational companies are attracted by the lower cost structure estimated to be one eighth (in R&D) to one-fifth (in manufacturing) compared to Western countries and identified the prospects of the Indian pharmaceutical industry as extremely positive (Dhar and Gopakumar, 2006). Positive impacts are also reported in Singapore due to absorbing FDI, establishing R&D and manufacturing facilities by multinational companies and higher training and qualifications for employees (Lim and Wei, 2010).

China is primarily known as the lowest cost source of pharmaceutical ingredients and generics. However, some of the major local generic companies have focused on innovative R&D. China has the language barriers and insecure institutional environment

for intellectual property protection, long registration approval processes, and regulatory favouritism towards local firms. The availability and pricing of approximately 90% of medicines in India and China, including most the WHO Model List of Essential Medicines should not be affected by the introduction of product patents (Grace, 2004). The impacts of TRIPS is also discussed as a source of concern in several other countries such as; Thailand (Supakankunti, 2001), Morocco (World Trade Organization, 2006) and Turkey (Semin and Güldal, 2008).

Recommendations for Concerned Countries

A study by Ryan and Graduno (2004) concludes comprehensive recommendations regarding intellectual property rights to develop a national strategy for supporting innovation. The summary of their recommendations along with the findings in other countries (Agrawal and Takkar, 1997; Dhar and Gopakumar, 2006; Erixon et al, 2008; Semin and Güldal, 2008; Chaudhry, 2009; Lim and Wei, 2010) can be summarised as follows:

- Enact a local patent protection law that gradually meets the international level.
- Expand the scope of patentable subjects to include different innovations.
- Establish a national framework for technology transfer by providing patent property rights to universities and national research centres.
- Build the capacity to engage in technology transfer offices.
- Provide broad education and training programmes on intellectual property use and management.
- Encourage the development of a world class intellectual property rights.
- Leverage the national innovation awards.
- Establish human and organisational capacities regarding international intellectual property diplomacy.
- Enhance intellectual property Enforcement.
- Provide additional training to judges focused on patent and trade secret arbitration.

Intellectual Property Rights (IPRs) in Iran

Based on the data published by the World Intellectual Property Organisation (2010), Iran is a member of the WIPO since 2002 and has joined several intellectual property treaties and joined the Convention for the Protection of Industrial Property (Paris Convention) in 1959. In December 2003, Iran became a member to the Madrid Agreement and the Madrid Protocol for the International Registration of Marks. In 2005 Iran joined the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, which ensures the protection of geographical names associated with products. Iranian laws and regulations provide specific legal rules respecting a number, but not all of the industrial properties. However, no patent application is acceptable for pharmaceutical products and processes. Trademarks are the most protected industrial property in Iran; therefore, a practical way for the owners of trade names and industrial designs is registering them as trademarks. The milestones of establishing the current IPRs in five-year development plans are presented in the Table 1.3 (Akhlaghi and Habiba, 2006).

Table 1.3 IP considerations in Iran's Development Plans (1990-2009)

Five Years Plan	The degree of considering IPRs in the documents of the plan	Clarity of special policies and strategies for improving IPRs system in the documents of the plan
First Five-Year Plan (1990-94)	None	Lack of a specific policy or strategy
Second Five-Year Plan (1995-99)	None	Lack of a specific policy or strategy
Third Five-Year Plan (2000-2004)	Reference to the defects in Iran's IPRs regime and the necessity of solving problems	Lack of a specific policy or strategy

Fourth Five-Year Plan (2005-2009)	Clear reference to the existence of many defects in Iran's IPRs regime and the necessity of removing them during the execution years	Obliging the government to plan and implement a comprehensive IPRs system

This Table shows that the Iranian policy-makers have recently paid increasing attention to strengthening national IPRs system. It should also be noted that Iran has not joined any international copyright agreements such as the Berne convention. Since Iran is planning to join WTO, it is necessary to join the relevant agreements as well. According to the 20 year development programme, the country has developed a strategy to be one of the major players in the region with the pharmaceutical industry as a priority.

The Act of Acceding to the Patent Cooperation Treaty was enacted by the Iranian parliament (*Majlis*) in 2007. Based on this law, the enforcement will become liable only after the process of acceding has been completed and also provided that enough facilities are made available. In March 2008, the "Law of Registration of Inventions, Industrial Designs and Trade Marks" was enacted (the 2008 Law), to be implemented for a five-year tentative period (Rasekh, 2009). The country has also a legal system to protect the proprietary and intellectual rights of works produced inside Iran as the Law for the Protection of Authors dated January 12, 1970, (Parstimes, 2010) supplemented in the Iranian year 1352 (1973) and the Iranian year 1379 (2000) (Ministry of Commerce, 2009). These laws however do not cover works from outside Iran as it is not a signatory to the Berne Convention for the Protection of Literary and Artistic Works, the WIPO Copyright Treaty, or a member of the WTO (Press TV, 2010).

According to the Iranian Law of Registration of Marks and Patents of 1931, a trademark is any type of logo, design, picture, number, letter, word, seal or wrapper etc. with essential requirement that the mark presented for registration should be distinctive. Article 30 of the law provides that any inventor or discoverer who holds an unexpired patent certificate outside Iran may apply for a patent in Iran. But if a person or company

has used the invention or discovery in Iran prior to the foreigner's application or has made preparations to exploit the same, the foreign patentee will not have the right to stop the operation of that person or company (Akhlaghi and Habiba, 2006).

The Registration of Patents, Industrial Designs and Trademarks Law, 2008

The Law of Registration of Patents, Industrial Designs and Trademarks were first passed by the Iranian parliament on 23 January 2008 for a trial period of five years, effective from May 5, 2008. In October 2007 Iran's parliament approved becoming a signatory to the Patent Cooperation Treaty (PCT) which enables inventors to register their patents in PCT member countries simply by filing a single application with the related national registration authority (Press TV, 2008).

The Majlis (Parliament) also approved a bill in May 2001 to recognise and enforce international arbitration awards, to grant companies greater protection over their property. By acceding to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards, commonly known as the New York Convention, Iran has agreed to enforce arbitration awards made in other countries. Awards issued in Iran will also be enforceable in other member countries. According to the State Registration Organisation of Deeds and Properties, a total of 9,570 national inventions were registered in Iran during 2008. Compared with the previous year, there was a 38-percent increase in the number of inventions registered by the organisation (Ministry of Commerce, 2009).

Patents are registered in Iran for 5, 10, 15 or 20 years, at the option of the applicant. Pharmaceutical formula and compounds are not patentable, but a patent application can be filed for processes related to the manufacture of pharmaceuticals. A trademark may be registered for ten years and can be renewed indefinitely for additional ten-year periods. The legal effect of Registration is to give exclusive right to an owner to use a trademark on the goods for which the trademark is registered (Alavi and Associates, 2010).

The Impact of WTO/TRIPS on Pharmaceutical Industry

Regardless of positive or negative approaches toward the WTO/TRIPS, it seems all countries around the world are gradually joining this global harmonisation, intending to be proactive and provoke innovation in local industry, absorbing foreign investment and promoting exports.

Apart from building up capacities in the knowledge system, Iran has also substantial technological capacity in the productive sector. It has a well developed manufacturing capacity in the automotive industry, telecommunications and pharmaceuticals. In general, enterprises only are involved in production but do not perform innovative activities. While such a strategy fits an import-substitution economy, it does not result in a dynamic capability for sustainable development. (Molanezhad, 2010). Iranian pharmaceutical manufacturers are disadvantaged by the poor intellectual property protection regime. Developing a molecule for combination therapies may qualify for patent protection in other countries. However, while weak patent protection continues in Iran, it is expected this will create significant challenges for Iranian companies pursuing trade on the global market (Business Monitor International, 2009).

The reviews in this chapter suggest that:

- WTO/TRIPS has caused many debates in developing countries with eventually success stories in most of them,
- Iran has a long history and strong infrastructure in the pharmaceutical industry,
- The improvement of the industry in recent years has not been sufficient for a well-established local and international presence,
- It is expected that the legal environment support innovativeness of the local industry,
- A stepwise patent protection is needed to support local companies' innovativeness and simultaneously, the international companies' presence and contribution. These steps would include granting protection to the locally developed processes and products and subsequently enforcement of international intellectual property rights,

- The Pharmaceutical industry and all relevant stakeholders need to study the current situation with respect to the future challenges and develop a roadmap to secure the sustainability of the local industry.

Aims and Objectives of the Study

Aim

The aim of this study is the development and application of instruments to study the impact of WTO/TRIPS on the sustainability of the pharmaceutical industry in Iran.

Objectives

- Develop and apply a validated rating scale for generating experts' consensus to identify the factors that influence the pharmaceutical industry in the post-WTO situation
- Rate the relative importance of the factors influencing the pharmaceutical environment in the post-WTO agreement
- Develop and apply a validated instrument to study the situation of the Pharmaceutical Industry in Iran
- Identify the future importance of the various parameters that reflect the industry's aspirations to meet the challenges
- Rank and prioritise the actions that need to be taken by the industry
- Propose scenarios for developing appropriate strategies to ensure the sustainability of the pharmaceutical industry
- A Gap analysis and introduce an index for measuring the Iranian industry's readiness for the post-WTO situation
- Develop a strategy map for the Iranian pharmaceutical industry in order to secure its post-WTO sustainability and translate the identified parameters into a series of balanced scorecards

Chapter 2

Study Rationale and Methodological Framework

STUDY RATIONALE

The origin of intellectual property (IP) rights and the evolution of the concept through history have been explained in chapter 1. The underlying principles for granting protection to innovators include the following:

- Legal aspects, through which the IP of any individual can be protected from unauthorised usage by others
- Economical/financial aspects, which involve using financial rewards as an effective way to promote the innovative attitude among talented people
- Social/people-related aspects, which involve not only facilitating the access of individuals to innovative knowledge by ensuring that innovators are protected by the law but also creating an idea-generating atmosphere in society

Chapter 1 also outlined how this protection has been combined with free trade agreements by the World Trade Organisation (WTO). In fact, enforcing worldwide IP protection has become a prerequisite for any country that wishes to join the WTO and become an active and responsible member of the international trade community.

In view of the pharmaceutical industry's high level of dependency on new patents and innovations, enforcing worldwide IP protection has created some complications, especially in developing countries. Accession to the WTO requires that all trade barriers, including importation tariffs and quotas, should be removed on the basis of a timetable decided through bilateral or multilateral negotiations. This, in turn, means that the free flow of finished medicines from developed countries can easily capture the home market of local industries. At the same time, enforcing worldwide IP protection based on the agreement on trade-related aspects of intellectual property rights (TRIPS) will require the local industry to either stop production of patented products or pay licence fees to innovators. Without sufficient preparation, the consequences of these legal adaptations may severely affect the viability of the local industry that have a key role in the access of patients to medicines. There appears to be very few comparable published studies of these effects. Therefore, this study proposes to gather the

necessary information from the pharmaceutical industry and other related sectors in order to;

- Identify those parts of the industry that could potentially be more vulnerable to the negative impacts of WTO/TRIPS;
- Provide further insight into the current situation with respect to the critical factors;
- Evaluate whether the current efforts are sufficient to sustain a profitable industry;
- Assess the impact of the companies' policies on their readiness to deal with the forthcoming situations.

Thus, this research aims to evaluate the impact of WTO/TRIPS on the sustainability of the pharmaceutical industry in Iran.

METHODOLOGICAL FRAMEWORK

Study Design

While designing a research study, it is necessary to first decide whether the study seeks to explain a new theory (hypothesis generating) or test existing ones (hypothesis testing).

In general, inductive strategies are used for generating a new hypothesis, whereas deductive strategies are used for hypothesis testing. Thus, during hypothesis generation, the researcher uses his or her initial observations as the starting point on which to formulate hypotheses. These hypotheses may be subsequently either rejected or modified based on the observations obtained during the study. In deductive procedures, however, a conceptual and theoretical structure is constructed prior to taking observations; this structure is then tested through experimental work (Cassel and Symon, 2004).

It is believed that the inductive strategy is more appropriate for social research because theory building and data collection are closely interlinked. Explanations of social phenomena based on systematic empirical research based on the data collected are

more reasonable and accessible. On the other hand, the deductive approach involves imposing a set of pre-assumptions upon the behaviour of social phenomena in order to explain the phenomena (Cassel and Symon, 2004).

This study is based on the inductive approach and hence will begin with systematic data collection, which will be followed by further analysis and subsequently, the suggestion of solutions to the research question.

The various ways to design a research study are as follows:

Single case study

In this method, every detail in a single sample is recorded and studied.

Multiple cases study

Under this method, details of multiple samples are recorded and studied so that quantitative data can be collected through the study for statistical analysis.

Panel study

In this method, the researcher obtains the consensus of experts, which can be very useful in defining terms and making predictions; this is the main objective of a panel study. The Delphi method is probably the most frequently cited technique for panel studies (Flynn, 1990). This method lends itself to the aims and objectives of this study and will be the focus of chapters 3 and 4 to generate baseline data for further analysis and conclusions. Therefore, this technique is explained here in more detail.

The Delphi technique:

The Delphi technique can be defined as a method for structuring a group communication process in such a manner that the process enables a group of individuals, as a whole, to deal with a complex problem (Linstone, 2002).

History; This method was developed by the RAND Corporation (Santa Monica, CA) in the 1950s but was published only ten years later because the project was defence-related and much of its content needed to be suppressed in the interests of national security (Meyrick, 2003).

Modifications; The Delphi method has undergone steady development since then, and this study discusses some major modifications that have been made to the conventional Delphi method. The conventional, also referred to as traditional or standard Delphi technique, involves reaching a consensus among experts.

- In 1970, the technique was modified into what came to be called the 'Policy Delphi technique', which aims at identifying the widest possible range of valid solutions to a policy problem (Linstone, 2002).
- Another modification involves convening a meeting between experts only after taking all the conventional steps to resolve the remaining conflicts between the panel members. It should be noted that due to the presence of certain constraints, this meeting cannot replicate the main panel members; moreover, the anonymity of the experts will also be breached by this process (Meyrick, 2003).
- A third modification involves preparing a list of issues in advance and presenting it to the panel members for further discussion, with the final objective of reaching a consensus (Meyrick, 2003). In conventional Delphi, this list is prepared by the panel members. Although such a process can save time and resources in conducting the study, it may, at the same time, deprive the study of a wider range of ideas.
- The George Washington University has introduced a modification in the Delphi method in that one Delphi round is repeated every two years. The final aim is to forecast the emerging technologies, with no intention of achieving consensus among the panel members (Halal, 1998).

Applications; Delphi initially was used for forecasting possible outcomes through discussions conducted by a panel of experts (Murphy, 1998). It systematically gathers inputs from the expert panel on a topic which may be beyond the expertise or experience of a lay person. The original experiment pertaining to this method in the 1950s involved a panel of seven experts attempting to estimate the bombing requirements for a hypothetical Soviet attempt to disable USA's production capacity and thereby its capacity to maintain a war effort (Meyrick, 2003). During the ensuing

years, however, the applications of the Delphi method have dramatically increased in terms of both how it is applied and to what it is applied.

While many people label Delphi as a forecasting tool because of its significance in that area, it has a variety of other applications, for example, examining the significance of historical events, evaluating possible budget allocation, revealing causal relationships in complex economic and social phenomena, distinguishing real and perceived human motivations and the prioritising of personal and social goals (Linstone, 2002). The Delphi technique has also been applied in a variety of health-related situations such as health education and the prioritising, planning and developing of clinical practice as well as health service organisations (Jones , 2000).

Selecting the participants; In order to deal with complex topics that arise when attempting to determine the best practice for a particular procedure, it is generally necessary to input the opinions of an 'expert', not those of the general population. Hence, a simple random sample is often unsuitable and it is crucial to secure the participation of the appropriate experts with in-depth knowledge and vision in the concerned field, thus ensuring the inclusion of a variety of viewpoints (Meyrickde, 2003). The experts should also be interested in and committed to participating in the study as efficiently as possible. Appropriate measures should be taken to minimise sampling and coverage errors (Brenson, 2009). Furthermore, the experts should be fully informed about the tasks they are required to perform.

In order to identify the experts, Delbecq et al. (as qouted by Okilo, 2004) have suggested the following multi-step iterative approach:

i. The first step involves preparing a knowledge resource nomination worksheet (KRNW) by categorising the experts before identifying them. This is mainly intended to avoid overlooking any important class of experts. The categories may be based on their organisations, disciplines or skills (the experts may be academics, practitioners, government officials or from non-governmental organisations (NGOs). It also includes reviewing relevant literature.

ii. The second step involves populating the KRNW with the names of the potential experts. There may be an overlap between the categories of experts. It is usually needed to utilise personal networks because of the need for cooperation between experts throughout the study.

iii. The third step includes the first round of contact-nominations for additional experts; the study objectives are explained to the existing experts, who in turn are asked to nominate new experts for inclusion in the list.

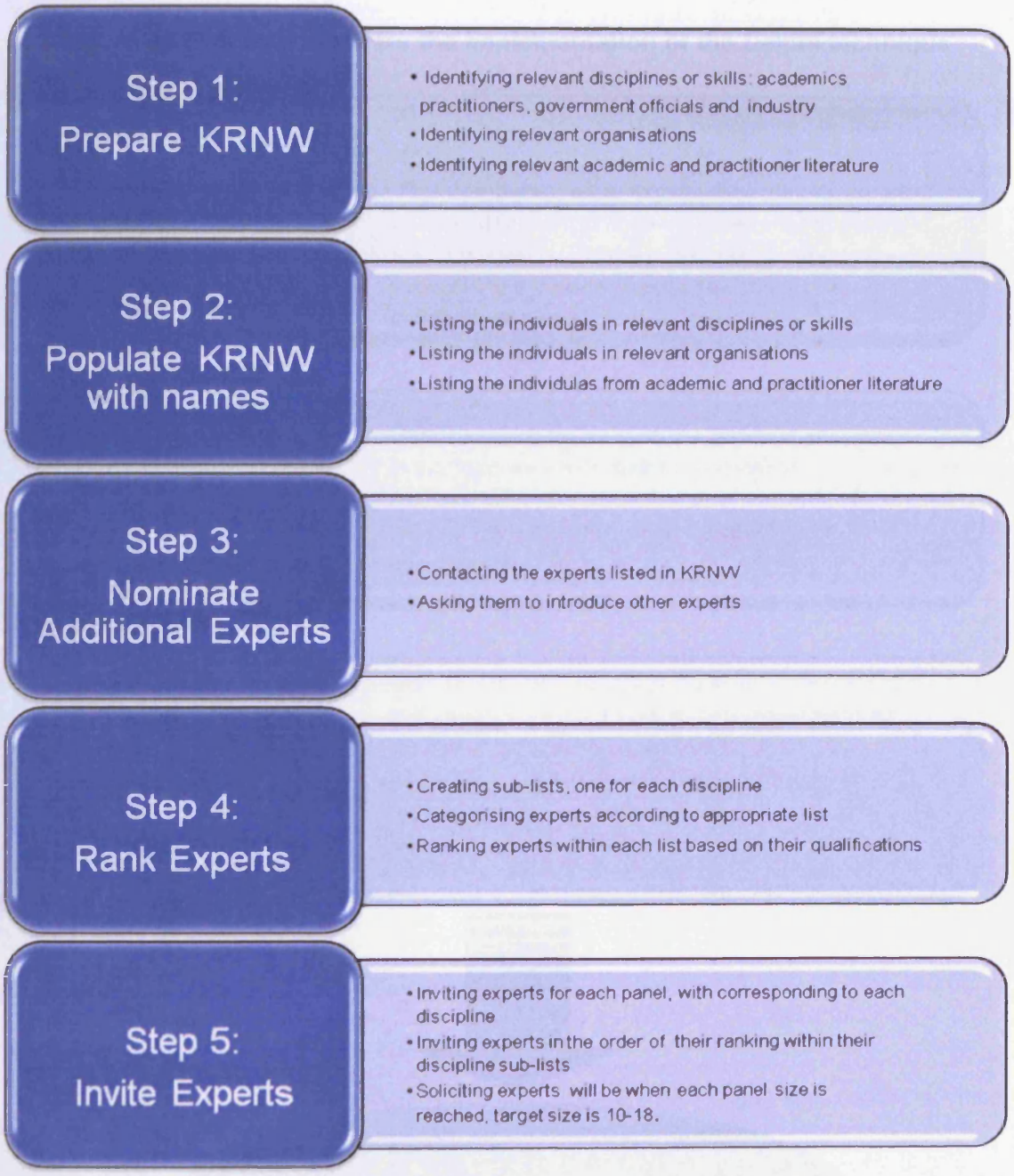
iv. The fourth step involves ranking the experts according to their qualifications.

v. In the final step, the experts are invited to join the study based on their rankings in order to form a panel with the optimum number of members. These steps are illustrated in Figure 2.1.

Practical steps; The administration procedure of the Delphi technique can be outlined based on the concepts of brainstorming (for collecting a wide range of expert opinions), narrowing down the original list to the most relevant ones and ranking the list of identified items (Okilo, 2004). These concepts will be used in this study in the following phases:

- First phase: Exploration of the subject by collecting information pertaining to each participant. This step commonly involves asking the participants open-ended questions. An open-ended question is one where the range of possible answers is not suggested to the participants; hence, the participants are expected to answer it in their own words (Brace, 2004).
- Second phase: Understanding the views of the group, mainly by exploring the level of their agreement or disagreement with the statements concluded from the first round and formulated as the first questionnaire.
- Third phase: Exploring the differences in the level of agreement and disagreement among the group members and analysing the underlying reasons. In this step, all the members are provided the opportunity to revise their answers through a second Delphi questionnaire. This questionnaire will include the median, maximum and minimum scores of the responses.

Figure 2.1 Key steps in the Delphi technique to identify and select experts

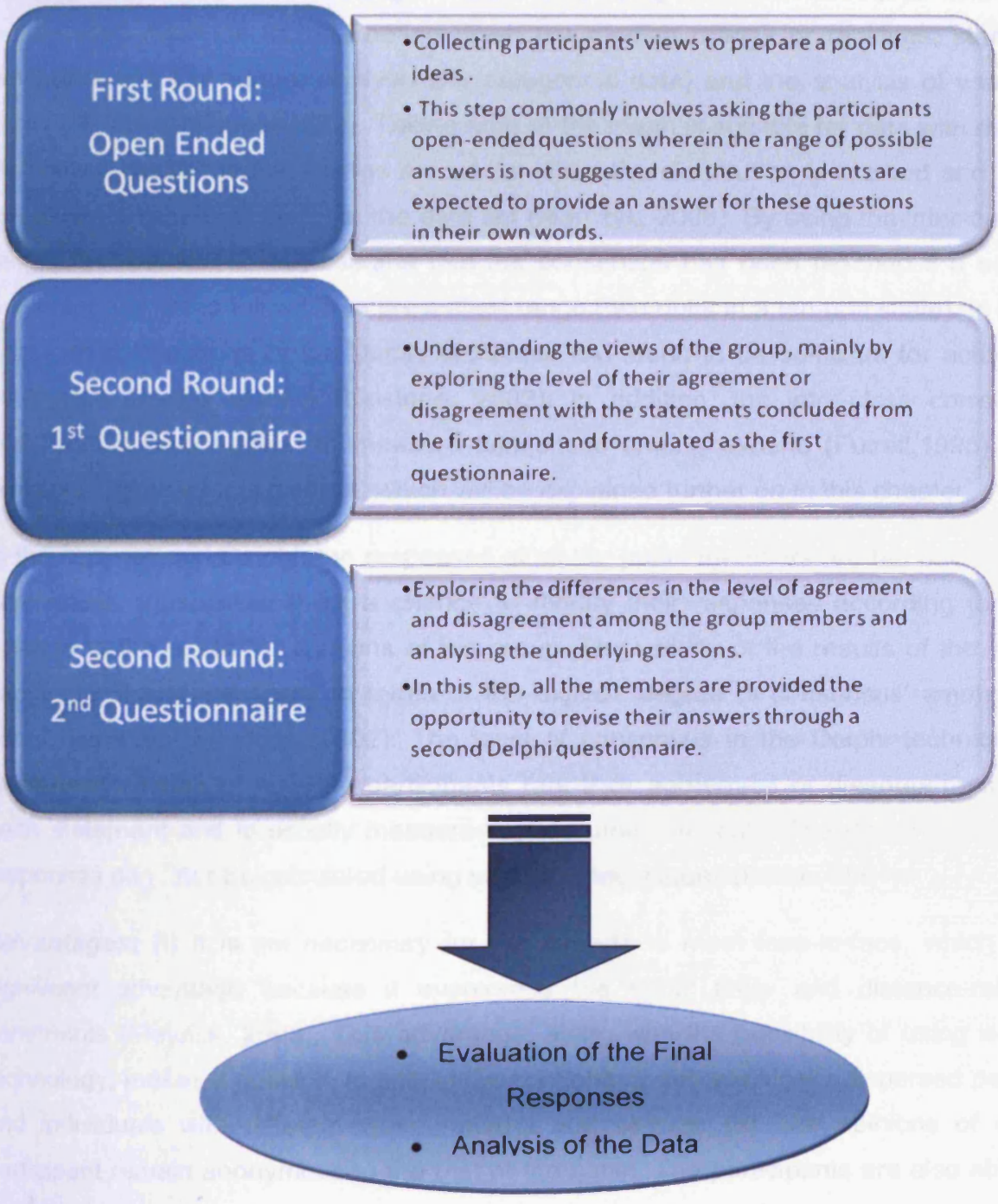


*Knowledge Resource Nomination Worksheet

Source: Adapted from Okilo, 2004

Ultimately, the final responses are evaluated and results are analysed. These phases are presented in Figure 2.2.

Figure 2.2 Practical steps for the implementation of the Delphi technique



Measuring the consensus; In many Delphi projects, achieving a real consensus is almost impossible especially with a broad and complex topic. In such cases, the 'multimodal consensus' or 'bimodal distribution' technique may be applied (Meyrick, 2003 and Linstone, 2002). The aim of these methods is to measure the degree of convergence or consensus among the experts by using statistical techniques. The most widely used methods include noting down the median ratings or rankings, standard deviations and Chi-square analysis (for categorical data) and the analysis of variance (ANOVA) (for continuous data). Taking note of the mean is suitable for data with normal distribution, while median ratings are useful when the distribution is skewed and there are extreme values (outliers) in the data set (Marczyk, 2005). By using the inter-quartile range, the researcher can assume that the consensus has been reached if a certain percentage of votes fall within a prescribed range (two units in a ten-unit scale). In most cases, three iterations of the Delphi technique are found to be sufficient for achieving consensus among experts (Linstone, 2002). In addition, the intra-class correlation coefficient is also applied to measure consensus among experts (Futrell,1995). The present study uses this method, which will be explained further on in this chapter.

In the conventional Delphi, the responses of all the panel members are fed back to the participants, thus giving them a chance to modify their responses according to their reaction to the collective opinions of the group. The validity of the results of the entire panel is typically measured in terms of the explicit 'degree of consensus' among the panel members (Linstone, 2002). The level of consensus in the Delphi technique is illustrated in terms of how the participants rate their agreement or disagreement with each statement and is usually measured on a numerical scale. The dispersion of the responses can later be calculated using statistical techniques (Brace, 2004).

Advantages; **(i)** It is not necessary for the experts to meet face-to-face, which is a significant advantage because it overcomes the usual time- and distance-related constraints (Meyrick, 2003). This advantage, along with the possibility of using e-mail technology, makes it possible to collect the opinions of geographically dispersed people and individuals with different work patterns and timings. **(ii)** The opinions of each participant remain anonymous to the rest of the panel. The participants are also able to

change their position in response to further input from the panel members (Meyrick, 2003). This anonymity provides a creative environment that is ideal for continuous innovative idea generation in the absence of all socio-psychological barriers. This is also important when the experts are required to comment on sensitive economic or political issues. Therefore, this technique enables the researcher to source ideas that cannot be generated using other research methods.

Pitfalls; Linstone (2002) lists eight basic pitfalls that can undermine the success of the Delphi method; these are as follows: *(1) Discounting the future*: The short planning horizon may happen when panel overlooks more sustainable solutions or additional options to deal with the currently unsolved problem. *(2) Prediction urge:* There is a tendency to forecast the future; however, there is a high degree of uncertainty in any forecast of the future and suppressing this uncertainty can mask the real significance of the Delphi. *(3) Simplification urge:* People normally prefer simplicity to complexity, and in scientific research, this temptation may lead researchers to overlook certain important aspects of the problem. *(4) Illusory expertise:* Bringing together a group of people with expertise in a particular subsystem does not necessarily result in a comprehensive conclusion regarding the total system. *(5) Sloppy execution:* In this regard, the sloppiness can be on the part of both the researcher and the participant. In the former case, it can include the poor selection of participants, poor interaction with panel members, poor formulation of the statements and superficial analysis of the participants' inputs. In the latter case, the participants may be tempted to 'get on with the job' or come to an 'artificial consensus', which is a potential limitation of this method. This may occur when some members who are not really convinced with the inputs provided by others, attempt to bring the process to a speedier end. This pretended conformity makes it important for researchers to select only committed experts as panel members. *(6) Optimism–pessimism bias:* Participants in the Delphi technique commonly tend to be over-pessimistic in their long-term forecasts and over-optimistic in their short-term forecasts. *(7) Overselling:* Repeated Delphi studies on the same subject will result in diminishing results. *(8) Deception:* It is absolutely possible for the Delphi technique to be used for data cooking and false inputs. The participants' anonymity may facilitate the deception process.

Despite the above pitfalls, the researcher's degree of familiarity with the topic of the study can ensure the success of the Delphi technique. It should be mentioned that although the Delphi technique appears to be a very simple concept that can be easily employed, ignoring its basic principles—such as a free environment for idea expression, efficient communication skills, an appropriate technique of summarising and presenting the responses, ensuring common interpretation of the statements and scales, and preventing the dissenters and non-motivated participants from being discouraged—can easily lead to the failure of a Delphi practice (Linstone, 2002).

Due to a lack of consensus among the experts and decision-makers regarding the research question of this study, it is concluded that the "panel study" is the most appropriate technique for identifying the influencing parameters. Chapters 3 and 4 will provide a detailed explanation of the use of the Delphi technique in a panel study, starting with an open-ended question that will be followed by two consequential iterations for creating a convergence of the ideas.

Focus group

This technique is similar to the panel study; however, in this approach, the group is physically assembled and its members' opinions are expressed orally rather than in the written form. The role of the facilitator who conducts the session is very important. The facilitator asks the questions, and every participant has the chance to express his or her opinion. Group members may discuss the question until they reach a consensus (Linstone, 2002). An important limitation of this method is the possibility of problems associated with face-to-face interaction, which may limit the range of generated opinions; the problems mainly result from the normative pressure for conformity, existence of dominant personalities, difficulties faced by members in contradicting their colleagues in higher positions and certain socio-psychological factors (Mead and Moseley, 2001).

Survey

This is a powerful tool for studying populations in an objective manner (Anon, 2000). The survey method relies on the self-reporting of factual data as well as opinions (Flynn,

1990). There are several different types of survey, based on their approaches and objectives, including snap-shot, baseline, longitudinal and comparative surveys. Snap-shot surveys offer a representative picture of the current situation. They can also be included in baseline surveys to provide a 'before' picture that can be used for comparison with an 'after' picture. This concept is most helpful for studying the impact or change taking place during a specific period of time. The longitudinal survey method involves using the same population to provide the 'after' picture, and it can be repeated over a period of time. In a comparative survey, two similar subgroups are compared (Anon, 2000). Surveys are also classified based on the method of data collection, for example, through mail, by telephone, through personal interviews and through web-mail and e-mail surveys (Falconer, 2001).

Sample selection; Generally, the more randomised the sample selection, the less biased are the results. Even if the samples are selected from a specific group, the actual sample should be drawn randomly. For example, if the study is at the plant level, the size of the company, number of employees and sales volume can be incorporated into the sample selection process (Flynn, 1990). A sample is the portion of a population that has been selected for analysis as the representative of the larger group. The results obtained from the sample are, therefore, generalised to the entire population. The sampling method is generally used because time- and resource-related constraints, in many circumstances, make it absolutely impossible to study the entire population under consideration. The sampling process begins with the definition of the sampling frame, which lists the items that constitute the population. There are two kinds of samples: probability samples and non-probability samples.

Probability sample: These samples are taken based on known probabilities. The four types of probability samples are as follows: (i) simple random samples are those in which every item within the frame has an equal chance of being selected (the table of random numbers is commonly used in this type of sampling); (ii) systematic samples are taken from the partitions within the sampling frame; (iii) stratified samples are selected from subdivisions in the frame, on the basis of common characteristics such as gender; (iv) cluster samples are taken from different clusters, such as territories.

Non-probability sample: Under this method, the samples are not selected according to their probability. Common types of non-probability sampling include convenient sampling, which is based on the availability of samples, and cost and judgement sampling, which involves obtaining the opinion of the pre-selected experts in the subject matter (Brenson, 2009).

Strengths; The strengths of the survey method can be summarised as follows (Anon, 2000 and Falconer, 2001):

- Ease of application and comparatively low administration cost
- Opportunity for including multiple participants
- Simple data analysis
- Possibility of preserving the anonymity and/or confidentiality of the participants
- Flexibility to generate different forms of quantitative and qualitative data and information
- Requiring relatively short period of time for data collection

The ultimate purpose of the survey studies is to be able to generalise the results to the entire population, and this is possible only if the errors in the study have been minimised. There are six types of survey errors:

- **Coverage error:** This occurs if a group of people is excluded from the sampling frame and results in a 'selection bias'.
- **Non-response error:** This arises from a failure to collect data from all cases in the sample and results in a 'non-response bias'.
- **Sampling error:** This results from a chance variation between samples, due to the probability of particular items being selected in particular samples, and is reported as a 'margin of error'.
- **Non-sampling error:** Non-sampling errors arise from mistakes made in areas such as the coding and data-entry processes of the survey; these errors include

not only the mistakes committed by interviewers but also those made during the development of the questionnaire (Brace, 2004).

- **Measurement error:** This error occurs when a study tool does not accurately measure the component it is designed to measure. This may be due to ambiguous wording in a questionnaire, the Hawthorne effect (the respondent's wish to please the interviewer) or respondent error (e.g. insufficient effort) (Brenson, 2009).

- **Social desirability bias (SDB):** SDB arises because participants like to appear to be different from their real selves. This can occur consciously, when participants want to manage the impression that they are projecting of themselves in terms of social responsibility, or subconsciously, when they believe themselves to be other than what they are, which is possibly a form of denial. Some of the common desirables include being a good citizen, being a well-informed and cultured person, fulfilling the expected moral and social responsibilities. A common technique to avoid SDB is to ensure confidentiality. Other techniques involve the removal of the interviewer, using the random response and question enhancement techniques, and asking face-saving questions and indirect questions (Brace, 2004).

Non-respondents analysis; In social sciences, the response rates generally exceed 40–60%, while in operations management these rates can be as low as 10–20%, which is really unreliable even if non-respondents are mined. In order to achieve results that are both reliable and can be generalised, it is necessary to obtain a response rate of 50%, along with non-respondent checking. There are several ways to increase the response rate, such as sending a reminder letter to the participants, ensuring confidentiality of the collected data, contacting potential participants and obtaining their commitment to the study, provision of feedback and other incentives, and appointing a coordinator in geographically dispersed studies (Flynn, 1990).

In cases where systematic differences are observed between the respondent and non-respondent groups, it generally becomes very difficult to generalise the results to the entire population. For example, firms with quality problems may not respond to a

questionnaire investigating quality, which means that those who do respond may not represent the entire population. Hence, it is necessary to analyse the important characteristics of the non-respondents in order to determine whether they are systematically different, which will be difficult if the questionnaires are distributed anonymously. However, if the non-respondents are identified, they may agree to answer some brief questions on the telephone. In fact, strict non-respondent analysis is especially recommended if the non-response rate is more than 50% (Flynn, 1990).

Limitations and challenges; The way in which questions are formulated can bias the responses, for example, if the questions have not been properly formulated in an unambiguous manner and convey different meanings to different participants. Questions can also reveal the bias of non-respondents; for instance, if the non-respondents are found to have some different characteristics from the participants, the results of the sample cannot be generalised to the entire population (Falconer, 2001).

The application of more than one method or mixed methods reportedly improves the value of a survey; for example, conducting a focus group first can help in the development of questions for a survey questionnaire. Conducting a survey first can assist in the development of questions for a focus group that will allow both confirmation and clarification or elaboration of the responses collected in the survey (Falconer, 2001). Engaging both quantitative and qualitative methods in one single study is regarded as an emerging approach in the field of research (Lunenburg , 2008). Some authors have explained the specific steps involved in mixed research design (Johnson, 2004).

The approach that will be undertaken in this study will be a mixed design including the current situation of the pharmaceutical industry and will use a specific rating scale in an attempt to collect the opinions of the study participants for further examination.

Data Collection Methods

An appropriate data collection method should be selected based on the study design and the nature of the data that are likely to be generated.

Data types

The collected data can be categorised in four main types of: nominal, ordinal, interval and ratio data.

Nominal data have no numerical meaning and include items such as dichotomies (responses that have only two options, such as yes/no, male/female) and categorical data (age-group or ethnicity). Nominal data are mainly descriptive and can be used in content analysis (Marczyk, 2005 and Milller, 2008). In the context of the present study, the nominal data are in the form of the participants' responses to demographical questions.

Ordinal data have a ranked order and are represented numerically; however, the differences between their values may not be equal. Therefore, ordinal data do not have a true numerical meaning. For example, responses to a question on how often the respondent uses online banking could be represented as ranging from the number zero (never uses online banking) to the number four (uses online banking at least once a week) (Somekh, 2005). Such responses may provide a higher level of measurement compared to that of the nominal data (Marczyk, 2005).

Interval data have true numerical values but no true zero, for example, a thermometer measuring temperature in degrees Celsius or Fahrenheit. While addition and subtraction are possible with this level of measurement, the lack of an absolute zero point makes division and multiplication impossible (Marczyk, 2005).

Ratio data, in contrast, do have a true zero, for example, the distances travelled to work (Somekh, 2005). Time, height, weight and money are other examples of this kind of data. Ratio data provide the highest level of measurement and allow for the use of more powerful statistical techniques (Marczyk, 2005). Variables containing nominal or ordinal data are sometimes referred to as *discrete variables*, whereas those containing interval or ratio data are sometimes referred to as *continuous data* (Somekh, 2005). In this study, the data will be obtained mainly from ordinal levels of measurement. The participants will be selecting figures from a range of response options on an ordinal scale to rate their agreement with the statements in the questionnaire.

Data collection

The commonly used data collection methods for studies of such nature are as follow:

- **Historical archive analysis:** The archival sources are used in many research projects. The researcher may intend to make the data public at the appropriate time or keep them as internal records. While access to the first group is always convenient, the second group is also accessible in some instances. Archival data are unbiased because the provider is unaware of how they will be used in subsequent studies. However, the user's lack of control on the data collection environment may be a limitation for using this kind of data. This method may be used in conjunction with a survey or panel study (Flynn, 1990).
- **Participant observation:** This method is frequently used in case studies for observing the participants of the study and recording their behaviour or their manner of doing things (Flynn, 1990; Cassel and Symon, 2004).
- **Outside observation:** This involves collecting data in a systematic manner, for example, by employing an unbiased observer. This method is suitable for both case studies and panel studies.
- **Content analysis:** Sometimes referred to as document analysis, this method deals with the systematic study of records or documents as sources of data (Singh, 2006). It is based on transforming the often qualitative, open-ended survey responses into quantitative data. This may involve developing coding procedures, establishing the reliability of the coding procedures, and developing careful data screening and cleaning procedures (Marczyk, 2005).
- **Interviews:** This method is based on collecting data through conversations with the participants while focusing on study-related topics. The following list includes some modifications to the simple interview method:

  i) Structured interview: The interviewer asks questions from a written form as well as new questions based on the direction taken by the conversation.

ii) Ethnographic interview: In this case, a hierarchy of questions is asked, and the next question is selected according to the previous responses. An interview using transcriptions adds value to the work. However, even though the transcripts can be used for further analyses, many interviewees do not like to be taped.

iii) Face-to-face CAPI: Computer-assisted personal interviewing (CAPI) involves the use of a portable computer; the questions and pre-codes are provided on the computer screen. The computer can be either a tablet computer with a touch screen, on which participants can record their responses by using a stylus, or laptop personal computers, wherein answers can be recorded by clicking the cursor on the appropriate box. Laptops may have multimedia capabilities. In central locations, desktop personal computers may be used. Personal digital assistants (PDAs) can be used in circumstances where the number of questions is relatively small (PDAs have also been used successfully as a self-completion medium). In computer-assisted telephone interviewing (CATI), the telephone is used instead of face-to-face interviews (Brace, 2004). The advantages and disadvantages of different interviewing media are summarised in Table 2.1:

Table 2.1 A comparison of face-to-face and telephone interviews (Brace, 2004)

Face-to-face interviews		Telephone Interwies	
Advantages	**Disadvantages**	**Advantages**	**Disadvantages**
-Response cards can be shown **-Stimulus materials can be shown** **More complex questions can be asked**	**-Self-presentation bias** **-Selection bias** **-Tird party bias**	**-Relative anonimity can reduce bias**	**- to use prompts** **- It is difficult to show stimulus material**

- **Questionnaires:** Questionnaires or rating scales are established methodologies used in research studies. Since it was decided to use the questionnaire method in this study, this type of data collection method will be explained in further detail in this chapter.

  Questionnaires and interviews are the most commonly used data collection methods. The key difference between them is that in the former, the respondent records the responses directly, while in the latter, the interviewer completes the questionnaire on the basis of the verbal answers of the respondent. With regard to the time, cost and logistic issues, questionnaire techniques are more appropriate for collecting a high volume of data or data from geographically dispersed participants. This method is also recommended when the sample population is oriented to this methodology (Trochim, 2002).

  A number of approaches for data collection methods are available while using rating scales. These are briefly described below:

  - ***Paper or electronic-mail-delivered questionnaire*** - For this method, a printed questionnaire is mailed to the participants, and they are asked to complete it at a convenient time.

    Advantages: The benefits of this method are that it requires only a modest amount of resources, the wishes of the study participants with respect to confidentiality and anonymity can be respected and the cost is low, especially if electronic methods are applied.

    Limitations: Administering questionnaires in this manner is time-consuming, and it is necessary to perform a follow-up in order to improve response rate and reduce bias; these are the main limitations of delivering questionnaires by mail. In addition, there is limited scope for routing the respondent to the appropriate next question (on the basis of their response to the previous question).

- ***Group administered questionnaire*** - Under this method, a group of participants are gathered together and asked to complete the questionnaire individually.

- ***Telephone administered questionnaire*** - This involves organising telephone interviews for data collection. The participants are telephoned according to an agreed time schedule. It is also possible to use an automated system for administering the questionnaire, where the users are connected to a computer-based interview system.
- ***Web-based questionnaire*** - This method has become more prevalent in recent years due to the developments in Web-based communications. Its strengths include faster data collection, cost benefits and the fact that the participants can reply at a flexible and convenient time; however, the participants must have access to computers and the Internet—this is the main limitation of this method. There are several different ways of carrying out surveys using the Internet. The questionnaire can either be delivered by e-mail or accessed via a Web page, either in the form of an *Open Web*—a Web site open to anyone who visits it or *a Closed Web*—wherein participants are invited to visit a specific Web site to complete a questionnaire. Other kinds of Web-based methods include the *e-mail URL embedded questionnaire*, where a respondent is invited to the data collection media survey site through an e-mail that contains a URL or Web address on which the respondent clicks, the *simple e-mail*, or an e-mail with questions contained in it, and an *e-mail attachment*, in which the questionnaire is sent in the form of an attachment to an e-mail. The participants also receive directions on how to download the questionnaire, complete it and then return it. However, questionnaires embedded within e-mails can have distorted layouts, depending on the e-mail software used to open them. Most practitioners now use questionnaires hosted on a Web site to which participants are invited or routed in some ways (Brace, 2004). The summary of the characteristics of interviews and self-completion methods is presented in Table 2.2:

Some studies may require the application of more than one method, for example, a study may use a combination of questionnaires, structured interviews and archival financial data (Flynn, 1990).

For this study a mixture of data collection methods will be used including the structured interview, as a part of the Delphi technique, and the development of rating scales in the format of e-mail attachments or closed web-based instruments.

Table 2.2 A comparison of interviewer-administered and self-completion questionnaires

	Interviewer-administered		**Self-administered**	
	Paper	Electronic	Paper	Electronic
Advantages	-Flexible -Inexpensive to set up	Allows complex routing; can route questions and responses, builds links between questions, uses advanced stimuli (face-to-face), no data entry and fast analysis.	-Flexible -Wide reaching	Allows complex routing, can route questions and responses, builds links between questions, uses advances stimuli, no data entry and fast analysis.
Disadvantages	-Requires data entry -Limited routing	Can be slow to set up, Software skills are needed for CAPI and CATI questionnaires.	Require high quality design, respondents can read through, spontaneous measures and limited circulation.	Requires high respondents commitments, response rate is low and questionnaire layout may be distorted.

Source: (Brace, 2004)

Data collection procedure

A confidential procedure will be used for data collection in this study. An identifier will be used to mark the participants in the Delphi technique in order to secure the traceability of the responses during different steps of the technique, as will be described in next chapters. The same policy will be followed in chapters 5, 6 and 7, when collecting data from the industry managers, considering the sensitivity of the collected data pertaining to the current situation in the companies. However, the confidentiality procedure will not be applied for collecting the data during the content validation steps in chapters 3 and 5 due to the purely linguistic nature of the data.

Information sources

The data required for carrying out this study will be sought from the following sources for each chapter:

- Chapter 3: Eleven experts will act as panel members in the first round of the Delphi technique
- Chapter 3: Eight experts will form the content validation panel for validating the Delphi technique questionnaire
- Chapter 4: Eighteen experts will be consulted in the second round of the Delphi technique in order to identify the influencing parameters of the study
- Chapter 5: Eighteen experts will perform content validation of the study instrument
- Chapter 6: A total of 109 managers from 25 pharmaceutical companies will be invited to evaluate the current situation and future aspirations of the pharmaceutical industry. The data will be used for further analysis in chapters seven and eight.

Development of the Study Instrument

In the absence of a suitable instrument, a questionnaire to identify the parameters influencing the sustainability of the industry in the post-WTO situation will be developed

to accommodate the use of the Delphi technique. In addition, an instrument will be developed to evaluate the current environment and future aspirations of the industry.

The major limitation pertaining to questionnaires is the complexity of generating a set of unambiguous items. Researchers often need to perform a pilot study or apply other techniques to ensure the validity of the questionnaire. Therefore, formulating a questionnaire is an important step towards reliable data collection. Good questionnaire design is a no- or low-cost option in any study, which reaps major benefits by delivering the best, or most accurate, responses (Brace, 2004). However, the real importance of creating a good questionnaire is often underestimated. After all, anybody can write a set of questions, 'but if those questions are the wrong questions, poorly phrased, or in the wrong order, the answers obtained may be worse than meaningless or at best misleading' (Brace, 2004).

In order to develop a robust study instrument, it is crucial to observe the following guidelines (Falconer, 2001):

- Declare the aim of the study and introduce who is administering the study
- State the confidentiality and/or anonymity of the participants
- Provide instructions for completing and returning the questionnaire
- Ask the appropriate number of questions
- Ask one item per question
- Ensure the linguistic clarity and completeness of the questions (use of appropriate wording)
- Offer incentives for efficient participation.

The present study used a multi-source and multi-stage process to develop the study instruments.

Step 1 – Conceptualisation

The instrument should be developed based on the age, population and characteristics of the study participants. Questions such as; do they require a simple and

straightforward tool or; do they have the necessary motivation and expertise to participate in a more technical and complicated data collection procedure were considered. In other words, a self-administered tool may be completed in five minutes, while an interview requires more active participation. In the population selection step, data can be obtained from individuals at the individual level. The target population that the instrument is intended for should be the determinants of the underlying concepts of the measuring instrument.

Step 2 - Item generation

This step involves probing the target audience in order to generate an initial pool of items reflecting the views of individual members of target population (Clark and Watson, 1995). Item generation may be continued until a saturation point is reached. It is also possible to borrow some items from existing instruments. The sample size may be fixed at this stage. The first round of the Delphi technique, which is characterised by open-ended questions, may be considered as the item generation phase in this study.

Step 3 - Item reduction

This step involves deciding if an item can be removed from the initial pool, based on the importance or priority of the generated items. This study will use the Friedman ranking method to prioritise the items.

Step 4 - Development of taxonomy

This includes generating a list of areas under which headings the items can be grouped and thereby categorised. In this study, the items were grouped based on their structure, content and context or according to industry departments such as R&D, marketing, and Good Manufacturing Practices (GMP).

Step 5 - Scale development

Selecting appropriate scale plays an essential role in determining the quality of the collected data and the sophistication of the data analysis. Since this study was based on the degree to which the participants agree with the statements provided by the study instruments, the *Likert scale* will be considered to be suitable for the study. This scale,

which is known as an 'agree–disagree' scale, is frequently used and is suitable for measuring intervals. Moreover, the data collected by using this scale can be easily analysed. The response options can be simply and flexibly arranged and their summated values can be obtained to measure a general construct. It should be mentioned that the study participants may tend to quietly mark the same response for each item; to deal with this, the direction of the questions may be changed thorough the questions (Flynn, 1990). The Likert scale was first published by the psychologist Rensis Likert in 1932. The scale presents respondents with a series of attitude dimensions, and they are asked whether, and how strongly, they agree or disagree with each of those dimensions, using one of a number of positions on a five-point scale (Brace, 2004). The nine-point Likert scale is also widely used, in which 1 shows strong disagreement and 9 shows strong agreement. While most researchers use Likert scales varying from three to seven points, the shorter scales give little scope to the study participants if they want to modify their responses during the study (Mead and Moseley, 2001; Linstone, 2002).

Whether to use an odd or even number of response options is an important issue in scale development. Some researchers prefer to use a scale with an even number of points to eliminate the neutral mid-point in an attempt to force those who would otherwise choose it to give an inclination one way or the other. In studies where it is expected that most people would have a view on a particular topic, for example, studies about an important social issue or a criminal action, it can be argued that most people hold an opinion even if they are unaware of doing so. It is therefore reasonable for a researcher to force a response in one direction or the other. Studies have shown, though, that including a neutral scale position significantly increases the number of neutral responses compared to accepting them spontaneously. This indicates that eliminating the middle neutral point does increase the commitment of respondents to be either positive or negative (Brace, 2004).

Psychometric evaluation of the study instruments

Psychometric evaluation involves assessing a number of measurement properties of an instrument. The psychometric properties assessed in this study will include applicability and acceptability, practicality, validity, reliability and sensitivity or responsiveness.

Applicability and acceptability for use

The applicability of the study instrument describes the suitability of an instrument for its intended use in terms of wording, linguistic clarity and simplicity (Higginson and Carr, 2001). It also assesses whether the content and emphasis of the measure fits the intended purpose of developing the instrument (Deyo, 1984). Another important criterion is how acceptable the study instrument is to the participants and whether they are comfortable answering the questions. It is also necessary to consider the instrument completion time and whether the questions are concise, clear and easy to understand (McLeod, 2008).

Practicality

The practicality of the study instrument includes the respondent burden, cost of administration, mode of administration of the instrument (e.g. interviews or self-administered questionnaires), ease of scoring and whether the instrument is understandable (Deyo, 1984). The indicators of respondent burden include high refusal rates, missing responses and high administration time (Ware, 1981).

Validity

Validity measures two things: First, does the instrument measure what it has been designed to measure? Second, does it measure anything else? For an instrument that is suitable for use in a research study, the response to both these questions must be positive (Flynn, 1990 and Lunenburg, 2008). There are three main types of validity:

Content validity: This is the degree to which an instrument measures an intended content area ensuring that the focus and emphasis of the instrument as a whole and its individual components are fit for the purpose for the intended area and respective population. This type of validity is very important in testing instruments. Content validity of an instrument is normally established based on the judgment of a panel of experts. This method will be used in the chapters 3 and 5 of this study.

Criterion validity: There are two types of criterion validity—*concurrent validity* shows the correlation between the results of two tests when both tests are administered at roughly the same time, while *predictive validity* is the ability of the test to predict how the individuals will perform in the future. This is especially important in cases where people are seeking admission to colleges or have applied for jobs. Criterion validity is often not carried out because of the resource limitations.

Construct validity: This is a very important form of validity because it evaluates what the instrument is really measuring. It justifies the use of the instrument in the research study and should ideally be evaluated by a series of studies due to the complexity of measuring the construct (Lunenburg, 2008). Factor analysis can also be used in establishing construct validity (Flynn, 1990).
A detailed content validation of the study instrument will be carried out and reported in the respective chapters.

Reliability

Reliability is measured by the extent to which a questionnaire or item which is repeatedly administered to a particular group will yield the same results (Flynn, 1990; Marczyk, 2005 and Lunenburg, 2008).

Test-retest reliability: This shows the extent to which the results of an instrument are consistent over time. Test-retest reliability can be determined from the correlation coefficient of the results of administering the instrument to a group of people twice, with an interval of one week (seven days) between the administrations.

Equivalent-form reliability: Equivalent forms are two instruments that are identical in all respects except for the actual items included in them. The correlation coefficient of the results of administering two equivalent forms of an instrument to a group of people indicates the degree of equivalent form reliability.

Inter-rater reliability: This is a type of inter-judge reliability which is often carried out for interviewer administered instruments and can be calculated by using correlation techniques. It also can be expressed as a percentage of agreement between the raters when they are observing or evaluating the performance of others (Marczyk, 2005).

Internal consistency reliability: This is a commonly used form of reliability, and there are different approaches to measure it:

i) **Cronbach's alpha reliability:** This method estimates the instrument's internal consistency reliability by determining how all the items in an instrument relate to one another and to the total instrument (UCLA.edu, 2009).

ii) **Intra-class correlation coefficient (ICC):** This test is a reliability index to assess the extent to which the ratings or classifications of an instrument are made on a consistent basis. ICC results of 0.61–0.8 illustrate substantial consistency, and any result exceeding 0.81 indicates near-perfect reliability (Futrell, 1995). ICC can be measured by using statistical software such as SPSS, and the equation to calculate the coefficient correlation is the same as that used to calculate Cronbach's alpha. The ICC interpretation guide is presented in Table 2.3:

Table 2.3 Interpretation of ICC values

Kappa or ICC	Interpretation
< 0	No agreement
0.0 — 0.20	Slight agreement
0.21 — 0.40	Fair agreement
0.41 — 0.60	Moderate agreement
0.61 — 0.80	Substantial agreement
0.81 — 1.00	Almost perfect agreement

iii) **Split-half reliability:** In order to measure split-half reliability, a single instrument is first split into two halves, such as items with odd and even numbers, and then the complete form as well as the halves are administered to a group. The correlation coefficient between the results indicates the split-half reliability (Lunenburg, 2008).

ICC will be used in this study to measure the consensus among the experts, while Cronbach's alpha will be used to test the reliability of the data.

Sensitivity

Sensitivity assesses the ability of the instrument to measure change over time (Higginson and Carr, 2001, McLeod, 2008). Study instruments that are designed to measure the differences between different groups of people are called discriminative instruments, while those designed to examine change over time are known as evaluative instruments (Guyatt, 1987).

Pilot study

A pilot test is an essential part of questionnaire development as it provides a practical understanding of how easy it is for the participants to complete the questionnaire and helps to identify the parts of the questionnaire that are vague, unclear or beyond the speciality or expertise of the participants. A pilot study is expected to provide answers to the following questions: Do the questions sound right? Do the interviewers understand the questions? Do the participants understand the questions? Have we included any ambiguous questions? Can the participants answer the questions? How long does the interview take or what is the completion time? (Brace, 2004). The procedure includes administering the developed version of the questionnaire to a small, typical group of participants, based on their availability and readiness. It may be concluded after the pilot study when the questionnaire needs some revision in order to make it more user-friendly. If the pilot study indicates that the questionnaire contains confusing items, it may be necessary to arrange an explanatory session prior to administrating the questionnaire to the intended study participants (Flynn, 1990).

Data Processing and Analysis

Data processing

It is important to carefully examine all the data obtained through data collection instruments in order to prevent data analysis errors. Incomplete or blank items, handwritten comments and inappropriate responses should be dealt with using standardised techniques.

Data processing and analysis in this study will be carried out using Microsoft Excel and SPSS version 17. Descriptive statistics such as mean, median, ranges and frequency charts will be used for quantitative data, with content analysis being performed to identify the major themes. The respective chapters will use descriptive tables and bar charts in order to illustrate the key characteristics of data distribution. One of the most difficult tasks in analysing data consists of selecting the most appropriate statistical technique that both addresses the research question and fits the data that have been collected.

Generating and testing the hypothesis

Hypothesis testing implies testing a theory that is accepted to be true or regarded as a basis for discussion. A hypothesis is the re-articulation of a research question (grounded in theory and/or literature) to form a precise statement, which may include the prediction of an outcome, in such a manner that it can be tested statistically (Somekh, 2005). In either case, two competing hypotheses are examined: the null hypothesis, denoted as H_0, and the alternative hypothesis, denoted as H_1.

The null hypothesis is regarded as the focal point and relates to the statement being tested, whereas the alternative hypothesis relates to the statement that will be accepted if or when the null hypothesis is rejected. The testing procedure begins with the assumption that the null hypothesis is true, and the aim of the process is to determine whether there is enough evidence to infer that the alternative hypothesis is true (keller, 2007).

If the value of the sample significantly differs from the expectation based on the null hypothesis, the null hypothesis will be rejected and the alternative hypothesis will be accepted. To evaluate the significance of the difference, it is possible to apply decision-making techniques such as t-distribution, p-value and critical value (Brenson, 2009). Two possible errors can occur while testing the hypothesis: A type I error occurs if a true null hypothesis is rejected, while a type II error involves failing to reject a false null hypothesis. The probabilities of type I and type II errors are denoted by α (which is also called the significance level) and β, respectively (keller, 2007)

Statistical analysis

Inferential statistics is defined as using the results of a small group (study sample) to make a conclusion about a larger population (Brenson, 2009). Statistical methods are divided into two main types: *parametric* and *non-parametric*.

Parametric statistics are based on the principles of the normal distribution curve. Therefore, in order to be able to use parametric statistics, the data must be normally distributed as one of its main required assumptions. The required sample sizes can vary according to the kind of research enquiry and respective statistical test; a general rule-of-thumb is to take a minimum sample of about 30. However, with the samples of less than 30, it is often better to use non-parametric statistics (Marczyk, 2005). Non-parametric tests are applied to non-normally distributed data (Motulsky, 1995). In identifying differences between groups (i.e. to understand if the differences between several groups are real or have occurred by chance), researchers use statistical tests that target differences and then use methods of calculating the statistical significance of those differences. Parametric techniques for identifying differences include the t-test (when there are only two groups) and the ANOVA (when there are more than two groups) (Marczyk, 2005).
Non-parametric techniques for identifying differences include the Mann-Whitney U test (the nonparametric equivalent of the independent sample t-test) and the Wilcoxon signed-rank test (the nonparametric equivalent of the paired sample t-test).

Non-parametric tests are more robust but less sensitive. They are sometimes referred to as assumption-free tests, and their techniques are based on ranking rather than exact differences. Non-parametric tests are appropriate for ordinal and nominal data. They can also be used when the necessary assumptions for parametric tests are not in place (e.g. absence of a normally distributed data set) (Somekh, 2005).

Statistical tests

This study will use the Friedman test and the binomial test, which are appropriate for ordinal data. This selection is based on the measurement levels and types of data as explained earlier in this chapter.

a) **Friedman test**

The Friedman test is a nonparametric test that compares three or more groups. This test is an alternative for the repeated measures ANOVA when normal distribution cannot be demonstrated. In this study, Friedman test will be used to rank the identified parameters in chapters four and six.

b) **Binomial test**

The binomial test is used with dichotomous data when each item in the sample is classified in one of two categories; it is used to find out whether the distribution of the items in each category is produced by chance or is the result of some pre-specified probabilities (Brenson, 2009). This test will be used in chapter six to evaluate the level of "satisfaction" or "importance" of the study parameters.

Gap analysis, a simple approach for prioritising improvement areas

The study of the gap plays an essential role in analysing the situation of the pharmaceutical industry in this research. The gap will be simply measured by subtracting the scores pertaining to the current situation from the future importance of the respective parameter. The questionnaire for this purpose will be designed with a rating scale investigating both the current situation and the future importance of each parameter. By the participants being questioned about both the present and the future, it will be possible to rank the potential areas for improvement in relation to the

importance of that parameter. It is expected that this gap will be filled by actions and corrections in order to reach the desirable condition.

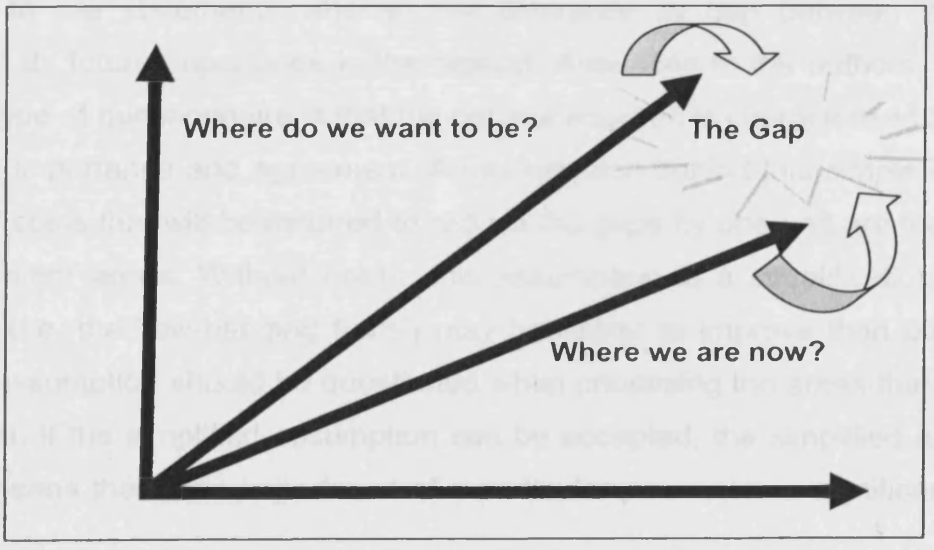
Gap analysis is the study of the existing distance between the current and the desirable situation and has been widely recognised as an appropriate method to analyse the situation when there is an intention to move from a starting point towards a desirable state. In fact, gap analysis is a very useful tool for helping industry managers and policy makers decide about the strategies they should follow. In later stages, the aim is to look at ways to bridge the gap by backward-chaining logical sequences of actions from the target state to the current state. This implies that the following questions should be answered in a gap analysis process (Figure 2.3):

What (b) must be in place, or must have happened, in order that this desired state (a) can exist?

Then, *what (c) must be in place, or must have happened, in order that this state (b) can exist?*

For analysing the gap, it becomes necessary to answer two questions: *Where are we now?* Where *do we want to be?* The gap is in essence, the difference between these two situations. The main question is how to overcome the gap and reach the target state. As shown in Figure 2.3 the lower line represents where a person will be if he or she does nothing. The upper line is where the person wants to be.

Figure 2.3 The concept of gap analysis



The next step is to close the gap. In general, strategies and tactics are targeted at closing the gap.

Another way to describe the gap is to measure the distance between two situations. In this method, each item can be evaluated in terms of its current and desirable situations by using a nominal scale. For example, the R&D budget at present and in the future may show a big or small gap throughout the industry. The extent of this gap may be different between companies, and companies may follow a special pattern in their different aspects. This leads to the recognition of a relative or comparative gap which reveals the differences in achievements in similar items and, needless to say, reflects the sustainability of single company as well as the entire industry in the future and identifies the high payback areas of improvement.

In addition, gap analysis provides a basis for comparing all items based on the extent of the gap. For instance, if the gap in GMP is bigger than the R&D budget, it may indicate the need for greater focus on the former item. The same argument is applicable to all the other areas of the pharmaceutical industry.

By asking the participants about both the current situation and its future importance, it is possible to rank the potential areas for improvements in accordance with the participants' perceptions of importance. This idea has been explained in detail by Dahlgaard-Park and Dahlgaard (2010) in 'Organisational Learnability and Innovability: a system for assessing, diagnosing and improving innovations'. The most important areas are related to the statements wherein the difference or gap between the current situation and its future importance is the highest. According to the authors, the theory behind this type of questionnaire is that the optimal situation is characterised by equality between the importance and agreement. An assumption behind this simple rule is that the marginal costs that will be incurred to reduce the gaps by one unit are the same for all the statement areas. Without doubt, this assumption is a simplification, because some areas (i.e. the 'low-hanging fruits') may be easier to improve than other areas. Hence, this assumption should be questioned when prioritising the areas that should be improved first. If the simplified assumption can be accepted, the simplified rule can be used. This means that if the importance of a particular parameter is significantly higher

than its current situation, the area should be improved. However, in some cases, the agreement measurements may be higher than the importance attributed to the parameters because the respondent believes that the company is investing in an area that is likely to have less importance in the future. It may be also a sign that the respondent has not really understood the importance of the statement or has over-estimated the current situation.

By using this simple approach, the gaps between various parameters will be analysed and the biggest gaps regarded as the participants' indications of where to begin the improvement process. Therefore, the first step in the simple approach is to rank the statements according to the size of the gaps (Dahlgaard-Park and Dahlgaard, 2010).

Measuring the opportunity score to recognise under-served areas

Measuring the opportunity score turns the study of the gap into a future-driven approach which enables the companies to reinvent themselves by exploring areas of opportunity. This refers to identifying the under-served areas which will be important in the future. These areas represent improvement opportunities, and if the right strategies are pursued, the opportunity is realised. To find growth opportunities, the industry must be able to determine how the importance of the parameters is likely to change with time and with respect to their abilities and potentials. This is only possible if they are actually able to determine the future importance of the current gap and identify which dimensions of the industry represent the greatest opportunity for improvement.

Ulwick (2009) explains that an opportunity exists when there is an important need that is not well-satisfied. The more important the need is, and the less satisfied the customers are, the greater is the opportunity for value creation.

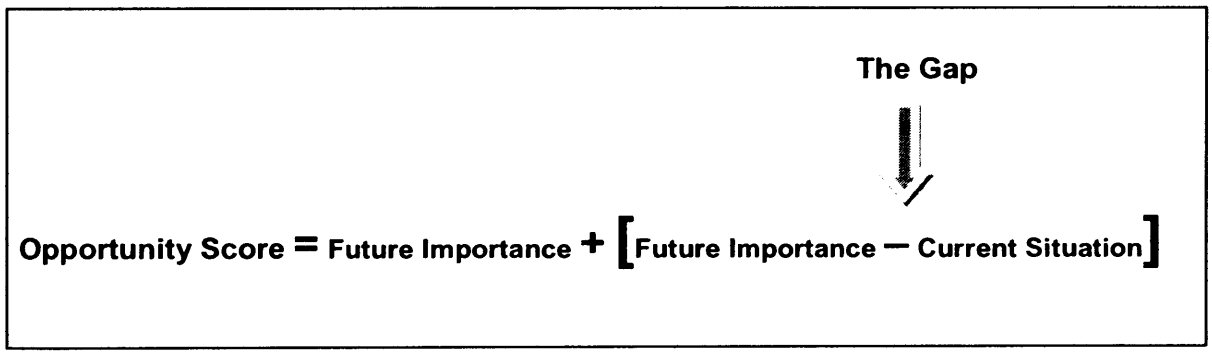
In a future-driven approach, the areas of opportunity are defined as under-served areas that will be important in the future but are not in a good condition at present. These under-served areas represent those measures of industry performance that need to be improved in the future. On the contrary, the areas that are likely to be unimportant

and/or are already satisfied represent little opportunity for improvement and consequently should not receive any resource allocation.

If it turns out that 'GMP and QA' is an important and unsatisfied area, then the future requires and would value a company that will improve this area more effectively. This opportunity area often goes unexplored and yet offers tremendous growth potential.

Using the future-driven approach rather than normal gap analysis or ranking parameters on the basis of their current situation or future importance in order to define where opportunities lie, provides companies with more reliable measures with which they can prepare for the future.
The opportunity algorithm is based on adding the future importance to the normal gap, as is illustrated in the equation given below (Figure 2.4).

Figure 2.4 The equation to calculate the opportunity score



If a statement is rated 8 in terms of importance and 4 in terms of satisfaction (out of a possible 10, where 10 represents the highest score), its opportunity score would be [8 + (8 – 4)] or 12. A statement with an importance of 7 and a satisfaction of 5, however, would have an opportunity score of [7 + (7 – 5)] or 9—a much less attractive target for improvement. Using this formula, the needs that are most important and least satisfied receive the highest priority. This algorithm has been used to explore unmet customer needs in order to identify value-creation areas for companies (Ulwick, 2002; Strategyn

Inc., 2004). This algorithm has also been used to explain outcome-driven innovation (Ulwick, 2007).

Introducing the (PIR) index as an indicator of pharmaceutical industry readiness

This part of the study will introduce a method for measuring the performance of the pharmaceutical industry in order to attain sufficient readiness for the post-WTO situation. This measure is called the Pharmaceutical Industry Readiness index or the 'PIR index'. The PIR index has values between zero and one, and the nearer the measure is to one, the better is the industry's performance in that area. In contrast, a low measure indicates that the performance of the industry in that area is poor and needs improvement.

To calculate the PIR index, the ratio of average scores of the current situation and its future importance is measured. For a statement with the current situation average of 7 and future importance of 8, the PIR index will be 7/8 or 0.875. To cite another example, a statement with the current situation average of 5 and future importance of 9 will have a PIR index of 5/9 or 0.555, which is obviously lower than the previous example and indicates that the area covered by this statement needs more development.

The examples presented below reveal the simple logic behind this measure: in optimal conditions, the averages of the current situation and its future importance are equal, and the index value will be 1.0. Conversely, in the worst-case scenario, the current situation may receive an average of zero against an importance average of 10, which will result in a PIR index value of 0 (zero). A PIR index of 1.0 indicates that the industry has excellent performance in that area, and zero indicates that the industry has done nothing to improve a very important area.

If the average current situation score is higher than that of the future importance, the PIR index may be misleading; hence, it is suggested that these results be removed from the calculations. This problem also occurs in gap analysis and, as explained before in this chapter, is mainly due to over-estimating the situation or under-estimating the parameter's importance.

The PIR index can be calculated for all areas that will be included in the Pharmaceutical Industry Transitional Instrument (PITI). It is possible to calculate the PIR index for all the

areas of pharmaceutical development, after which their average will provide the index for the related area. The average index for all the areas will result in the total index. It is also possible to use the average of the scores of each area or the total average of all the areas for measuring the index of the related areas or total index. The assumption behind this calculation is that all the areas have the same importance and for this reason, they should carry equal weight when calculating the scores for the area or total index. If the assumption of equal weights for areas or the activities is not valid, then it should be decided what weight be given to them.

In this study, the weights of all pharmaceutical areas, activities will be assumed to be equal. Thus it would be possible to calculate the index for the areas or activities. The basis for this argument is that the origin of the PITI statements can be traced back a long way from the Delphi technique for pooling the opinions of experts for the pilot testing of the instrument for exploring the importance and relevance of the articulated statements in such a manner that we can finally claim that all important criterions are included and conversely, that the irrelevant issues are excluded from the instrument.

It should be noted that the managers of companies can calculate this index in order to determine their readiness for the post-WTO situation. In the event that the indices of different companies need to be compared, it would be necessary to use a harmonised scoring procedure. However, the PIR index is a strong tool for internal benchmarking, prioritising company goals and deciding improvement plans.

SUMMARY

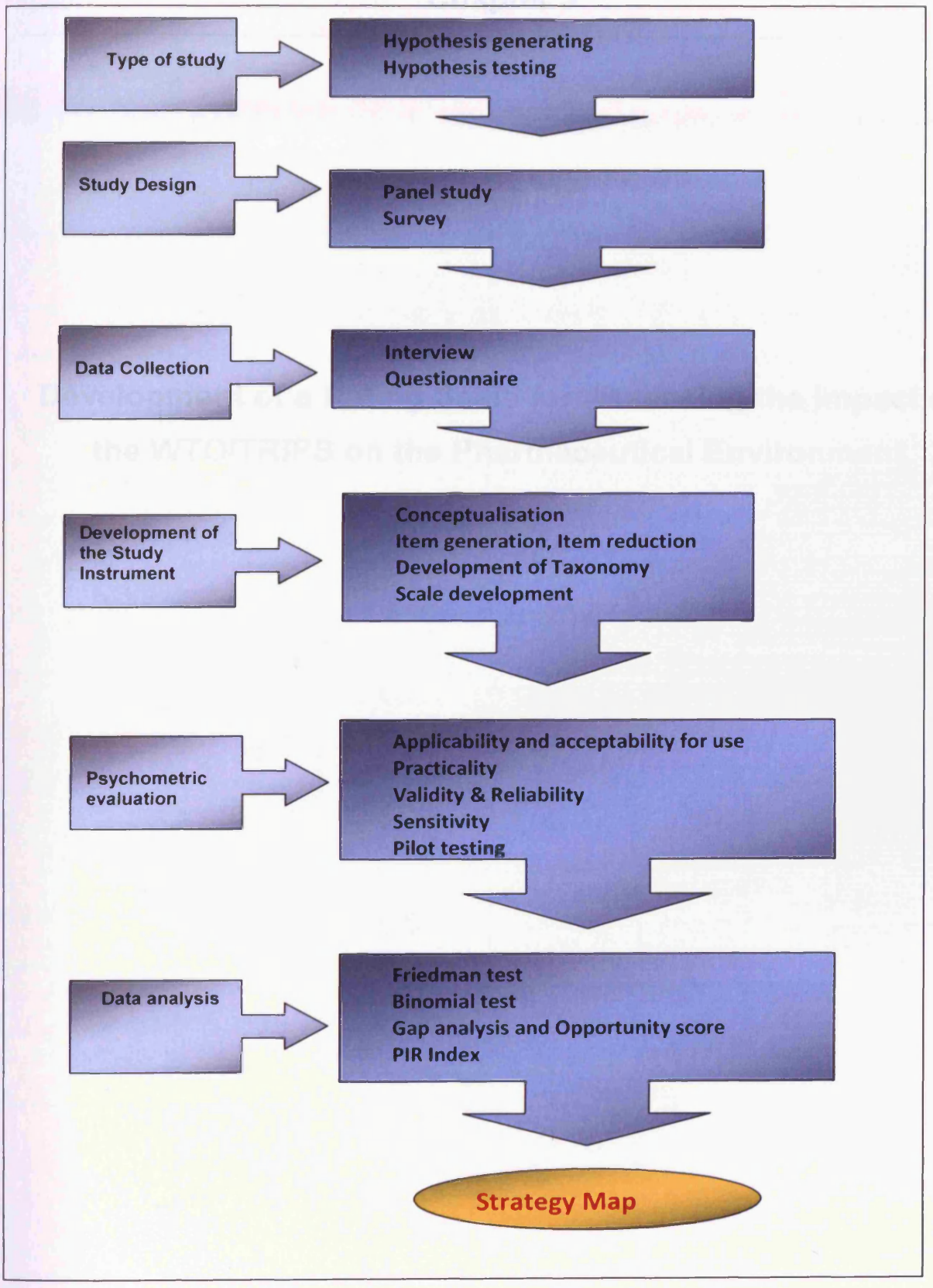
- This study aims to identify the impacts of WTO/TRIPS on the pharmaceutical industry; for this, a group of experts will be selected according to the Delphi technique and their opinions will be pooled together through structured interviews. The collected ideas will thereafter be used to design a questionnaire for the second round of the Delphi technique. The identified parameters will be used to develop the Pharmaceutical Industry Transition Instrument (PITI) in order to collect data from the pharmaceutical industry

- Two instruments will be developed, tested and applied for data collection in this study. The steps of item generation, item reduction, development of taxonomy and scale development will be followed while developing the study instruments
- Psychometric evaluation of the developed instruments will be also carried out. The validity and reliability of the instruments will be tested using a content validation procedure, and the reliability of the collected data will be examined by calculating either ICC or Cronbach's alpha
- The PITI will be also evaluated for applicability, acceptability and practicality, which will be determined on the basis of a pilot study
- Data processing and analysis will be carried out using Microsoft Access, Microsoft Excel and SPSS. While the mean, median and standard deviation will be used for the quantitative data, statistical analysis will be performed by applying the binomial test and Friedman test
- Thereafter, gap analysis and evaluation of development opportunities will be performed, which will be continued by introducing an index for assessing the readiness of the pharmaceutical industry (the PIR index) for the post-WTO/TRIPS situation

- The study will conclude with the development of a strategy map based on the results and conclusions of the previous steps of the study.

The methodological aspects considered in this study are presented in Figure 2.5.

Figure 2.5 Methodological structure of the study



Chapter 3

Development of a Rating Scale for Assessing the Impact of the WTO/TRIPS on the Pharmaceutical Environment

INTRODUCTION

Over the last few decades, joining the WTO and implementing TRIPS regulations have had a dramatic impact on the pharmaceutical industry. These changes have been particularly significant for the pharmaceutical industry because of its dependence on innovative products and technologies at the cutting edge of human knowledge. In many situations, the local industries receive a significant amount of protection owing to high importation tariffs. In other words, joining the WTO will have a major negative impact on an unprepared local pharmaceutical industry, which in turn is likely to have tremendous socioeconomic consequences. To address such a complicated issue, it is important to take into consideration the opinions of experienced and informed people in different fields associated with the pharmaceutical industry.

A systematic literature review has demonstrated the lack of this kind of study. Before commencing such a project, it was necessary to design an instrument to measure the parameters that would be considered by such a study. This chapter focuses on collecting the ideas of experts for designing and validating a rating scale that can be used for measuring the study parameters, which will be described in the next chapter.

OBJECTIVES

The objectives of this chapter were to:

- Identify the factors that influence the pharmaceutical industry in the post-WTO situation
- Develop a rating scale for generating experts' consensus for the identified factors
- Establish content validity for the developed rating scale.

METHODS

This study applied the consensus-based Delphi technique in order to generate expert opinions regarding the impact of trade liberalisation and international intellectual property rights protection on the Iranian pharmaceutical industry. The process was initiated by a semi-structured interview, followed by two rounds of self-reported questionnaire administration using the Delphi technique. The following practical steps were carried out in this process:

- Selection of expert participants
- Conducting a semi-structured interview with the experts (first round of the Delphi technique)
- Analysis of the interview contents and preparation of the preliminary list of study factors
- Preparation of the rating scale
- Content validation of the rating scale.

Study Participants

Phase1. Delphi technique

Regarding the methodology of the Delphi technique, it is very important to ensure that the study participants consist of experts with an in-depth knowledge and vision of the field and that they are able to offer a substantial variety of viewpoints (Meyrick, 2003). Based on this fundamental guideline, the present study included 30 experts divided into three groups namely academicians, industry representatives and regulatory officials (8, 13 and 9 respectively). Finally a group of 11 experts was selected based on their qualifications, familiarity with the topic, availability and willingness to cooperate (with 3, 4 and 4 experts from each of the groups mentioned above, respectively). The inclusion factors for all experts were minimum 10 years of experience in their field of activity with

good knowledge of pharmaceutical practice and drug development. The interviews were continued until a consensus was reached.

Phase 2. Content validation

A group of content validation experts was selected, including eight linguistic experts from CMR International and the British Council in Tehran to validate the content of the rating scale. The first inclusion factor was fluency in the English language and the second one was familiarity with the research area.

Data Collection

Phase 1. Interviewing the study participants for developing the rating scale

According to the work flow of the Delphi technique presented in chapter 2, all panel members participated in separate interviews as a part of the item-generation phase. The participants were asked the following questions:

> *As you know, the environment of the pharmaceutical industry practice in Iran is characterised by relatively high importation tariffs with limited or no patent protection law, which are contrary to the WTO and TRIPS regulations. In view of the accession procedure towards full membership by 2016, what will be the impact on the sustainability of the Iranian pharmaceutical industry? Which parts of the industry are more susceptible to negative impacts?*
>
> *How can these negative effects be prevented?*

The panel members were asked to consider all industry aspects when responding to these questions, including the following aspects:

- Hardware, equipment and facilities
- Software, management and human resources
- Regulatory environment and key players in society

These three groups of parameters were later labelled as structure, content and context, respectively. All the interviews with experts were recorded and their contents were analysed in order to prepare the list of study parameters.

Phase 2. Data for content validation of the instrument

A special rating form was designed for this group of experts, which enabled them to rate their agreement on the validity of each statement with regard to the following criteria:

Linguistic Clarity: The item should be clear, unambiguous, jargon-free and elicit a spontaneous rather than a delayed response after some reflection.

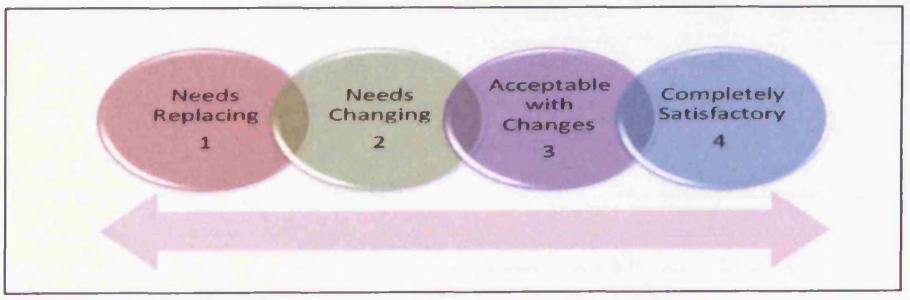
Completeness: The sentences pertaining to each item should be complete and should clearly articulate the underlying concept, with emphasis in the right places.

Relevance: The item should be relevant to the area of study and focus on what needs to be measured.

Scoring: The response options on the rating scale (ranging from 1 strongly disagree to 9 for strongly agree) and its anchors should fit the item's sentence structure and phrasing.

The content validation experts were asked to indicate their opinions regarding each statement based on the four criteria of linguistic clarity, completeness, relevance and scoring as follows: 1 for 'completely satisfactory', 2 for 'acceptable with changes', 3 for 'needs changing' and 4 for 'needs replacing'. These options are presented in Figure 3.1.

Figure 3.1 Response options for the content validation experts



The content validation experts were also asked for their suggestions at the end of each statement. The content validation procedure was performed in two steps. In the first step, the opinions of the content validation experts were collected; after modifying the

questionnaire accordingly, it was sent back for their review. The questionnaire was in an electronic format and it was sent to the content validation experts via email. The cover page of the questionnaire contained directions for answering the questionnaire, and the experts had to rate their opinions simply by clicking on the circle in front of each item. The questionnaire also had enough space for the experts to jot down their suggestions. All 8 experts returned their responses by email in both steps of the content validation process. Figure 3.2 illustrates how the statements appeared in the content validation questionnaire. The cover page of the questionnaire provided to the experts for the two steps of content validation is presented in appendix 1.

Figure 3.2 A sample statement of the rating form for content validation

1. WTO/TRIPS agreement will impact the allocation of R&D expenditure.

1	2	3	4	5	6	7	8	9
Strongly Disagree								Strongly Agree

	Completely Satisfactory	Acceptable with Changes	Needs Changes	Needs Replacement
Language Clarity	☐	☐	☐	☐
Completeness	☐	☐	☐	☐
Relevance	☐	☐	☐	☐
Scoring	☐	☐	☐	☐

Suggestions.....

.....

Data Analysis

Phase 1: Interviewing the study participants for developing the rating scale

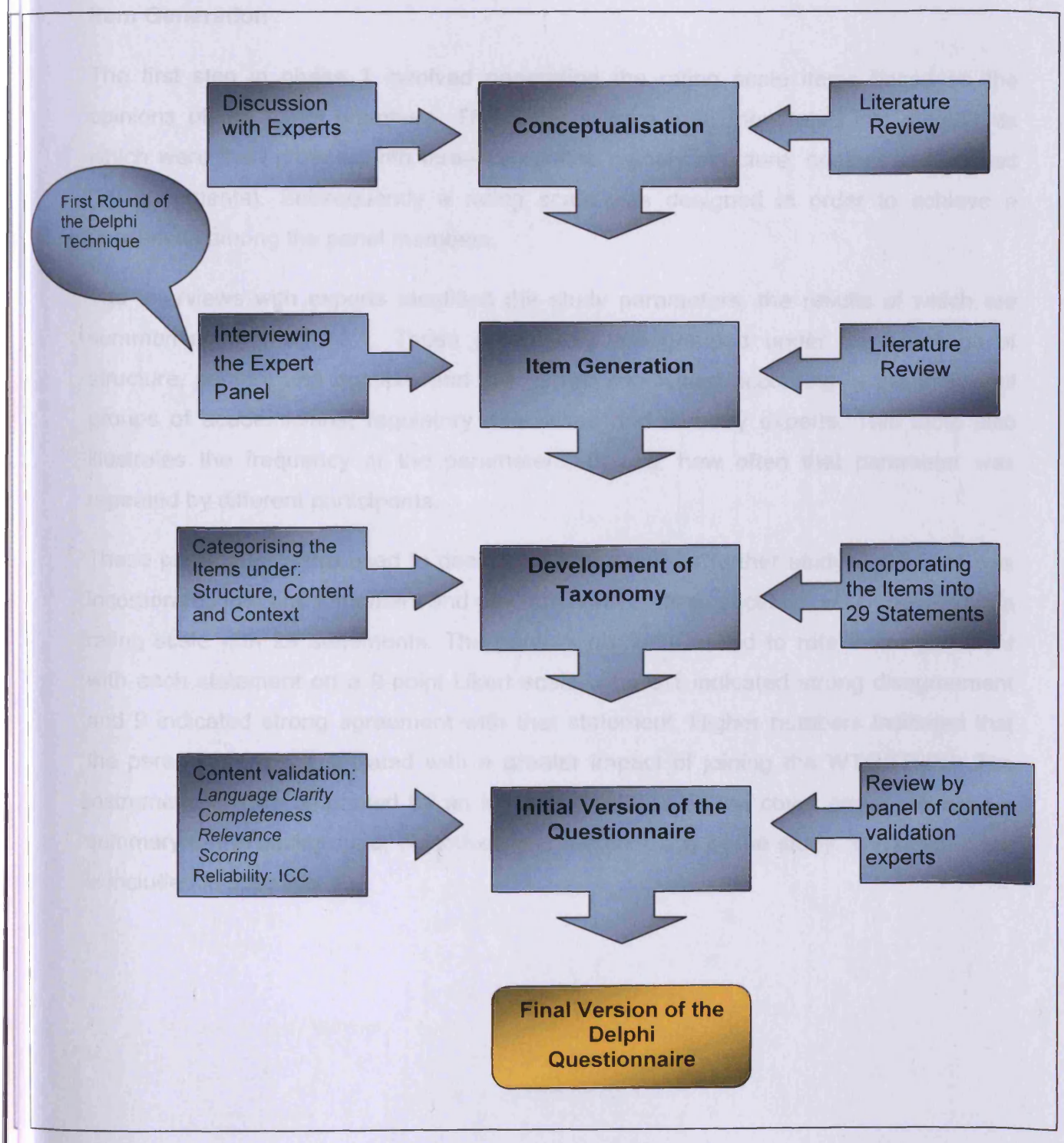
- Step 1. A list of the factors was prepared from the experts' interviews.
- Step 2. From these factors a number statements were developed
- Step 3. A scale ranged from 1 (strongly disagree) to 9 (strongly agree) were assigned to each statement.

Phase 2: Data for content validation of the instrument

- Step1.The responses of the content validation panel for rating language clarity, completeness, relevance and scoring for each statement were compiled from the four options listed in figure 3.2.
- Step 2. The intra-class correlation coefficient (ICC) was used to measure the agreement between the content validation panel responses.

The practical steps and work flow of this chapter are summarised in Figure 3.3.

Figure 3.3 Steps for developing the study instrument in the first round of the Delphi technique



RESULTS

Phase 1. Interviewing the study participants for developing the rating scale – Item Generation

The first step in phase 1 involved generating the rating scale items based on the opinions of the panel members. These items were then formulated into statements which were then grouped into three categories namely structure, content and context (29 statements). Subsequently a rating scale was designed in order to achieve a consensus among the panel members.

The interviews with experts identified the study parameters, the results of which are summarised in Table 3.1. These parameters are grouped under the headings of structure, content and context, and are further subdivided according to the individual groups of academicians, regulatory executives and industry experts. This table also illustrates the frequency of the parameters, that is, how often that parameter was repeated by different participants.

These parameters were used to design a rating scale for further study. Each item was incorporated into one statement and placed in one of three sections, which resulted in a rating scale with 29 statements. The participants were asked to rate their agreement with each statement on a 9-point Likert scale, where 1 indicated strong disagreement and 9 indicated strong agreement with that statement. Higher numbers indicated that the parameter was associated with a greater impact of joining the WTO/TRIPS. The instrument was accompanied by an introductory letter on the cover page, providing a summary of the background, objectives and methodology of the study. The cover page is included in appendix 1.

Table 3.1 Study parameters identified by the interviews

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
1) Structure Parameters					
a) Hi–tech Products	The local industry needs to adopt new technologies such as biotechnology, nanotechnology, new drug delivery systems and new formulations in product development.	A1 A4	4	3	3
b) R&D Infrastructures	The required equipment, facilities, people and information should be provided for research and development.	A2 A3 A11	4	4	3
c) Production Technology	The current production lines need to be replaced by more advanced ones.	A6	2	1	3
d) GMP Standards	More compliance with the GMP requirements will be encouraged. This will be mainly due to the necessity of exporting the products or technical cooperation with international companies.	A5	4	4	4
e) Automation and Machinery	Manual production and packaging as well as manual environmental control (such as air handling systems) should be replaced in order to remove human errors.	A6 A5	1	1	4

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
f) New Methods and Systems	The local industry needs to improve operating procedures in order to increase quality assurance and decrease the cost of production.	A7 A10	3	1	3
g) Product Packaging	The packaging of the products should be improved for both better appearance and enhanced protection of the products.	A8	1	4	2
h) Distribution System	The distribution system should become more efficient and more reliable with respects to the handling and storage condition.	A9	2	2	3
2) Content Parameters					
a) Management Knowledge and Skills	The industry directors and managers will require more knowledge and skills especially in the fields of human resources, corporate finance, marketing strategies and international business.	B1	3	2	4

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
b) Organisational Culture	The norms and values of the companies should support sustainability in a competitive situation e.g. Respect to the customers' needs, hard working colleagues and innovative attitudes.	B2	1	1	2
c) Innovation and Creativity	The local industry needs to encourage innovation and creativity of the employees throughout the organisations.	B3	2	2	4
d) Human Resource	The employees should be hired, trained, rewarded and promoted in accordance to the future needs of the industry.	B4 B5	2	3	3
e) Personnel Training	Any special training needed for employees, especially in the areas of GMP, should be provided.	B5	3	1	3
f) Under Licence Production	Production of the new products under the licence of the innovative companies will facilitate the local industry's improvement.	B6	3	3	3
g) Strategic Alliance and Mergers	Mergers, acquisitions and strategic alliances are possible ways for the local industry to gain more resources and decrease costs.	B9	2	2	4

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
h) Technology Transfer Agreements	The local industry needs to acquire the needed technologies from international companies to speed up development procedures.	B6	2	2	1
i) Marketing and Advertising	One of the characteristics of the competitive situation is the need for marketing and advertising activities that are not so developed in the current situation.	B7	3	3	4
j) Customers Behaviour (Doctors & Patients)	The local industry should study the needs of its customers and monitor their behaviour in order to meet their expectations.	B8	3	2	3
k) Ownership and Holding	The efficiency of the way of management in the large organisations and holding companies should be re-evaluated.	B10	1	1	3
l) Privatisation	The majority of large pharmaceutical companies are now linked to the governmental organisations that should be changed in a competitive situation that will result in the post-WTO condition.	B10	2	2	2

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
3) Context Parameters					
a) Patent protection Law	TRIPS regulation will enforce a patent protection law that prevent the local industry from copying the protected products.	C2	3	2	3
b) Tariffs and Custom Taxes	Post -WTO reduction of the importation tariff will negatively affect local companies and they will have major challenges to compete with the international rivals.	C1	2	2	3
c) Local Production Support and Subsidies	In the post -WTO situation the government will change the policies for paying the subsidies.	C8	2	2	3
d) Pricing Policy	The local companies should evaluate the prices of their products in comparison with their international rivals.	C4	4	4	4
e) Expenditure on Medicines	Removal of the illegally copied products from the market will increase the price of medicines.	C7	1	2	NR**
f) Bargaining Power of the Payers and Customers	The competitive environment will provide more choices for the patients and doctors that may negatively impact the local industry.	C3 C5	4	3	2

Study Parameter	Description	Corresponding Statement (s)*	Frequency of Results		
			Academia	Regulatory officials	Industry
g) Regulatory Affairs and Drug Registration	The regulatory body will adapt itself to the international norms and standards for the quality of the submitted documents.	C6	1	3	3

*The column includes the related number of the statements in the sections of the instrument (section A for structure, section B for content and section C for context parameters).

** No Response

Looking at table 3.1 reveals some of the differences in the opinions of the experts based on their area of activity. Some of these differences are expected because of the different experiences and backgrounds of the experts while some of them were surprising for the research team.

It was expected that industry experts place more emphasis on the need for automated operations and controls to reduce human errors (four industry experts mentioned this parameter against only one expert from each group of academia and regulatory officials). The subject of the ownership of the companies is also expectedly mentioned more by industry that reflects the importance of this topic in comparison with the two other groups of experts.

Conversely, it was surprising that the need for improved packaging was only highlighted by regulatory authorities while industry experts were supposed to be aware of the technical and cosmetic defects of the product packaging. This finding suggests the need for measuring customer satisfaction in the pharmaceutical companies. It may also indicate that the regulatory officials have some information including patients or physicians complaints about the quality of the packaging of local products. This kind of information must be shared with the industry as soon as convenient. Similar results

obtained for the parameters such as GMP and pricing policies illustrate a common understanding within the three groups of experts with regard to these topics.

It should be noted that the above parameters were identified from the experts' interviews responding to the open ended question about the impact of WTO/TRIPS on the local pharmaceutical industry in Iran. It is anticipated that listing and sorting the parameters will result in a re-evaluation of the responses by the experts.

Phase 2. Validation of the Instrument

This phase aimed to validate the content of the instrument by developing a specific rating form for the content validation panel. After measuring the reliability of this specific rating form as well, the final step involved refining the instrument by incorporating the outcomes of the validation phase. The respective results for the four validity criteria of language clarity, completeness, relevance and scoring are presented in Table 3.2.

Refinement and development of the instrument statements is presented in Table 3.2. The suggested changes were categorised as follows:

- Editorial modifications made the statements to be more understandable preventing misunderstanding and biased responses. These kind of changes are applied to the statements A1, A8, A10, B1, B4, B9, C1, C2, C5 and B8.
- Adding or removing words or phrases specified the scope and clarified meaning for such statement A2, A3, A11, B6, B7, C3, C4 and C6.
- Restructuring the statements differentiated the natural consequences from the legal obligations of joining WTO illustrated in statements A4, A5, A6, A7, A9, B2, B3, B5 and C8.

Table 3.2 content validation results for the four validity criteria in two steps

Statements Before Content Validation	Median of the Responses				Statements After First Step of Content Validation	Median of the Responses				Final Statements
	Language Clarity	Completeness	Relevance	Scoring		Language Clarity	Completeness	Relevance	Scoring	
Structure Statements										
A1. WTO/TRIPS agreement will create an environment which would encourage innovation in the pharmaceutical sector, resulting in new molecules and/or processes.	3	3	4	4	WTO/TRIPS agreement will create an environment which would encourage innovation in the pharmaceutical sector, for example: new molecules or new processes.	4	4	4	4	WTO/TRIPS agreement will create an environment which should encourage innovation in the pharmaceutical sector, for example: new molecules or new processes.
A 2. WTO/TRIPS agreement will impact the allocation of R&D expenditure.	3	3	3	3	WTO/TRIPS agreement will impact the R&D expenditure by local pharmaceutical companies.	4	3	4	4	WTO/TRIPS agreement will impact the R&D expenditure by local pharmaceutical companies
A 3. WTO/TRIPS agreement will influence requirements for specific skills in R&D staff.	3	3	3	3	WTO/TRIPS agreement will result in need for new and specific skills among R&D staff in local industry.	4	4	4	4	WTO/TRIPS agreement will result in the need for new and specific skills among R&D staff in local industry.
A 4. WTO/TRIPS agreement will influence deployment of modern technologies like biotechnology and nanotechnology in drug development.	3.5	3	3.5	4	WTO/TRIPS agreement will encourage the deployment of new technologies such as biotechnology and nanotechnology in drug development.	4	4	4	4	WTO/TRIPS agreement will encourage the deployment of new technologies such as biotechnology and nanotechnology in drug development.
A 5. WTO/TRIPS will influence the pharmaceutical industry adherence to manufacturing standards (GMP).	3.5	3	3	3	The changes resulting from implementing WTO/TRIPS agreement could have an impact on adherence to Good Manufacturing Practices (GMP) by the local pharmaceutical industry.	4	4	4	4	The changes resulting from implementing WTO/TRIPS will encourage the adherence to Good Manufacturing Practices (GMP) by the local pharmaceutical industry.
A 6. WTO/TRIPS will influence adoption of modern manufacturing techniques and machinery.	3	3	3	3	The changes resulting from the implementation of WTO/TRIPS will encourage the adoption of modern	4	4	4	4	The changes resulting from the implementation of WTO/TRIPS will encourage the adoption of modern

Statements Before Content Validation	Median of the Responses				Statements After First Step of Content Validation	Median of the Responses				Final Statements
	Language Clarity	Completeness	Relevance	Scoring		Language Clarity	Completeness	Relevance	Scoring	
					manufacturing techniques and the installation of new machinery.					manufacturing techniques and the installation of new machinery.
A 7. WTO/TRIPS agreement will influence the required competency in operational management.	3	3	3	3	The changes resulting from the implementation of WTO/TRIPS agreement will necessitate improvement of operational management in local industry.	4	4	4	4	The changes resulting from the implementation of WTO/TRIPS will encourage the improvement of operational management in local industry.
A8. WTO/TRIPS agreement will change the competitive environment and leads to increased demand for improved packaging.	2.5	3	3	3	WTO/TRIPS agreement will change the competitive environment leading to more improved product packaging.	4	4	4	4	WTO/TRIPS agreement will change the competitive environment leading to more improved product packaging.
A 9. WTO/TRIPS agreement will demand more efficient distribution system.	3	3	3	3	Changes resulting from adoption of the WTO/TRIPS agreement require a more efficient distribution system for local pharmaceutical industry.	4	4	4	4	The changes resulting from adoption of the WTO/TRIPS agreement will require a more efficient distribution system for local pharmaceutical industry.
A 10. Competitive environment after WTO/TRIPS agreement will require the reduction of production cost.	3	3.5	3	4	The competitive environment after WTO/TRIPS agreement will necessitate the reduction of production cost.	4	4	4	4	The competitive environment after WTO/TRIPS agreement will necessitate the reduction of production costs.
A11. WTO/TRIPS agreement needs stronger regulatory affairs and patent review departments.	3	3.5	4	3.5	WTO/TRIPS agreement will result in the need for more efficient patent review departments in the local industry.	4	4	4	4	WTO/TRIPS agreement will result in the need for patent review departments to be set up in the local industry.
Content Statements										
B1. WTO/TRIPS agreement influences the need for improved management knowledge and skills.	3.5	4	3	4	WTO/TRIPS agreement will promote the need for improved management knowledge and skills.	4	4	4	4	WTO/TRIPS agreement will promote the need for improved management knowledge and skills.
B 2. WTO/TRIPS will change organisational culture in order to support productivity.	3	4	3.5	4	WTO/TRIPS agreement will necessitate organisational culture which supports	4	4	4	4	WTO/TRIPS agreement will encourage organisational culture which supports

Statements Before Content Validation	Median of the Responses				Statements After First Step of Content Validation	Median of the Responses				Final Statements
	Language Clarity	Completeness	Relevance	Scoring		Language Clarity	Completeness	Relevance	Scoring	
					productivity in local industry.					productivity in local industry.
B 3. WTO/TRIPS agreement necessitates promoting employees based on innovation and creativity.	3	3.5	3	3	WTO/TRIPS agreement will necessitate the promotion of employees to be based on their innovation and creativity.	4	4	4	4	WTO/TRIPS agreement will encourage the promotion of employees to be based on their innovation and creativity.
B 4. WTO/TRIPS agreement will require higher qualifications for jobs in all organisation levels.	3.5	4	3	4	WTO/TRIPS agreement will result in higher qualifications for jobs in all organisational levels.	4	4	4	4	WTO/TRIPS agreement will result in the need for higher qualifications for jobs at all organisational levels.
B 5. Training for employees will be much more important after WTO/TRIPS.	4	3	3	4	WTO/TRIPS agreement will necessitate more training for employees in local pharmaceutical industry.	4	4	4	4	WTO/TRIPS agreement will necessitate more training for employees in local pharmaceutical industry.
B 6. WTO/TRIPS will encourage licence and technology transfer agreements.	3.5	4	3.5	4	WTO/TRIPS agreement will encourage licence and technology transfer agreements between local and international companies.	4	4	4	4	WTO/TRIPS agreement will encourage licence and technology transfer agreements between international and local companies.
B 7. WTO/TRIPS will influence marketing strategies and marketing expenditure to maintain or gain market share.	3.5	4	3.5	4	WTO/TRIPS agreement will influence marketing expenditure in order to maintain or gain market share.	4	4	4	4	WTO/TRIPS agreement will influence marketing expenditure in order to maintain or gain market share.
B 8. WTO/TRIPS agreement will increase the role of customer satisfaction and company image.	3	3	3	4	WTO/TRIPS agreement will result in companies giving more attention to customer satisfaction.	4	4	4	4	WTO/TRIPS agreement will result in companies giving more attention to customer satisfaction.
B 9. WTO/TRIPS agreement will influence the tendency for mergers and strategic alliances between companies.	3	4	3.5	4	WTO/TRIPS agreement will have an impact on the tendency for mergers and strategic alliances between companies.	4	4	4	4	WTO/TRIPS agreement will have an impact on the tendency for mergers and strategic alliances between companies.
B 10. WTO/TRIPS agreement will stimulate privatisation of pharmaceutical companies.	3.5	4	4	4	WTO/TRIPS agreement will stimulate the privatisation of pharmaceutical companies.	4	4	4	4	WTO/TRIPS agreement will stimulate the privatisation of pharmaceutical companies.

Statements Before Content Validation	Median of the Responses				Statements After First Step of Content Validation	Median of the Responses				Final Statements
	Language Clarity	Completeness	Relevance	Scoring		Language Clarity	Completeness	Relevance	Scoring	
Context statements										
C 1. WTO/TRIPS agreement will impose decreasing of the importation tariffs.	3	3	3	3	WTO will require the reduction of the importation tariffs which has deep impact on local companies.	4	4	4	4	WTO will require the reduction of the importation tariffs which will have a major impact on local companies.
C 2. WTO/TRIPS agreement will enforce a strong patent protection law.	3.5	3	3.5	3	Enforcing a strong patent protection law by WTO/TRIPS will have deep impact on local pharmaceutical industry.	4	4	4	4	Enforcing a strong patent protection law by WTO/TRIPS will have a major impact on local pharmaceutical industry.
C 3. WTO/TRIPS agreement supports the bargaining power of payers.	3	3	3	4	One important impact of the WTO/TRIPs agreement will be to increase the bargaining power of the payers, e.g. insurance companies.	4	4	4	4	One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of payers for medicines, e.g. insurance companies.
C 4. WTO/TRIPS will alter the pricing policy for medicines.	3	4	4	4	A consequence of the WTO/TRIPS agreement will be to alter the pricing policy of the local pharmaceutical industry.	4	4	4	4	A consequence of the WTO/TRIPS agreement will be to alter the pricing policy of the local pharmaceutical industry.
C 5. WTO/TRIPS agreement will increase the bargaining power of nongovernment organisations (e.g. patients' associations).	4	4	4	4	One important impact of the WTO/TRIPs agreement will be to increase the bargaining power of nongovernmental organisations, e.g. patient associations.	4	4	4	4	One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of nongovernmental organisations, e.g. patient associations.
C 6. WTO/TRIPS agreement will influence regulatory system and registration procedure in the ministry of health.	3	4	3.5	4	WTO/TRIPS agreement will influence the regulatory system for medicinal products operated by the ministry of health.	4	4	4	4	WTO/TRIPS agreement will influence the regulatory system for medicinal products operated by the ministry of health.
C 7. WTO/TRIPS agreement will change per capita expenditure for medicines.	3	3.5	4	3	WTO/TRIPS agreement will change the per capita expenditure on medicine.	4	4	4	4	WTO/TRIPS agreement will change the per capita expenditure on medicines.
C 8. WTO/TRIPS agreement will affect the policies for paying subsidies.	3	4	4	4	WTO/TRIPS agreement will result in changes in the governmental policies for	4	4	4	4	WTO/TRIPS agreement will result in changes in the governmental policies for

Statements Before Content Validation	Median of the Responses				Statements After First Step of Content Validation	Median of the Responses				Final Statements
	Language Clarity	Completeness	Relevance	Scoring		Language Clarity	Completeness	Relevance	Scoring	
					paying the subsidies.					paying the subsidies.

Some of the statements remained unchanged during the steps of content validation (statements B10, C7). The improvement of the scores in two steps of content validation is illustrated in Figure 3.4.

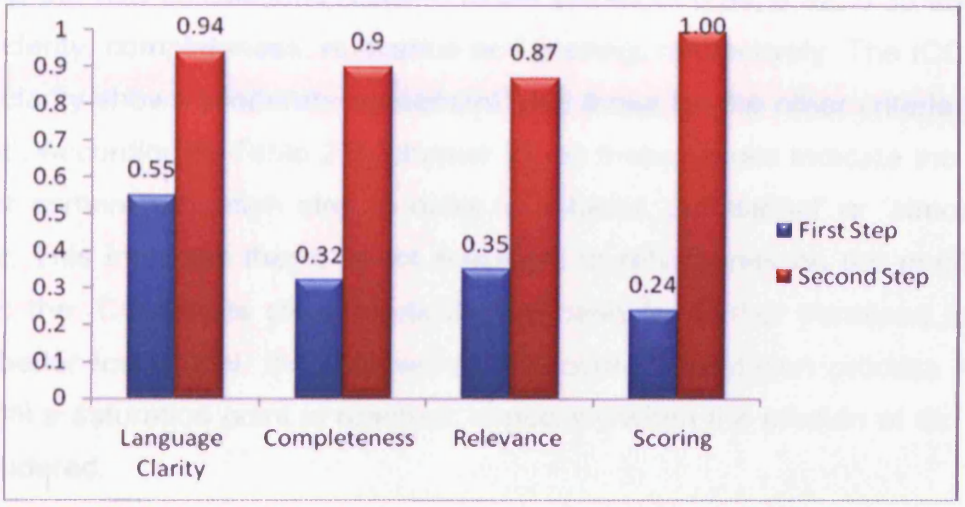
Figure 3.4 Summary of the median scores in the two steps of the content validation

According to the designed rating form, the content validation responses ranged from 1 to 4. In the first step of content validation, the median of the responses was 3.08, 3.18, 3.11 and 3.25 for language clarity, completeness, scoring and relevance respectively which subsequently improved to 3.83, 3.88, 3.91 and 3.98 indicating that the content validation experts were satisfied with the structure and formulation of the statements. Each of the statements showed similar results. These data also demonstrate a high degree of satisfaction between the content validation experts regarding the completeness of the statements, the results of which improved from 3.45 in the first step to 3.97 in the second step.

Reliability of the content validation rating form

The intra-class correlation coefficient (ICC) was used to differentiate the consensus reached among experts from those that could be achieved by chance. The calculations were performed using the SPSS version 17 (Figure 3.5).

Figure 3.5 The ICC values for the two steps of the content validation



Interpreting these results in the light of Table 2.4 (chapter 2) reveals that the level of agreement among content validation experts improved from 'fair agreement' to 'almost perfect agreement' during the two steps of content validation.

The interpretation table also indicates that there was a lack of agreement between the members of the panel for content validation in the first step that is reflected in a low value obtained for ICC (ICC values of 0.55, 0.32, 0.35 and 0.24 for language clarity, completeness, relevance and scoring respectively). ICC values of more than 0.7 indicate that the agreement among the experts has not occurred by chance. In the first step, none of the questionnaire attributes were valid, since all ICC values were less than the acceptance level (0.7); however, incorporating the comments of the experts significantly improved the results in the second step (ICC values of 0.94, 0.90, 0.87 and 1.00 for language clarity, completeness, relevance and scoring respectively). These results demonstrate the importance of using ICC for evaluating the reliability of this kind of data. It should be noted that while the ICC value helps evaluate the agreement between experts, it has no implication on the validity of the results (Futrell, 1995).

The average values of results in step one were 3.19, 3.45, 3.36 and 3.60 for language clarity, completeness, relevance and scoring, respectively (Table 3.3). These values were all higher than 3, which can be interpreted as acceptable on a 4-point form and

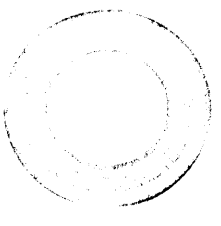
may subsequently indicate that the developed instrument has been 'validated'. Conversely, the ICC calculations resulted in the values of 0.55, 0.32, 0.35 and 0.24 for language clarity, completeness, relevance and scoring, respectively. The ICC value for language clarity shows 'moderate agreement' and those for the other criteria show 'fair agreement'. According to Table 2.3 (chapter 2), all these results indicate the necessity for another content validation step in order to achieve 'substantial' or 'almost perfect' agreement. This indicates that it is not advisable to rely merely on the median of the responses: the ICC results clearly indicate the need for further iterations in order to design a better instrument. In other words, the content validation process should be iterated until a saturation point is reached, especially when the median of the results is being considered.

By comparing the results of the two content validation steps, as illustrated in Table 3.4, we can see a dramatic increment of ICC values, which indicates a significant improvement between the two steps. The highest difference between the two ICC values pertains to the 'scoring' criteria, mainly due to the different opinions of the content validation experts during the first step, specifically regarding the use of an odd or even number of points (see chapter 2). In the second step, all the experts accepted a 9-point scale, which improved results.

Language clarity has the highest ICC value in the first step, which indicates that the developed questionnaire had better language clarity to begin with, as compared to the other criteria. Nevertheless, it should be emphasised that the results for the first content validation step were not acceptable and it was imperative to conduct a second validation step in order to formulate a clear, easy-to-understand and applicable questionnaire.

Final Version of the Instrument

Completing the first phase of this study, which was to interview the study participants for developing the rating scale on the basis of the Delphi technique and of the second phase, which was validating the developed instrument, has resulted in a more refined version of the instrument. This instrument is referred to as the final version of the world



trade organisation, pharmaceutical industry (WTO, PI) impact rating scale (Figure 3.6). Being refined by means of the content validation process, the WTO, PI impact rating scale is characterised by a high degree of consensus among the content validation experts, which made it suitable for its further use in the study. The cover pages of the final rating scale are presented in appendix 2.

Figure 3.6 The final version of the WTO, PI Impact Rating Scale

Please rate your agreement with the following statements, taking into account:
a- The research evidence
b- Your opinion/experience
c- The realities of pharmaceutical industry situation
It would be helpful if you answer all questions, but if you feel that a question is outside your area of practice, leave it blank.

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Section A: Structure Variables

1. WTO/TRIPS agreement will create an environment which should encourage innovation in the pharmaceutical sector, for example: new molecules or new processes.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

2. WTO/TRIPS agreement will impact the R&D expenditure by local pharmaceutical companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

3. WTO/TRIPS agreement will result in the need for new and specific skills among R&D staff in local industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

4. WTO/TRIPS agreement will encourage the deployment of new technologies such as biotechnology and nanotechnology in drug development.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

5. The changes resulting from implementing WTO/TRIPS will encourage the adherence to Good Manufacturing Practices (GMP) by the local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

6. The changes resulting from the implementation of WTO/TRIPS will encourage the adoption of modern manufacturing techniques and the installation of new machinery.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

7. The changes resulting from the implementation of WTO/TRIPS will encourage the improvement of operational management in local industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

8. WTO/TRIPS agreement will change the competitive environment leading to more improved product packaging.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

9. The Changes resulting from adoption of the WTO/TRIPs agreement will require a more efficient distribution system for local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

10. The Competitive environment after WTO/TRIPS agreement will necessitate the reduction of production costs.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

11. WTO/TRIPS agreement will result in the need for patent review departments to be set up in the local industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

Section B: Content Variables

1. WTO/TRIPS agreement will promote the need for improved management knowledge and skills.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

2. WTO/TRIPS agreement will encourage organisational culture which supports productivity in local industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

3. WTO/TRIPS agreement will encourage the promotion of employees to be based on their innovation and creativity.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

4. WTO/TRIPS agreement will result in the need for higher qualifications for jobs at all organisational levels.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

5. WTO/TRIPS agreement will necessitate more training for employees in local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

6. WTO/TRIPS agreement will encourage licence and technology transfer agreements between international and local companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

7. WTO/TRIPS agreement will influence marketing expenditure in order to maintain or gain market share.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

8. WTO/TRIPS agreement will result in companies giving more attention to customer satisfaction.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

9. WTO/TRIPS agreement will have an impact on the tendency for mergers and strategic alliances between companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

10. WTO/TRIPS agreement will stimulate the privatisation of pharmaceutical companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

Section C: Context Variables

1. WTO will require the reduction of the importation tariffs which will have a major impact on local companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

2. Enforcing a strong patent protection law by WTO/TRIPS will have a major impact on local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

3. One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of payers for medicines, e.g. insurance companies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

4. A consequence of the WTO TRIPS agreement will be to alter the pricing policy of the local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

5. One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of nongovernmental organisations, e.g. patient associations.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

6. WTO/TRIPS agreement will influence the regulatory system for medicinal products operated by the ministry of health.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

7. WTO/TRIPS agreement will change the per capita expenditure on medicines.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

8. WTO/TRIPS agreement will result in changes in the governmental policies for paying the subsidies.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

If you believe that an important topic(s) has not been included in the above statements, please feel free to list them below.

.....

.....

.....

DISCUSSION

The ideas that were discussed during the interviews in the first step of the Delphi technique were the focal point of the review for all the experts throughout this part of the study. The experts were mainly concerned about the sustainability of the local industry, underlining that it has not been developed in order to be competitive in a situation that would result from the country's accession to the WTO. They also stressed the need for initiating such a project to explore the impact and discuss the strategies that can be adopted by the local industry in order to minimise the negative consequences of implementing the WTO/TRIPS.

This part of the study sought to address three major topics, namely, item generation, categorisation and instrument development.

The first major challenge was to select the most relevant parameters from a group of important items. This complexity was overcome by forming a balanced group of experts from the three areas of academia, industry and regulation. The results of this chapter establish that the Delphi technique is an efficient method for designing such a study. This fact was also emphasised by the experts in the course of the interviews, who especially realised the consensus-generating nature of the technique when they learnt that the study participants comprised a balanced group of academicians, regulatory executives and industry experts.

Taxonomic categorisation of the items was instrumental to the participants' understanding of the structure, content and context of the measurement technique. It is clear that a large number of criteria are likely to play a key role in the outcome when the industry joins the WTO; grouping together these parameters can facilitate their evaluation by not only researchers and experts but also all those that participate in such studies. The feedback received from the experts during the study supported the simplification role of this grouping and highlighted the different aspects of this multi-dimensional approach.

Encapsulating the thought process of the study participants through the item generation and categorisation resulted in the development of a robust, valid and reliable instrument. This is a major step forward in understanding the impact of WTO accession on the sustainability of the local pharmaceutical industry.

The methodology followed in this study, including the brain storming procedures in the context of Delphi technique and iterations of content validation that resulted in developing a comprehensive and sophisticated instrument, was not traced in similar studies.

The study of Supakankunti et al. (2001) about the impact of WTO/ TRIPS agreement on the pharmaceutical industry in Thailand was mainly based on a literature review of relevant research and statistical analysis of the impact assessments and surveys. The Delphi technique and instrument development were not reported in their study. The parameters that they identified and discussed were: drug registration, technology transfer and foreign direct investment (FDI), R&D, spending on healthcare, patent law

and prices of the drugs. They also discussed TRIPS related topics such as compulsory licensing, exclusive marketing rights and burden of proof (Supakankunti, 2001).

The case study of Turkey published by Semin and Güldal (2008) regarding the growing dependency of developing countries and the globalisation of the pharmaceutical industry was also based on literature review and secondary data sources. They discussed the effects of globalisation on the pharmaceutical sector's structural characteristics, the production, patent, trade, prices, profit, and consumption in this sector (Semin and Güldal, 2008).

The study of Vogel about the impact and the implications of TRIPs in a knowledge-based global economy (a developing country's perspective) also focused on reviewing the impact with regards to the published laws and regulations and relevant discussion and assessments. Topics such as technology transfer policies, strength of protection of intellectual property rights, internationalisation of production and R&D were discussed in this study (Vogel, 2006).

The above review underlines the uniqueness of the WTO, PI impact rating scale developed and validated in this study and highlights the value of the consensus generating concept for identifying the influencing parameters through the laborious work of interviewing a balanced group of pharmaceutical sector's experts.

SUMMARY

- This chapter focused on the development of a questionnaire with the view to identifying the parameters influencing the post-WTO sustainability of the pharmaceutical industry. This questionnaire was prepared by interviewing a panel of experts in line with the first round of the Delphi technique.
- In all, a total of 29 items were identified and categorised into three groups and designated as structure, content and context parameters.
- This questionnaire was also successfully validated through two content validation steps by a second group of experts, and it was made sure that the final questionnaire was complete, written in clear language, relevant, and had an appropriate scoring system.

- The consensus among the experts during the two steps of content validation was investigated by measuring the ICC for each of the above mentioned criteria; according to the interpretation tables, the final results were in almost perfect agreement.
- Based on the Delphi technique, this instrument namely "WTO, PI impact rating scale" will be utilised for creating consensus among the experts participating in the study and this process will be further described in the next chapter.

Chapter 4

Evaluation of the Parameters Influencing the Post-WTO Sustainability of the Pharmaceutical Industry

INTRODUCTION

The in-full WTO-PI Impact Rating Scale was described in chapter 3 and has provided the necessary tool for carrying out the Delphi technique for creating consensus among a panel of experts on the elements required for the development of the strategies in preparing for the post-WTO/TRIPS agreement in Iran. This procedure was based on collecting the ideas and perceptions of well-known professionals and authorities regarding the assessment of the impact of the introduction of the WTO/TRIPS agreement on the pharmaceutical industry in the near future. This is an important undertaking because its output will later be used to determine the way forward for a concerned industry.

The previous chapter has described how the study commenced with interview sessions with a balanced group of experts (from academia, industry and regulatory authority). The contents of these interviews were later analysed in order to identify and list the necessary items with a view to developing a rating scale for further analysis. This process was based on the first round of the Delphi technique for creating consensus among experts. This chapter describes how the WTO-PI Impact Rating Scale will be used by the panel members to rate their agreement with the statements provided. This helped obtain the basic data for understanding the opinions of the participants and provided the researchers the opportunity to compare and prioritise the items that reflected the concerns and aspirations of the study participants.

The content validation expert panel assisted in the development of the instrument, where the final version consisted of 29 independent and categorised statements. It was, nevertheless, a challenging task to ensure that the statements were comprehensive, complete, relevant and clear. These concerns were the rationale behind the content validation process described in chapter 3.

This chapter will also demonstrate the instrument's capacity to create a consensus among the panel members and identify the divergence of their opinions in a reliable manner.

OBJECTIVES

The objectives of this chapter were to:

- Present the study instrument to the expert panel and to obtain their opinions regarding the study parameters
- Rate the relative importance of the factors influencing the pharmaceutical environment post-WTO agreement
- Measure the degree of consensus among experts representing academia, industry and regulatory authority using the Delphi technique

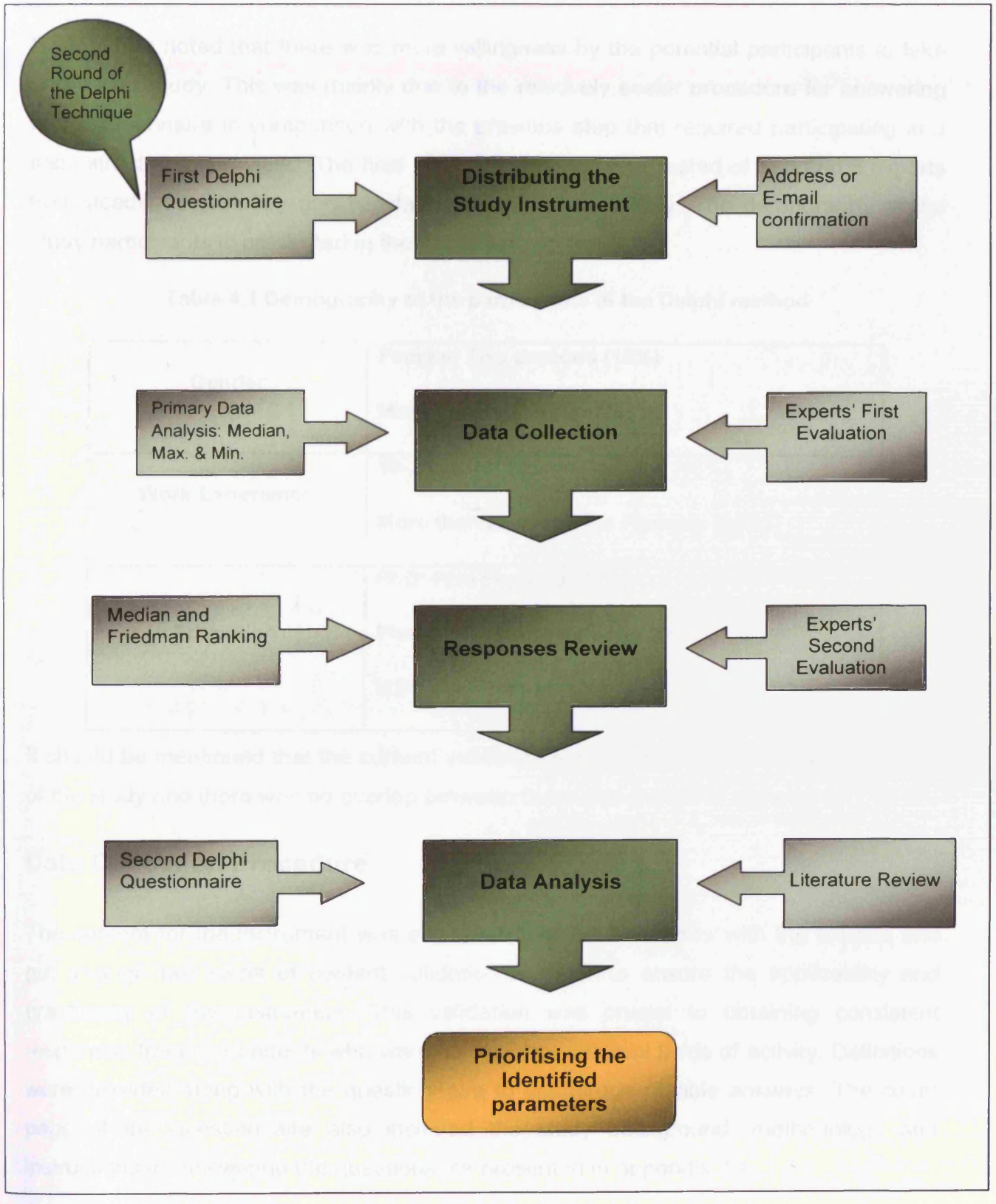
METHODS

The methodological approach for this chapter in order to rate the relative importance of the factors influencing the post-WTO sustainability of the pharmaceutical industry is presented in Figure 4.1. Data considered in this chapter were obtained by means of the instrument whose development was described in the previous chapter. This process was carried out according to the methodology of the second round of the Delphi technique.

Study Participants

The expert panel consists of seventeen experts, of which eleven had already been involved in the previous step (chapter three) and in addition, there were six new participants. The main reason for including more experts in this step was to strengthen the resulting consensus and improve the generalisation of the final results.

Figure 4.1 The methodological flow chart for the second round of the Delphi technique



It should be noted that there was more willingness by the potential participants to take part in this study. This was mainly due to the relatively easier procedure for answering the questionnaire in comparison with the previous step that required participating in a semi-structured interview. The final group of 17 experts consisted of 5, 6 and 6 experts from academia, industry and regulatory officials respectively. The demography of the study participants is presented in the Table 4.1.

Table 4.1 Demography of the participants in the Delphi method

Gender	**Female: Two persons (12%)** **Male: Fifteen Persons (88%)**
Work Experience	**10-20 years: Eleven Persons (65%)** **More than 20 years: Six Persons (35%)**
Education	**PhD: Five Persons (29%)** **Pharm. D: Eleven persons (65%)** **MSc: One Person (6%)**

It should be mentioned that the content validation experts did not participate in this step of the study and there was no overlap between these two groups of experts.

Data Collection Procedure

The content for the instrument was extracted from the interviews with the experts and put through two steps of content validation in order to ensure the applicability and practicality of the instrument. This validation was crucial to obtaining consistent responses from respondents who were hailing from different fields of activity. Definitions were provided along with the questionnaire to encourage reliable answers. The cover page of the questionnaire also included the study background, methodology and instructions for answering the questions, as presented in appendix 3.1.

The final version of the WTO-PI Impact Rating Scale was e-mailed to the participants. They were asked to return their responses within the proposed deadline for data collection. During this period, telephone contact was maintained with all the participants in order to make sure that they understood how to complete the questionnaire and to remind them of the timetable for data collection. Respondents were instructed to rate their opinions about each statement on a scale ranging from one to nine (1–9), where 1 means strong disagreement and 9 means strong agreement with that statement. They were also encouraged to comment on the statement and propose items that had not been identified so far. This step is mentioned as "Experts' first evaluation" in Figure 4.1. After the participants had submitted their responses, the data were used to calculate the median, maximum and minimum of the responses, which were incorporated into the questionnaire.

The experts' second evaluation was started by resending the modified questionnaire to the experts, who could also look at the group's responses; hence, they had the opportunity to modify their own responses. This instrument will be referred to as the second Delphi questionnaire. As explained in chapter 2, this step of the Delphi technique plays a crucial role in creating consensus among the experts. Figure 4.2 contains a sample statement of this questionnaire:

Figure 4.2 A sample statement of the second Delphi questionnaire

The changes resulting from the adoption of the WTO/TRIPS agreement will require a more efficient distribution system for the local pharmaceutical industry.

1 2 3 4 5 6 7 8 9

Strongly Disagree Strongly Agree

Your Score = 6 Median of the group = 5.5 Max = 9 Min = 2

Data Processing and Analysis

All collected data were entered into a database and quality controlled for preventing data entry errors. The data were subject to further analysis, as follows:

- The median of the responses was calculated for all the statements in order to explore the central tendency of the experts' opinions regarding each criterion.
- Cronbach's alpha was used to measure the reliability of the collected data and to indicate the internal consistency of the results.
- The Friedman test was used to rank the study parameters in order to determine the most important items from the viewpoint of the experts.

The calculations were carried out using SPSS software version 17.0. The work flow of this part of the study is presented in Figure 4.1.

RESULTS

The scores given by all the participants in their first evaluation were collected, and the medians of the responses were calculated and used for further analysis. Table 4.2 groups together the data pertaining to the responses for each section of the questionnaire (sections A, B and C) from the relevant group of experts.

This step involved providing the experts with the opportunity to revise their answers after reviewing the median of the group as well as their own answers. As described in the methodology of the Delphi technique in chapter two, this is an essential step in consensus-building among experts through the convergence of ideas. The median of the scores given to the instrument statements by each group of experts (academicians, regulatory officials and industry experts) is summarised in Table 4.2.

Table 4.2 The median scores given by each group of experts from the fields of academia, industry and regulatory regulation in their first and second evaluations using the WTO-PI Impact Rating Scale

WTO-PI Rating Scale Statements	Academia		Regulatory Authority		Industry		Total	
	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation
Structure Statements								
1. WTO/TRIPS agreement will create an environment which should encourage innovation in the pharmaceutical sector, for example: new molecules or new processes.	6.5	6	6	6	7	6.5	6.5	6
2. WTO/TRIPS agreement will impact the R&D expenditure by local pharmaceutical companies.	7	7	7	7	7	6	7	7
3. WTO/TRIPS agreement will result in the need for new and specific skills among R&D staff in local industry.	7.5	8	7	7	8	8	7.5	8
4. WTO/TRIPS agreement will encourage the deployment of new technologies such as biotechnology and nanotechnology in drug development	7	7	5	5	7	5	7	5
5. The changes resulting from implementing WTO/TRIPS will encourage the adherence to Good Manufacturing Practices (GMP) by the local pharmaceutical industry.	7.5	8	9	9	7.5	7.5	8	8
6. The changes resulting from the implementation of WTO/TRIPS will encourage the adoption of modern manufacturing techniques and the installation of new machinery.	6.5	7	7	7	6	6.5	6.5	7

WTO-PI Rating Scale Statements	Academia		Regulatory Authority		Industry		Total	
	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation
7. The changes resulting from the implementation of WTO/TRIPS will encourage the improvement of operational management in local industry.	6.5	7	6	6	7	6.5	6.5	6.5
8. WTO/TRIPS agreement will change the competitive environment leading to more improved product packaging.	7.5	7	8	8	7	7.5	7.5	7.5
9. The changes resulting from adoption of the WTO/TRIPS agreement will require a more efficient distribution system for local pharmaceutical industry.	6	6	5	5	5	6.5	5.5	5.5
10. The Competitive environment after WTO/TRIPS agreement will necessitate the reduction of production costs.	7	7	5	5	7	8	6	6
11. WTO/TRIPS agreement will result in the need for patent review departments to be set up in the local industry.	8	8	8	8	7	7.5	7.5	8
Content statements								
1. WTO/TRIPS agreement will promote the need for improved management knowledge and skills.	7.5	8	7	7	8	8.5	7.5	8
2. WTO/TRIPS agreement will encourage organisational culture which supports productivity in local industry.	7	7	7	7	7	8	7	7
3. WTO/TRIPS agreement will encourage the promotion of employees to be based on their innovation and creativity.	7.5	7	6	6	6	5.5	6.5	6
4. WTO/TRIPS agreement will result in the need for higher qualifications for jobs at all organisational levels.	7.5	8	6	6	6	7	7	7

WTO-PI Rating Scale Statements	Academia		Regulatory Authority		Industry		Total	
	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation
5. WTO/TRIPS agreement will necessitate more training for employees in local pharmaceutical industry.	7.5	7	7	7	8	8.5	7.5	7.5
6. WTO/TRIPS agreement will encourage licence and technology transfer agreements between international and local companies.	8	8	7	7	7	7	7	7
7. WTO/TRIPS agreement will influence marketing expenditure in order to maintain or gain market share.	8.5	8	6	6	8	7.5	8	8
8. WTO/TRIPS agreement will result in companies giving more attention to customer satisfaction.	7	7	8	8	8	8	8	8
9. WTO/TRIPS agreement will have an impact on the tendency for mergers and strategic alliances between companies.	8	8	8	8	7	6.5	7	7.5
10. WTO/TRIPS agreement will stimulate the privatisation of pharmaceutical companies.	7.5	8	6	6	6	6.5	6.5	6.5
Context Statements								
1. WTO /TRIPS will require the reduction of the importation tariffs which will have a major impact on local companies.	8.5	8	8	8	8	7	8	8
2. Enforcing a strong patent protection law by WTO/TRIPS will have a major impact on local pharmaceutical industry.	8.5	8	8	8	6	5	7	7
3. One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of payers for medicines, e.g. insurance companies.	6	6	5	5	8	6.5	6	6
4. A consequence of the WTO TRIPS agreement will be to alter the pricing policy of	7.5	7	8	8	8	7.5	8	7.5

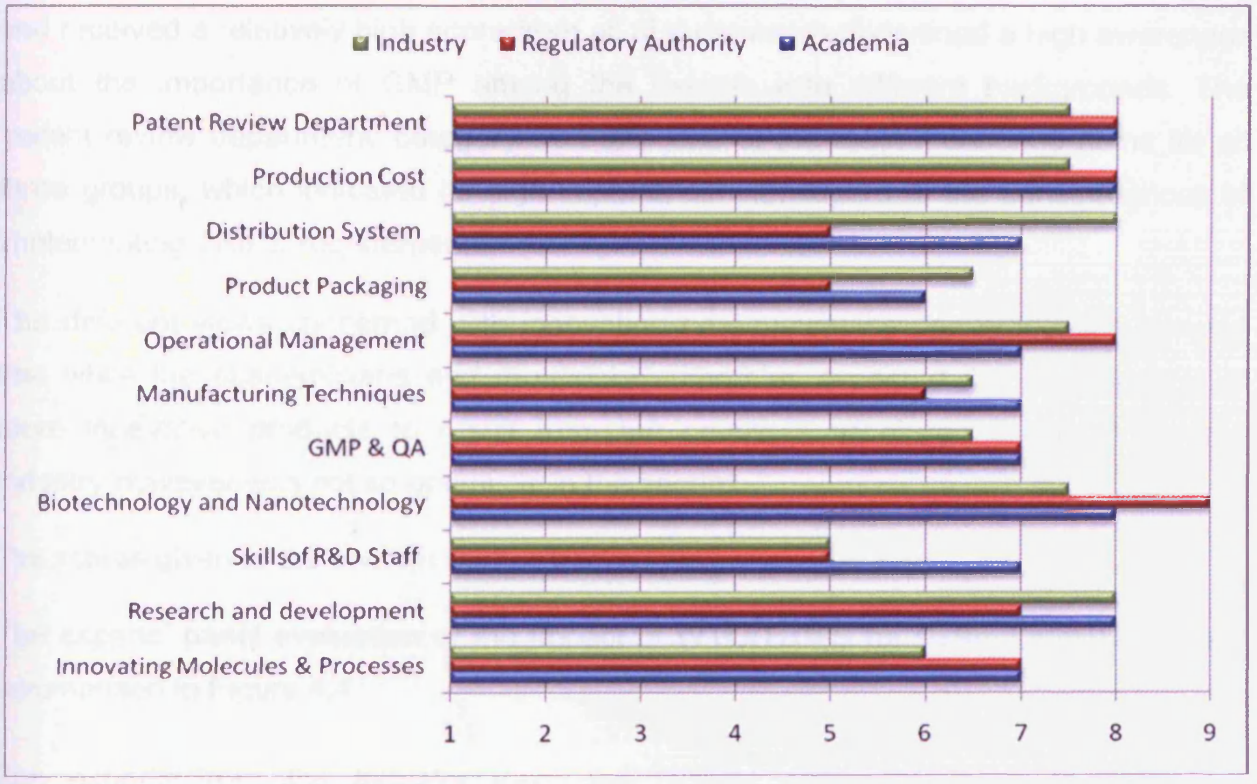
WTO-PI Rating Scale Statements	Academia		Regulatory Authority		Industry		Total	
	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation	First Evaluation	Second Evaluation
the local pharmaceutical industry.								
5. One important impact of the WTO/TRIPS agreement will be to increase the bargaining power of nongovernmental organisations, e.g. patient associations.	4	5	6	6	6	5.5	5.5	5.5
6. WTO/TRIPS agreement will influence the regulatory system for medicinal products operated by the ministry of health.	7.5	8	6	6	7	7	7	7
7. WTO/TRIPS agreement will change the per capita expenditure on medicines.	8	8	7	7	6	6	7	7
8. WTO/TRIPS agreement will result in changes in the governmental policies for paying the subsidies.	7.5	8	6	6	7	7.5	7	7.5

The above table shows that the median scores given by academics have increased in 10 statements decreased in 8 statements and remained constant in the remaining 11 statements. Surprisingly, the median scores given by regulatory authorities remained unchanged for all statements which shows the dominant tendency in this group of experts to reiterate their original scores. The responses of the industry experts were incremental for 11 statements while decreased for 12 statements and remained constant for 6 statements. In general the median of the scores given by the experts in the two steps of evaluations remained constant for 19 statements and slightly changed for the rest of the statements (increased for 6 and decreased in case of 4 statements). The fact that the scores in the two steps of evaluation only slightly changed, underlines the reproducibility of the data collected by WTO-PI impact rating scale.

Relative importance of the structure parameters

The importance of the panel responses to the structure statements are presented in Figure 4.3.

Figure 4.3 The expert group's responses to the 'Structure' statements



The regulatory authorities rated that the 'WTO/TRIPS agreement will encourage the deployment of new technologies such as biotechnology and nanotechnology in drug development' as the most important in this group (with the median of 9). This item received high ratings (medians of 8 and 7.5) from the academic and industry group, respectively (Figure 4.3). The items associated with the 'patent review departments', 'production cost' and 'R&D expenditure' also received high scores from all the experts, while the items relating to the 'distribution system' showed the biggest gap between the industry and regulatory authorities, thus reflecting the different priorities for these two groups of experts. This inter-group difference in the rating of statements was also

observed for the 'skills of R&D staff', which received a score of 7 from the academics, while industry and regulatory experts did not rate that higher than 5. This is contrary to expectation because the importance of the skills of R&D staff should have been highlighted by the industry experts. One reason may be that these experts mainly have their experiences from the production departments, Industry experts also rated 'product packaging' higher than academia and regulatory experts which was expected. Interestingly, GMP appeared to be a common concern for all three groups of experts and received a relatively high score from all of them which underlined a high awareness about the importance of GMP among the experts with different backgrounds. The 'patent review department' category was also one of the most mentioned items for all three groups, which indicated its high importance with regard to the consequences of implementing TRIPS requirements.

The different views concerned with innovating new molecules and processes showed that while the academicians and regulatory authorities expected the development of more innovative products to result from the country's accession to the WTO, the industry however was not so optimistic in this regard.

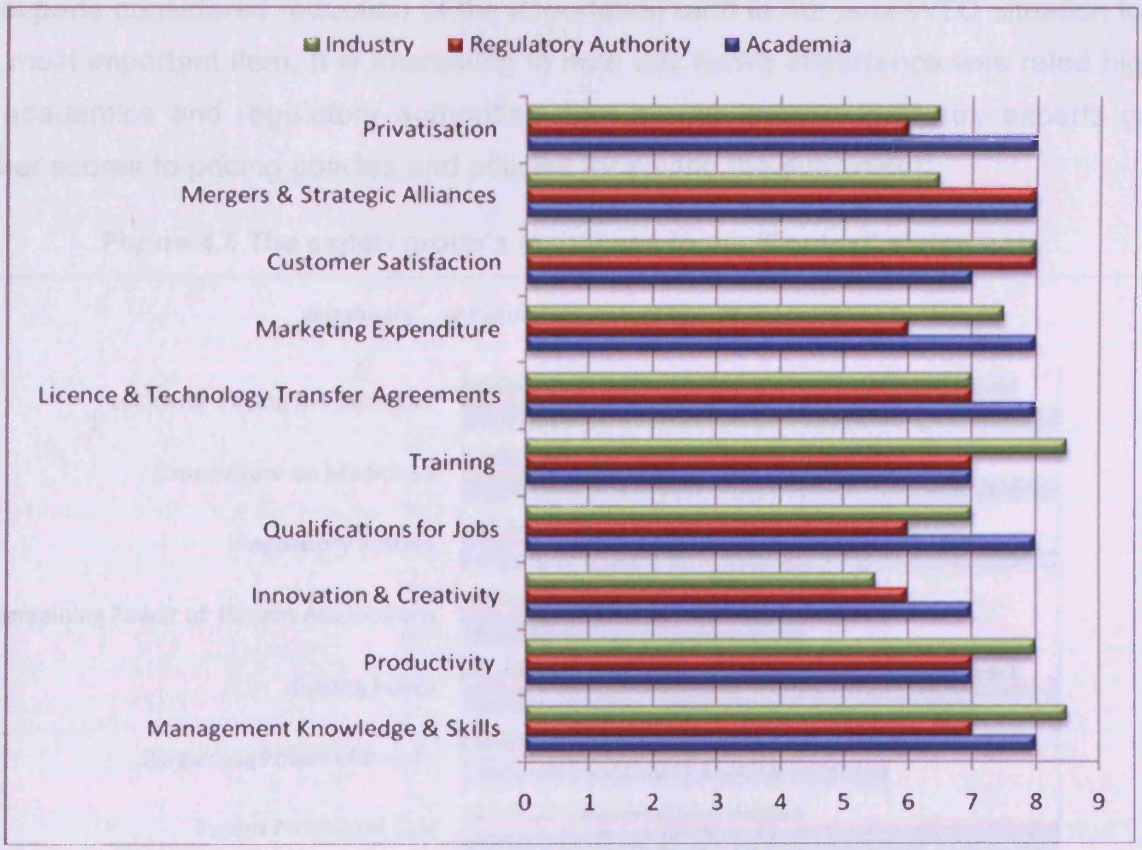
The scores given to the content related items

The experts' panel evaluation of the impact of WTO/TRIPS on content statements are summarised in Figure 4.4.

The experts from the industry gave the highest scores to items 'management knowledge and skills' and 'employees' training' (Figure 4.4). These items were important for other groups of experts as well. However, 'promotion of employees on the basis of their innovation and creativity' received the lowest figure from the industry experts which is contrary to expectations. The expert groups gave differing scores to marketing expenditure, the academics and industry experts gave higher scores compared with the regulatory authorities and these data indicate that the academics and industry experts seem to be more aware of the significance of focusing on marketing activities in the pharmaceutical industry, while the regulatory authorities are

regulatory authorities are critical of the international companies with respect to their marketing efforts. Both academicians and regulatory authorities gave higher ratings to mergers and strategic alliances than did the industry experts. This is surprising because more consideration was expected from the industry experts.

Figure 4.4 The expert group's responses to the 'Content' statements



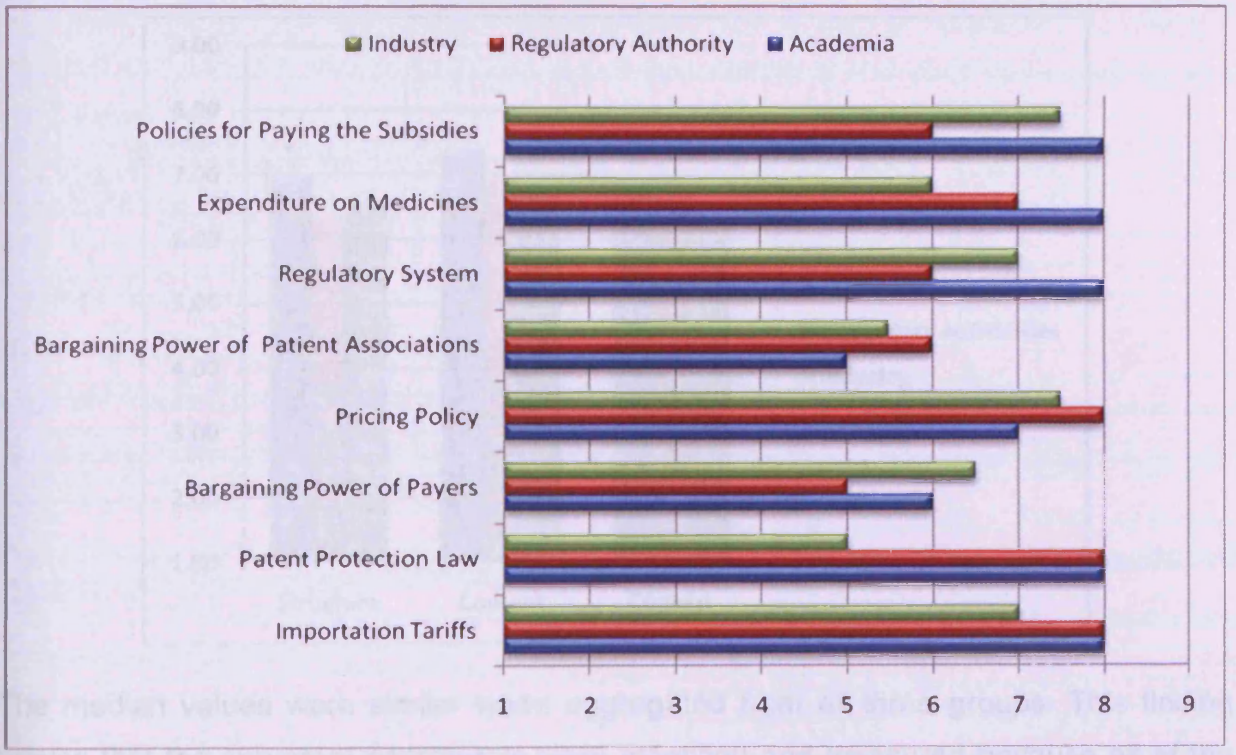
Customer satisfaction received an equally high score (with the median of 8) from both industry and regulatory authorities, while this item appeared less important for academics in the post-WTO situation. This may be due to the lack of appreciation with respect to the importance of this item in the academic environment.

The importance of the contextual items

WTO/TRIPS will provoke a series of changes in the pharmaceutical environment with direct and indirect effects on the industry. The expert panel responses to the context statements reflect these environmental challenges (Figure 4.5).

All experts considered reduction of the importation tariff in the post-WTO situation to be the most important item. It is interesting to note this item's importance was rated higher by academics and regulatory authorities than by the industry (industry experts gave higher scores to pricing policies and policies for paying the subsidies).

Figure 4.5 The expert group's responses to the 'Context' statements

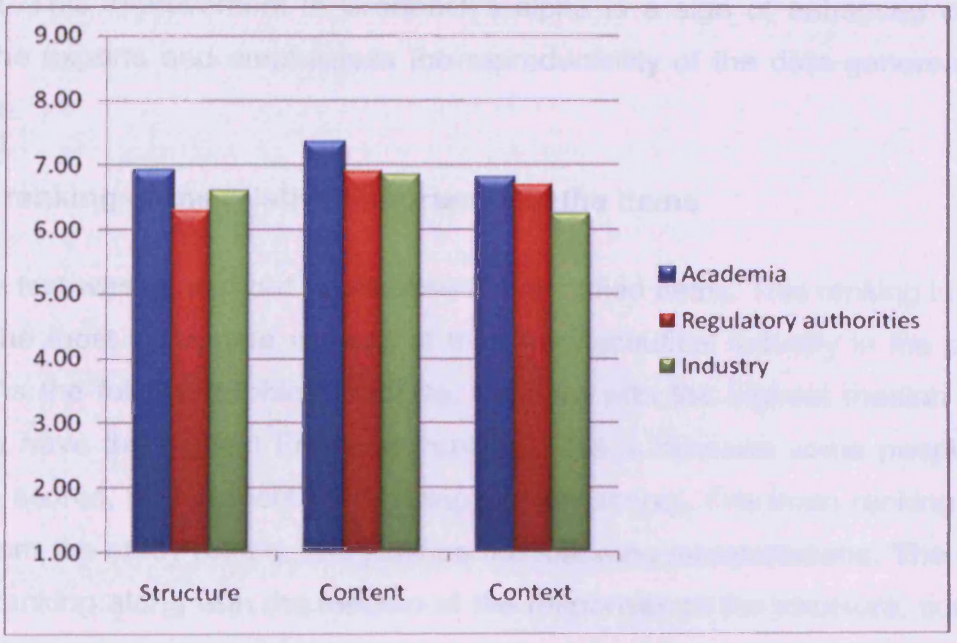


The industry experts, moreover, gave their lowest scores to the consequences of a strong patent protection law (with the median of 5); this item received relatively high scores from the other two groups of experts (with the median of 8 from both of them) which was absolutely contrary to expectations. It will be discussed later in this chapter that strong patent protection will be a major challenge for local generic companies that

illegally copy patented products. The item related to the bargaining power of NGOs such as patients' associations was rated as the least affected area by academics as well as industry experts, while the regulatory authorities gave the lowest scores to the bargaining power of payers.

The total median of the scores given by all three groups of experts was consistently 7, although the scores given by the industry experts are relatively lower than those given by the other groups of panel members (Figure 4.6).

Figure 4.6 Median of the scores given by experts to each section of the WTO-PI Impact Rating Scale in the second evaluation (second step)



The median values were similar when aggregated from all three groups. This finding proves that the important parameters were identified and measured because all of the medians were between 6 and 7 (Figure 4.6). Furthermore, it may be deduced that in general, the content parameters (section B of the items in the study instrument) received slightly higher figures from all the panel members.

general, the content parameters (section B of the items in the study instrument) received slightly higher figures from all the panel members.

Internal consistency reliability of the scores

The 29 items of the questionnaire were tested for reliability by measuring Cronbach's alpha in order to explore the internal consistency of the results. The result of the first evaluation was 68%, which is within the range of 'substantial agreement' according to the interpretation in Table 2.3 (chapter 2). Although the reliability result was within the acceptable range, the second round of the Delphi technique produced even better consistency among the scores. Cronbach's alpha for the second instrument was 0.73 which is higher than that for the previous step and still within the range of substantial agreement. This improvement in Cronbach's alpha is a sign of enhanced consensus between the experts and emphasises the reproducibility of the data generated by the rating scale.

Friedman ranking of the relative importance of the items

Friedman's test was carried out to prioritise the identified items. This ranking is helpful in exploring the most vulnerable aspects of the pharmaceutical industry in the post-WTO situation. As the following tables illustrate, the item with the highest median need not necessarily have the highest Friedman ranking. This is because some people tend to select high scores, while others tend to support low scores. Friedman ranking removes this bias from the study results and justifies the following interpretations. The results of Friedman ranking along with the median of the responses to the structure, content and context statements are presented in Table 4.3.

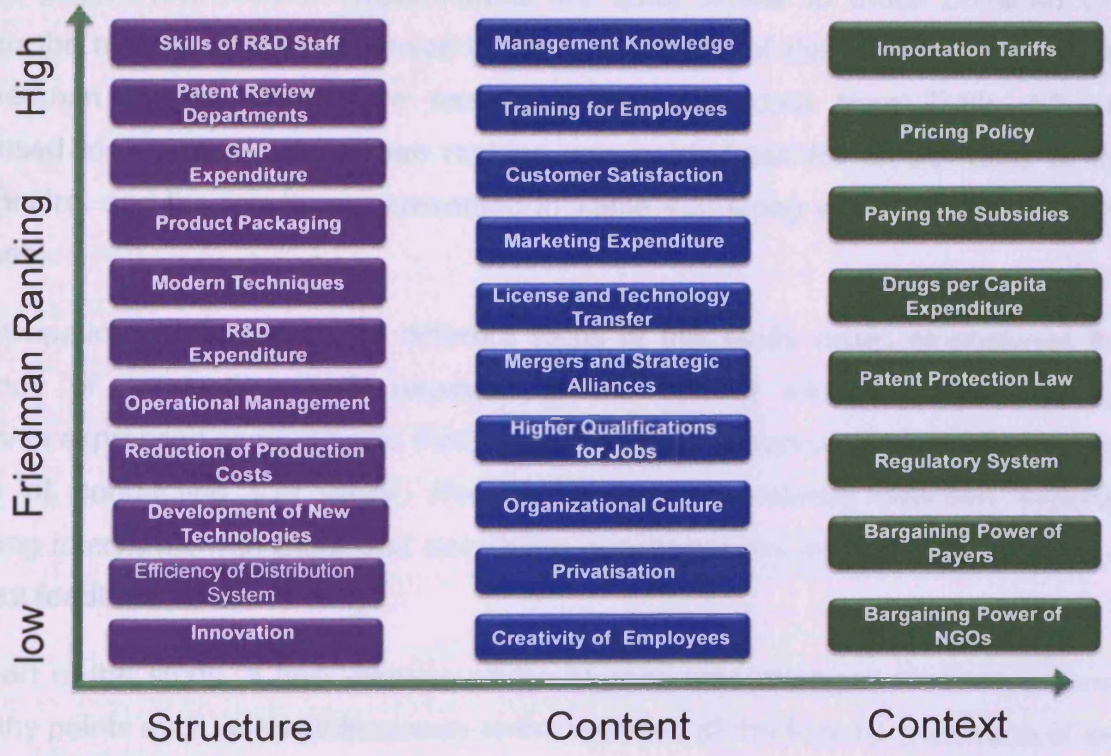
Table 4.3 Friedman ranking of the parameters influencing sustainability of the pharmaceutical industry

Friedman Rank	Statements		Median
1	C1	Importation Tariff	8
2	B1	Management Knowledge & Skills	8
3	B5	Training for Employees	7.5
4	A3	Skills of R&D Staff	8
5	B8	Customer Satisfaction	8
6	A11	Patent Review Departments	8
7	B7	Marketing Expenditure	8
8	A5	Good Manufacturing Practices (GMP)	8
9	B6	Licence and Technology Transfer	7
10	C4	Pricing Policy	7.5
11	B9	Mergers and Strategic Alliances	7.5
12	C8	Policies of Paying the Subsidies	7.5
13	A8	Product Packaging	5.5
13	B4	Need for Higher Qualifications for Jobs	7
15	C7	Per Capita Expenditure on Medicines	7
16	C2	Patent Protection law	7
17	A6	Adoption of Modern Manufacturing Techniques	7
18	C6	Regulatory System for Medicinal Products	7
19	B2	Organisational Culture which Supports Productivity	7
20	A2	R&D Expenditure	7
21	B10	Privatisation of Pharmaceutical Companies	6.5
22	A7	Improvement of Operational Management	6.5
23	B3	Innovation and Creativity of Employees	6
24	A10	Reduction of ProductionCosts	6
25	A4	Development of New Technologies	5
26	C3	Bargaining Power of Payers	6
27	A9	Efficiency of Distribution System	6
28	A1	Innovation (new molecules or new processes)	6
29	C5	Bargaining Power of Nongovernmental Organisations	5.5

As presented in the above table, 'importation tariff' was ranked first among all 29 items, followed by 'management knowledge and skills' and 'training for employees'. The lowest-ranked items were related to the distribution system, innovation of new molecules and the bargaining power of NGOs.

Friedman ranking of all the items grouped according to structure, content and context are presented in figure 4.7.

Figure 4.7 Friedman ranking of the three groups of items



In relation to structure parameters 'skills of R&D staff', 'patent review departments' and 'GMP expenditure' were seen to be the most important ones. In contrast, 'development of new technologies', 'efficiency of distribution system' and 'innovation' were seen to receive the lower ranks. All three items were already identified as important items based

on the analysis of their medians. It is interesting to note that the orders indicated by the median analysis and the Friedman ranking are the same, with the exception of the last two structure items.

The highest-ranked content statement was 'management knowledge and skills'. This item was followed by 'training for employees', 'customer satisfaction' and 'marketing expenditure'. The items associated with the privatisation of the industry and innovation of the employees did not receive a high position within this group of items. The Friedman and median ranking orders are mostly similar for content statements as well.

The 'importation tariff' and 'pricing policy' have the highest position among the context items, while the lowest positions were occupied by the items related to the bargaining power of payers and NGOs. These results are quite similar to those obtained with regard to the median of the responses in the earlier parts of this chapter, the median and Friedman ranking orders are exactly similar. The data from Table 4.3 are summarised in Figure 4.8. Friedman ranking was carried out for all 29 items of the questionnaire, and the results are presented in Table 4.3, along with the median of the responses.

The participation of the experts in different steps of this study again emphasises the importance of conducting such research in the current situation. Many of the participants expressed several times that awareness itself is part of the solution, and the initiative of conducting this study, through arranging meetings between experts, conducting interviews with them and circulating questionnaires among them, elicited a significant feedback.

In this part of the study, a final meeting of the experts was arranged to discuss some noteworthy points such as the differences in the opinions of the experts from each of the three fields. The panel experts' level of confidence in the questionnaire is reflected by the significant Cronbach's alpha values, which support the process of idea extraction and questionnaire design that was presented in the previous chapter. In other words, the practicality and applicability of the instrument, designed earlier in this study, was tested and approved in this part of the research.

It should be noted that these relative important factors are identified by a balanced group of experts in three areas of the pharmaceutical sector and could not have been achieved if one group of experts had been invited to participate in the study.

DISCUSSION

The WTO-PI Impact Rating Scale was used to identify the top ten influencing parameters which will now be reviewed in order of priority.

1. Importation tariff: The essential purpose of WTO is to help trade flow as freely as possible, which can be achieved by lowering trade barriers such as customs duties (importation tariffs), import bans or quotas and even issues such as bureaucracy and exchange rate policies. According to the WTO's recommendations, high importation tariffs should be abolished and the tariff rates for industrial goods should be gradually decreased to less than 4% (WTO, 2005). The importation tariff of 60% for medicines which can be locally produced is currently too high to comply with WTO requirements. It is assumed that the rigorous consequences of removing this relatively strong importation barrier will underline why this item received such a high ranking from the expert panel. Even if the differences are negligible, it should be noted that the academic experts have given higher scores to the importation tariff, while the industry has given it the lowest scores (Table 4.2).

Phasing out the importation tariff is already on the task list of the authorities during the accession procedure. However, the reduction in importation tariffs triggers a set of consequences resulting from the corresponding reduction in the price of imported competitor products. Thus, it is vital to prepare a strategy for empowering the susceptible industries because without preparation it will be a threat for the local industry without preparation.

2. Management knowledge and skills: According to the study instrument, the WTO/TRIPS agreement will increase the need for improved management knowledge and skills. Under these circumstances, it is necessary to improve the existing level or hire knowledgeable people with sufficient competence to deal with international

business and trade challenges. This will be a necessary qualification if the industry executives want the sector to progress while maintaining its sustainability in the future.

3. **Training for employees:** The need for better trained employees is complementary to the previous item and emphasises companies' need for more talented and better educated human resources, which would enable them to better deal with the situation. It has been reported that in most South-East Asian countries, the employment scenario worsened in the post-WTO period (The Mahbub ul Haq Human Development, 2004). This demonstrates the need for higher qualified people in the post-WTO situation, and being prepared for it beforehand can prevent the negative impact on employment indicators. An increasing skill premium, accompanied by increasing levels of equality in the developing countries, underlines the need for better trained people. It has been predicted that countries that are relatively rich in low-skilled labour will specialise in the production of unskilled-labour intensive goods (Goldberg, 2006). However a modern pharmaceutical industry requires highly skilled human resources.

4. **Skills of R&D staff:** A tough, competitive environment with strong patent protection laws will require the industry to design new products and processes as vital tools for the industry's survival. Skilled R&D employees enable the use of modern R&D tools including software, databases, equipment and facilities. In a competitive and rapidly changing environment, R&D staff should not only have the ability to identify which molecules might produce medicines of real value but also understand the payer's economic perspective during the R&D process (PricewaterhouseCoopers, 2009). R&D management and human resources are already considered as a basic need for the development of the pharmaceutical industry in India (Joshi, 2003). In order to improve R&D efficiency, it is recommended that transnational corporations (TNCs) be established for the globalisation of R&D, especially between the developing and developed countries (United Nations, 2005).

5. **Customer satisfaction: Customer satisfaction is an important** element of sustainable excellence for achieving a global competitive advantage (Langroudi et al, 2008). Management models such as the European Foundation for Quality Management

(EFQM) Excellence Model can measure the customer orientation of a firm in terms of 'customer results' (Dahlgaard-Park, 2008). It is important to identify those characteristics of the product or process that are critical to the customer's requirements for quality performance and those which contribute to customer satisfaction (Dahlgaard and Dahlgaard-Park, 2006). Customer satisfaction and loyalty can also be measured using the European Customer Satisfaction Index (Ciavolino and Dahlgaard, 2007). In the current situation, government policies protect the industry from its international rivals; however, the industry does not have enough motivation to be customer-oriented. For an industry to start monitoring its customers' needs and responding to their demands in a timely and cost-efficient manner, it needs to be challenged by the consequences of free-market competition. International companies are better adapted to these situations in the global market than the Iranian industry and are ready to satisfy the customers' ever-increasing desires.

6. Patent review departments: At present, intellectual property rights, including pharmaceutical patents, are not protected by law. This means that companies are not obliged to review the patent situation for their current and in-house development products. In the post-WTO situation, however, the industry will be compelled to reinforce its capabilities in this regard in order to mitigate the harsh consequences of patent infringement in the local and international markets. On the other hand, the pharmaceutical companies can play an important role in generic substitution by suggesting new generic products based on their patent expiration date, as generics remain a strong threat to original brands. For example, in April 1998, Abbott paid the generics manufacturer Geneva (a subsidiary of Novartis) $4.5 million on a monthly basis to prevent it from marketing a generic version of Hytrin (terazosin), and the payments continued until the agreement ended in August 1999. This meant that no other generic could be launched in the meantime (Seget, 2003).

'Patent review departments' ranked as the first or second-most important item in the interviews conducted during the first round of the Delphi technique. However, in the second round of the Delphi technique, the experts unexpectedly gave a higher priority to parameters such as management knowledge and skills. This change, according to the experts, was because parameters such as 'importation tariff', 'management knowledge

and skills', 'training for employees', 'skills of R&D staff' and 'customer satisfaction' are prerequisites for having a successful patent review.

7. **Marketing expenditure:** Aggressive marketing strategies are among the most important characteristics of the global pharmaceutical industry. Pharmaceutical companies commonly spend a considerable amount on advertising, marketing and lobbying. According to the Association of the British Pharmaceutical Industry (ABPI), in the United Kingdom, around 14% of the industry's expenditure is on promotion and marketing (House of Commons, 2005). In the United States, drug companies spend $19 billion a year on promotion. There are approximately 100,000 pharmaceutical sales representatives in the United States at present, pursuing some 120,000 pharmaceutical prescriptions. This number doubled in the four years from 1999 to 2003. In China, for example, nearly three-quarters of the information that doctors receive about new medicines comes from meetings with sales representatives and conferences (PricewaterhouseCoopers, 2009). The pharmaceutical industry in the United States is a large and important industry and spends an enormous amount of money on marketing. For example, it spends more than any other industry on its sales force ($ 7 billion annually) and a very large sum on media advertising ($ 2.8 billion annually. It also spends more on marketing than on R&D (e.g., the top nine firms spend 2.5 times the amount on marketing than on R&D)) (Manchanda P, 2005). Studies show that marketing a product increases the demand for that product, although this effect becomes weaker at higher levels of marketing expenditure. On average, pharmaceutical marketing significantly reduces doctors' price elasticity of demand. An increase of 1% in the marketing expenditure results in a 0.3% increase in sales. Of this increase, approximately 35% results from a decrease in the sales of competing products, while the remaining 65% is due to market growth (Laat, 2002). Subsequently, this item has direct impact on the local industry's capacity to retain its markets, considering the sophistication of its international rivals. Marketing strategy and technological development have been described as two important obstacles in the international competition of the pharmaceutical industry in South Korea (Gross, 1999). In India, the marketing efforts of local companies have acted as barriers for the entry of multinational companies in the local market (Joshi, 2003). Ironically, the marketing activities of

multinational companies in the third world have evoked considerable criticism (Smith, 1991).

Joint marketing activities can create synergy between innovative and generic companies (Attridge, 2005). In this regard, it is important to note that there is increasing resistance to 'irresponsible' marketing practices. In May 2007, the member governments of the World Health Organisation (WHO) passed a resolution to enact or enforce legislation banning the 'inaccurate, misleading or unethical promotion of medicines' (PricewaterhouseCoopers, 2009). At the heart of this problem may be the industry's current trend to be ever-increasingly driven by its marketing forces, while the world needs an industry which is led by the values of its scientists, not those of its marketing forces (House of Commons, 2005).

8. Good manufacturing practice (GMP): A world-class market requires a world-class manufacturing standard. GMP is a recognised precondition for pharmaceutical production, and its main focus is upgrading facilities, equipment, control and monitoring systems, and documentation. The Iranian pharmaceutical industry would need to establish GMP and compete with foreign companies in the local market, obtain the necessary approval from the targeted markets and be accepted as a local partner for the multinational companies. It is interesting that the regulatory and academic experts gave higher scores to this item (Figure 4.3). This highlights the government's role in stipulating production standards for local and international companies with no discrimination, in line with the WTO regulations. Concerns regarding the GMP level of pharmaceutical plants and the government's role in setting regulations and defining deadlines for the compliance of the local industry have been underlined as part of a significant post-WTO impact on India and China (Yeung, 2002 and Grace, 2004). In India, leading companies, such as Ranbaxy, Dr Reddy's, Sun Pharmaceuticals and Lupin have patiently invested in manufacturing facilities that meet the exacting EU and US GMP standards and built strategic alliances with US- and EU-based generic marketing companies. This has resulted in the current strong position of the Indian pharmaceutical manufacturing industry, as compared to those of other nations, in terms of the US FDA-approved plants launched and US Drug Master Files held by the

industry. The industry is now achieving dramatic growth in export sales of active ingredients to the US and EU (Attridge, 2005).

9. Licence and technology transfer agreements: The post-WTO situation will create an environment wherein Iranian companies are likely to become more involved in technical cooperation with multinational companies. This will help the Iranian companies' access new technologies more easily. The international companies in cooperation with local companies will then enter the market faster. Licence agreements give a well-established generic company the right to produce a patented product, not only to supply it to the local market, but also to sell it to other emerging markets, including the least developed markets, or even sell it back to the developed countries (Attridge, 2005).

10. Pricing policy: Pricing policies will play a crucial role in enabling the Iranian pharmaceutical industry to strengthen its infrastructure, especially its technical capabilities. Without a rational price structure, the industry cannot prepare itself for the post-WTO situation. The experts believe that the current government policy to maintain low prices for the local generic products, which favours patients and insurance companies, has prevented the local industry from investing in R&D and plant renovation. The government's pricing and reimbursement policies in the post-WTO situation should be transparent, with no discrimination between local and imported products. In some cases, countries have undermined this law to support local products. For example, the unofficial margins for selling local products to hospitals in South Korea led to protests from foreign companies (Gross, 1999). Hence, the phasing-out period before the accession procedure's completion provides the government an opportunity to empower the local companies. Differential pricing is one policy that resolves the conflict between patent protection and the affordability of medicines in developing countries; it refers to different prices for different markets based on the 'Ramsey pricing' principles, price sensitivity and demand elasticity (Danzon, 2001). A report published in 2004 predicted that the availability and pricing of 90% of the medicines manufactured in India and China, including most of the medicines in the WHO model list of essential medicines, should not be affected by the introduction of product patents (Grace, 2004).

This discussion essentially presents a summary of the top ten parameters identified by the experts in this study and does not imply that the other parameters are unimportant or do not influence the industry in the post-WTO situation. For instance, process patenting is an important policy that empowers the pharmaceutical industry during the transition phase before strong product patent laws are enforced. During the process patent regime, Indian firms developed competence in applied research for developing production-process technologies, particularly for synthetic bulk drugs (Chaturvedi, 2006).

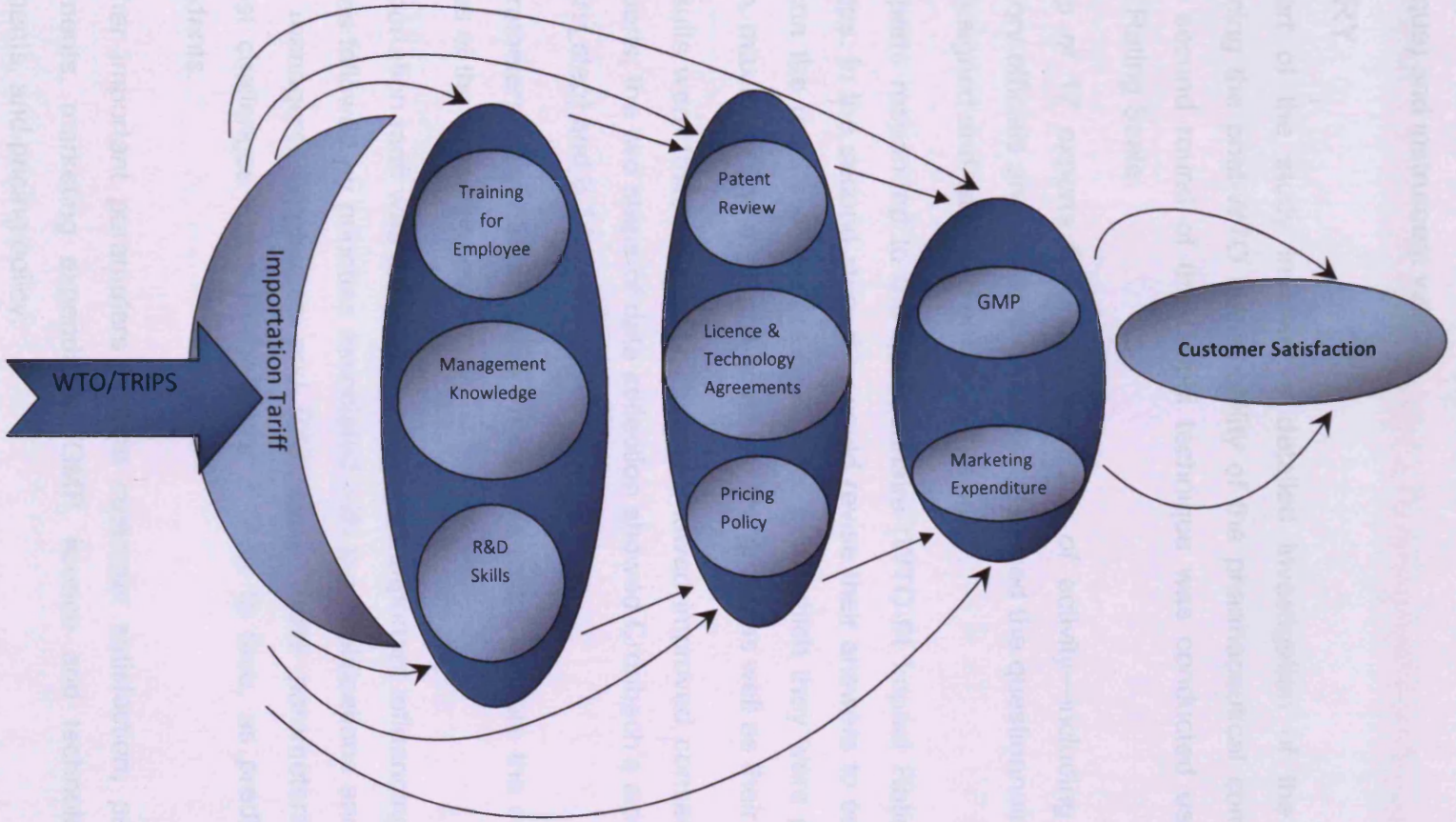
The ten important parameters that were explained in this section of the study can be clustered as depicted in Figure 4.8.

The first barrier to fulfilling the WTO/TRIPS requirements is the importation tariff policies. In the transition period, which is likely to be provided for the Iranian pharmaceutical industry to prepare itself, factors such as management knowledge, employees' training and skills for R&D staff will be the main areas of focus. Thereafter, the industry should invest in patent review to select the best patentable products which will allow the companies to obtain reasonable prices due to the innovative nature of the products in the generic market. At this stage, the industry should commence negotiating with brand holders and technology owners in order to sign licence and technology-transfer agreements. These achievements should motivate the industry to improve its GMP and invest further in marketing activities. The final outcome of this procedure will be greater customer satisfaction, which will only make the industry more competitive and sustainable in the post-WTO/TRIPS situation.

The overall results of this chapter are in accordance with the findings of other similar studies. For instance, Yeung (2002) has mentioned importation tariff, R&D capabilities and production capabilities as the major implications of WTO accession for the pharmaceutical industry in China. From this study, it would appear (Figure 4.5) that the people-related parameters scored higher than the other parameters, which is supported by other studies (Dahlgaard-Park and Dahlgaard, 2010).

This chapter successfully presented the WTO-PI, Impact Rating Scale to the expert panel and identified the parameters influencing the pharmaceutical industry in the post-

Figure 4.8 Clustering of the top ten parameters identified as influencing the post-WTO/TRIPS situation



WTO situation. These results were obtained while a high degree of consensus was created among the study participants as an outcome of the methodological fitness (Delphi technique) and instrument validity.

SUMMARY

- This part of the study involved a detailed investigation of the parameters influencing the post-WTO sustainability of the pharmaceutical companies. For this, a second round of the Delphi technique was conducted using WTO-PI Impact Rating Scale.
- A group of 17 experts from different fields of activity—including academics, regulatory officials and industry experts—answered the questionnaire which had been designed and validated earlier in this study.
- The experts responded to the questionnaire (WTO-PI Impact Rating Scale) in two steps. In the second step, they could revise their answers to each question based on the results of the previous step, from which they were provided the median, maximum and minimum scores of the group as well as their own score.
- The results were tested for reliability and showed improved consensus among the experts; the two steps of data collection showed Cronbach's alpha values of 0.68 (first step) and 0.73 (second step).
- The parameters were ranked using Friedman's test to explore the concerns and priorities of the expert panel.
- The importation tariff was identified as the most important influencing parameter. This was followed by priorities associated with the qualifications and knowledge of the managers, employees and R&D staff. These parameters reflect the foremost challenges which the industry is likely to face, as predicted by the respondents.
- The other important parameters include customer satisfaction, patent review departments, marketing expenditure, GMP, licence and technology transfer agreements, and pricing policy.

Chapter 5

Development and Psychometric Evaluation of the Pharmaceutical Industry Transition Instrument (PITI)

INTRODUCTION

Chapters 3 and 4 of this thesis focused on exploring the parameters influencing the post-WTO situation of the pharmaceutical industry in Iran. This procedure mainly involved collating the opinions of a panel of experts and by using the Delphi technique resulted in the identification of a total of 29 influencing parameters. In the absence of a suitable instrument with which to assess the industry's position in the transition period, it was decided that this study would first develop an instrument specifically for this purpose. This chapter, therefore, will focus on describing the development of this instrument. According to its conceptualisation, such an instrument should be capable of assessing the industry's readiness to respond to the implementation of the WTO/TRIPS agreement by measuring the gap between the industry's present and future situations. Furthermore, it is hoped that the process and outcome of this study will help both the industry and policy makers to prepare the right environment for this event.

OBJECTIVES

The objectives of this study were to:

- Select the appropriate parameters from the results obtained in the previous chapter
- Utilise the selected parameters for the development of the Pharmaceutical Industry Transition Instrument (PITI)
- Develop the instrument to be suitable for measuring the current situation and future importance of each parameter
- Examine the psychometric properties of the PITI (applicability, practicality and reliability).

METHODS

A standardised methodology was adopted for the development of the PITI; it is briefly described as follows:

Step 1 - Conceptualisation: In line with the research question of the study, it is necessary to explore the industry's situation with respect to the identified parameters,

such as GMP or R&D capabilities. It should be kept in mind that this is a topical issue with sensitive socio-economic implications. Asking people employed in companies about their own company's readiness to survive in a competitive situation may put psychological pressure on the respondents and create a false sense of optimism. In addition, it is clearly inappropriate to request companies to divulge the real figures of their expenditures or revenues due to the confidential nature of this kind information. On the basis of these facts, it was necessary to design an instrument that could be used for performing a gap analysis by comparing the current situation and future importance of each statement.

It was also concluded that the questions pertaining to the scope of the study should be presented to management-level employees of pharmaceutical companies, since these people are involved in the development, manufacturing and marketing of medicines. Ideally, data should be collected from several people in each company in order to obtain different views from the company. Collecting data at the plant level is a much easier process, but it could result in the collection of less precise data. Managers, however, have sufficient information to respond to our questions in a limited period of time; therefore, the instrument should be detailed and straightforward. With respect to the potential participants, a web-based electronic version of the instrument was designed. Development of the electronic version was based on similar experiences in order to incorporate maximum advantages of online data collection (UMD, 2010).

In this study, the companies were selected randomly as probability samples. The number of companies sampled can be calculated based on the sample volume equation, which will be explained in the next chapter.

Step 2 - Item generation: The basic information obtained for the construct of the instrument, is described here. The inclusion criteria were mainly the relevance of the parameters to the objectives of this study, i.e. evaluation of the industry situation. These were mainly categorised as structure and content parameters, and 2–8 items were included in each category in order to collect a variety of data about each category.

Step 3 - Item reduction: It was decided that the items categorised as context parameters, which are mainly related to the industry environment, should be excluded from the PITI because the instrument is focused on the capabilities and infrastructures of the industry.

Step 4 - Development of taxonomy: Considering the familiarity of the participants with respect to the topic of this study, a proper taxonomy would be based on the names of departments or management topics in the industry, such as GMP expenditure, product packaging and so on.

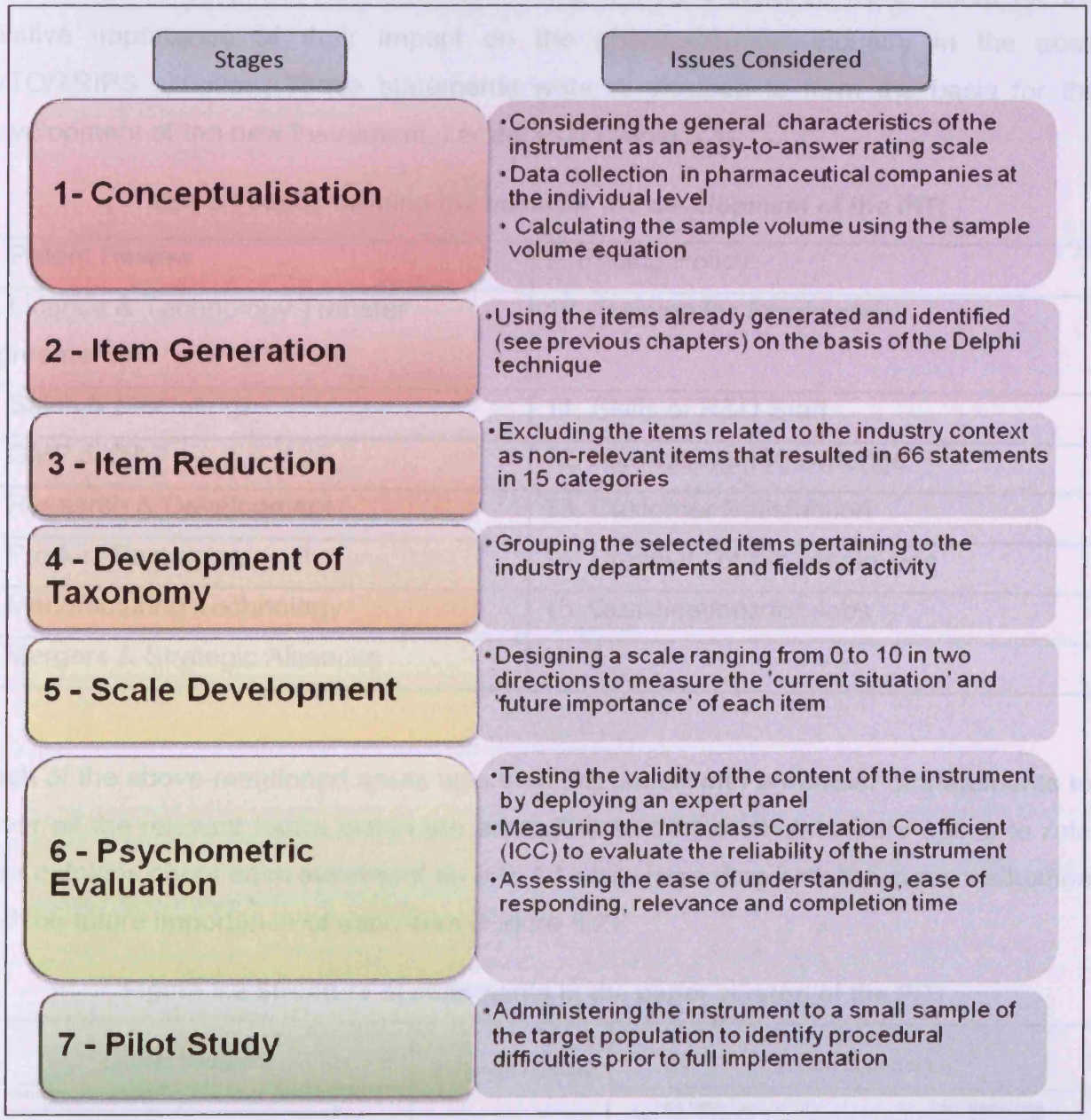
Step 5 - Scale development: This instrument should preferably have a scale to measure the current situation and future importance of each item. A scale with a wide range of 0 to 10 is useful as it provides the participants with extensive response options.

Step 6 - Psychometric evaluation: In this step, the questionnaire designed according to the above requirements would be reviewed by a group of experts for content validation. This step of content validation of the questionnaire is based on the method formerly discussed and explained in chapters 2 and 3. In this part of the study, a group of 18 experts were selected on the basis of their familiarity with the research methodology to determine the validity of the instrument. In addition, the internal consistency of the scores was measured to determine the reliability of the collected data. Psychometric evaluation was also carried out during the pilot study phase by asking the respondents whether the statements were clear, easy to understand, easy to respond to, relevant and convenient in terms of the time required for completion.

Step 7 - Pilot study: As explained earlier in chapter 2, an initial pilot study test is an essential part of questionnaire construction and includes administering the questionnaire to a small, typical group of participants, based on their availability and readiness. The pilot study may lead to the conclusion that the questionnaire needs to be revised in order to make it more user-friendly and comprehensive. If the pilot study indicates that the questionnaire contains confusing points, the questionnaire may be revised further before being distributed. It may also be necessary to arrange for an

explanatory session prior to administrating the instrument to the respondents (Flynn B, 1990). The seven steps of developing the rating scale are illustrated in the Figure 5.1.

Figure 5.1 Development steps of the Pharmaceutical Industry Transition Instrument (PITI)



Study Data origin

As was described in chapter 2, the phrasing and format of the questionnaire directly influences the practicality and applicability of the study instrument as well as its reliability and validity. The PITI was designed using the statements generated in chapter 4, where a list of parameters identified using a Delphi process were tested for the relative importance of their impact on the pharmaceutical industry in the post-WTO/TRIPS situation. These statements were re-grouped to form the basis for the development of the new instrument, i.e. the PITI (Table 5.1).

Table 5.1 Areas forming the basis for the development of the PITI

1. Patent Review	9. Pricing Policy
2. Licence & Technology Transfer Agreements	10. Training for Employees
3. Sales & Marketing	11. Skills of R&D Staff
4. GMP & QA	12. Management Knowledge
5. Research & Development	13. Customer Satisfaction
6. Product Packaging	14. Creativity of the Employees
7. Manufacturing Technology	15. Qualifications for Jobs
8. Mergers & Strategic Alliances	----------

Each of the above-mentioned areas was then populated with a number of statements to cover all the relevant topics within the area. The study participants were asked to rate their opinions about each statement on a 0–10 scale regarding both the current situation and the future importance of each item (Figure 5.2).

Figure 5.2 Structure of statements in the paper version of the PITI

Current Situation											1. Patent Review	Future Importance										
absolute compliance ◄										► no compliance		◄ not important at all									► very important
10	9	8	7	6	5	4	3	2	1	0	We review intellectual property rights when exporting products.	0	1	2	3	4	5	6	7	8	9	10

Data processing and analysis

Psychometric evaluation data: The data for the psychometric evaluation of the questionnaire were obtained in electronic format. The use of electronic instruments not only greatly improved the quality of the data but also prevented the errors associated with incorrect handwriting interpretation and manual entry of data into the database.

The collected data were subjected to further analysis as follows:

- The medians of the content validation panel members' responses pertaining to the language clarity, completeness, relevance and scoring of the instrument were calculated through two content validation exercises in order to explore the median of the experts' opinions for each criterion.
- ICC was used to measure the consensus between the experts and regarded as an indicator of the internal consistency of the instrument (Trochim, Research Methods , 2002).

Pilot study data: In the pilot study, the responses were collected in both paper and electronic format (e-mail attached). Data obtained through electronic sources were directly entered from the mailbox into the database. The paper format responses were quality controlled for handwriting or other problems. Data entry was double-checked prior to data analysis in order to prevent data entry errors. The analysis procedure of the pilot study results included the following calculations:

- Mean of the responses to each category and statement
- The gap between the responses pertaining to the current situation and those associated with the future importance of each item
- ICC to assess the internal consistency reliability of the responses

The analyses were carried out using SPSS version 17 and Microsoft Excel 2007.

RESULTS

The results of this chapter are presented in three parts namely Part I to describe development of the instrument, Part II to explain how the psychometric properties of the instrument were evaluated and Part III to report the pilot study results.

Part I - Instrument development

The instrument contained 66 statements divided into 15 categories under the headings presented in Table 5.1. Each of the 15 categories contained a series of statements to collect data pertaining to that particular category. It also contained a section with general questions covering respondent-related information such as gender, age, education and organisational position as well as general company characteristics such as company ownership, company name, total sales, number of employees, expenditure on R&D and percentage of net profit per sales. In addition, the question regarding company characteristics was optional, as indicated. The instrument was prepared in electronic and paper formats.

The respondents were asked to rate the level of their agreement with each statement with regard to both the current situation in the industry and its future importance. The current situation was considered to determine the current efficiency of the industry in different areas of the business, while the future importance of each aspect was explored in order to understand its importance after the implementation of WTO/TRIPS.

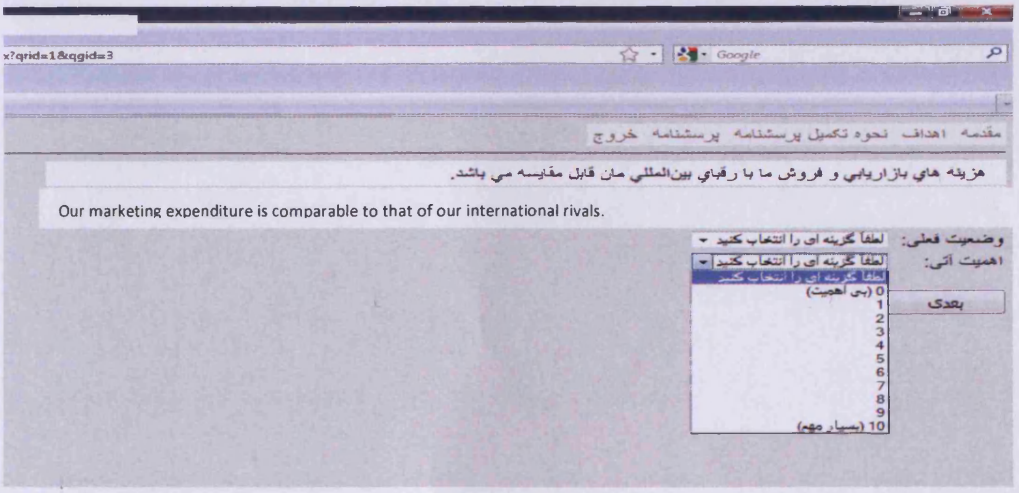
For comprehensive data collection, the respondents were provided with instructions covering some necessary information. Thus, the introductory pages of the instrument introduced the study and explained its background, study rationale, objectives, methodology, study participants, how to complete the questionnaire and the confidentiality terms (appendix 5.1).

Paper version: The study participants also received a paper version of the instrument. The instructions were given in the cover pages, and the structure of the statements was similar to those in the electronic version. Previous experiences indicated that receiving both paper and electronic versions of the data collection instruments suit the

preferences of a greater number of respondents, which may positively influence the participation rate. The design of the paper version of the PITI is presented in Figure 5.2.

Electronic version: The electronic data collection mode was considered for this study because of its precision. A website was designed for this purpose, and the rating scale was uploaded onto the website, which could be accessed by the study participants by using the personal username and password provided to them. Instructions similar to those provided in the cover pages of the paper version were also provided in the electronic version; the statements were provided in both Persian and English. A report generator was designed to create real-time online reports. Therefore, during the data collection period (35 days), it would be possible to monitor the emerging results. This closed Web-based instrument (see chapter 2) and electronic method of data collection made the subsequent data processing and analysis easier and very efficient. The design of the electronic version of the instrument received positive feedback from the study participants (Figure 5.3). The respondents could click on 'choose an item', which was a drop-down menu, and select their choice from 0 to 10 for both the current situation and future importance.

Figure 5.3 A sample statement of the electronic version of the



Part II - Psychometric evaluation

Validity: The validity of the instrument was assessed by a panel of content validation experts. To this end, it was necessary to design a rating form to collect the opinions of the panel members. Although the rating form was designed in both electronic and paper versions, all the panel members preferred to receive the electronic format via e-mail. The cover pages contained instructions indicating the background to the study and explaining how the questions were to be answered. The cover pages provided to the content validation panel members were similar to the Delphi rating scale presented in appendix 3.1.

The study participants were asked to express their views on the language clarity, completeness, relevance and scoring of each statement. A comment box was also provided. The respondents could click on the 'choose an item' tab, which was a drop-down menu, and select their choice from the four options provided, namely, 'strongly agree', 'agree', 'disagree' and 'strongly disagree'. These options were coded as 4, 3, 2 and 1, respectively, for analysis purposes. With respect to the validity of the instrument, 17 out of 18 distributed instruments were collected, with the response rate of 94.4%. All the responses were e-mailed to the study participants. Figure 5.4 shows how the statements appeared in the content validation rating form.

Figure 5.4 Design of the content validation rating form

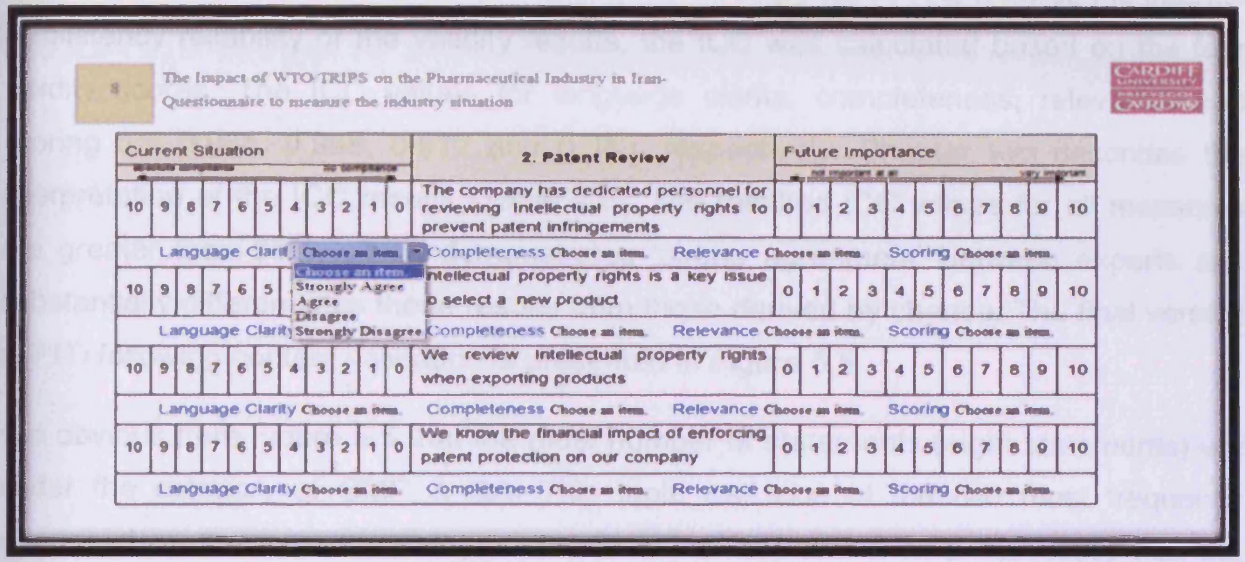


Table 5.2 presents the results of psychometric evaluation; the scores given by the responding experts are indicated as ranging from 1 to 17.

Table 5.2 Median scores given by each content validation panel member

Respondent	Language Clarity	Completeness	Relevance	Scoring
1	✓ 3.81	! 3.17	! 3.10	! 3.21
2	✗ 2.95	✗ 2.97	! 3.14	! 3.11
3	✓ 3.83	✓ 3.97	✓ 3.56	! 3.03
4	✓ 3.82	✓ 3.80	✓ 3.52	✓ 3.59
5	✓ 3.94	✓ 3.91	✓ 3.82	! 3.12
6	! 3.29	! 3.28	! 3.03	! 3.00
7	✓ 3.88	✓ 3.91	✓ 3.97	✓ 3.98
8	✗ 2.91	! 3.03	✗ 2.89	! 3.14
9	✓ 4.00	✓ 4.00	✓ 3.79	✓ 4.00
10	✓ 3.85	✓ 3.60	✓ 3.72	! 3.02
11	✓ 3.62	! 3.28	! 3.29	✗ 2.97
12	✓ 3.88	✓ 3.60	✓ 3.53	✓ 3.98
13	! 3.20	! 3.15	! 3.42	! 3.14
14	! 3.26	! 3.14	! 3.12	! 3.18
15	✓ 3.80	✓ 3.65	✓ 3.82	✓ 3.63
16	✓ 3.80	✓ 3.82	! 3.48	✓ 3.68
17	! 3.00	✗ 2.71	✓ 3.58	! 3.09
Median	**3.80**	**3.60**	**3.52**	**3.14**

✓ When the value is greater than 3.5 ! When the value is between 3.0 and 3.5 ✗ When the value is less than 3.0

The median of the scores given by the experts to each criterion is greater than 3, which implies that the results are between 'agree' and 'strongly agree'. As regards the internal consistency reliability of the validity results, the ICC was calculated based on the four validity scores. The ICC values for language clarity, completeness, relevance and scoring are 0.981, 0.988, 0.972 and 0.989, respectively. Chapter two describes the interpretation of the ICC results (Table 2.3). The resulted ICC values for all measures are greater than 90%, which demonstrates 'strong agreement' between experts and substantially differentiates these results from those derived by chance. The final version of PITI following content validation is presented in Figure 5.5.

It is obvious from Figure 5.5 that the most number of statements (eight statements) are under the category of GMP & QA. This topic was one of the two most frequently discussed by the expert panel (chapter 3, Table 3.1) and it was necessary that the instrument cover all areas related to this category. Research and development was also mentioned frequently by the expert panel and subsequently six statements were allocated to this topic in the PITI formulation

Part III - Pilot study

Pilot studies are commonly used to confirm that the instrument is practical and applicable for measuring the research question (Flynn, 1990). For the purpose of the pilot study, the instrument was sent to 30 managers from three companies (10 managers per company). The questionnaire also contained a psychometric evaluation section, titled 'evaluation of the questionnaire', which asked the following questions in an effort to explore the respondents' experience of completing the questionnaire:

1. Were the statements clear and easy to understand?
2. Were the statements easy to respond to?
3. Were the statements related to the topic of study?
4. How long did it take to complete the questionnaire?

All 30 questionnaires were collected and the responses were analysed. Two responses were excluded because they were incomplete.

Figure 5.5 The final version of the PITI

Current Situation												Future Importance										
← absolute compliance										no compliance →	**1. Patent Review**	← not important at all									very important →	
10	9	8	7	6	5	4	3	2	1	0	Our company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	An intellectual property right is a key issue in the selection of a new product.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We review intellectual property rights when exporting products.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The financial impact of enforcing patent protection on our products has been studied.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											**2. Licence & Technology Transfer Agreement**	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Having licensed products is a strategic goal for our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The infrastructure of our company satisfies the requirements of reputable licensors.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have licence agreements with innovator companies.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have technology transfer agreements with technology owners.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Licensed or technology transferred products constitute an important part of our total sales.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											**3. Sales &Marketing**	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Our marketing expenditure is comparable to that of our international rivals.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company regularly increases the ratio of marketing expenditure to total sales.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The company measures the effectiveness of marketing expenditure.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our marketing activities contribute to capturing the market share.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our marketing activities have increased our customer loyalty.	0	1	2	3	4	5	6	7	8	9	10

Cont. Figure 5.5 The final version of the PITI

Current Situation											4.GMP&QA	Future Importance										
absolute compliance ◄										► no compliance		not important at all ◄									► verry important	
10	9	8	7	6	5	4	3	2	1	0	Our company allocates sufficient budget to improve our GMP.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have the GMP approval of international inspectors.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have a validation master plan in our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have an appropriate documentation system for GMP.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have a change control system for all related departments.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our manufacturing areas are updated and renovated regularly.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	GMP improvement is a strategic goal for our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The effectiveness of the GMP expenditure is measured in our company.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											**5. Research and Development**	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Our company allocates sufficient budget for the R&D department.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The effectiveness of R&D expenditure is measured in our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	R&D investment plays a major role in the competitiveness of our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	A major part of our company revenue comes from exclusive products.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	There are common projects with R&D institutions outside our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have innovative new formulations.	0	1	2	3	4	5	6	7	8	9	10

Cont. Figure5.5 The final version of the PITI

Current Situation											6. Products Packaging	Future Importance										
absolute compliance ◄										no compliance ►		not important at all ◄									verry important ►	
10	9	8	7	6	5	4	3	2	1	0	The attractiveness of the packaging is a strong point of our products.	0	1	2	3	4	5	6	7	8	9	10
10	9	8		6	5	4	3	2	1	0	We invest in improving our product packaging.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our packaging lines are similar to those of the international rivals of the company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The role of packaging in creating customer satisfaction is measured in our	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The quality of packaging is competitive with that of the international competitors of our company.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											7. Manufacturing Technology	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Our company regularly improves the production lines.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The automation level in this company is similar to that of our international rivals.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our manufacturing technology is in compliance with environmental standards.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our manufacturing procedures are well documented and well executed.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We regularly update the manufacturing procedures for our product.	0	1	2	3	4	5	6	7	8	9	10

Cont. Figure 5.5 The final version of the PITI

Current Situation absolute compliance ← → no compliance											8. Mergers & Strategic Alliances	Future Importance not important at all ← → verry important										
10	9	8	7	6	5	4	3	2	1	0	We have strategic alliances with some of our partners.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company is evaluating possible mergers and acquisitions.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Being a subsidiary of a holding company facilitates strategic alliances.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											**9. Pricing Policy**	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	We have competitive pricing in comparison with our international rivals.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have price flexibility in comparison with our rivals.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											**10. Training for Employees**	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Qualifications are considered very important when recruiting people in our company.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have training programmes for every job.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We are increasing the training hours per capita for our employees.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company measures the effectiveness of the training programmes.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The capabilities of our employees are comparable with those of our international rivals.	0	1	2	3	4	5	6	7	8	9	10
											11.skills of R&D staff											
10	9	8	7	6	5	4	3	2	1	0	Our company regularly improves the skills of the R&D staff.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our R&D team develop innovative products.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	A considerable part of our company revenue is the result of innovation in R&D.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	The skills of our R&D staff have created advantages for our company.	0	1	2	3	4	5	6	7	8	9	10

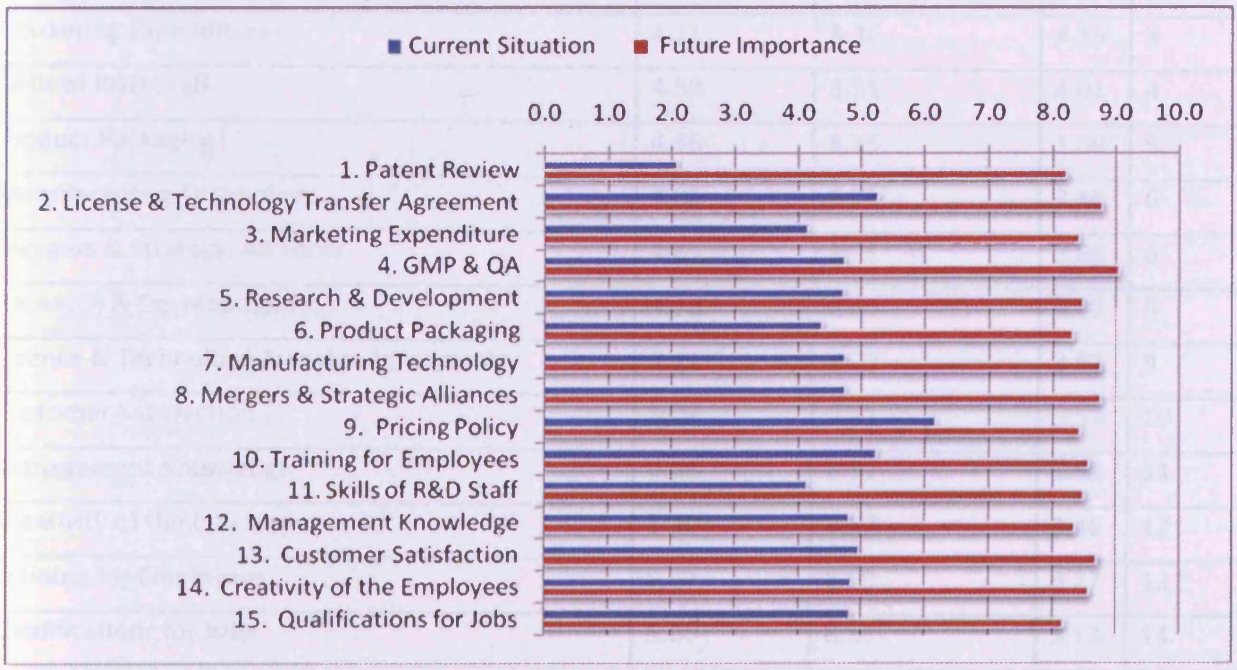
Cont. Figure 5.5 The final version of the PITI

Current Situation											12. Management Knowledge	Future Importance										
absolute compliance ◄										► no compliance		not important at all ◄									► very important	
10	9	8	7	6	5	4	3	2	1	0	We have qualified persons in all managerial positions.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We measure the efficiency of the decisions taken by our managers.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	There are adequate numbers of management graduates in our managerial team.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											13. Customer Satisfaction	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	We have internal programmes to meet the customers' requirements.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have categorised our customers into different groups and have communication programmes for each group.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company knows the needs of target customers.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We regularly measure the satisfaction levels of our customers.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											14. Creativity of the Employees	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	Our organisation encourages innovation.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	We have utilised the innovativeness of our employees to create value.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Innovation plays an important role in maintaining our competitiveness.	0	1	2	3	4	5	6	7	8	9	10
Current Situation											15. Qualifications for jobs	Future Importance										
10	9	8	7	6	5	4	3	2	1	0	The minimum qualifications have been increased in our organisation in recent years.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company has access to people with the required qualifications.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company can afford to employ highly qualified people.	0	1	2	3	4	5	6	7	8	9	10
10	9	8	7	6	5	4	3	2	1	0	Our company has offered scholarships to obtain employees with the required qualifications.	0	1	2	3	4	5	6	7	8	9	10

Demography of the respondents: The respondents were requested to specify their gender, age, education and organisational position. The distribution of their age was as follows: 50% of the respondents were 40–45 years old, and the rest were distributed normally within the age ranges of less than 35, 35–40, 45–50 and more than 50 years old. From the educational level point of view, 71% of the respondents were pharmacists or physicians, 21% had completed their BS and 7% had an MS degree. The organisational positions of the respondents were as follows: 15% were managing directors and board members, 50% were managers, 25% had other managerial designations and the positions of the rest were not mentioned.

Scores given to the PITI statements: The respondents rated their agreement with the statements distributed among 15 categories, including Patent Review, Licence & Technology Transfer Agreements, Sales & Marketing etc. the category-wise mean of their responses to the statements in terms of current situation and future importance are shown in the Figure 5.6.

Figure 5.6 The mean of the scores in the pilot study



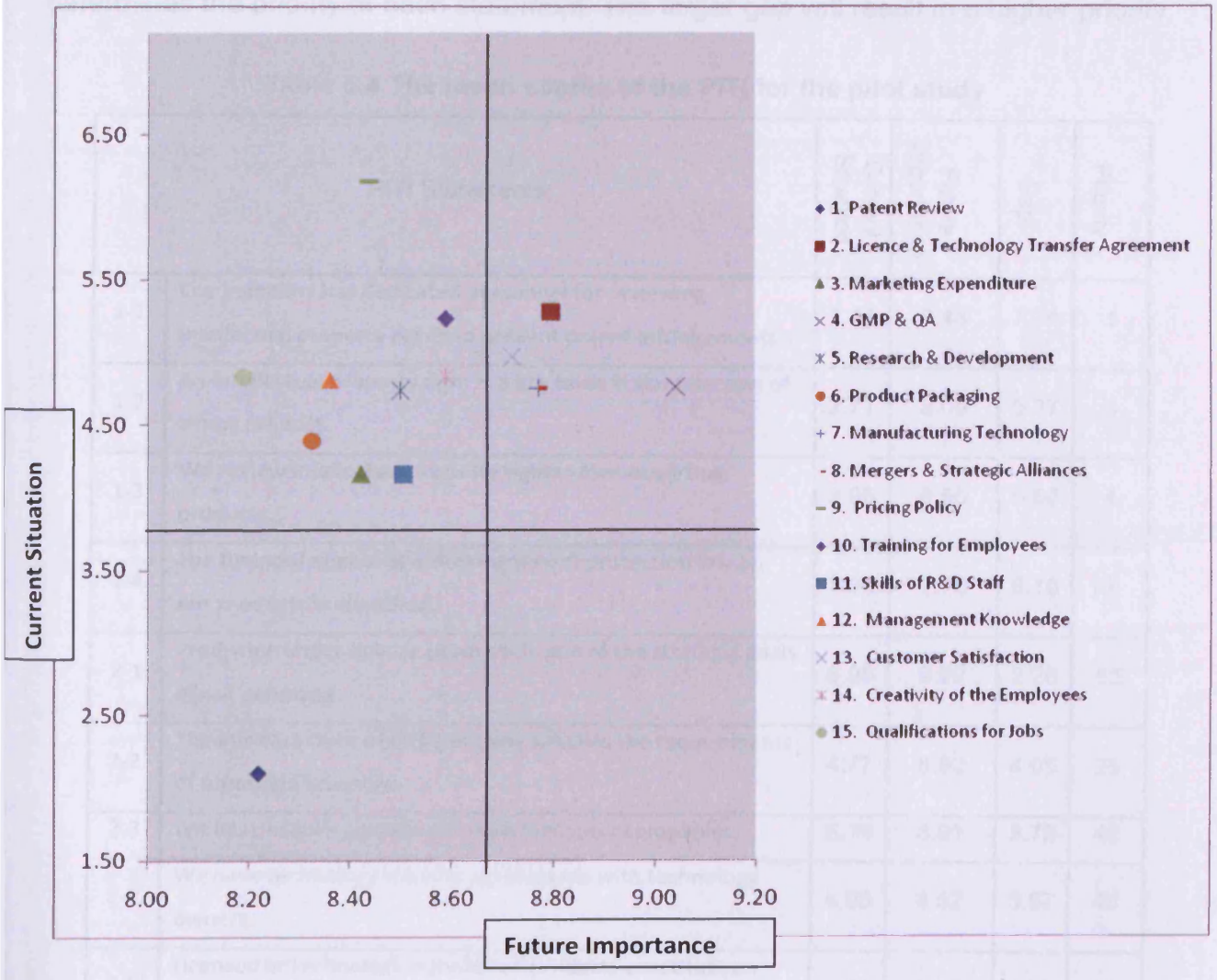
The figure indicates that the scores for the current situation are relatively lower than those for future importance. Conversely, all the scores pertaining to future importance are higher than 8, thus representing the importance and relevance of the selected items. The lowest figure, which also represents the biggest difference from among the other categories, is related to patent review departments. This reflects the significance of reviewing the patent situation of the products and the lack of adequate capabilities at present. All the categories are ranked according to the extent of the gap, with the biggest gap receiving the highest priority (Table 5.3).

Table 5.3 The priority based on the category-wise mean scores in the pilot study

Instrument Categories	Current Situation	Future Importance	Gap	Priority
Patent Review Department	2.04	8.25	6.21	1
GMP & QA	4.75	9.00	4.25	2
Marketing Expenditure	4.21	8.36	4.15	3
Skills of R&D Staff	4.50	8.51	4.01	4
Product Packaging	4.36	8.25	3.89	5
Manufacturing Technology	4.85	8.71	3.86	6
Mergers & Strategic Alliances	4.85	8.71	3.86	6
Research & Development	4.78	8.45	3.68	8
Licence & Technology Transfer Agreements	5.11	8.73	3.62	9
Customer Satisfaction	5.08	8.61	3.53	10
Management Knowledge	4.81	8.32	3.51	11
Creativity of the Employees	5.10	8.57	3.46	12
Training for Employees	5.32	8.59	3.27	13
Qualifications for Jobs	5.00	8.13	3.13	14
Pricing Policy	6.67	8.34	1.67	15

Based on these data (gap analysis), the patent review department was given the highest priority, followed by GMP and marketing expenditure. It is interesting to note that the pricing policy received the lowest rank, which may indicate that the industry has fewer concerns pertaining to price competition. The results for all the statements will be presented and discussed in the next chapter, after describing the main data collection. The distribution of different categories between the axis of future importance and current situation is visualised in Figure 5.7.

Figure 5.7 The relationship between the current situation and future importance of the PITI categories



The above diagram shows the category of Patent Review as positioned at some distance from the other items, which re-emphasises the significant importance of working on this area. At the same time, Pricing Policy also occupies a unique position in the opposite direction in the diagram. The other items have similar positions in terms of the current situation and are differentiated similarly as regards their future importance. The scores given to each statement and their ranking according to the size of the gap are provided in the Table 5.4. The statements are ordered based on the PITI structure, the first figure in the left column shows the PITI category and the second figure presents the position of the statement in the category. The median of the 'Current Situation' and 'Future Importance' scores are presented for all statements and the size of the gap determines the priority of each statement. The larger gap will result in a higher priority.

Table 5.4 The mean scores of the PITI for the pilot study

PITI Statements		Current Situation	Future Importance	Gap	Priority
1-1	Our company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements.	1.14	8.48	7.34	1
1-2	An intellectual property right is a key issue in the selection of a new product.	2.71	8.09	5.37	5
1-3	We review intellectual property rights when exporting products.	2.95	8.55	5.60	4
1-4	The financial impact of enforcing patent protection law on our products is identified.	1.60	7.76	6.16	2
2-1	Producing under-licence products is one of the strategic goals of our company.	6.95	9.22	2.26	65
2-2	The infrastructure of this company satisfies the requirements of reputable licensors.	4.77	8.82	4.05	25
2-3	We have licence agreements with innovator companies.	5.19	8.91	3.72	42
2-4	We have technology transfer agreements with technology owners.	4.95	8.52	3.57	48
2-5	Licensed or technology transferred products constitute an important part of our total sales.	4.52	8.52	4.00	28
3-1	Our marketing expenditure is comparable to that of our	2.42	8.04	5.63	3

PITI Statements		Current Situation	Future Importance	Gap	Priority
	international rivals.				
3-2	Our company regularly increases the ratio of marketing expenditure to total sales.	3.68	8.27	4.59	11
3-3	We measure the effectiveness of our marketing expenditure.	4.17	8.04	3.88	35
3-4	Our marketing activities have contributed to capturing the market share.	5.50	8.88	3.38	51
3-5	Our marketing activities have increased our customer loyalty.	5.04	8.87	3.83	37
4-1	This company allocates sufficient funds to improve the GMP level.	4.78	9.13	4.35	19
4-2	We have the GMP approval of international inspectors.	3.74	9.09	5.35	6
4-3	We have a validation master plan for GMP.	4.32	9.22	4.90	10
4-4	We have an appropriate documentation system for GMP.	6.22	9.30	3.09	55
4-5	We have a change control system for all related departments.	3.82	8.91	5.09	9
4-6	The manufacturing areas of this company are regularly updated and renovated.	4.13	8.48	4.35	19
4-7	GMP improvement is a strategic goal for our company.	6.71	9.43	2.73	59
4-8	The effectiveness of GMP expenditures is evaluated in our company.	4.30	8.78	4.48	15
5-1	Our company allocates sufficient funds for the R&D department.	4.57	8.70	4.13	23
5-2	The effectiveness of R&D expenditures is measured in our company.	3.39	8.61	5.22	7
5-3	R&D investment plays a major role in our competitiveness.	4.63	9.08	4.46	16
5-4	A major part of this company revenue comes from exclusive products.	5.42	8.13	2.71	60
5-5	We have joint R&D projects with institutions outside our company.	5.64	8.09	2.45	63
5-6	We have innovative new formulations.	4.75	8.38	3.63	45
6-1	The attractiveness of the packaging is a strong point of our products.	4.62	8.73	4.12	24
6-2	We invest in improving our product packaging.	5.08	8.42	3.35	52

	PITI Statements	Current Situation	Future Importance	Gap	Priority
6-3	Our packaging lines are comparable with those of our international rivals.	4.12	8.13	4.01	27
6-4	The role of packaging in creating customer satisfaction is measured in our company.	3.81	7.96	4.15	21
6-5	The quality of the packaging is comparable with that of our international competitors.	4.35	8.38	4.04	26
7-1	Our company regularly improves the production lines.	4.21	8.75	4.54	13
7-2	The automation level in this plant is comparable with that of our international rivals.	3.33	8.54	5.21	8
7-3	The manufacturing technology in this company is in compliance with environmental standards.	4.65	8.48	3.83	38
7-4	The manufacturing procedures in this company are well documented and well executed.	6.43	9.09	2.65	61
7-5	We regularly update the manufacturing procedures for our products.	5.09	9.00	3.91	33
8-1	Our company has strategic alliances with some of our partners.	4.40	8.35	3.95	29
8-2	Our company is evaluating possible mergers and acquisitions.	4.22	8.00	3.78	39
8-3	Being a subsidiary of a holding company facilitates strategic alliances.	4.50	7.94	3.44	50
9-1	Our company has competitive pricing in comparison with our international rivals.	5.96	8.42	2.46	62
9-2	Our company has price flexibility in comparison with our rivals.	6.38	8.46	2.08	66
10-1	Qualifications are considered very important while recruiting people in this company.	5.22	8.69	3.47	49
10-2	We have training programmes for every job.	5.54	8.81	3.27	54
10-3	We are increasing our training hours per capita.	5.77	8.62	2.85	57
10-4	Our company measures the effectiveness of our training programmes.	4.62	8.50	3.88	34
10-5	The capabilities of our employees are comparable with our	5.00	8.32	3.32	53

	PITI Statements	Current Situation	Future Importance	Gap	Priority
	international rivals.				
11-1	Our company regularly improves the skills of the R&D staff.	4.43	8.57	4.14	22
11-2	Our R&D team can develop innovative products.	4.27	8.64	4.36	17
11-3	A considerable part of the revenue of our company results from innovation in R&D.	3.86	8.23	4.36	18
11-4	The skills of our R&D staff have created competitive advantages for our company.	4.05	8.59	4.55	12
12-1	We have qualified persons in all managerial positions.	5.60	8.64	3.04	56
12-2	Our company measures the efficiency of the decisions taken by the managers.	4.36	8.28	3.92	31
12-3	There are adequate numbers of management graduates in our managerial team.	4.48	8.16	3.68	43
13-1	We have internal programmes to meet the customers' requirements.	4.88	8.79	3.92	32
13-2	We have categorised our customers into different groups and have communication programmes for each group.	4.63	8.50	3.88	36
13-3	Our company knows the needs of its target customers.	4.96	8.54	3.58	47
13-4	We regularly measure the satisfaction levels of our customers.	5.38	9.04	3.67	44
14-1	Our organisation encourages innovation.	5.00	8.60	3.60	46
14-2	Our company has utilised the innovativeness of its employees to create value.	4.72	8.44	3.72	41
14-3	Innovation plays an important role in maintaining our competitiveness.	4.79	8.72	3.93	30
15-1	The minimum qualifications have been increased in our organisation in recent years.	5.75	8.58	2.83	58
15-2	Our company has access to people with the necessary qualifications.	6.04	8.42	2.38	64
15-3	Our company can afford to employ highly qualified people.	4.42	8.17	3.75	40
15-4	Our company has offered scholarships to obtain employees with the required qualifications.	3.08	7.58	4.50	14

The largest gap belonged to the 'Patent Review' and was related to dedicating personnel to review the patent situation of their products. This is absolutely understandable especially when considering that the companies participating in the pilot study were three large companies. The second gap was realised in evaluating the financial impact of enforcing TRIPS regulations regarding patent protection. The third priority showed the industry concerns about "marketing expenditure of their international rivals'. Again, the fourth and fifth priority were reviewing the patent situation while developing new products or exporting the products to other countries. The next important priority reflects the gap in obtaining GMP approval from international inspectors that may indicate the lack of sufficient investment in this area. At the same time, the industry is not measuring the effectiveness of its marketing expenditures (the seventh priority). Automation level from the category of 'Manufacturing Technology' is the eighth priority and it is not surprising that a change control system and validation master plan (ninth and tenth priorities) are again related to the GMP and QA. Therefore, patent review, GMP & QA, marketing expenditure as well as the manufacturing technology are the ten major sources of concerns in the pilot companies.

Comparing the results of the pilot study and the Delphi technique: The results of the pilot study using PITI, with the final ranking of the parameters resulted from the Delphi technique applying WTO-PI Impact Rating Scale, are presented in the Table 5.5. Friedman ranking of the statements listed in the WTO-PI Impact Rating Scale are compared to the future importance of the PITI statements to realise the perceptions of the two group of respondents regarding the post-WTO situation. It should be remembered that the respondents to the PITI were all managers from the industry, while the respondents to the Delphi questionnaire were a balanced group of experts from different fields of regulatory authority, academia and industry. In other words, the results given in this chapter are more indicative of the opinions of the industry mindset, and comparing these two results may reveal the differences between the two groups of participants in the study. The greatest increase in the rankings given by the PITI respondents occurred in the category of Creativity of the Employees (+16 points), followed by the categories of Manufacturing Technology (+14 points) and Research & Development (+11 points). This means that the pilot study respondents were more concerned about incorporating innovation into their R&D and using new technologies

and this is why people from industry have put these categories much higher than the expert panel. They also upgraded the categories of GMP & QA, Mergers & Strategic Alliances and Licence & Technology Transfer Agreements (+7 points).

Table 5.5 Comparison of the results of the pilot study and the Delphi technique

Delphi Technique		Pilot Study		Rank Changes
Friedman Ranking	WTO-PI Impact Rating Scale statements	Future Importance Scores	PITI Categories	
1	Importation Tariff*	9.00	GMP & QA	+7
2	Management Knowledge & Skills	8.73	Licence & Technology Transfer Agreements	+7
3	Training for Employees	8.71	Manufacturing Technology	+14
4	Skills of R&D Staff	8.71	Mergers & Strategic Alliances	+7
5	Customer Satisfaction	8.61	Customer Satisfaction	0
6	Patent Review Departments	8.59	Training for Employees	-3
7	Marketing Expenditure	8.57	Creativity of the Employees	+16
8	GMP	8.51	Skills of R&D Staff	-4
9	Licence & Technology Transfer Agreements	8.45	Research & Development	+11
10	Pricing Policy	8.36	Marketing Expenditure	-3
11	Mergers & Strategic Alliances	8.34	Pricing Policy	-1
12	Policies of Paying the Subsidies*	8.32	Management Knowledge	-10
13	Product Packaging	8.25	Patent Review Department	-7
14	Higher Qualifications for Jobs	8. 25	Product Packaging	-1
15	Per Capita Expenditure on Medicines*	8.13	Qualifications for Jobs	-1
17	Modern Manufacturing Techniques			
20	R&D Expenditure			
23	Innovation & Creativity of the employees			

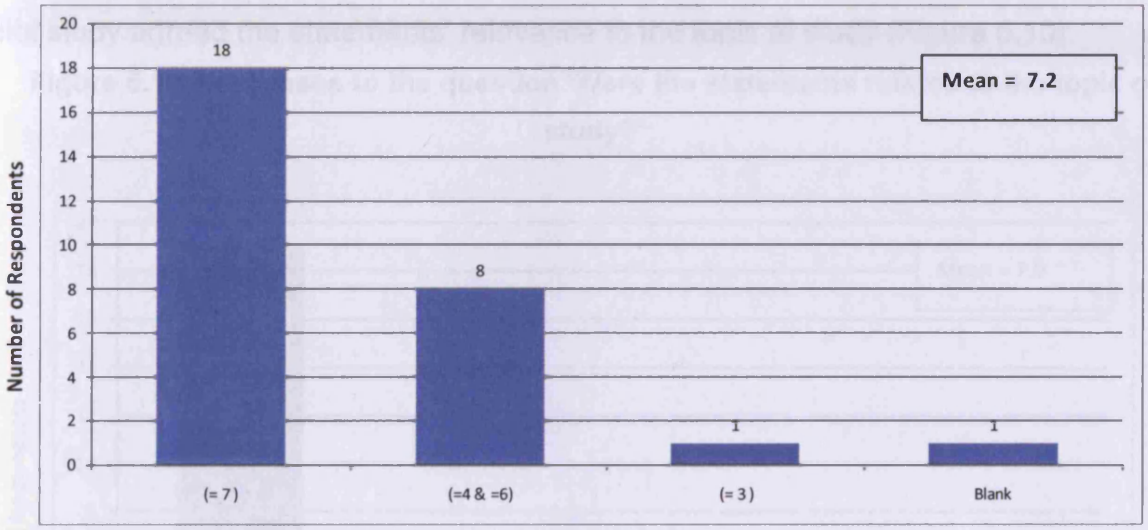
*No correspondent PITI category

Unexpectedly, they dramatically reduced the importance of the Management Knowledge (−10 points) in the post-WTO situation. This implies that the pilot study respondents were less concerned about their knowledge levels and gave greater priority to other issues. They also downgraded Patent Review (-7), Skills of R&D Staff (-4 points) and Training for Employees (-3 points). The other categories underwent little or no change in their importance. These results will be compared with the final scores in subsequent chapters in order to determine which results are common for the entire group of respondents.

Applicability and Practicality of the PITI: In this part of the pilot study, the respondents were asked to rate their agreement with the statements relating to their ease of understanding and completing the instrument. The scale ranged from 1 to 9, with 1 representing 'totally disagree' and 9 representing 'totally agree'.

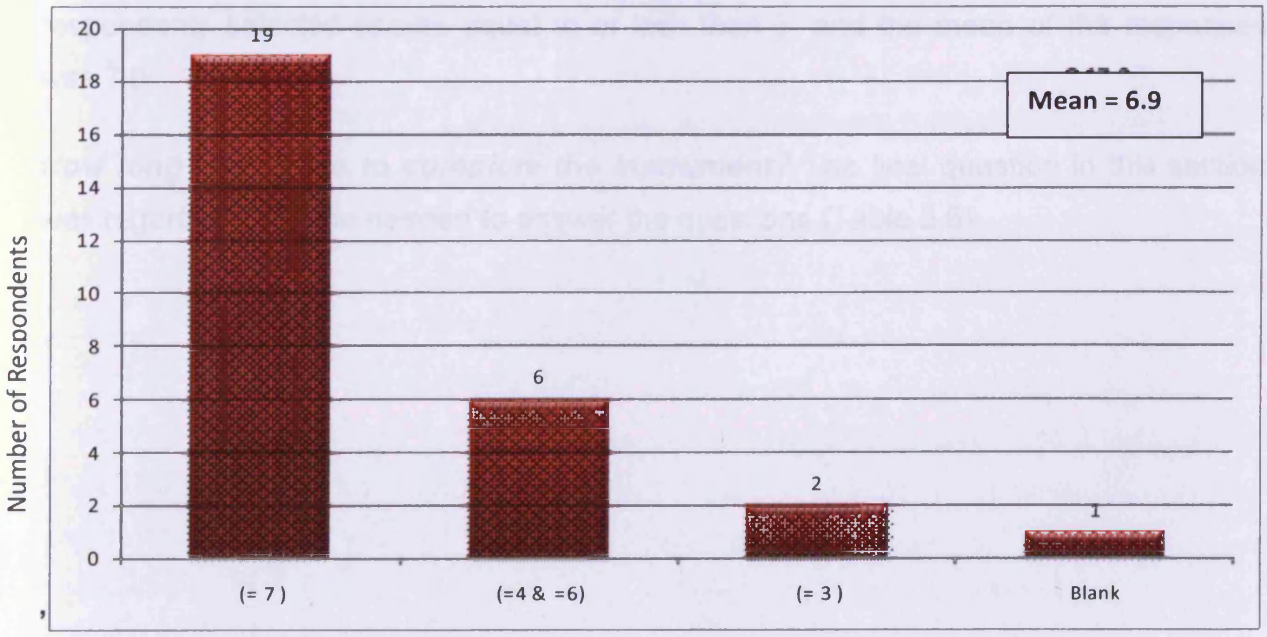
Were the statements clear and easy to understand? In general, the industry participants found the statements of the PITI as "easy to understand' (Figure 5.8).

Figure 5.8 Responses to the question 'Were the statements clear and easy to understand?'



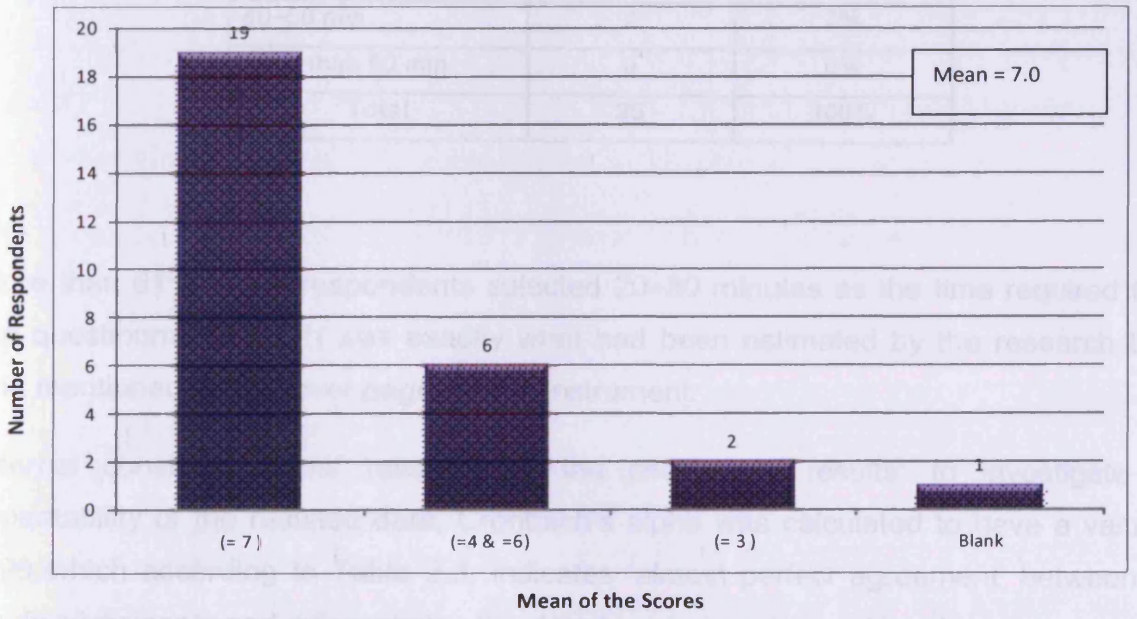
Were the statements easy to respond to? Even more of the respondents labelled these statements as 'easy to respond to'. While 68% of the respondents accorded scores of 7 or more to this question, only two respondents gave it scores of equal to or less than 3. The mean of the scores for this question is 6.9 (Figure 5.9).

Figure 5.9 Responses to the question 'Were the statements easy to respond to'?



Were the statements related to the topic of study? Overall, the participants in the pilot study agreed the statements' relevance to the topic of study (Figure 5.10).

Figure 5.10 Responses to the question 'Were the statements related to the topic of study?'



With 64% of the respondents giving this question a score exceeding 7. Only two respondents selected scores equal to or less than 3, and the mean of the responses was 7.0.

How long did it take to complete the instrument? The final question in this section was regarding the time needed to answer the questions (Table 5.6).

Table 5.6 Responses to the question 'How long did it take to complete the questionnaire?'

Time	Frequency	Percentage
20–30 min	17	61%
30–40 min	6	21%
40–50 min	2	7%
More than 60 min	0	0%
Total	**25**	**100%**

More than 61% of the respondents selected 20–30 minutes as the time required to fill the questionnaire, which was exactly what had been estimated by the research team and mentioned in the cover pages of the instrument.

Internal consistency and reliability of the pilot study results: to investigate the repeatability of the resulted data, Cronbach's alpha was calculated to have a value of 0.99 which according to Table 2.3, indicates 'almost perfect agreement' between the study participants and differentiates the data from being obtained by chance.

DISCUSSION

It was a significant challenge to develop a study instrument that would fit the requirements of this research, mainly due to the absence of such an instrument in the literature. In fact, defining the inclusion and exclusion factors was the first barrier to the design and development of a robust research instrument. The current study overcame this problem by using the methodology of the Delphi technique (chapter 4), whereby an expert panel generated the items that would subsequently be used as the framework of the study instrument. This methodology resulted in the development of the PITI containing 15 categories (by excluding certain statements that were related to contextual issues), which were then populated with a number of statements with the help of the research team. Developing the electronic version of the rating scales especially the Web-based PITI, contributed to facilitating the data collection procedures with respect to the time horizon of the study. The willingness of the study participants

played a major role in the success of the electronic data collection and in process communication. The study participants and other research groups gave a positive feedback to the procedures used for the content validation of the study instrument. The psychometric evaluation of the PITI yielded acceptable results in the first stage, while this process had previously required two stages for completion, as described in chapter 3. The results of the psychometric evaluation in the pilot study also supported the conceptualisation procedure for developing the instrument. The pilot study with the industry participants did not require that the PITI should be changed or refined thus establishing the validity and reliability of the instrument.

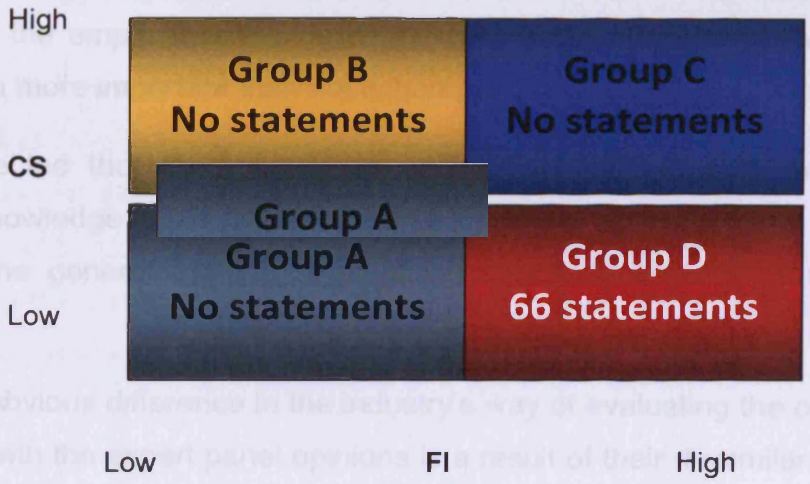
The pilot study revealed a significant difference between the scores given to the current situation and those given to the future importance of the statements, which clearly indicates the strength of the developed study instrument when it comes to identifying the parameters influencing the sustainability of the industry in the post-WTO situation.

With regard to the current situation (CS) and future importance (FI) of each statement, there were four possibilities:

- Group A: Areas that the industry neither complies with in the current situation (low CS score) nor are likely to be important in the future (low FI score)
- Group B: Areas that are satisfactorily developed at present (high CS score) but are not important in the post-WTO/TRIPS situation (low FI scores)
- Group C: Areas that are not only considered important at present (high CS score) but also have significant importance in the post-WTO/TRIPS environment (high FI scores)
- Group D: Areas that are not complied with in the current situation (low CS score) but will have significant importance in the post-WTO/TRIPS environment (high FI scores)

These possibilities are illustrated in Figure 5.11.

Figure 5.11 The distribution matrix of the statements against CS and FI



This matrix indicates that all the statements of the developed instrument are distributed within group D, with low scores in terms of the current situation but high scores as regards future importance. This group represents the important, insufficiently developed areas that are likely to have severe consequences for the industry if no action plan is defined to address them in time. This matrix also demonstrates the identification of the categories, which confirms the value of the Delphi technique and the precise elaboration of the statements in this study.

The fact that the pilot study was carried out in pharmaceutical companies differentiates the results from the outcomes of the expert panel with participants from academia, the regulatory authority and industry. It should be also noted that the pilot companies were three major firms with considerable market share. These companies have been inspected by foreign teams both for exportation of their products or licence agreements. Therefore, the complications of receiving GMP approval from international bodies are clear for them and this is why they have put GMP and QA at the top of the list of their future concerns in a position much higher than the expert panel did before. They have also underlined the importance of licence and technology transfer agreement by putting this category in the second position to bridge the technology gap and produce innovative products. The industry, at the same time, believes that manufacturing technology will have a remarkable role in the competitive situation post-WTO.

Comparing these results with the expert panel opinions revealed the fact that the industry is more focused on hard structural parameters while the expert panel highlighted softer aspects of the industry such as knowledge of the management and the skill level of the employees. Conversely, industry has considered the creativity of employees much more important than the expert panel.

It was not expected that the industry, in contrast to the expert panel, would put management knowledge at the bottom of their future concerns, but this may be interpreted by the general trend of highlighting structural aspects by this group of respondents.

In general, the obvious difference in the industry's way of evaluating the consequences of joining WTO with the expert panel opinions is a result of their dissimilar backgrounds and experiences while at the same time underlines the necessity of a more intra-field discussion for creating a consensus among various players in the pharmaceutical environment. It will be important to see the results of carrying out the study throughout the industry before a final conclusion is reached. It should be also mentioned that the respondents were those that had and had not been inspected by GMP auditors. Therefore they have had different levels of experience in this regard.

SUMMARY

This chapter described the development of the Pharmaceutical Industry Transition Instrument (PITI) as identified by the steps delineated in Figure 5.1.

- The items used for designing the PITI were identified using the Delphi technique, as explained in the previous chapters.
- In order to study the industry situation, the items categorised under 'content' and 'structure' were selected, while the 'context' parameters, which basically focused on the industry environment, were excluded.
- The items were later grouped into different categories pertaining to various industry departments and activities, such as the 'patent review department', 'GMP expenditure' etc. And these categories were thereafter populated with several statements, which resulted in a total of 66 statements in the final instrument.

- This instrument was also evaluated for psychometric criteria such as validity, reliability and completion time with acceptable results.
- Finally, the instrument was pilot tested on a group of 30 participants from three different pharmaceutical companies with 28 acceptable responses (response rate of 93%). The results of the content validation were also supported by the responses to the applicability and practicality questions in the pilot study.
- The ranking of items resulting from the industry participants (pilot study) was compared with that obtained by using an expert panel in the Delphi exercise (Table 5.6), thus highlighting the differences between the priorities given to the items by the two groups of respondents.

Chapter 6

Evaluation of the Current Environment and Future Aspirations of the Pharmaceutical Industry in Iran

INTRODUCTION

The main focus of chapters 3 and 4 was to identify the parameters that are likely to influence the pharmaceutical industry in the post-WTO situation. These parameters were utilised in chapter 5 to design an instrument to determine the current situation and the future importance of these parameters within the industry. The instrument was titled the 'Pharmaceutical Industry Transition Instrument' (PITI) and this instrument was then evaluated for validity and reliability and a pilot study conducted to ensure its applicability and practicality. In this chapter, the PITI will be used to evaluate the current situation and future aspirations of the pharmaceutical industry and this evaluation will be based on the data collected from managers of several pharmaceutical companies.

This chapter will play a crucial role in answering the research question on the 'post-WTO/TRIPS sustainability of the pharmaceutical industry in Iran'. The data generated at this stage of the study will provide the information necessary to explore the extent to which the industry is aware of the upcoming challenges and the way in which it understands the current situation. The scores regarding the future importance of the parameters will reveal whether the industry is ready to meet the future challenges. The pattern of scoring for the current situation will indicate the extent to which the industry is prepared for WTO/TRIPS implementation. Comparing the current situation and future importance of the parameters will identify the existing gap, which can help managers and policy makers decide how to prioritise and verify critical issues and thereby develop strategies to allocate national or organisational resources to meet these challenges.

OBJECTIVES

The data collected in this part of the study, using the PITI as the data collection instrument, will be used to evaluate the situation of the pharmaceutical companies by assessing the gap between the industry's readiness to meet future challenges. The objectives of this study were to:

- Study the current situation of the industry by identifying its strengths and weaknesses

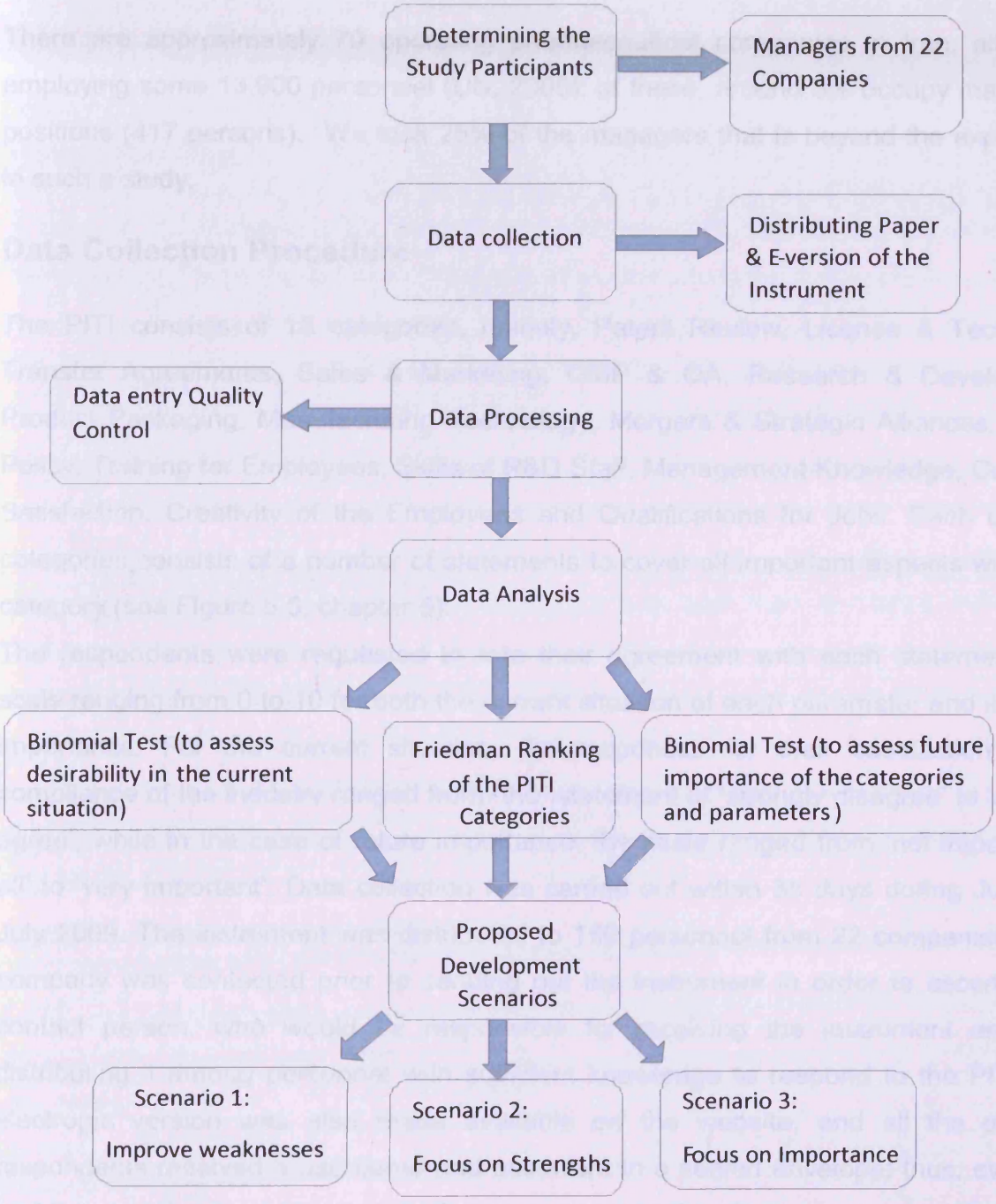
- Identify the future importance of the various parameters that reflect the industry's aspirations to meet the challenges
- Rank and prioritise the actions that need to be taken by the industry
- Explore the statistical significance of the study findings
- Propose scenarios for developing appropriate strategies to ensure the sustainability of the pharmaceutical industry

METHODS

In this study, the PITI was used to assess the current environment and future aspirations of the pharmaceutical industry in Iran. The practical steps that were carried out in this part of the study are as follows (Figure 6.1):

- The participants were selected according to their eligibility and contacted to ensure their willingness to participate in the study
- A website was designed and registered to upload the study instrument to facilitate the web-based data collection procedure
- The study instrument (PITI) was distributed among the study participants in both paper and electronic formats
- The resulting data were quality controlled and transferred into the data base
- Friedman's test was carried out to rank the categories of the parameters
- The Binomial test was used to evaluate the current situation and future importance of the PITI categories and statements
- Three development scenarios are proposed on the basis of study results in order to improve the industry weaknesses, focus on industry strengths and concentrate on the future importance of the identified categories of parameters.

Figure 6.1 The study methodology flowchart



Study Participants

There are approximately 70 operating pharmaceutical companies in Iran, altogether employing some 13,900 personnel (UN, 2005); of these, around 3% occupy managerial positions (417 persons). We took 25% of the managers that is beyond the expectation in such a study.

Data Collection Procedure

The PITI consists of 15 categories, namely, Patent Review, Licence & Technology Transfer Agreements, Sales & Marketing, GMP & QA, Research & Development, Product Packaging, Manufacturing Technology, Mergers & Strategic Alliances, Pricing Policy, Training for Employees, Skills of R&D Staff, Management Knowledge, Customer Satisfaction, Creativity of the Employees and Qualifications for Jobs. Each of these categories consists of a number of statements to cover all important aspects within the category (see Figure 5.5, chapter 5).

The respondents were requested to rate their agreement with each statement on a scale ranging from 0 to 10 for both the current situation of each parameter and its future importance. For the current situation, the responses for their satisfaction of the compliance of the industry ranged from the statement of 'strongly disagree' to 'strongly agree', while in the case of future importance, the scale ranged from 'not important at all' to 'very important'. Data collection was carried out within 35 days during June and July 2009. The instrument was distributed to 150 personnel from 22 companies. Each company was contacted prior to sending out the instrument in order to ascertain the contact person, who would be responsible for receiving the instrument and then distributing it among personnel with sufficient knowledge to respond to the PITI. The electronic version was also made available on the website, and all the potential respondents received a username and password in a sealed envelope; thus, everyone had the opportunity to choose whether to respond to the electronic or paper version of the PITI. The recipients of the instrument were subsequently contacted by phone and/or e-mail to determine the likelihood of their participation in the study and to understand the distribution of the instrument throughout the company. An electronic reminder of the data collection deadline was sent one week before the end of data collection. The

companies that did not return the questionnaires by the deadline were subsequently contacted either to discuss the possibility of late data provision or to confirm that the company or some of its respondents would not participate.

Response Rate

A total of 150 questionnaires were distributed among 22 companies, out of which 90 were returned from the same number of companies; thus, the response rate was 60%. In view of the response rate of 93% in the pilot study (28 respondents from a total of 30), the overall response rate was 66%. Of out the 90, from this, 9 responses were excluded due to the high number of missing items. According to the follow up of the non-respondent cases, the main reason they decided not to participate in the study was lack of sufficient knowledge, which prevented the person from completing the questionnaire. In other words, the real number of people with sufficient information regarding the issues investigated in this study was less than our initial expectation. There were other reasons for the non-respondents, namely, the data were not readily available in the company or could not be made available within the given time frame or the concerned person was unwilling to provide information due to reasons of confidentiality. As a result of the pilot and main study we had 109 evaluable responses and because no amendment was required, the results of the pilot and the main study are combined.

Data Processing and Analysis

Once the questionnaires were returned, the data were reviewed to determine data quality. Any returned instrument with several unanswered questions was excluded from the study.

The respondents were encouraged to provide data using the electronic version, which had been designed as a Web-based questionnaire using the Microsoft ASP.NET 3.5 technology and SQL server 2008 database. The respondents were requested to enter their specific username and password to open the instrument pages on the Web page www.pharmeconomics.com, which was specifically designed for this study using Visual Web Developer 2008. This software can be used for creating online reports for both

demographic and study questions. The use of an electronic instrument considerably improved the quality of the data, thus eliminating the need for additional data handling steps and the complications resulting from manually entering data into the database.
The data were processed using Microsoft Access 2007. Both Microsoft Access 2007 and Microsoft Excel 2007 were used to obtain descriptive statistics of the data, while SPSS version 17 for Windows XP was used to run statistical analyses on the data. These analyses included the following calculations:

- The mean of the responses to all statements regarding the current situation and future importance was calculated, and the gap between the current situation and the future importance was determined.
- The internal consistency of the data was tested by calculating Cronbach's alpha to determine the repeatability of the results.
- The Friedman test was carried out to assess whether the ranking of the categories and parameters is significant.
- Binomial tests were carried out to investigate the significance of categorising the parameters as 'desirable' with regard to the current situation and 'important' in terms of the future importance. (The tests were carried out for categories as well as statements.)

This chapter explains the above process and its practical steps, which are presented in Figure 6.1.

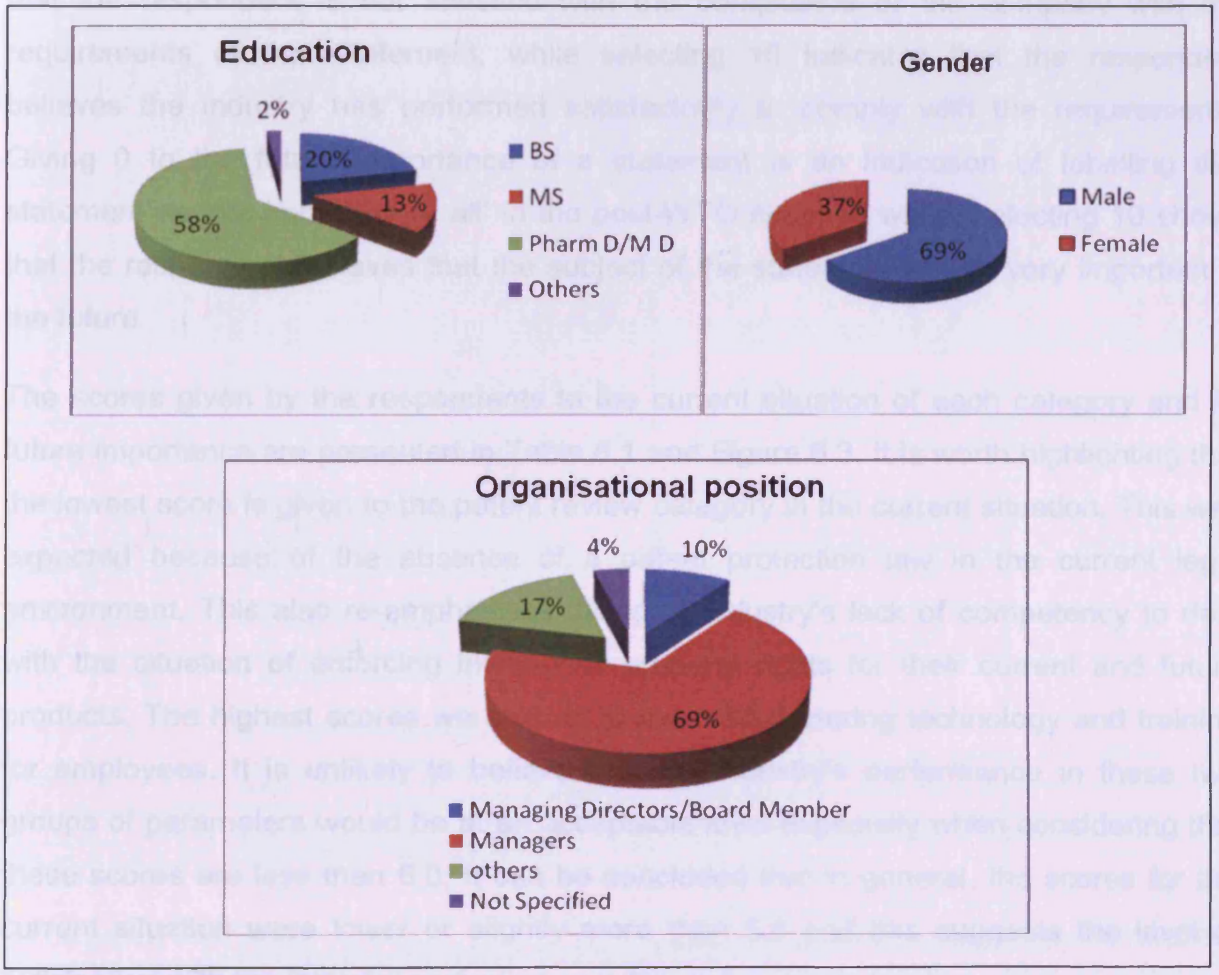
RESULTS

Demographics of the Respondents

In terms of gender, 69% of the respondents were males, while 37% were females. Their educational profile was as follows: 20% had completed their BS; 13%, MS; 58%, Pharm. D or MD; and 7%, PhD. The educational qualifications of 2 respondents (2%) were not provided. The organisational positions of the respondents were as follows: 10% were board members and managing directors, 69% were managers, 17% were employed in other managerial positions and the designations of 4% were not specified.

In addition, 90% of the participants were from companies that manufactured finished products (Figure 6.2).

Figure 6.2 Demographics of the respondents



Reviewing the results showed there were not significant differences between the responses of different groups of participants apart from the fact that there were more missing items in the non-pharmacist responses.

The Perceptions of the Respondents in View of the PITI Categories

The findings of this chapter revealed the fact that the Iranian pharmaceutical industry is ill prepared to face the challenges from joining WTO and implement TRIPS regulations. The situation of the industry was evaluated and the important areas were identified by using the Pharmaceutical Industry Transition Instrument (PITI) developed in the

previous chapter. This instrument asks the respondents to express their opinions about the current situation and future importance of each statement by selecting a figure within the anchor of the points from 0 to 10. Selecting 0 for the current situation means that the respondent is not satisfied with the compliance of the company with the requirements of that statement, while selecting 10 indicates that the respondent believes the industry has performed satisfactorily to comply with the requirements. Giving 0 to the future importance of a statement is an indication of labelling that statement as 'not important at all' in the post-WTO situation while, selecting 10 shows that the respondent believes that the subject of the statement will be very important in the future.

The scores given by the respondents to the current situation of each category and its future importance are presented in Table 6.1 and Figure 6.3. It is worth highlighting that the lowest score is given to the patent review category in the current situation. This was expected because of the absence of a patent protection law in the current legal environment. This also re-emphasises the local industry's lack of competency to deal with the situation of enforcing intellectual property rights for their current and future products. The highest scores were given to the manufacturing technology and training for employees. It is unlikely to believe that the industry's performance in these two groups of parameters would be at an acceptable level especially when considering that these scores are less than 6.0. It can be concluded that in general, the scores for the current situation were lower or slightly more than 5.0 and this suggests the level of satisfaction with the industry performance is low or barely moderate.

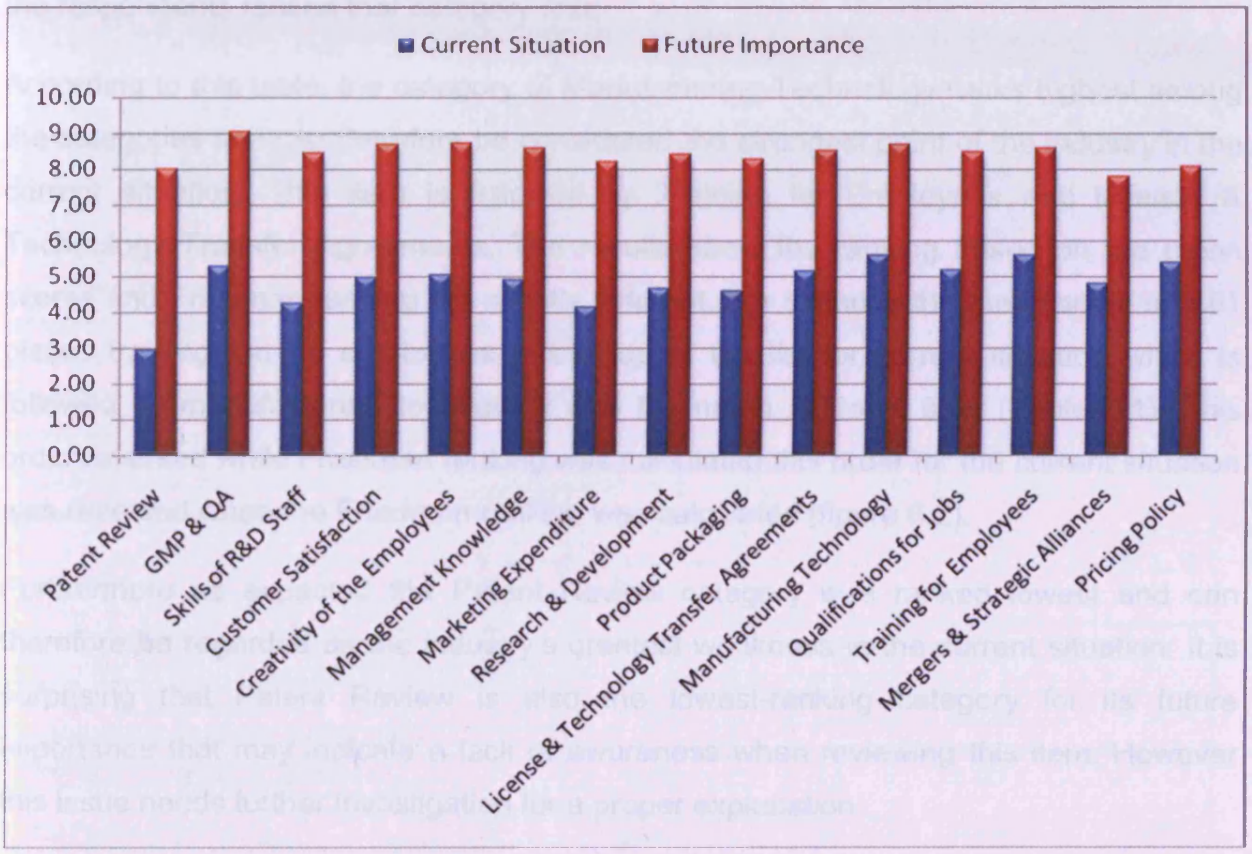
Conversely, the scores given to the future importance of the statements are fairly high and clearly more than those for the current situation. GMP & QA has received the highest score of 9.05, indicating the importance of this item in the coming situation. It is interesting to note that the future importance of both Management Knowledge and Training for Employees were rated equally by the respondents (both received a score of 8.61).

Table 6.1 The mean scores for the current situation and future importance

Categories of Parameters	Current Situation	Future Importance
Patent Review	2.93	8.01
GMP & QA	5.29	9.05
Skills of R&D Staff	4.26	8.46
Customer Satisfaction	4.99	8.70
Creativity of the Employees	5.04	8.73
Management Knowledge	4.91	8.61
Marketing Expenditure	4.15	8.23
Research & Development	4.68	8.42
Product Packaging	4.58	8.30
Licence & Technology Transfer Agreements	5.15	8.53
Manufacturing Technology	5.60	8.71
Qualifications for Jobs	5.20	8.50
Training for Employees	5.61	8.61
Mergers & Strategic Alliances	4.80	7.82
Pricing Policy	5.38	8.08

Even though patent review received low satisfaction in the current situation (mean score of 2.93), the industry gave a relatively high future importance score to recognise this area as a considerable consequence of joining WTO and implementing TRIPS regulations. The mean scores given to each of the statements are presented in Appendix 7.1.

Figure 6.3 The mean scores of the PITI categories



Internal Consistency Reliability

To assess the reliability of the data generated by the PITI, Cronbach's alpha was measured for all 66 statements; it resulted in a value of 0.94 for the current situation and 0.98 for future importance. According to the interpretation presented in chapter 2 (Table 2.3), both results are acceptable and indicate almost perfect agreement among the respondents.

Prioritising the PITI Categories Using the Friedman Test

All 15 categories of the identified parameters were ranked using the Friedman test (Table 6.2). The column of mean rank shows the calculated mean of the ranks based on the given responses to the related statements. Since the instrument consists of 15

categories, the maximum possible mean rank for a particular category would be 15 if all the respondents ranked that category first.

According to this table, the category of Manufacturing Technology ranks highest among the categories and can therefore be considered the strongest point of the industry in the current situation. This item is followed by Training for Employees and Licence & Technology Transfer Agreements. The results show the ranking based on the mean scores and Friedman ranking are slightly different. For instance the mean score of 5.61 places training for the employees at the top of the list for current situation which is followed by manufacturing technology with the mean score of 5.60 (Table 6.1). This order reversed while Friedman ranking was calculated this order for the current situation was reversed when the Friedman ranking was calculated (figure 6.2).

Furthermore as expected the Patent Review category was ranked lowest and can therefore be regarded as the industry's greatest weakness in the current situation. It is surprising that Patent Review is also the lowest-ranking category for its future importance that may indicate a lack of awareness when reviewing this item. However this issue needs further investigation for a proper explanation.

As indicated by this table, GMP expenditure is likely to be the most important category in the future. The fact that this category ranked fifth in the current situation implies that the current GMP levels do not match the future importance of this category that suggests more improvements in this area. The other potential area for improvement is creativity of the employees with a low Friedman rank of 10 in the current situation and a high importance ranking of 4.

Table 6.2 Prioritisation of the PITI categories using Friedman test

PITI Categories	Current Situation		Future Importance		Ranking Change
	Friedman Ranking	Mean Rank	Friedman Ranking	Mean Rank	
Manufacturing Technology	1	10.02	2	9.04	−1
Training for Employees	2	9.66	5	8.42	−3
Licence & Technology Transfer Agreements	3	9.38	8	8.16	−5
Qualifications for Jobs	4	9.19	9	8.02	−5
GMP & QA	5	9.11	1	10.77	+4
Pricing Policy	6	8.85	12	7.06	−6
Customer Satisfaction	7	8.80	3	8.89	+4
Mergers & Strategic Alliances	8	8.28	13	6.49	−5
Management Knowledge	9	8.20	6	8.37	+3
Creativity of the Employees	10	8.10	4	8.87	+6
Research & Development	11	7.96	10	7.60	+1
Product Packaging	12	7.07	11	7.34	+1
Skills of R&D Staff	13	6.13	7	8.17	+6
Marketing Expenditure	14	5.39	14	6.47	0
Patent Review	15	3.88	15	6.34	0

The changes in the rankings of parameter categories also presented in Table 6.2. The largest changes occur in the category of "Creativity of the Employees" and Skills of R&D staff which each shows a 6-point increase in rank. This means that these two categories have relatively low ranks in the current situation as compared to their future importance. These are followed by GMP & QA and Customer Satisfaction, which show a 4-point increase in rank; hence, they represent the second group of unmet categories, followed by Management Knowledge (3-point increase in rank). Meanwhile, Marketing

Expenditure and Patent Review do not show any change in ranking, which is surprising considering the importance of these two categories in the post-WTO/TRIPS situation.

Statistical significance of the Friedman ranking was determined to support its application in designing improvement plans for identified areas. Using SPSS version 17 confirmed the significance of the above ranking for both current situation and future importance of the categories ($P<0.05$).

Performance of the Industry with Respect to the Study Parameters

To assess the performance of the industry a hypothesis was generated for each PITI statement as follows:

- Study Hypothesis: The performance of the industry with respect to this statement is satisfactory (mean > 5).

By applying the binomial test, it is possible to evaluate each statement in order to determine whether it is significant (P value<0.05) and the hypothesis is accepted (observed probability more than 0.5) or rejected (observed probability less than 0.5).

Future Importance of the Study Parameters

The importance of the statements in the post-WTO/TRIPS situation was also evaluated by testing the following hypothesis:

- Study Hypothesis: This statement will be important in the post-WTO/TRIPS situation (mean > 5).

An accepted research hypothesis implies that more than 50% of the respondents give a score higher than 5 to the concerned statement and that the parameter is either satisfactory (in the current situation) or important (for the future), while a rejected research hypothesis implies that the parameter is neither satisfactory nor important. It should be noted that a P value of more than 0.05 indicates an inordinately large variation between the responses, which means that the test result is not significant (Table 6.3).

Table 6.3 Performance of the industry and the future importance of the PITI statements

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	1. Patent Review						
1-1	Our company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements.	0.15	0.001	rejected	0.86	0.001	accepted
1-2	An intellectual property right is a key issue in the selection of a new product.	0.33	0.002	rejected	0.86	0.001	accepted
1-3	We review intellectual property rights when exporting products.	0.26	0.001	rejected	0.83	0.001	accepted
1-4	The financial impact of enforcing patent protection on our products has been studied.	0.11	0.001	rejected	0.85	0.001	accepted
	2. Licence & Technology Transfer Agreements						
2-1	Producing under-licence products is one of the strategic goals of our company.	0.58	0.155	not significant	0.91	0.001	accepted
2-2	The infrastructure of our company satisfies the requirements of reputable licensors.	0.52	0.760	not significant	0.97	0.001	accepted
2-3	We have licence	0.45	0.358	not	0.93	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	agreements with innovator companies.			significant			
2-4	We have technology transfer agreements with technology owners.	0.51	0.001	not significant	0.96	0.001	accepted
2-5	Licensed or technology transferred products constitute an important part of our total sales.	0.35	0.006	rejected	0.87	0.001	accepted
	3. Sales & Marketing						
3-1	Our marketing expenditure is comparable with that of our international rivals.	0.09	0.001	rejected	0.85	0.001	accepted
3-2	Our company regularly increases the percentage of marketing expenditure to total sales.	0.23	0.001	rejected	0.93	0.001	accepted
3-3	We measure the effectiveness of our marketing expenditure.	0.32	0.001	rejected	0.94	0.001	accepted
3-4	Our marketing activities have contributed to capturing the market share.	0.4	0.067	not significant	0.96	0.001	accepted
3-5	Our marketing activities have increased our customer loyalty.	0.4	0.052	not significant	0.94	0.001	accepted
	4. GMP & QA						
4-1	Our company allocates sufficient funds to improve the GMP level.	0.54	0.543	not significant	0.97	0.001	accepted
4-2	We have the GMP approval	0.24	0.001	rejected	0.97	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	of international inspectors.						
4-3	We have a validation master plan for GMP.	0.44	0.301	not significant	0.97	0.001	accepted
4-4	We have an appropriate documentation system for GMP.	0.66	0.002	accepted	0.98	0.001	accepted
4-5	We have a change control system for all related departments.	0.4	0.079	not significant	0.97	0.001	accepted
4-6	The manufacturing areas of our company are regularly updated and renovated.	0.47	0.614	not significant	0.96	0.001	accepted
4-7	GMP improvement is a strategic goal for our company.	0.74	0.001	accepted	1	0.001	accepted
4-8	The effectiveness of GMP expenditures is evaluated in our company.	0.36	0.007	rejected	1	0.001	accepted
	5. Research & Development						
5-1	Our company allocates sufficient funds for the R&D department.	0.41	0.104	not significant	0.98	0.001	accepted
5-2	The effectiveness of R&D expenditures is measured in our company.	0.16	0.001	rejected	0.92	0.001	accepted
5-3	R&D investment plays a major role in increasing our competitiveness.	0.45	0.363	not significant	0.96	0.001	accepted
5-4	A major part of our company's revenue comes from exclusive products.	0.51	0.920	not significant	0.93	0.001	accepted
5-5	We have joint R&D projects	0.33	0.001	rejected	0.87	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	with institutions outside our company.						
5-6	We have innovative new formulations.	0.27	0.001	rejected	0.89	0.001	accepted
	6. Product Packaging						
6-1	The attractiveness of the packaging is a strong point of our products.	0.39	0.035	rejected	0.93	0.001	accepted
6-2	We invest in improving our product packaging.	0.49	0.920	not significant	0.92	0.001	accepted
6-3	Our packaging lines are comparable with those of our international rivals.	0.34	0.002	rejected	0.92	0.001	accepted
6-4	The role of packaging in creating customer satisfaction is measured in our company.	0.25	0.001	rejected	0.9	0.001	accepted
6-5	The quality of the packaging is comparable with that of our international competitors.	0.24	0.001	rejected	0.92	0.001	accepted
	7. Manufacturing Technology						
7-1	Our company regularly improves the production lines.	0.46	0.480	not significant	0.97	0.001	accepted
7-2	The automation level in this plant is comparable with that of our international rivals.	0.28	0.001	rejected	0.9	0.001	accepted
7-3	The manufacturing technology in our company is in compliance with	0.56	0.305	not significant	0.94	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	environmental standards.						
7-4	The manufacturing procedures in this company are well documented and well executed.	0.65	0.006	accepted	1	0.001	accepted
7-5	We regularly update the manufacturing procedures for our products.	0.58	0.129	not significant	0.96	0.001	accepted
	8. Mergers & Strategic Alliances						
8-1	Our company has strategic alliances with some of our partners.	0.38	0.026	rejected	0.91	0.001	accepted
8-2	Our company is evaluating possible mergers and acquisitions.	0.38	0.029	rejected	0.83	0.001	accepted
8-3	Being a subsidiary of a holding company facilitates strategic alliances.	0.44	0.289	not significant	0.82	0.001	accepted
	9. Pricing Policy						
9-1	Our company has competitive pricing in comparison with our international rivals.	0.51	0.917	not significant	0.89	0.001	accepted
9-2	Our company has price flexibility in comparison with our rivals.	0.45	0.407	not significant	0.89	0.001	accepted
	10. Training for Employees						
10-1	Qualifications are considered very important while recruiting people in our company.	0.58	0.137	not significant	0.96	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
10-2	We have training programmes for every job.	0.51	0.842	not significant	0.94	0.001	accepted
10-3	We are increasing our training hours per capita.	0.56	0.271	not significant	0.91	0.001	accepted
10-4	Our company measures the effectiveness of our training programmes.	0.43	0.228	not significant	0.94	0.001	accepted
10-5	The capabilities of our employees are comparable with those of our international rivals.	0.49	0.920	not significant	0.93	0.001	accepted
	11. Skills of R&D Staff						
11-1	Our company regularly improves the skills of the R&D staff.	0.41	0.082	not significant	0.92	0.001	accepted
11-2	Our R&D team develops innovative products.	0.31	0.001	rejected	0.92	0.001	accepted
11-3	A considerable part of our company revenue is the result of innovation in R&D.	0.24	0.001	rejected	0.89	0.001	accepted
11-4	The skills of the R&D staff have created advantages for our company.	0.31	0.001	rejected	0.93	0.001	accepted
	12. Management Knowledge						
12-1	We have qualified persons in all managerial positions.	0.52	0.839	not significant	0.99	0.001	accepted
12-2	Our company measures the efficiency of the decisions taken by the managers.	0.33	0.001	rejected	0.96	0.001	accepted
12-3	There are adequate	0.36	0.010	rejected	0.94	0.001	accepted

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
	numbers of management graduates in our managerial team.						
	13. Customer Satisfaction						
13.1	We have internal programmes to meet the customers' requirements.	0.4	0.054	not significant	0.98	0.001	accepted
13.2	We have categorised our customers into different groups and have communication programmes for each group.	0.43	0.189	not significant	0.93	0.001	accepted
13.3	Our company knows the needs of its target customers.	0.42	0.155	not significant	0.96	0.001	accepted
13.4	We regularly measure the satisfaction levels of our customers.	0.47	0.614	not significant	0.98	0.001	accepted
	14. Creativity of the Employees						
14.1	Our organisation encourages innovation.	0.36	0.007	rejected	0.98	0.001	accepted
14.2	Our company utilises the innovativeness of its employees to create value.	0.36	0.007	rejected	0.98	0.001	accepted
14.3	Innovation plays an important role in maintaining our competitiveness.	0.4	0.070	not significant	0.96	0.001	accepted
	15. Qualifications for Jobs						

		Current Situation			Future Importance		
No.	**Category/Statement**	Observed probability*	P value§	Hypothesis result‡	Observed probability*	P value§	Hypothesis result‡‡
15.1	The minimum qualifications have been increased in our organisation in recent years.	0.66	0.002	accepted	0.97	0.001	accepted
15.2	Our company has access to people with the necessary qualifications.	0.59	0.0851	not significant	0.97	0.001	accepted
15.3	Our company can afford to employ highly qualified people.	0.41	0.104	not significant	0.95	0.001	accepted
15.4	Our company has offered scholarships to obtain employees with the required qualifications.	0.3	0.001	rejected	0.85	0.001	accepted

*Observed probability: represents the percentage of respondents who gave a rating higher than 5 to the respective statement.

§ P value: is the observed error.

‡The hypothesis testing may generate one of the following results: *Accepted (satisfactory):* observed probability > 0.5 (=50%), P value < 0.05, *Rejected (unsatisfactory):* observed probability < 0.5 (=50%), P value < 0.05, *Not significant:* P value > 0.05.

‡ ‡The hypothesis testing may generate one of the following results: Accepted (important): observed probability > 0.5 (=50%), P value < 0.05, Rejected (not important): observed probability < 0.5 (=50%), P value < 0.05, Not significant: P value > 0.05.

Table 6.3 reveals that the test results for the current situation are 'not significant' for 34 statements, representing 52% of the total statements. The research hypothesis is accepted for only 4 statements namely: 4.4 (GMP documentation), 4.7 (GMP improvement), 7.4 (compliance with environmental standards) and 15.1 (increase in the required level of qualification). This suggests that the current situation for only a limited number of the statements is recognised as satisfactory, and rejected for 28 statements, which constitute 6% and 42% of the total statements, respectively.

1. Patent Review

With regard to the Patent Review category, respondents from different companies admitted that they did not review patents when selecting or exporting products, either because they did not have the personnel to do so or because they were unaware of the financial implications of enforcing patent protection laws. The observed probabilities for the statements are merely 15%, 33%, 26% and 11%, respectively.

2. Licence and Technology Transfer

In the case of Licence & Technology Transfer Agreements, there was a consensus for rejecting the importance of licensed and technology transferred products in the companies' total sales. With respect to the results of the former category, it is not surprising because of the dependence of licence agreements on their patents protection in the host country. As regards the other statements, including the importance of a strategic approach to this parameter, creating better infrastructure and forging new agreements, the respondents' opinions are very varied, which may be due to the existence of different situations in different companies.

3. Marketing Expenditure

The respondents concurred to say that their company's marketing expenditure was not comparable with that of the company's rivals. Also, it did not increase as a part of the company's total sales and the company did not measure its effectiveness (the study hypotheses were rejected, with the observed probability of 9%, 23% and 32%, respectively). The role of the marketing activities in capturing the market share and increasing customer loyalty show considerable variations, which means that some companies may have captured the market share and increased customer loyalty through their marketing expenditures, while others have not.

4. GMP & QA

The respondents expectedly regarded a strategic approach to GMP improvement and having appropriate GMP documentation, with the observed probability of 74% and 66%, respectively, as satisfactory in the current situation, while they looked upon obtaining international GMP certificates and increasing the effectiveness of GMP expenditures as unsatisfactory (the study hypotheses were rejected, with the observed probability of 24% and 36%, respectively). The lack of international GMP certificates is the most

important finding and this is not surprising because they do not have required funds and resources. In addition, there are considerable variations in the responses pertaining to the adequacy of GMP budgeting, having validation master plans, change control systems, and plant renovation (the results are not significant). This means that the importance of dedicating enough research in this area is not realised or there is not enough resources to dedicate to this vital issue.

5. R&D Expenditure

The respondents labelled the effectiveness of R&D expenditure, joint R&D projects and innovative formulations as 'unsatisfactory' in the current situation (with the observed probability of 16%, 33% and 27%, respectively), while they had varied views on the adequacy of R&D expenditure, R&D-induced competitiveness and the accrual of revenue from exclusive products (the results are not significant).

6. Product Packaging

The binomial test results reveal that according to the study participants, the attractiveness of packaging, use of world-class packaging lines, measuring the role of packaging in customer satisfaction and world-class product packaging are unsatisfactory in the current situation,. The results for the statement 'We invest in improving our product packaging' are not significant, implying that the companies have different policies when it comes to investing in upgrading the quality of their packaging.

7. Manufacturing Technology

Documentation of the production procedures is the only parameter labelled as 'satisfactory' in the Manufacturing Technology category, with the observed probability of 65%, while automation level has been categorised as 'unsatisfactory', with the observed probability of 28%. The results for the regular improvement of the production line, compliance with environmental standards and regular updating of the manufacturing procedures indicate high variations between the responses and are categorised as 'not significant'.

8. Mergers and Strategic Alliances

Having strategic alliances and considering mergers and acquisitions are regarded as unsatisfactory, with both statements showing an equal observed probability of 38%, while the role played by holding companies in facilitating strategic alliances remains somewhat controversial probability because a majority of the companies are state owned.

9. Pricing policy

Pricing policy however plays a great role in the survival of the pharmaceutical industry in the post-WTO situation. The fact that competitive pricing has been labelled as 'not significant', indicates that while some of the companies are revising their pricing policies, others are not maybe because they are comfortable with the current situation. Maybe after WTO/TRIPS, these companies will be out of their comfort zone. Price flexibility has also received scores with high variations.

10. Training for Employees

The results for all statements in the Training for Employees category have emerged as 'not significant', which indicates that companies are following different policies in this regard. This high variation is surprising because it was expected that at least the basic elements of employees training such as having training programmes would be similar within the companies.

11. Skills of R&D Staff

The development of innovative products by R&D staff, role of R&D innovations in company revenue and creating competitive advantages through R&D skills have been classified as 'unsatisfactory' in the current situation, therefore the study hypothesis was rejected (with the observed probability of 31%, 24% and 31%, respectively). However, 'improving the skills of the R&D staff' was classed as not significant.

12. Marketing Knowledge

While the experts agreed on the importance of employing qualified persons in managerial positions, they also admitted that 'the efficiency of the managers' decisions are not measured' and that 'the company does not employ sufficient numbers of

management graduates' (the study hypotheses were rejected, with an observed probability of 33% and 36%, respectively).

13. Customer Satisfaction

The divergence of opinions pertaining to customer satisfaction resulted in 'not significant' labels for all the statements in this category, including 'having programmes to meet customer requirement', 'customers categorisation', 'knowing the needs of the target customers' and 'regular measurement of customer satisfaction levels'. That means some of the companies still have not realised the important role of the customer related issues.

14. Creativity of the Employees

The respondents rejected the importance of encouraging innovation and utilising employees' innovativeness for value creation in the current situation, both statements having observed probability of 36%; however, the scores for the role of innovation in maintaining the competitiveness of the company show considerable variations. This means that some companies have not recognised the importance of innovation but they will have to place it as a high priority in the future if the industry wants to be sustainable.

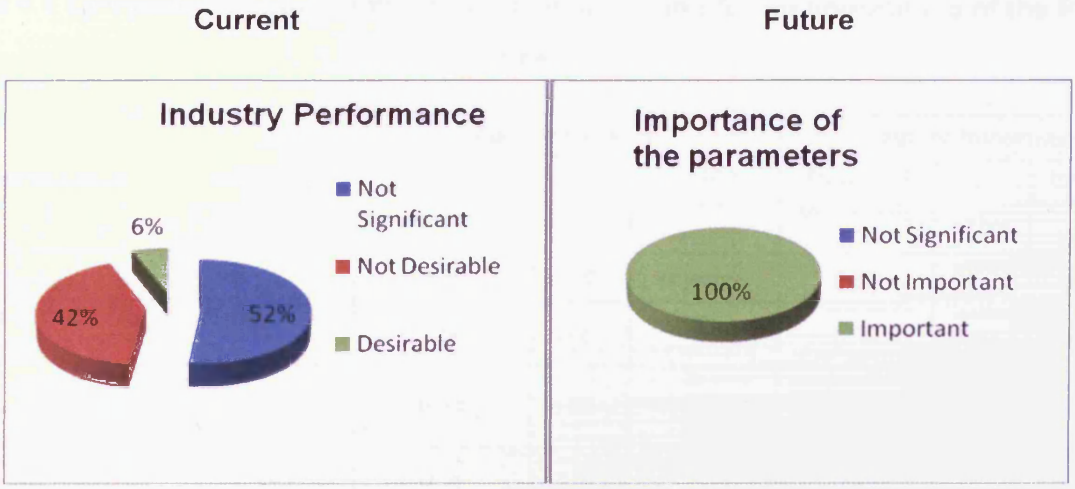
15. Qualifications for Jobs

The respondents agreed on classifying the need to increase minimum qualifications in recent years as 'satisfactory', revealing the fact that companies are now more conscious about the importance of their employees' capabilities. Access to people with the necessary qualifications and being able to compensate the services of highly qualified persons show some variations in the results, but at the same time, the companies do not appear to support scholarship programmes for obtaining employees with the necessary qualifications. This may be due to the fact that the current managers do not welcome the challenges that could result from working with qualified persons.

The test results indicate that the study hypotheses accepted for all statements in terms of their future importance. This means that the respondents categorised all the parameters covered by the statements as 'important' in the future. The observed

probability was higher than 90% for 52 statements and 80–90% for 14 statements. This is clearly higher than 50%—the cut-off point for the binomial test. This relatively high observed probability, (p value <0.001), not only makes the study hypothesis perfectly acceptable but also clarifies the fact that there was strong agreement among the participants regarding the future importance of the study parameters. The overall results of the binomial tests for the statements are presented in Figure 6.4.

Figure 6.4 Results of the binomial tests for the study parameters



Performance of the Industry in Terms of the PITI Categories

In order to determine the industry performance in terms of the categories, it is necessary to evaluate the following hypothesis for each category of parameters (15 hypotheses):

- Study Hypothesis: The current situation of this category is 'satisfactory' (mean > 5).

In order to confirm these hypotheses, a binomial test was carried out for each of the categories. A binomial test is used when each item in the sample is classified in one of two groups; the test reveals whether the distribution of the items in each group has been produced by chance or is the result of some pre-specified probabilities (Brenson M L, 2009). In this study, since there are two groups of classification, 'satisfactory' (mean > 5) and 'unsatisfactory' (mean ≤ 5), on a rating scale ranging from zero to ten, binomial tests were conducted to determine the statistical significance of labelling these groups

as 'satisfactory' and 'unsatisfactory'. The data analysis results are presented in Table 6.4. A P value that is greater than the standard error of 0.05 indicates a large variation between the means, which makes the conclusion statistically impossible and this condition is represented as 'not significant'. Observed probability is the percent of the respondents that rated the category with a score more than 5. Therefore, if the P value is less than 0.05, an observed probability of more than 0.5 (50%) will group the category as 'satisfactory' and less than 0.5 indicates that the category is unsatisfactory.

Table 6.4 Comparison between the current situation and future importance of the PITI categories

Category/Statement	Current Situation			Future Importance		
	Observed probability*	P§ value	Hypothesis test result‡	Observed probability *	P§ value	Hypothesis test Result‡ ‡
1. Patent Review	0.20	0.001	rejected	0.87	0.001	accepted
2. Licence & Technology Transfer Agreements	0.56	0.27	not significant	0.96	0.001	accepted
3. Sales & Marketing	0.34	0.001	rejected	0.92	0.001	accepted
4. GMP & QA	0.56	0.32	not significant	0.95	0.001	accepted
5. Research & Development	0.44	0.27	not significant	0.93	0.001	accepted
6. Product Packaging	0.44	0.27	not significant	0.92	0.001	accepted
7. Manufacturing Technology	0.57	0.19	not significant	0.95	0.001	accepted
8. Mergers & Strategic Alliances	0.41	0.12	not significant	0.89	0.001	accepted
9. Pricing Policy	0.51	0.92	not significant	0.90	0.001	accepted
10. Training for Employees	0.62	0.02	not significant	0.91	0.001	accepted
11. Skills of R&D Staff	0.35	0.001	rejected	0.89	0.001	accepted
12. Management Knowledge	0.47	0.68	not significant	0.93	0.001	accepted
13. Customer Satisfaction	0.46	0.55	not significant	0.93	0.001	accepted
14. Creativity of the Employees	0.42	0.13	not significant	0.94	0.001	accepted
15. Qualifications for Jobs	0.52	0.76	not significant	0.95	0.001	accepted

*Observed probability: represents the percentage of respondents who gave a rating higher than 5 to the respective statement.

§ P value: is the observed error.

‡The hypothesis testing may generate one of the following results: *Accepted (satisfactory):* observed probability > 0.5 (=50%), P value < 0.05, *Rejected (unsatisfactory):* observed probability < 0.5 (=50%), P value < 0.05, *Not significant:* P value > 0.05.

‡ ‡The hypothesis testing may generate one of the following results: Accepted (important): observed probability > 0.5 (=50%), P value < 0.05, Rejected (not important): observed probability < 0.5 (=50%), P value < 0.05, Not significant: P value > 0.05.

Developing 15 categories allowed the calculation of summarised scores which established better communication with senior executives in comparison with discussing 66 statements. Out of the15 categories, three were rejected namely patent review, sales and marketing and research and development. This means that for these categories, the current situation is definitely unsatisfactory. The above results are statistically significant and would need to be addressed as a priority in developing strategies and action plans. Only one hypothesis was accepted namely the training for the employees and this is also statistically significant ($P<0.05$) indicating that the training for the Iranian pharmaceutical industry is satisfactory. The outcome for 11 categories of "not significant" means they are neither satisfactory nor unsatisfactory and this can result from intercompany variation or is related to the way in which the individuals evaluate the parameters. In order to have a better understanding, it is necessary to look at the results of single companies.

DISCUSSION

This chapter focused on evaluating the post-WTO sustainability of the pharmaceutical industry in Iran by assessing the performance of the industry with regard to the selected parameters. Simultaneously, the future importance of the parameters was determined using the PITI as the data collection instrument. The study was unique from the view of the conceptualisation and the empirical data collection with a systematic approach to identify the study parameters. Experts from different fields of activities in the pharmaceutical environment, which would be potentially affected by the outcomes of joining WTO, were involved in the study. This process made the results relevant and

understandable for many participants. The instrument was formulated by developing several statements for each topic to cover the whole area. For example the picture that is now available for the situation of GMP & QA from the view of the funds, international approvals, validation master plans, documentation, change control system, renovation of the plants, GMP strategic importance and effectiveness of the GMP expenditure could not be obtained without incorporating a sufficient number of statements under this heading. In general, there were 3 - 4 statements in each category; however in some areas more statements were required to effectively cover all aspects. It should be also noted that having an electronic version of the instrument helped to collect this information as the study was successful in considering the ideas and evaluations of 109 managers in 25 companies. The performance of the industry can be presented as follows:

The PITI was formulated (chapter 5) on the basis of parameters identified as likely to have a considerable impact on the sustainability of the industry in the post-WTO/TRIPS situation; these parameters were selected based on the following characteristics:

- The parameters were expected to reflect the priorities and concerns of the regulatory officials, academics and industry experts who participated in the Delphi panel as well as the industry managers who responded to the PITI.
- It was hypothetically accepted that the study's objective is to identify the unmet requirements of the industry for post-WTO/TRIPS sustainability.
- It was also expected that the parameters would be of significant value in the post-WTO/TRIPS scenario. This characteristic was expressed in this study in terms of the future importance of the parameters.

The results in this chapter confirm the first and second points based on the low scores given by the respondents to the current situation of the parameters (Figure 6.3). The figure also displays the high scores given to the future importance of the parameters. In fact, the research team had not expected such a substantial difference in the ratings given to the current situation (satisfactory performance of the industry) and future importance (significance in the post-WTO/TRIPS situation) of the same parameters. This occurrence underlines the suitability of the research methodology and the sensitivity of the PITI as the study instrument. The binomial tests conducted confirmed

the above scoring pattern, as shown by the observed probability results presented in Table 6.3 for all the PITI statements and Table 6.4 for parameter categories.

In order to fully understand the industry situation, it is also important to categorise the parameters as 'satisfactory' or 'unsatisfactory' in terms of the current situation and 'important' or 'not important' in terms of the future. Such a classification was carried out on the basis of the binomial test results, which indicated that the current performance of the industry in only 6% of the parameters are satisfactory, while all of them are considered to be important in the post-WTO/TRIPS situation (Figure 6.3). From among the 66 PITI statements, the current situation for only 4 statements was classified as satisfactory:

- *We have an appropriate documentation system for GMP.*
- *GMP improvement is a strategic goal for this company.*
- *The manufacturing procedures in this company are well documented and well executed.*
- *The minimum qualifications have been increased in our organisation in recent years.*

The fact that the industry managers classified only these four statements as satisfactory indicates that the industry needs significant preparation before it can handle the challenges of joining the WTO and implementing the TRIPS regulations.

It was also interesting to note the substantial levels of agreement among the industry managers participating in the study in terms of classifying some of the statements as 'important' in the post-WTO situation, based on the binomial test which was used to confirm the study hypotheses (Table 6.3). However, the study hypotheses for the current situation of parameters was rejected for the Patent Review, Marketing Expenditure and Skills of R&D Staff categories, which supports the low Friedman ranking of these items with regard to the current situation. The table also indicates that the study hypotheses were accepted only for statements pertaining to the Training for Employees category, which implies that the current situation of this category is satisfactory and thus explains the position of these items in the Friedman ranking table. The conclusion that 11 categories are 'not significant' indicates that the current situation

needs to be separately evaluated in each company. Nevertheless, this study successfully used binomial tests to confirm the statistical significance regarding all the PITI categories as 'important' with regard to the future.

The statistical confirmation of the unsatisfactory performance of the present situation and the importance of future challenges make it necessary to prioritise parameters in order to develop improvement strategies for the industry. The Friedman ranking of the parameter categories, as presented in Table 6.2, shows that the order of categories in the current situation represents the industry's current degree of compliance with the requirements of each category, which in turn indicates that the industry is in a stronger position with regard to the higher-ranking categories in the table. As the rank decreases, however, the level of compliance decreases accordingly, and the weaknesses of the industry are exposed. For instance, the category of Manufacturing Technology received the mean score of 5.6 with regard to the current situation, which is the highest score among all 15 categories (Table 6.1); this category is therefore located at the top of the Friedman ranking list (Table 6.2). These results indicate that the industry is well prepared in this regard, and manufacturing technology can be regarded as a strong point of the industry. Conversely, Patent Review received the lowest mean score of 2.93 and was consequently placed at the bottom of the Friedman ranking table. Therefore, this category can be regarded as a weakness of the industry as it attempts to tackle the post-WTO challenges.

Based on this argument, the industry can define different scenarios for improvement, while focusing on its strengths and weaknesses. Another approach would involve adopting development strategies on the basis of the importance of the categories presented in Table 6.2. These three different proposed scenarios are illustrated in Figure 6.5.

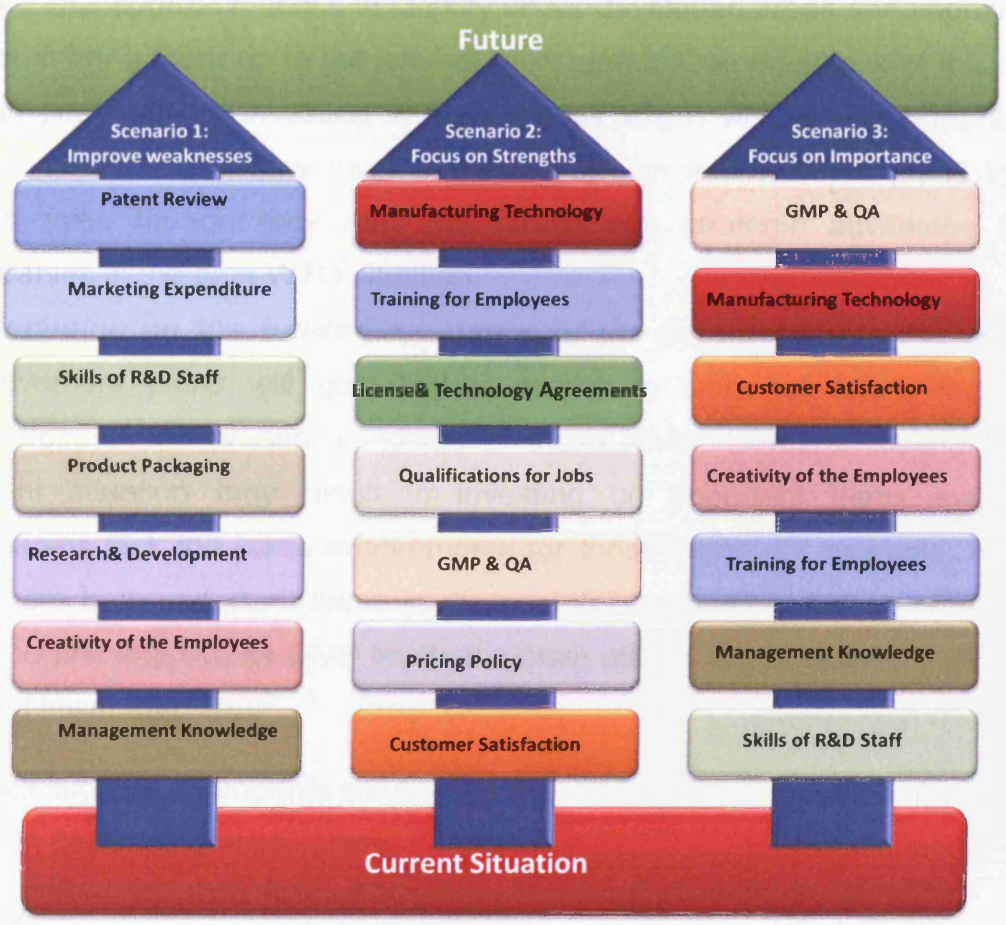
The first proposed scenario involves focusing on the current weaknesses of the industry; this implies giving a higher priority to the least developed aspects of the industry by allocating the necessary funds and defining improvement plans for the industry. This strategy would result in an inverted approach to the ranking of the categories in Table 6.2 in terms of the current situation, because it would involve addressing the least developed item first, which is Patent Review. This would be

followed by improving marketing expenditure, with skills of the R&D staff taking third place.

The second proposed scenario suggests starting from the strengths of the industry, which is manufacturing technology. The logic behind this scenario is that the industry is already in a better situation in terms of higher expertise in and familiarity with the parameters that are its strong points. One of the pitfalls of this scenario, however, is the relatively low priority given to customer satisfaction. Despite a low degree of expertise in and familiarity with this aspect, the industry should pay greater attention to this category as a major future challenge.

The third proposed scenario suggests attributing a higher priority to the most important item for the future. This approach underlines the fact that the main impetus for investing in the improvement of items is their importance in the post-WTO situation, not their present condition. Accordingly, the first item that needs to be addressed is that which is likely to be the most important one in the future, which is GMP and QA, according to Table 6.2. Following this, the industry should focus on improving manufacturing technology and customer satisfaction.

Figure 6.5 Three proposed scenarios for the improvement of the pharmaceutical industry



There are three ways in which action plans can be prepared and critically evaluated:

- ***On the basis of the most improved areas:*** The category that is ranked highest in Table 6.2, has the highest average scores for its statements and indicates the most improved areas. In this approach, improvement plans can be prioritised by starting from these most developed areas, which can be turned into competitive advantages in the future. One drawback of this method is that the industry may end up investing in certain areas which will not be of most importance in the future, while it may correspondingly fail to develop alternative areas of greater importance in the future.

- ***With regard to the current weaknesses:*** The lowest-ranking category in Table 6.2 also has the least score and consequently can be regarded as the weakest areas. This approach seeks to identify under-developed areas and improve them so as to bring them up to the level of other areas. One drawback of this method is the possibility of investing in weaknesses which will be unimportant in the future situation and may involve expenditure on improvement plans in these areas even though they may not create any strategic advantage for the companies in the post-WTO situation.
- ***By focusing on the future importance of the parameters:*** In this approach, improvement plans will give higher priority to items of future importance, regardless of the present condition of those items. However, overlooking the present situation may result in investing on important items even when companies lack the basic requirements for those items, for example, R&D and GMP are both important items in the post-WTO situation, but a company may need to first improve its GMP levels to obtain official approval even if this item is ranked lower than R&D.

This study will suggest appropriate solutions in the next chapters to overcome the above pitfall in developing action plans.

SUMMARY

- This chapter described the deployment of the PITI for studying the situation of the pharmaceutical industry in Iran. This, study collected and analysed the responses of 118 individuals working at managerial levels in 25 pharmaceutical companies; the overall response rate was 65.6%. The main results presented in this chapter can be summarised as follows:
- The mean of the scores for all statements and categories were calculated and presented in diagrams and tables. The scores for the current situation were less than or close to 5, which on an 11-point scale can be interpreted as a low industry compliance with the requirements of the post-WTO situation except for four areas namely GMP documentation, GMP improvement, compliance with environmental standards and increase in the required level of qualification.

- The future importance of the statements received substantially higher scores, revealing the fact that the instrument does, in fact, measure relevant items.
- Binomial tests were used to analyse the respective scores at two levels; categories and statements. These tests indicated that the responses for the current situation had substantial variations with 52% of the statements classified as 'not significant'. This finding emphasises the need for studying the situation of single companies separately. The Friedman test was also carried out to rank the parameter categories.
- The rankings of the categories were thereafter used to define three different improvement scenarios based on the weaknesses and strengths of the industry and future importance of the parameter categories.

Chapter 7

Gap Analysis and Assessment of Improvement Opportunities for the Current and Future Situations

INTRODUCTION

The previous chapters have elucidated the development and application of the pharmaceutical industry transition instrument (PITI), which was used in this study to collect data from the industry regarding the current situation and future importance of certain industry-related parameters. The Friedman test was used to rank the categories and statements of the instrument, while the binomial test was carried out to identify the areas that can be labelled as 'satisfactory' for the performance of the industry or 'important' in the post-WTO situation. As expected, these findings confirmed the substantial importance of the identified parameters in the post-WTO situation by relatively high scores given by the participating industry managers. However, the considerably low scores given to the performance of the industry to label all of them as unsatisfactory and confirming that the industry do not do well was surprising.

The low ranking for the "Patent Review" category in this study was contrary to the impression given following discussion with individual participants. This was further explained by the results of the pilot study, which measured the gap between the scores pertaining to the current situation and future importance of the study parameters. In fact, this finding emphasised the crucial importance of studying the gaps between the current situation and future importance of the parameters. It is also important to realise the extent of the gap between the present and desirable conditions in order to allocate the necessary funds and prioritise action plans to close this gap. The concepts of measuring the normal gap and opportunity score are used in this study to demonstrate the distance between the present and the desirable situation in order to help the industry and its decision makers to develop the appropriate improvement plans.

OBJECTIVES

The main objectives of this study were to:

- Measure the gap between the present and future situations and rank the study categories accordingly
- Explore the improvement opportunities with respect to the future importance in terms of the 'opportunity score'

- Introduce an index for measuring the industry's readiness for the post-WTO situation
- Compare the results of the different models for ranking the study parameters based on their future importance, gap and opportunity score in facing the challenges of the post-WTO situation.

METHODS

This chapter will explain the gap analysis between the current situation and future importance of the study parameters, the determination of their opportunity scores and the formulation of the PIR index. The methodologies and techniques used in this study have been fully described in chapter 2.

The discussion presented in chapter 6 underlines the limitations of ranking the items on the basis of their strengths, weaknesses and future importance. Alternatively, calculating the gap between current situation and future importance can provide a better understanding and logical approach for prioritising the items (see chapter 2). When forecasting or developing plans for the future, it is crucial to consider the future condition and more desirable to formulate methods which give appropriate weight to aspects that will be important in the future. In 2002, Anthony Ulwick introduced such a method, called the 'opportunity algorithm', which could measure the opportunity score by adding the score of the future importance to the gap (Ulwick A. W., 2002). This chapter, therefore, will focus on measuring the gap and opportunity scores in order to demonstrate the differences in the resultant rankings and discuss the advantages of each method. In addition, this chapter will also explain the development of an index for measuring the pharmaceutical industry readiness (PIR) index. This index will generate a readiness percentage that makes it possible to quantify and compare the companies and their trends (see chapter 2).

The gap between the industry's current situation and future importance, opportunity score and the PIR index were measured using standard techniques. The findings presented in this chapter will potentially play a crucial role in helping the industry and its policy makers to prepare the industry for accession to the WTO and implementation the

of TRIPS regulations. It should be remembered that these measurements are based on the assumption of giving equal weight to all statements and categories (see chapter 2).

Processing and Analysis of the Data

The data were processed using both Microsoft Access and Microsoft Excel to obtain descriptive statistics pertaining to the data, while SPSS for Windows was used to carry out statistical analyses.

RESULTS

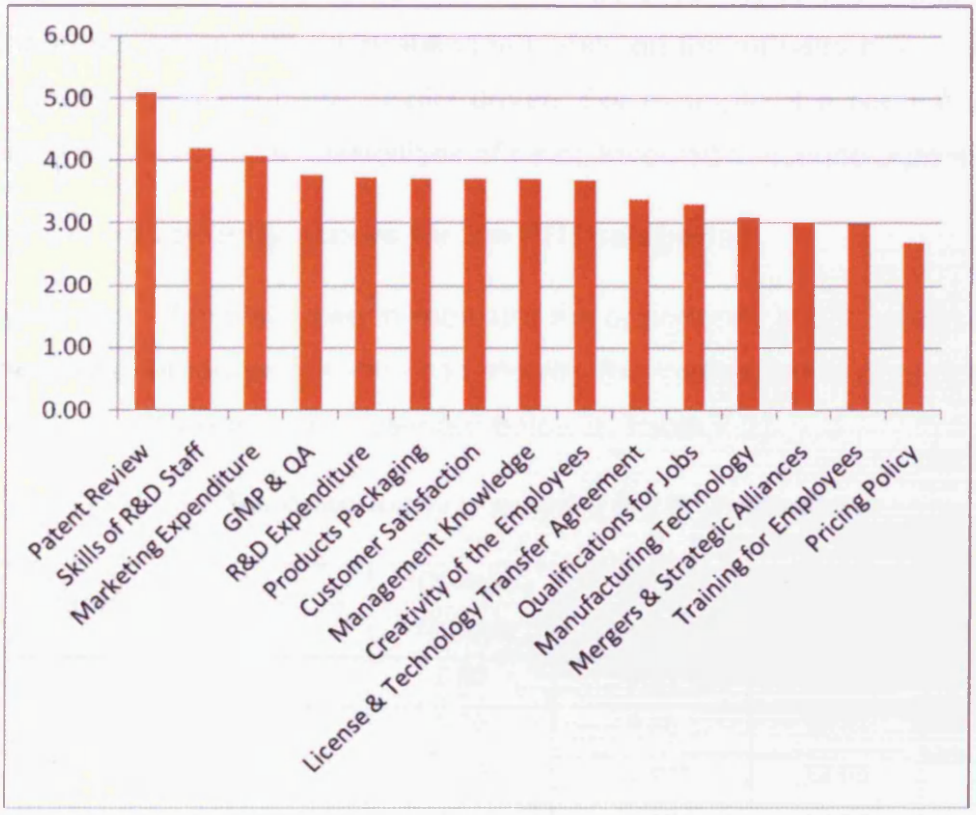
Gap analysis for the parameter categories

As mentioned above, the gap between the current situation and future importance scores was measured and the parameter categories were ranked according to the size of the gap (Table 7.1 and Figure 7.1).

Table 7.1 Gap analysis and ranking of the PITI categories

Category	Current Situation (CS)	Future Importance (FI)	Gap	Ranking
Patent Review	2.93	8.01	5.08	1
Skills of R&D Staff	4.26	8.46	4.20	2
Marketing Expenditure	4.15	8.23	4.08	3
GMP & QA	5.29	9.05	3.76	4
R&D Expenditure	4.68	8.42	3.74	5
Product Packaging	4.58	8.30	3.72	6
Customer Satisfaction	4.99	8.70	3.71	7
Management Knowledge	4.91	8.61	3.70	8
Creativity of the Employees	5.04	8.73	3.68	9
Licence & Technology Transfer Agreements	5.15	8.53	3.38	10
Qualifications for Jobs	5.20	8.50	3.31	11
Manufacturing Technology	5.60	8.71	3.11	12
Mergers & Strategic Alliances	4.80	7.82	3.02	13
Training for Employees	5.61	8.61	3.00	14
Pricing Policy	5.38	8.08	2.70	15

Figure 7.1 The gap between the current situation and future importance for the PITI categories



In terms of gap, the highest-ranking category is Patent Review, followed by Skills of R&D Staff, Marketing Expenditure, GMP & QA and R&D Expenditure. The large gap for Patent Review, which is substantially larger than the gaps for the other categories, underlines the extent of the effort required to close the gap. In fact, prior to WTO accession, it is absolutely necessary to assess the patent situation of currently manufactured products as well as those under development. Furthermore, the results indicate that the companies should improve the capabilities of their R&D staff in order to modify the life cycle of their current products or develop new ones. This should be followed by developing a better understanding of the market needs and demands, while at the same time adopting the necessary measures for GMP improvement. The quality of product packaging is the next category in the ranking of gaps (Table 7.1) and can be regarded as a quick-fix—something that would require relatively little resources and effort. Following this, the companies should focus on increasing the knowledge of their

managers in order to foster innovation in their organisations. These findings demonstrate that gap analysis can be easily used to plan improvement strategies, while the magnitude of the scores indicates the size and complexities of the effort required to close the gap between the present and the desired situation of the under-developed areas. Furthermore, areas with an enabling influence on the industry have been ranked higher than areas which are more results driven. For example, if a company improves its GMP, then it will have more possibilities of being involved in licence agreements.

Measures of the opportunity scores for the PITI categories

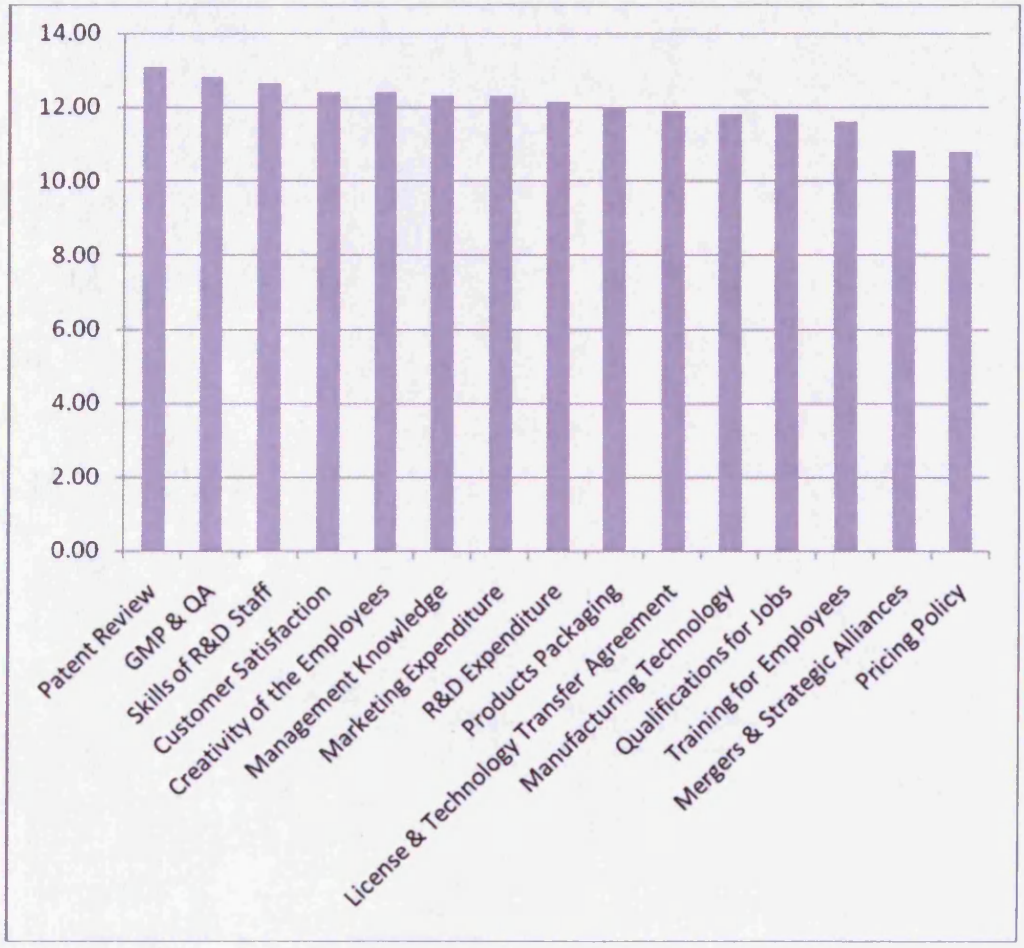
The opportunity algorithm was used to measure the opportunity score, which adds more weight to the future importance in order to identify the improvement opportunities. The results for the PITI categories are presented below in Table 7.2.

Table 7.2 The opportunity scores for the PITI categories

Category	Current Situation	Future Importance	Opportunity Score	Opportunity Rank
Patent Review	2.93	8.01	13.09	1
GMP & QA	5.29	9.05	12.81	2
Skills of R&D Staff	4.26	8.46	12.66	3
Customer Satisfaction	4.99	8.70	12.42	4
Creativity of the Employees	5.04	8.73	12.41	5
Management Knowledge	4.91	8.61	12.31	6
Marketing Expenditure	4.15	8.23	12.30	7
R&D Expenditure	4.68	8.42	12.15	8
Product Packaging	4.58	8.30	12.02	9
Licence & Technology Transfer Agreements	5.15	8.53	11.91	10
Manufacturing Technology	5.60	8.71	11.82	11
Qualifications for Jobs	5.20	8.50	11.81	12
Training for Employees	5.61	8.61	11.60	13
Mergers & Strategic Alliances	4.80	7.82	10.84	14
Pricing Policy	5.38	8.08	10.78	15

These results are illustrated in Figure 7.2:

Figure 7.2 Opportunity scores for the PITI categories



As shown in the above table and figure, the category with the highest opportunity score is Patent Review, followed by GMP & QA, Skills of R&D Staff and Customer Satisfaction. The next two important categories are Creativity of the Employees and Management Knowledge. An overview of these results indicates that based on the existing opportunities, the industry can draft a roadmap for investing in reviewing the patent situation of currently manufactured and new products, followed by improving its GMP and QA systems and the skills of the R&D staff. This will provide internal advantages to the company, enabling it to study the customer requirements. The results also reveal that the Creativity of the Employees and Management Knowledge categories need attention prior to Marketing and R&D Expenditure. In this way, the company can become eligible for participating in licence and technology transfer agreements and acquiring modern manufacturing technologies, which necessitate the presence of higher qualified and better trained employees. Finally, the company will be

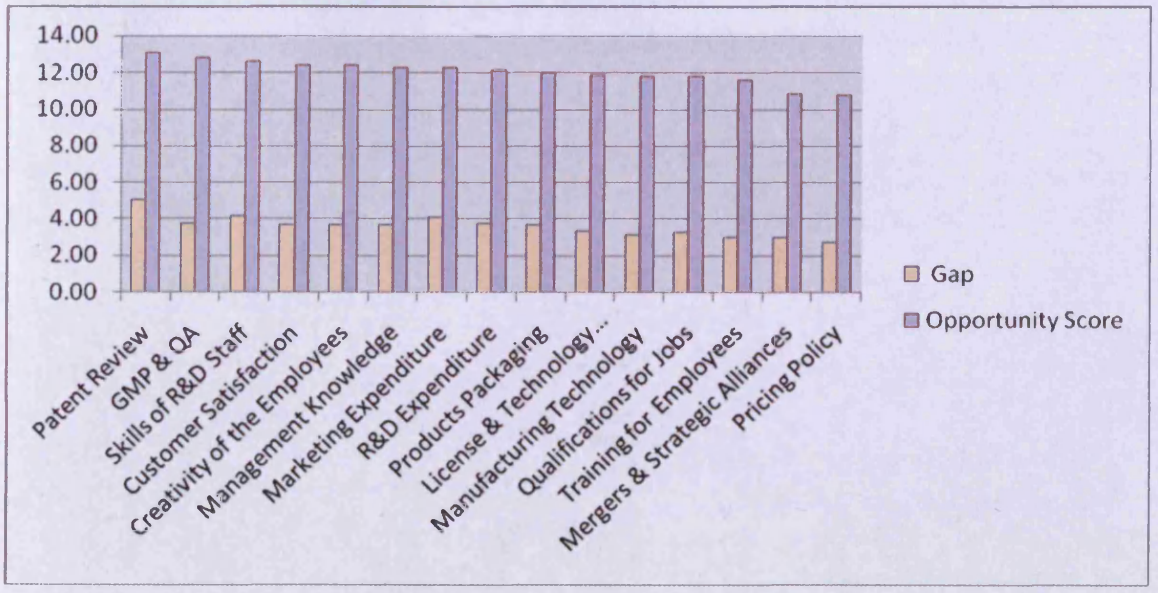
able to participate in possible mergers and can determine its pricing policies for optimum revenues.

Comparing the results of the gap analysis and opportunity scores

The differences between the sectional rankings, based on the gap and opportunity scores, explain the respondents' different viewpoint regarding the importance of the future opportunities and will be discussed further subsequently in this chapter. Figure 7.3 compares the gap and opportunity score results for each category:

This figure presents the opportunity score in decreasing order and demonstrates that the gaps do not follow the same order. For example, the Skills of R&D Staff category has a larger gap than GMP & QA, but its opportunity score is lower and this is shown in ranking in Table 7.2. This argument is also applicable to the Marketing Expenditure and Management Knowledge categories. In contrast, Patent Review occupies the first position in both the scenarios.

Figure 7.3 The gap and opportunity score for each PITI categories



The results of measuring the Pharmaceutical Industry Readiness (PIR) index for the PITI categories

The PIR index for each category was measured by dividing the average scores for the statements in the current situation by the average score of the statements in future importance. It was also possible to measure the index for all statements and then calculate the average of the resulting indices. Finally, the average of the PIR index for all categories was calculated to obtain the total value of the index for the industry. This index represents the pharmaceutical industry's overall readiness to cope with the post-WTO situation.

Table 7.3 Pharmaceutical Industry Readiness (PIR) indices for the PITI categories

PITI Categories	Current Situation	Future Importance	PIR Index
Patent Review	2.93	8.01	37%
Skills of R&D Staff	4.26	8.46	50%
Marketing Expenditure	4.15	8.23	50%
Product Packaging	4.58	8.30	55%
R&D Expenditure	4.68	8.42	56%
Management Knowledge	4.91	8.61	57%
Customer Satisfaction	4.99	8.70	57%
Creativity of the Employees	5.04	8.73	58%
GMP & QA	5.29	9.05	58%
Licence & Technology Transfer Agreements	5.15	8.53	60%
Qualifications for Jobs	5.20	8.50	61%
Mergers & Strategic Alliances	4.80	7.82	61%
Manufacturing Technology	5.60	8.71	64%
Training for Employees	5.61	8.61	65%
Pricing Policy	5.38	8.08	67%
	Overall industry readiness: 57%		

The PIR Index results show that if the cut off point of 2/3 is selected as the minimum required readiness, there is only one category, pricing policy, where the industry is ready for the post-WTO situation. This means the industry is least ready with regard to the Patent Review category, with a PIR index of 0.37. The Skills of R&D Staff and

Marketing Expenditure categories both have the same index value of 0.5. The degree of readiness gradually increases as one moves from Product Packaging to R&D Expenditure, which has the indices of 0.55 and 0.56, respectively. The PIR index for both Management Knowledge and Customer Satisfaction is 0.57, while that for Creativity of the Employees and GMP & QA is 0.58. The index also progressively increases from Licence & Technology Transfer Agreements to Qualifications for Jobs, Mergers & Strategic Alliances, Manufacturing Technology and Training for Employees, with the index values of 0.60, 0.61, 0.61, 0.64 and 0.65, respectively. The highest index is 0.67—for the Pricing Policy category—which indicates that this item will face the least problem in terms of industry readiness. It should be mentioned that this pricing policy only pertains to the decisions made by the industry itself and does not reflect the industry's current problems with the governmental pricing policies that were mentioned by the experts as described in chapters 3 and 4. Nevertheless, this highest index is still too far short of the maximum possible value of 1.0 and indicates the intensity of challenges that the industry must face to reach an acceptable readiness index. The overall industry readiness index is 0.57, which is almost half of the maximum possible value of this index and reflects the poor performance of the industry and its low levels of readiness to deal with the post-WTO situation.

The gap analysis, opportunity score and Pharmaceutical Industry Readiness

It was explained earlier on in this chapter that the categories would be evaluated using the average scores of the results of their statements, based on the assumption that each statement would have equal weight. However, for a more precise analysis, and especially for identifying future strategy roadmaps and using this methodology at the company level, it is necessary to know the results for all the PITI statements. These results are presented in Table 7.4.

Table 7.4 The gap, opportunity scores and PIR Index for the PITI statements

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
	1. Patent Review								
1-1	Our company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements.	2.16	7.99	5.82	2	13.81	3	-1	27%
1-2	An intellectual property right is a key issue in the selection of a new product.	3.95	8.23	4.29	10	12.52	19	-9	48%
1-3	We review intellectual property rights when exporting products.	3.68	7.90	4.22	15	12.11	38	-23	47%
1-4	The financial impact of enforcing patent protection on our products has been studied.	1.93	7.93	6.00	1	13.92	2	-1	24%
	2. Licence & Technology Transfer Agreements								
2-1	Producing under-licence products is one of the strategic goals of our company.	6.23	8.57	2.34	65	10.91	62	3	73%
2-2	The infrastructure of our company satisfies the requirements of reputable licensors.	5.42	8.92	3.51	39	12.43	24	15	61%
2-3	We have licence agreements with innovator companies.	4.78	8.48	3.70	30	12.19	34	-4	56%
2-4	We have technology transfer agreements with technology	4.94	8.75	3.81	23	12.56	17	6	56%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
	owners.								
2-5	Licensed or technology transferred products constitute an important part of our total sales.	4.38	7.91	3.54	38	11.45	54	-16	55%
	3. Sales & Marketing								
3-1	Our marketing expenditure is comparable to that of our international rivals.	2.42	7.84	5.42	4	13.27	6	-2	31%
3-2	We regularly increase the percentage of marketing expenditure to total sales.	3.74	7.86	4.12	16	11.97	42	-26	48%
3-3	We measure the effectiveness of our marketing expenditure.	4.03	8.45	4.42	7	12.88	9	-2	48%
3-4	Our marketing activities contribute to capturing the market share.	5.37	8.67	3.30	45	11.98	41	4	62%
3-5	Our marketing activities have increased our customer loyalty.	5.19	8.30	3.12	50	11.42	55	-5	62%
	4. GMP & QA								
4-1	We allocate sufficient funds to improve our GMP	5.81	9.13	3.32	43	12.45	22	21	64%
4-2	We have the GMP approval of international inspectors.	3.44	8.92	5.48	3	14.40	1	2	39%
4-3	We have a well-planned validation master plan for GMP.	4.85	9.12	4.27	11	13.40	4	7	53%
4-4	We have an appropriate documentation system for GMP.	6.08	9.21	3.13	49	12.34	27	22	66%
4-5	We have a change control	4.82	8.88	4.06	21	12.93	8	13	54%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
	system for all related departments.								
4-6	Our manufacturing areas are updated regularly.	5.50	8.82	3.32	44	12.13	37	7	62%
4-7	GMP improvement is a strategic goal for our company.	7.12	9.35	2.23	66	11.57	51	15	76%
4-8	We measure the effectiveness of our GMP expenditure.	4.65	8.97	4.31	9	13.28	5	4	52%
	5. Research & Development								
5-1	We allocate sufficient funds for our R&D department.	5.26	8.84	3.58	36	12.41	25	11	60%
5-2	We measure the effectiveness of our R&D expenditure.	3.63	8.37	4.74	5	13.11	7	-2	43%
5-3	R&D investment plays a major role in our competitiveness.	5.36	8.97	3.61	35	12.58	16	19	60%
5-4	A major part of our revenue comes from exclusive products.	5.69	8.32	2.63	58	10.95	61	-3	68%
5-5	We have close relations with R&D institutions outside our company.	4.08	7.82	3.74	28	11.57	52	-24	52%
5-6	We have innovative new formulations	4.07	8.19	4.12	17	12.31	29	-12	50%
	6. Product Packaging								
6-1	The attractiveness of the packaging is a strong point of our products.	4.95	8.42	3.47	40	11.90	44	-4	59%
6-2	We invest in improving our product packaging.	5.33	8.34	3.01	53	11.34	57	-4	64%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
6-3	Our packaging lines are comparable with those of our international rivals.	4.53	8.19	3.66	33	11.85	45	-12	55%
6-4	We measure the role of our packaging in creating customer satisfaction.	3.80	8.18	4.38	8	12.55	18	-10	46%
6-5	The quality of our packaging is comparable with that of our international competitors.	4.31	8.37	4.06	20	12.43	23	-3	52%
	7. Manufacturing Technology								
7-1	We regularly improve our production lines.	5.40	8.59	3.19	48	11.78	47	1	63%
7-2	The automation level in our plant is comparable with that of our international rivals.	4.07	8.19	4.12	18	12.30	30	-12	50%
7-3	Our manufacturing technology is in compliance with environmental standards.	5.91	8.65	2.75	56	11.40	56	0	68%
7-4	Our manufacturing procedures are well documented and well executed.	6.52	9.10	2.58	63	11.68	49	14	72%
7-5	We regularly update the manufacturing procedures for our products.	6.10	9.01	2.91	54	11.92	43	11	68%
	8. Mergers & Strategic Alliances								
8-1	We have strategic alliances with some of our partners.	4.72	8.15	3.43	42	11.58	50	-8	58%
8-2	We are evaluating possible mergers and acquisitions.	4.61	7.63	3.02	52	10.64	65	-13	60%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
8-3	Being a subsidiary of a holding company facilitates strategic alliances.	5.07	7.67	2.61	61	10.28	66	-5	66%
	9. Pricing Policy								
9-1	We have competitive pricing in comparison with our international rivals.	5.52	8.14	2.62	59	10.76	64	-5	68%
9-2	We have price flexibility in comparison with our rivals.	5.24	8.01	2.78	55	10.79	63	-8	65%
	10. Training for Employees								
10-1	Qualifications are considered very important while recruiting people in our company.	6.07	8.76	2.69	57	11.45	53	4	69%
10-2	We have training programmes for every job.	5.64	8.68	3.04	51	11.73	48	3	65%
10-3	We are increasing our training hours per capita.	5.85	8.43	2.58	64	11.01	60	4	69%
10-4	We measure the effectiveness of our training programmes.	5.12	8.58	3.46	41	12.03	40	1	60%
10-5	The capabilities of our employees are comparable with those of our international rivals.	5.37	8.58	3.21	47	11.79	46	1	63%
	11. Skills of R&D Staff								
11-1	We regularly improve the skills of our R&D staff.	4.90	8.60	3.70	31	12.30	31	0	57%
11-2	Our R&D team can develop innovative products.	4.38	8.62	4.24	14	12.86	11	3	51%
11-3	A considerable part of our revenue is the result of	3.67	8.27	4.60	6	12.87	10	-4	44%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
	innovation in R&D.								
11-4	The skills of our R&D staff have created advantages for us against our rivals.	4.09	8.35	4.25	12	12.60	13	-1	49%
	12. Management Knowledge								
12-1	We have qualified persons in all managerial positions.	5.62	8.90	3.28	46	12.18	35	11	63%
12-2	We measure the efficiency of the decisions taken by our managers.	4.55	8.63	4.07	19	12.70	12	7	53%
12-3	There are adequate numbers of management graduates in our managerial team.	4.55	8.31	3.75	27	12.06	39	-12	55%
	13. Customer Satisfaction								
13-1	We have internal programmes to meet the customers' requirements.	5.05	8.82	3.77	25	12.59	14	11	57%
13-2	We have categorised our customers into different groups and have communication programmes for each group.	4.62	8.46	3.83	22	12.29	32	-10	55%
13-3	We know the needs of our target customers.	5.12	8.66	3.54	37	12.20	33	4	59%
13-4	We measure the satisfaction levels of our customers.	5.15	8.87	3.71	29	12.58	15	14	58%
	14. Creativity of the Employees								
14-1	Our organisation encourages innovation.	4.96	8.73	3.77	26	12.49	21	5	57%
14-2	We have utilised the innovativeness of our	5.00	8.67	3.67	32	12.34	28	4	58%

Category/ Statement	PITI Statements	Current Situation	Future Importance	Gap	Gap Rank	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index
	employees to create value.								
14-3	Innovation plays an important role in maintaining our competitiveness.	5.16	8.78	3.62	34	12.40	26	8	59%
	15. Qualifications for Jobs								
15-1	The minimum qualifications have been increased in our organisation in recent years.	6.12	8.71	2.59	62	11.29	59	3	70%
15-2	We have access to people with the required qualifications.	6.07	8.69	2.61	60	11.30	58	2	70%
15-3	Our company can afford to employ highly qualified people.	4.94	8.72	3.78	24	12.49	20	4	57%
15-4	We have offered scholarships to obtain employees with the required qualifications.	3.66	7.91	4.25	13	12.16	36	-23	46%

The statement with the highest rank, considering the gap between the current situation and the future importance, is 'The financial impact of enforcing patent protection on our products has been studied' from the Patent Review category, which is also the category with the first rank. Since this statement shows the largest gap, it reflects the extent of attention required by this area and shows the study participants' concerns regarding the financial consequences of patent infringements by their companies. The industry also shows the poorest readiness levels of 24% with regard to evaluating the financial impacts of patent protection. The subsequent ranks are occupied by the statements 'This company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements', 'Our marketing expenditure is comparable to that of our

international rivals' and 'We have the GMP approval of international inspectors', with PIR indices of 27%, 31% and 39%, respectively.

If a PIR index of 66% is regarded as an acceptable readiness level, 11 statement out of 66, will pass this condition: updating the manufacturing procedures, competitive pricing, compliance with the environmental standards, considerable revenue from exclusive products, considering qualifications while hiring people, increasing training hours, access to the qualified persons, increased minimum qualifications for job documentation of the manufacturing procedures and strategic approach to licensed products and GMP improvement. Meanwhile, the item related to obtaining GMP certificates from international inspectors lies in the top three ranks, with the largest gap and opportunity score and a PIR index as low as 39%. It is interesting to note that the second-highest PIR index was 73%, concerning the strategy of having licensed products, while having licence agreements with innovator companies, which may be a result of this policy, received a PIR index of 56%. These two examples reveal the fact that conducting a detailed analysis of the above results for all statements will provide a clearer picture of the pharmaceutical industry in this transition state.

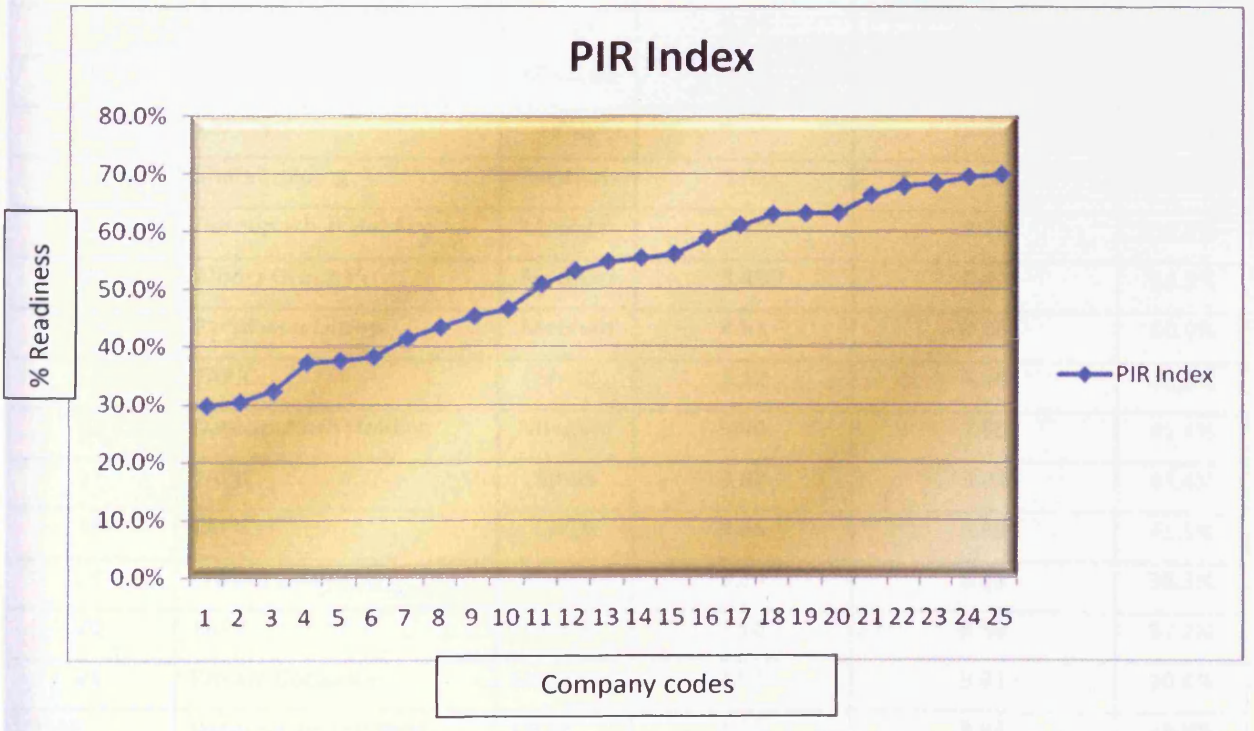
Table 7.4 also shows that the highest-ranking statement in terms of the opportunity scores is 'We have the GMP approval of international inspectors'. This also underlines the future orientation of the opportunity score, because having international GMP certificates will be a crucial point in increasing the competitiveness of the companies in the future. Another interesting observation is that the highest-ranking statement does not belong to the highest-ranking category—a fact that underlines the necessity of conducting analysis at the level of statements. The second rank devolves on the statement 'The financial impact of enforcing patent protection on our products has been studied', followed by 'This Company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements' and 'We have a validation master plan for GMP'. These results indicate that statement-level analysis acts as a strong tool for determining how the industry should allocate its resources in a more efficient manner.

The readiness of the pharmaceutical companies

The PIR indices for the pharmaceutical companies were located in the relatively wide range of 69.9% to 29.8%. While the indices pertaining to individual companies cannot be disclosed due to the confidentiality promised to the study participants, the anonymised results are presented in Figure 7.4.

This figure presents the PIR index of each company, while the numbers ranging from 1 to 25 codify the company name. The figure illustrates the gradual increase in the index between the companies; however, the substantial difference between the lower and higher levels underlines the vital need for undertaking improvement plans in many of the companies. The figure also reveals the fact that none of the companies studied has a readiness index of more than 70%—the cut-off point for being considered a 'ready' company.

Figure 7.4 The Pharmaceutical Industry Readiness (PIR) indices for 25 companies



This study collected detailed data regarding the size and ownership of the companies in order to explore the possible roles played by these items in deciding the company's

readiness (Table 7.5). On the whole, this indicates that large, small, public and private companies do not show any clear relationship between their degree of readiness and their size and/or ownership attributes.

Table 7.5 Pharmaceutical Industry readiness (PIR) indices for the companies based on their ownership and size

Company Codes	Ownership	Size	Current Situation (average score)	Future Importance (average score)	PIR Index
1	Daroupakhsh Holding*	Large	5.68	8.13	69.9%
2	Parsdarou Group**	Large	6.23	8.96	69.5%
3	Daroupakhsh Holding	Large	5.81	8.50	68.4%
4	Daroupakhsh Holding	Medium	6.12	9.02	67.9%
5	Private Company	Medium	5.11	7.70	66.4%
6	Private Company	Medium	5.64	8.91	63.3%
7	Daroupakhsh Holding	Medium	5.60	8.86	63.2%
8	Shafa Holding***	Large	5.41	8.57	63.1%
9	Shafa Holding	Medium	5.61	9.17	61.2%
10	TAPIC§	Large	4.33	7.36	58.8%
11	Shafa Holding	Medium	5.52	9.94	55.5%
12	Daroupakhsh Holding	Medium	4.54	8.29	54.8%
13	Alborz Group§§	Medium	3.45	6.47	53.3%
14	Parsdarou Group	Medium	4.61	9.06	50.9%
15	TAPIC	Small	3.12	6.70	46.6%
16	Daroupakhsh Holding	Medium	3.40	7.50	45.4%
17	TAPIC	Small	3.92	9.02	43.4%
18	TAPIC	Large	2.86	6.89	41.5%
19	Private Company	Medium	3.19	8.31	38.3%
20	TAPIC	Small	3.20	8.58	37.2%
21	Private Company	Large	2.92	9.61	30.4%
22§§§	Daroupakhsh Holding	Large	2.64	8.84	29.8%

* consists of 14 pharmaceutical companies involved in manufacturing and distributing human and veterinary products. Its main shareholder is Tamin Pharmaceutical Investment Co. (TPICO).

** consists of 5 companies involved in manufacturing and distributing medicines. Its main shareholder is TPICO.

*** consists of 7 companies operating in the areas of production and distribution of medicines.

§ includes 7 companies operating in the field of finished products and active pharmaceutical ingredients. Its main shareholder is TPICO.

§§ consists of 6 pharmaceutical companies.

§§§three of the companies did not belong to the holding companies

The general characteristics of the size and ownership of the companies can be related to their degree of readiness as follows:

- **Company size:** The three highest indices of 69.9%, 69.5% and 68.4% are distributed among the five largest companies in the country. At the same time, the lowest index of 29.8% also belongs to one of the largest five. In general, large and medium-sized companies tend to occupy the higher ranks, while small-sized companies tend to occupy the middle or lower positions.

- **Company ownership:** The main shareholder of the top four companies is a social security organisation (three of them belong to Daroupakhsh holding), while the fifth and sixth positions are occupied by private firms. Interestingly, the last company is also from the Daroupakhsh group. The table also shows that private companies tend to be distributed in the middle or bottom of the table, indicating their relatively lower readiness indices.

The results of the gap analysis, opportunity score and PIR index of the PITI categories are presented below in Table 7.6. The positions of three categories have remained unchanged in all three measurements: Patent Review shows the largest gap (5.08), the highest opportunity scores (13.09) and the lowest PIR index (36.6%), indicating that the industry should focus more on this item by analysing all the relevant statements (Table 7.6); Skills of R&D Staff occupies the second rank in terms of the gap and PIR index, which is 50.4%. With regard to the opportunity score, this category ranks third. Marketing Expenditure also ranks third for both gap and PIR index, but seventh in terms of opportunity rank. This suggests that the priority accorded to this category is reduced if its future importance is considered. The fourth rank for the PIR index belongs to product packaging (55.2%), but it ranks sixth and ninth in terms of gap analysis and opportunity score, respectively. R&D Expenditure occupies the fifth rank for gap and readiness index (55.6%), but its opportunity score is ranked eighth, which may indicate

that the respondents have underestimated its future importance, to some extent.

While Management Knowledge has the PIR index of 57% and the sixth rank for both readiness and opportunity scores, it occupies the eighth rank in terms of gap priority. Customer Satisfaction and Creativity of the Employees, with the readiness indices of 57.3% and 57.8%, respectively, have the seventh and eighth ranks in terms of PIR index priority, with similar gap rankings (i.e. seventh and ninth) but higher opportunity ranks—fourth and fifth, respectively—thus indicating their greater future importance.

Table 7.6 The gap analysis, opportunity scores and PIR indices for the PITI categories

PITI Categories	Current Situation	Future Importance	Gap	Ranking	Opportunity Score	Opportunity Rank	Ranking Change	PIR Index (%)	PIR Index Rank
Patent Review	2.93	8.01	5.08	1	13.1	1	0	36.6	1
Skills of R&D Staff	4.26	8.46	4.20	2	12.66	3	-1	50.4	2
Marketing Expenditure	4.15	8.23	4.08	3	12.30	7	-4	50.4	3
Product Packaging	4.58	8.30	3.72	6	12.02	9	-3	55.2	4
R&D Expenditure	4.68	8.42	3.74	5	12.15	8	-3	55.6	5
Management Knowledge	4.91	8.61	3.70	8	12.31	6	2	57.0	6
Customer Satisfaction	4.99	8.70	3.71	7	12.42	4	3	57.3	7
Creativity of the Employees	5.04	8.73	3.68	9	12.41	5	4	57.8	8
GMP & QA	5.29	9.05	3.76	4	12.81	2	2	58.4	9
Licence & Technology Transfer Agreements	5.15	8.53	3.38	10	11.91	10	0	60.4	10
Qualifications for Jobs	5.20	8.50	3.31	11	11.81	12	-1	61.1	11
Mergers & Strategic Alliances	4.80	7.82	3.02	13	10.84	14	-1	61.4	12
Manufacturing Technology	5.60	8.71	3.11	12	11.82	11	1	64.3	13
Training for Employees	5.61	8.61	3.00	14	11.60	13	1	65.2	14
Pricing Policy	5.38	8.08	2.70	15	10.78	15	0	66.6	15

The GMP & QA category receives the second priority for opportunity score and the fourth priority for gap, but the industry readiness for this item has been given the ninth rank, with the PIR index of 58.4%, which implies that while this area requires some improvements, there are poorer areas in terms of readiness. The other areas occupy more or less similar positions based on the three measurement methods.

DISCUSSION

Further analysis was conducted on the scores given by the respondents to the PITI statements. In the first step, the size of the gap between the average scores of the current situation and the future importance was calculated for each category. It was explained that the bigger the gap, the higher should be the priority for improvement.

In the next step, the opportunity scores were measured by using the opportunity algorithm, which in turn was based on adding the importance score to the gap. This analysis resulted in a ranking of categories which was different from the ranking produced by measuring the gap. The logic behind calculating the opportunity score, after adding the future importance to the size of the gap, generates an opportunity-algorithm-based ranking that is more future-oriented; hence, the higher ranked categories in this system of ranking are likely to be of greater importance in the future. In other words, when items are ranked based on the size of the gap, it is possible to accord a high rank to an item that may be of low future importance.

In the final step, the PIR index was introduced as an indicator to measure the industry readiness based on the collected data. This index recommends some areas for improvement that are different from the priorities suggested by the other two measurements—gap and opportunity score—for some of the statements and categories. The advantages of this method, in comparison with gap analysis and opportunity score, are as follows:

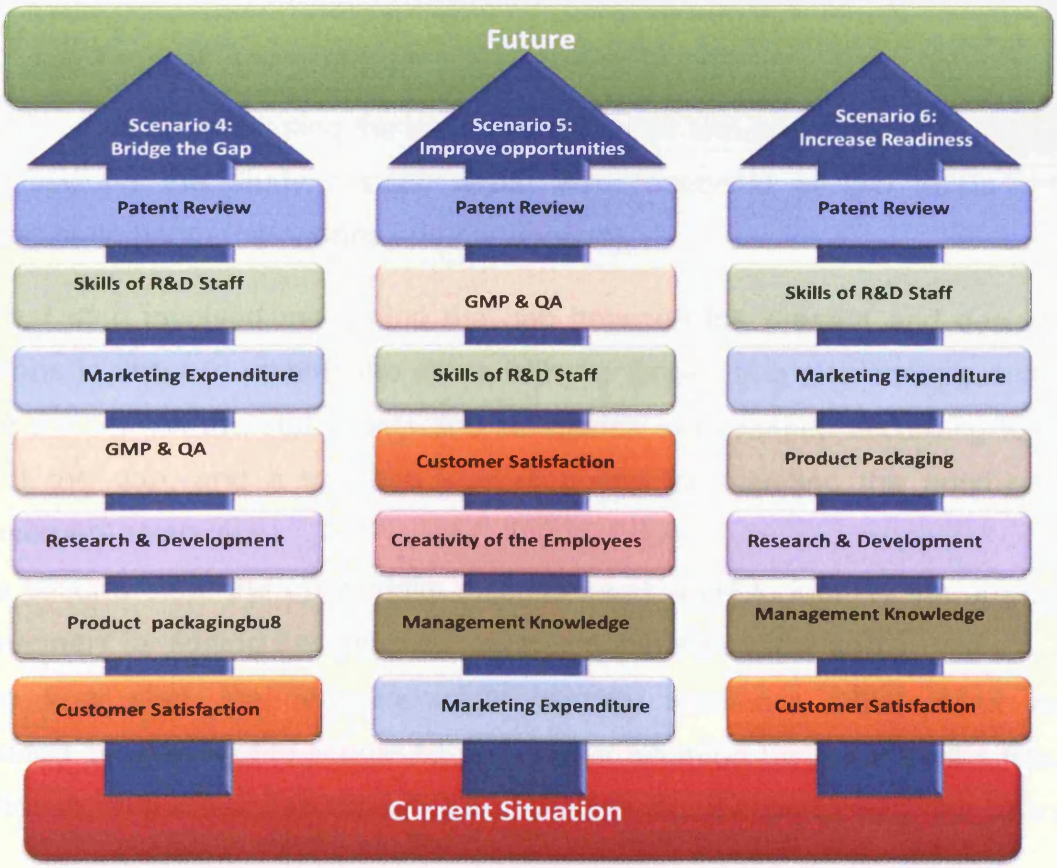
- The PIR index represents the overall readiness of the industry as well as its readiness at the level of individual statements and categories.
- Since this index can be measured at the company level, the situation of the companies can be compared with each other.

- The companies can evaluate their performance with regard to the overall index of the industry.
- It is possible to study the general trend of industry readiness over time, for example, by comparing the PIR indices on an annual basis.

However, all the above-mentioned methods can be applied to explain the current situation and future aspirations of the pharmaceutical industry from different points of view. For developing the appropriate improvement plans, the decision-makers can apply the most appropriate method for studying their case, and the data presented in this study can be used as a directive for this selection.

With regard to the gap analysis, opportunity scores and readiness index, it is possible to define three different scenarios for planning improvement programmes for the industry. Following the three scenarios proposed in the previous chapter, we will label these as scenarios 4, 5 and 6, as follows:

Figure 7.5 Three scenarios based on gap, opportunity scores and PIR index



Scenario 4 suggests that the higher priority be given to the biggest gap. Based on this scenario, the industry should start with improving the patent review process, skills of the R&D staff and marketing expenditure. This should be followed by concentrating on GMP & QA, R&D expenditure, product packaging and customer satisfaction.

Scenario 5 is based on ascribing priorities according to the opportunity scores. Again, the starting point is patent review, followed by GMP & QA, skills of the R&D staff and customer satisfaction. Thereafter, two human-resource-related areas with good improvement opportunities should be addressed—creativity of the employees and management knowledge—while marketing expenditure should be improved in the next step.

Scenario 6 proposes improving areas on the basis of the PIR index, which reflects the levels of industry readiness. The first three steps of this scenario are similar to those of scenario 3 discussed earlier; however, product packaging now occupies the fourth position in the list of readiness priorities. Figure 7.5 presents the list of selected priorities in all three of the above-described scenarios.

SUMMARY

This chapter focused on prioritising the improvement areas and proposing improvement scenarios based on the study results, which were analysed at two levels—PITI categories and statements (categories and parameters).

- The first step involved measuring the gap between the present and desirable situations in order to identify the areas with the largest gap and consequently a higher priority. All the statements and categories were ranked according to the size of the gap, and a scenario was proposed for planning the appropriate improvement strategies.
- In the second step, the opportunity algorithm was used to identify the areas of improvement by adding the future importance to the size of the gap.
- In the final step, the pharmaceutical industry readiness (PIR) index was calculated by dividing the scores for the current situation by those for the future importance; this index has the unique characteristic of representing the overall

industry readiness in one figure. The overall PIR index for the industry was 57%, which does not indicate a significant level of readiness.

- The seven most important improvement areas according to scenario 4, which is based on the size of the gap, were identified as patent review, skills of the R&D staff, marketing expenditure, GMP & QA, R&D expenditure, product packaging and customer satisfaction.
- Scenario 5 repeated five of the above areas, albeit with different rankings, but replaced R&D expenditure and product packaging with the two human-resource-related areas of creativity of the employees and management knowledge.
- The last scenario, scenario 6, repeated six of the above-mentioned areas, while replacing GMP & QA with management knowledge.
- At the level of statements, the lowest readiness indices indicated the categories that showed the highest priority in terms of this indicator. The PIR index ranged from 24% to 76%. It is interesting to note that the statements with higher indices are more closely related to future planning, and not to the obtained results. In addition, the PIR indices of all the sampled companies were within the range of 29.8% to 69.9%, with no specific relationship associated with their size and ownership.

Chapter 8

Development of a Strategy Map to Secure the Post-WTO Sustainability of the Pharmaceutical Industry in Iran

INTRODUCTION

The study of the post-WTO/TRIPS sustainability of the pharmaceutical industry in Iran resulted in proposing six different scenarios on the basis of the strengths, weaknesses, future importance, gap analysis, development opportunities and industry readiness. This gives the pharmaceutical companies and other stakeholders the opportunity to define specific preparation plans with respect to their situation and resources and the fitness with one of the proposed scenarios.

This chapter will study the possibility of giving a more holistic solution to cover some limitations of the scenarios such as the step by step approach which is inherent in the priority-oriented decision-making. This chapter focuses on developing a strategic map as a toolbox to uphold the priority concept as well as causal effect, lead and lag indicators and balanced improvements. The outcome of this new approach should enable the interested individuals and firms to incorporate their own priorities and concerns into the plans and simultaneously take into account a long term view and the dynamics of the environmental changes.

OBJECTIVES

The objectives of this study were to:

- Develop a working and practical strategy map for the Iranian pharmaceutical industry in order to secure its post-WTO sustainability
- Determine the relationships between the parameters by using the standardised logical order (concept of lead and lag indicators)
- Translate the identified parameters into a series of balanced scorecards
- Inform the policy makers as to how they should develop their strategy in synergy with that of the industry

METHODS

The key methodologies to achieve the objectives of this chapter and facilitate the interpretation of the results were to develop balanced score cards and a strategy map. For the strategy map, it was necessary to use the concept of lead and lag indicators as

well as cause and effect relationships between the study parameters. The idea of balanced score cards was first introduced by R. Kaplan and D. Norton in 1992 as a tool for the development and improvement of organisational performance. They believed that balanced scorecards provide the tool for future competitive success (Kaplan and Norton, 1996). They defined this concept later in 2000 as a visualised plan to present the goals and interrelations between required actions in a strategic plan.

Balanced scorecards can be defined as a conceptual framework which translates the corporate strategies into measurable indicators and then creates a balanced distribution between the key organisational aspects. In this way, it is a powerful and integrated tool for controlling the key areas of the financial, customer, processes and growth & learning. A strategy map is used by half of Fortune 1000 companies and by more than two thirds of international corporations (Person, 2009). This methodology is also used in many pharmaceutical companies such as Novartis, Novo Nordisk and Bristol Myers Squibb (Francesco G.G.Zingales, 2003). The step by step procedures for developing balanced scorecards and drawing Strategy Maps are explained by Person (2009) and Stettinius et al. (2005). According to Person (2009), the advantages of balanced scorecards are to:

- **Clarify strategy.** The discussions during developing the strategy map create an atmosphere of clarity and understanding between the departments in an organisation.
- **Translate strategy into action and executing it.** A clear road map will be given if a strategy map is combined with a tactical action and implementation plan. The balanced scorecards will help to monitor execution of the strategies.
- **Aligning business units around the strategy.** A strategy map and tactical action plans require that the walls between departments come down and the whole organisation becomes unified to follow the road map.
- **Communicate the strategy to all levels.** The process of cascading the balanced scorecards through the executive and operational levels gives the opportunity to all of them to contribute to organisational success.

- **Monitoring and managing strategic execution.** Using balanced scorecards helps executives to focus on strategic leadership instead of concentrating on operational performance.

Balanced scorecards are known as a tool to close the gap between the strategic levels of vision, mission, values and strategies with daily action and they fill this gap by implementation and focusing on strategies and strategic initiatives. In other words, balanced scorecards enable the organisations to remove the barriers for the successful implementation of their strategies. In addition, an important aspect of balanced scorecards is the cause and effect relationship between different parameters. For example financial sustainability needs customer satisfaction which is dependent on the efficiency and quality of the internal processes such as GMP and QA that needs to be supported by the skills and training of the employees. It takes its name from the fact that it uses balanced perspectives of what drives business and strategy including financial, customer and marketplace, internal processes and learning and growth. Some of the key terms of balanced scorecards and a strategy map are defined as follows (Kaplan and Norton, 1996; Person, 2009):

Financial perspective - These are related to profitability by operating income, return on capital employed or economic value added as well as sales growth or generation of cash flow.

Customer perspective - The core outcome measures include customer satisfaction, customer retention, new customer acquisition, customer profitability, short lead time and on time delivery as well as a constant stream of innovative products and the ability to anticipate customers' emerging needs.

Internal processes - The parameters that cause overall excellence throughout operational and logistical processes are included in this area. These processes enable the industry to deliver the value propositions that will attract and retain customers and satisfy shareholder expectations of excellent financial returns.

Learning and growth perspective - Organisational procedures examine alignment of employee incentives with overall organisational success factors (Kaplan and Norton, 1996). Norton and Kaplan explained there are three categories of intangible assets in

this perspective: human capital (skills, talents and knowledge of the employees), information capital (databases, information systems, networks and technology infrastructures) and organisation capital (culture, knowledge share, people alignment with strategies) (Kaplan and Norton, 2004).

Strategy gap - The distance between the operational plan for today's business and the grand vision for what the business needs to become is called the "strategy gap" (Coveney et al, 2003).

Strategic theme - This is generally a vertical slice within the strategy map and is a subset of the overall strategy consisting of a distinct set of related strategic objectives (Kaplan and Jackson, 2007). Strategic themes are defined to concentrate the resources at critical points. It is recommended to define three to five strategic themes. There are three financial themes that drive the business strategy: revenue growth (new products, new applications, new customers and markets, new relationships, new product and service mix and new pricing strategies), cost reduction, productivity improvements and asset utilisation. Kaplan and Jackson (2007) recommended that the strategy map is preferred to have maximum of 24 objectives depending on the size of the company.

Causal effect - A strategy is a set of hypotheses about cause and effect. Causal links show the hypotheses of how the success in one objective drives the success in another. The entire chain of cause and effect relationships was established as a vertical vector through the four balanced scorecards perspectives.

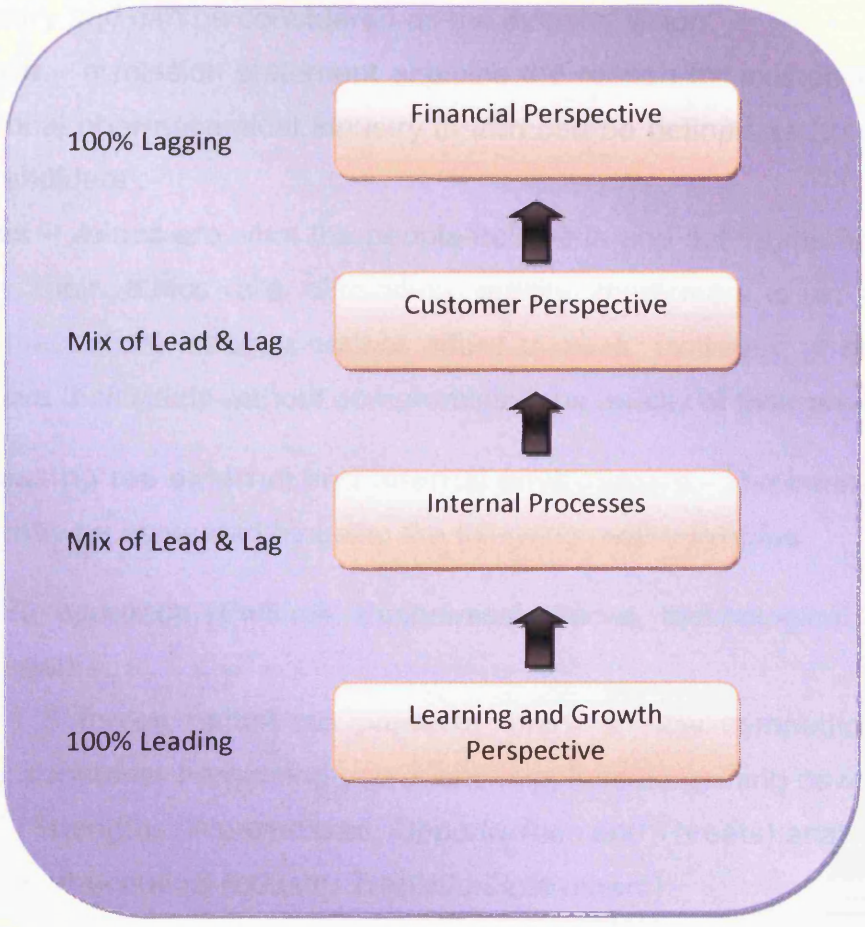
Measures and Metrics - Measure is the unit by which the progress to the objective is evaluated. If you cannot measure, you cannot manage your objectives and the measurement system changes the behaviour of people. Metrics are a quantifiable evaluation of the measures. It is important to pinpoint a "critical few" metrics which means being focused and one must not select too many metrics. Metrics can be divided into two groups: leading and lagging metrics. In our example, the number of new products in the pipeline and the time to market are metrics for the defined measures. Leading metrics drive an objective and are the arrowhead of the causal link while lagging metrics are the result of an objective. Measures in the financial perspective are all lagging while measures in learning and growth perspective are all leading indicators.

They drive progress in the internal processes and customer perspectives. Internal operations and customer perspectives are a mixture of both lead and lag indicators.

Initiatives - These are collections of actions or projects that are scheduled in order to achieve the strategic objectives. Identifying the right projects, motivating the people and developing operational and executive dashboards are key elements for a successful strategy implementation.

The starting point for developing a strategy map will be in the learning and growth perspective in order to organise the developments for the internal processes of the companies. It is obvious that the learning of the employees and management is a prerequisite for investing in processes and technological aspect. For instance, investing in new technologies or higher GMP levels without prior training of the employees and managers will be simply wasting the financial resources. After improving the internal processes, the company can focus on attracting customer satisfaction because only improved processes can create value for the customers that should be advertised and proved to them. Finally having loyal customers will secure long term profitability for the shareholders in the financial perspective. Due to the financial constraints, it is necessary that the learning and growth layer be supported by the pricing policy in order to generate the required financial resources. It should be noted that the pharmaceutical industry is highly influenced by the regulatory environment that puts the pricing policy into a regulatory context (Figure 8.6). The key message of this concept is to emphasise the importance of preparing the ground for lag indicators such as customer or financial results to be achieved by prior investment on lead indicators such as internal processes and learning and growth perspectives. These relationships are presented in Figure 8.1.

Figure 8.1 the lead and lag metrics in balanced scorecards perspectives



RESULTS

The results of this chapter are presented in two parts. The first part describes the development of the strategy map and the second part explains how the industry can operationalise the subsequent strategy.

Part 1 - Development of a Strategy Map

To develop a strategy map for the pharmaceutical industry seven steps were involved:

Step 1: Defining the Vision, Mission and Values - these key terms are defined in this study as follows:

- **Vision – a vision** statement describes what the industry will be like in the future. Sustainable profitability in the post-WTO situation is the major aspiration of the industry and can be considered as the industry vision.
- **Mission** – a mission statement explains the reason for existence. The vision of the local pharmaceutical industry in Iran can be defined as "to create value for stakeholders".
- **Values** – values are what the people believe in and determine how they act and what their ethics are. Providing quality medicines is a value that the pharmaceutical industry cannot afford to miss. However, a company should achieve their goals without compromising the quality of their product.

Step 2: Assessing the external and internal environment - The internal and external environment may be evaluated by using the following methodologies:

- PESTEL approach (Political, Economical, Social, technological, Environmental and Legal),
- Porter's 5 forces (substitute products, entry of new competitors, competitive rivalry, consumer bargaining power and suppliers bargaining power),
- SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis,
- PITI (Pharmaceutical Industry Transition Instrument)

In this study the external and internal environment were analysed using PITI and the study parameters were identified based on this analysis.

Step 3: Development of the balanced scorecards - Norton and Kaplan introduced the balanced scorecards in order to monitor the strategy from different points of views. Strategic objectives are categorised into four perspectives of the balanced scorecards as follows:

- **1. Financial perspective:** Financial measures are valuable in summarising the measurable economic consequences of actions already taken. In this study, sustainable profitability, international sales, local market sales, improving cost structure and increasing asset utilisation were considered to be the key financial aspirations of the local industry in the post-WTO/TRIPS situation.

- **2. Customer perspective:** This perspective includes several core or generic measures of the successful outcomes from a well formulated and implemented strategy. In this study customer satisfaction, quality improvements and innovation are included.
- **3. Internal processes perspective:** The areas considered in this context were: manufacturing technology, mergers and strategic alliances, qualifications for jobs, research and development, licence and technology transfer agreements, GMP and QA, product marketing and patent review.
- **4. Learning and growth perspective:** This perspective identified the infrastructure that the organisation must build to create long term growth and improvement. The three principal sources for organisational learning and growth are: people, systems and procedures. Employee-based measures are: employee satisfaction, retention, training and skills (including particular skills required for a new competitive environment). Information systems capabilities can be measured by real time availability of the accurate information critical for customer and internal processes of the front line of decision-making and action. Therefore, training for the employees, management knowledge, creativity of employees and skills of R&D staff were included for the strategy map.

The role of the balanced scorecards to fill the gap between the strategy and operation is illustrated in the Figure 8.2.

The main objective of the pharmaceutical industry balanced scorecards is to close the gap between the strategic and operational level. In practice, strategies are defined by higher managerial levels and are not efficiently communicated with the operational levels of company. A balanced scorecard, as will be described further in this chapter, provides a robust tool to translate the strategies into operation. It should be noted that there is a temptation to rely on financial results to measure the performance of organisations while they only show the results of what has happened before and only a balanced view will drive the industry towards superior performance (Figure 8.1).

Figure 8.2 Closing the gap between strategy and operation by balanced scorecards

Source: adapted from (Kaplan & Norton, 2004)

Step 4: Determining the strategic themes. It is important that the strategic themes differentiate the company from its competitors and guarantees its sustainability in the future. Therefore, each company should identify the appropriate strategic theme on the basis of its unique capabilities. In general, this study selected the strategic themes of increasing local and international sales (as revenue growth strategy), increasing asset utilisation and the improvement of cost structure (as productivity strategies) for the Iranian pharmaceutical industry.

Step 5: Identifying the strategic objectives. Industry objectives are goals that help to accomplish the strategic theme and all PITI categories were considered as appropriate industry objectives. The following objectives were derived from other categories because of their critical role for the industry's sustainability.

- In terms of financial perspective, sustainable profitability was considered as the ultimate objective. International sales and local market share were also considered under revenue growth strategy while increasing asset utilisation and improving cost structure were placed under productivity strategies.
- In terms of customer perspective two objectives of quality improvement (as a result of GMP and QA system) and innovative products (as a result of improvements in research and development) were added.
- Product packaging was not considered as an objective, but was reviewed as part of the quality improvement in customer perspectives.

Step 6: Synthesis of the casual links between objectives. The relationship between objectives were interpreted in terms of causal effects in the strategy map are described later in this chapter. It is important to note the essential role of this concept in an effective resource allocation. For instance, investing in modern technology without having well trained employees and managers will not only result in better performance, but waste the financial resources for other basic needs of the industry. To realise the most important causal effects in a company and also at an industry level, it is important to communicate the subject with the employees and industry experts in order to take the right decisions.

Figure 8.3 illustrates that:

- Improvement in management knowledge drives success in research and development as does hiring qualified managers and employees, entering into mergers and strategic alliance agreements as well as improving manufacturing technologies. In fact this objective in learning and growth perspective has tremendous influence on all other objectives in this area.
- This objective will indirectly facilitate GMP & QA, licence and technology transfer agreements and marketing expenditure.
- These improvements will drive success in innovative products and quality improvements that finally will result in customer satisfaction.
- Satisfied customers will create sustainable profitability through revenue growth and productivity achievements.

In this figure indirect effects are illustrated by thin arrows as an example. Indirect effects are not presented in the next diagrams but can be discussed and assessed for better understanding of the objectives causal relationships (Figure 8.3).

Figure 8.3 The causal effects arising from management knowledge

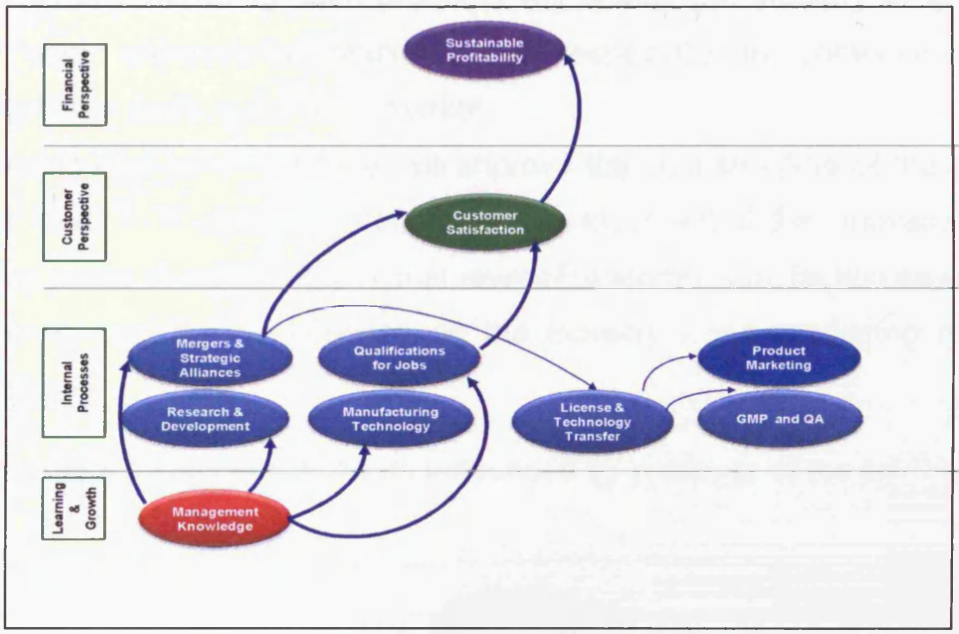
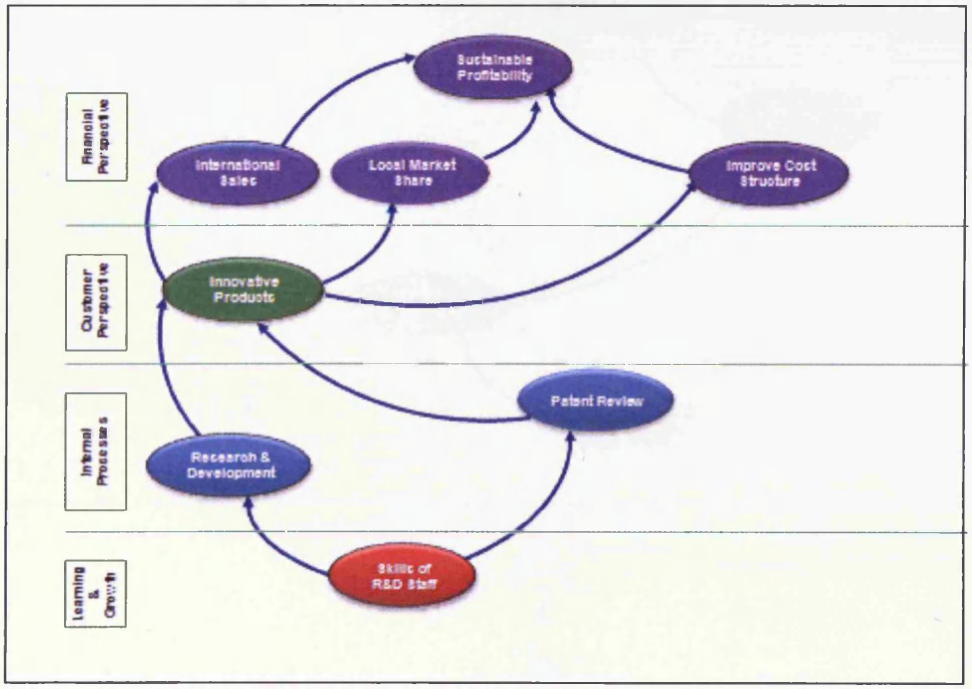


Figure 8.4 The causal effects arising from skills of R&D staff



According to Figure 8.4:

- Skills of R&D staff will directly support successful implementation of the research and development projects. It will also prepare appropriate resources for the industry to review the patent situation of their current and developing products.
- Innovative products will be developed in light of the availability of the above infrastructures.
- Success in developing such products will enable the industry to achieve more local and international market share especially in competition with the international rivals in the local market.
- Producing high value products will improve the cost structure of the industry that finally leads to sustainable profitability. Development of the innovative product is the key factor in achieving a higher level of customer satisfaction as well as lower marketing cost that is imposed on the industry when producing plain generic medicines.

Figure 8.5 The causal effects influenced by creativity of the employees.

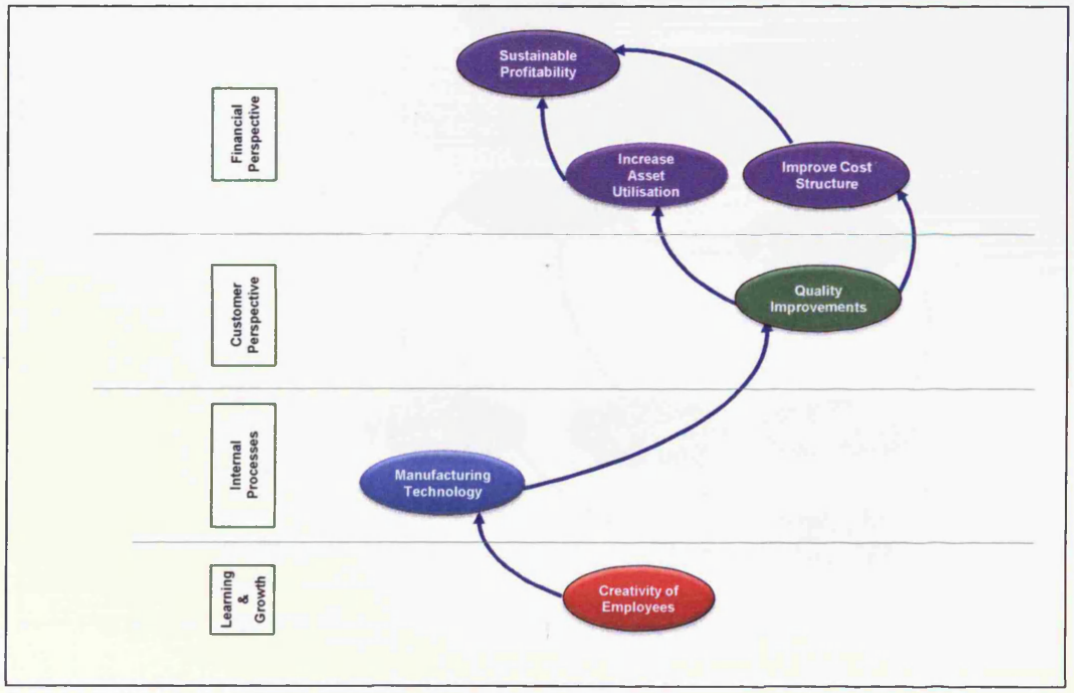


Figure 8.5 presents:

- Creativity of the employees in the learning and growth perspective which enables the industry to develop or deploy more advanced manufacturing technology
- The quality of the products will be improved by using a higher level of the manufacturing technologies
- Higher quality will enable the industry to satisfy their customers needs and meet their expectations
- The cost structure will be improved by better operational performance and less waste and reworks which are obtained by modern technology. The resulting production continuity will also improve asset utilisation. All of these achievements facilitate responding to the customers' needs
- The sustainable profitability for the industry will be then achieved in the light of these consecutive improvements.

Figure 8.6 The causal effects arising from training for employees

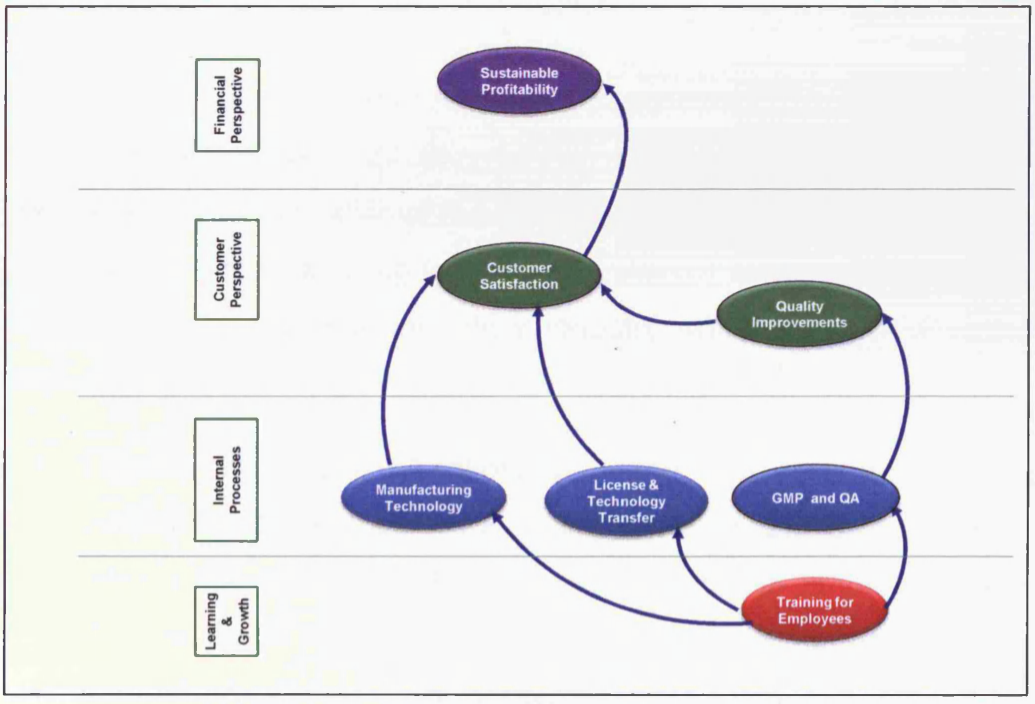


Figure 8.6 shows:

- Training for employees will facilitate implementation of GMP and quality assurance systems as well as licence and technology transfer agreements and improvement of manufacturing technologies
- As a consequence of the above achievements, the quality of the products will be significantly improved
- Higher quality products will result in improved customer satisfaction
- More satisfied customer will support the sustainable profitability of the industry in a competitive environment in the post-WTO situation.

Examination of the causal effects revealed the relationship between strategic objectives which are not limited to the above cases and therefore several direct and indirect effects may be realised on the basis of different experiences and backgrounds.

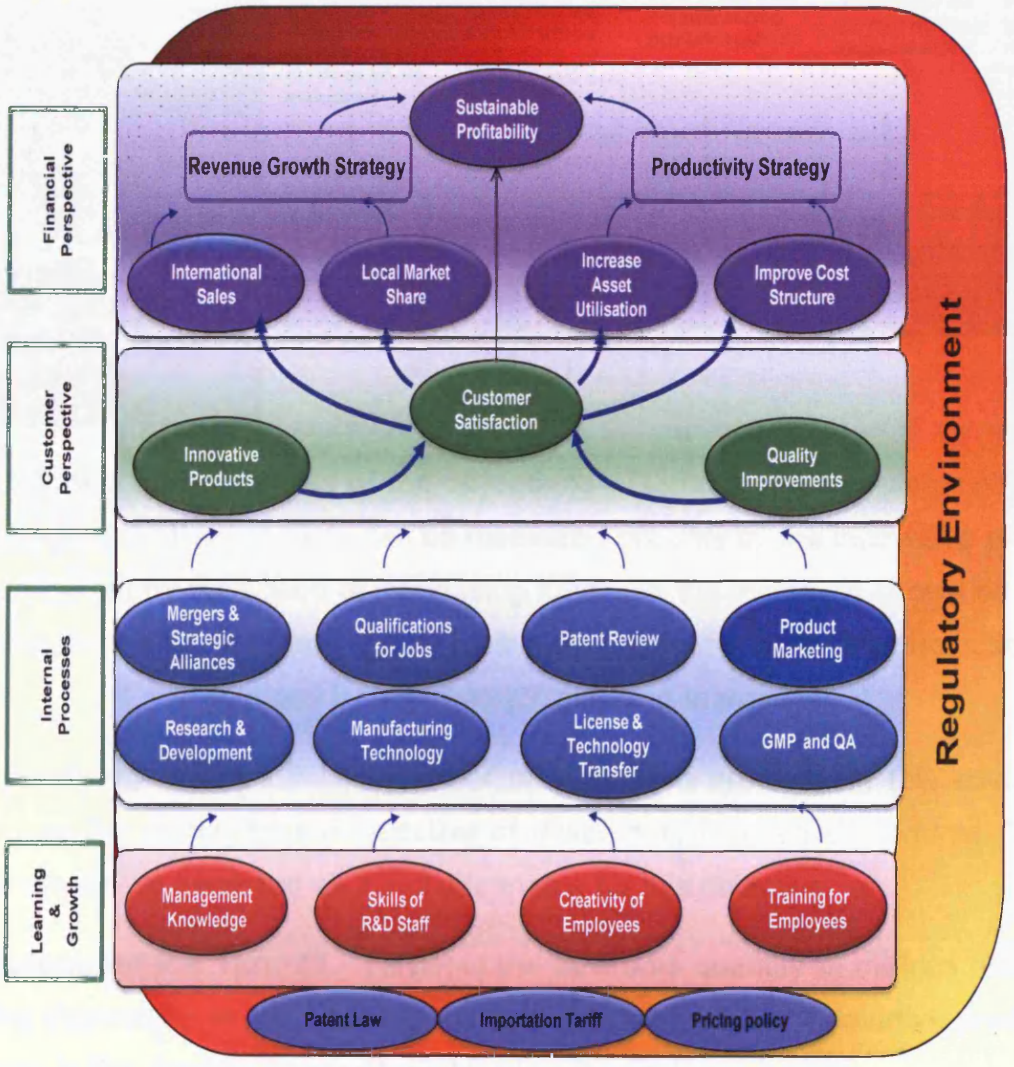
Step 7: Drawing the strategy map. Merging the four figures (8.3, 4, 5 and 6) described in step six results in the strategy map for the pharmaceutical industry presented in the Figure 8.7.

In this map three parameters of patent law, pricing policy and importation tariff underline the important role of the regulatory environment on sustainability of the pharmaceutical industry in Iran. A review of the value of the balanced scorecards, the cause and effect concept together with the lead and lag indicators, provide the necessary information to develop a strategy map of the pharmaceutical industry which was developed with the following considerations:

- Learning and growth; A rational pricing policy at the governmental level supports the four objectives in the learning and growth perspectives namely the skills of R&D staff, creativity of the employees as well as the training for the employees and management knowledge.
- Internal processes; Eight strategic objectives in the internal company process perspective including patent review, mergers and strategic alliances, manufacturing technology, qualification for jobs, product marketing, research and development, GMP & QA and licence & technology transfer agreements are influenced by the objectives in the learning and growth perspective.

- Customer perspective; All the above mentioned objectives are likely to influence customer satisfaction in the context of the customer prospective.
- Financial perspective; Finally, attaining profitability in the financial perspective will secure post-WTO sustainability of the pharmaceutical industry.

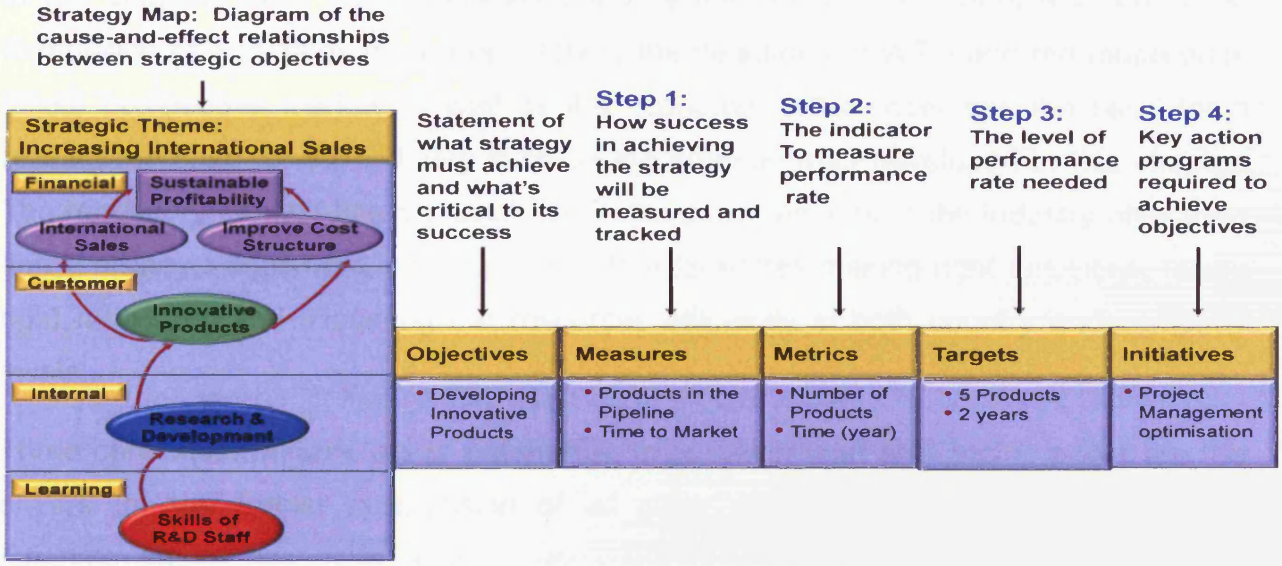
Figure 8.7 The strategy map to secure the post-WTO sustainability of the pharmaceutical industry in Iran



Part II - How to operationalise the strategy map

Having now the generic strategy map, as a prototype, the following steps should be taken to operationalise this map in the companies (Figure 8.8):

Figure 8.8 The steps to operationalise the strategy map as an example



Step1: Defining the measures of the objectives - Success in the strategic objective of developing innovative products can be measured not only by the innovative products in the pipeline but by the speed of introducing them into the market. It should be noted that defining too many measures should be avoided while the important ones should be selected by the strategic planning teams.

Step2: Specifying metrics - The number of innovative products in this example is considered as the metric for the objective of developing innovative products. Time to market can be also considered as a suitable metric for this objective.

Step3: Determine the Targets - Target is the desirable quantity of metrics needed to achieve the objectives. In our example the target quantity of the innovative products is five products in the pipeline and the target for time to market is 2 years.

Step 4: Develop initiative plans - The initiatives are defined by brainstorming and it is important to prioritise them with regards to the industry situation. In our example, the

objective of innovating products will be supported by project management optimisation. It should be emphasised that this initiative is mentioned just as an example and the strategy planning team may recognise budget allocation or R&D expenditure as the critical initiative.

DISCUSSION

In this chapter, study parameters identified by the industry managers resulted in the formulation of a strategy map. Approaching the deadlines of WTO and the tough price driven competitive market as well as the economic crisis underlines the need for a reliable roadmap for the industry such as the strategy map developed in this chapter. The regulatory context has a crucial role in the achievements of the industry objectives and a strategic alignment is the only way that facilitates making right decisions, taking right measures and allocating the resources efficiently in both country and company levels.

Three contextual parameters of patent law, importation tariff and pricing policy are the drivers for the further progression of all other scorecard perspectives. Without a rationale patent law, it is almost impossible to anticipate sensible investments in research projects by local companies or the granting of manufacturing licences by the multinational companies. Pricing rewards for any degree of product or process innovation, quality awareness or GMP improvement stimulates movement in all layers of the strategy map. A gradual decrease in the importation tariff in parallel with supportive policies will also differentiate the responsive parts of the industry and determine its future survival. It should be taken into consideration that the sustainability of the local industry has an inevitable contribution to the success of national plans for the accessibility of patients to safe and affordable medicines.

The industry associations have a key role to play in this strategy and define the measures and initiatives for the whole industry in an agreement with the regulatory officials and industry associations. These associations and holding companies can use the concept of a corporate scorecard to create additional value throughout the industry or a group of companies (Norton, 1999).

The outcome from this chapter can be used by companies and modified to their specific priorities and concerns. This map is the outcome of a country-wide study based on established methodology which is hoped will be acceptable at an executive and operational level and reduces psychological barriers of bias or irrelevant judgements. It should be noted that balanced scorecards fail for a variety of reasons such as; lack of senior management commitment, lack of a driving need for change, determining too many inappropriate metrics, too long plans and cultural mismatch (dictatorial executives and low performance norms) (Person, 2009). Therefore a successful implementation requires qualified teams to define and prepare the ground work with respect to the requirements of each company. The PITI statements are a good source of initiatives and improvement plans that can be used to translate strategies to operational plans.

Finally the findings of this chapter should be communicated to shareholders, patients' associations and physicians in order to obtain their cooperation and support by highlighting the threats of industry failure for their future benefit. It is important to note that strategy is a hypothesis that makes assumptions about outcomes that can be achieved and its proper communication to all stakeholders has an important role in this achievement (Norton, 1999).

SUMMARY

This chapter focused on a strategy map using a balanced scorecard concept in the following way:

- The study parameters from previous chapters were refined to be considered as strategic objectives for the industry.
- The objectives were distributed in four balanced scorecard perspectives namely financial, customer, internal processes and learning and growth.
- An additional level was considered as the regulatory environment included the three parameters of pricing policy, patent law and importation tariff.
- The causal effect relationship between the strategic objectives were then analysed and merged to formulate a strategy map.

- Examples of defining measures, metrics, targets and initiatives were provided to demonstrate how to operationalise this map and translate the strategies into operational plans.
- The map can then be cascaded down by using the PITI statements to define initiatives and improvement projects

Chapter 9

General Discussion

INTRODUCTION

In the practice of Zen Buddhism, the true master is able to discover the few key elements that drive all variables and bring them back to their purest form. There are no quick fixes, to do the things in the right way, it is important to know that the journey is the destination. (Buytendijk, 2008)

The role of all the experts and industry managers that participated in this study was to shape the study hypotheses, conclusions and discussions that highlighted the inductive approach as a powerful dynamic for creating and sharing the knowledge within a wide range of professionals in different organisations. Furthermore, the use of primary data as opposed to secondary data highlights the importance of the study. In fact, many studies focusing on the WTO impact on the pharmaceutical industry have collected financial and quantitative data such as research and development expenditure, number of employees working in marketing or R&D departments, the budget allocated for GMP improvements and the market value of the revenue resulting from innovative products and process developments. Quantitative research philosophy was not followed in this study for two reasons: the first was the confidential nature of the required data that could substantially affect the data collection procedure and the second was the complexity of the data manipulation and comparing the results for making decisive conclusions. The advantage of the interpretative philosophy applied in this study is the opportunity for self-assessment and self evaluation given to the study participants and this prevents the study results from being disputed for their inaccuracy due to the ambiguities in financial figures and the ways that different companies categorise their expenditures.

An important result of this study was the development of a quantitative measure, the Pharmaceutical Industry Readiness (PIR) index, to evaluate the readiness of the industry for joining WTO and the implementation of TRIPS. This evaluation was carried out for all 66 parameters and the relevant 15 categories. This measure is also applicable for determining the readiness for a company, a group of companies and for the whole industry. This study showed that the overall readiness of the pharmaceutical industry to face the WTO/TRIPS challenges is 57%. The ability of the developed methodology and relevant instruments to measure this index is considered as a unique

feature of this study. This is supported by a recent study (Farzandi and Mostafavi, 2010) where twenty companies listed in Tehran stock market were analysed. It was concluded that the overall performance of these companies was 62%. With regards to the standardised European Foundation for Quality Management (EFQM) model and the totally different methodology that was applied in this study, the correlation of 62% quality management performance with the 57% readiness, underlines the significance of the findings of this study.

The findings from this study are comparable with a number of previously reported studies in this area. For example: licence and technology transfer agreements (Supakankunti et al, 2001; Grace, 2004; Goyal, 2006 and Chaudhry, 2009), R&D investment (Grace, 2004; Dhar and Gopakumar, 2006; Chaudhry, 2009), training of the employees and qualifications for jobs (Lim and Wei, 2010), knowledge management (Lim and Wei, 2010), customer focus, marketing investment, patent review (Hason and Shimotake, 2006), importation tariff (Yeung, 2002) (Semin and Güldal, 2008), price changes (Chaudhry, 2009), strategic reorientation of the firms (Dhar and Gopakumar, 2006) and many other factors that are explored and discussed in this study are refered to in other countries' studies. Therefore, the findings of this study are comparable with similar research projects, with some differences, that reflect a different scope and objectives. For instance detailed legal aspects of TRIPS implementation or FDI were not deeply analysed in this study because contextual factors were not included in the PITI and the focus of this study was mainly on direct industrial issues. However, none of the reviewed studies collected this amount of data from the pharmaceutical companies nor developed the robust study instruments as in the case of this study. Proposing alternative scenarios and developing a strategy plan were also not reported in these studies. This study may contribute to the current limited knowledge in this area in general and provides seminal information and strategic direction for Iran's situation in particular.

Current Challenges to the Post-WTO Sustainability of the Pharmaceutical Industry in Iran

As a result of the findings of this study, the following fifteen challenges were identified:

1. Patent Review - Due to the lack of a strong patent protection law, the industry has not dedicated sufficient personnel to review the patent situation of their products. It is surprising that this evaluation is not carried out even when the companies intend to export their products into other countries. Although the common exporting destinations for Iranian pharmaceutical companies are countries such as Afghanistan, Iraq and some African countries who do not respect the TRIPS agreement, a considerable risk to the industry is imposed in the case of litigation. It would therefore be expected that the industry would review the patent situation when selecting products for development to protect their investment in the post-WTO/TRIPS situation. It was concluded that a separate study should evaluate the financial impact of enforcing the TRIPS agreement. Patent review is a top priority to address the industry weaknesses (see scenario 1 in chapter 6), but is also the first priority to bridge the gap between the current situation and future importance, improve opportunities and increase the post-WTO/TRIPS readiness of the Iranian pharmaceutical industry (see scenarios 4, 5 and 6 in chapter 7).

2. Licence and Technology Transfer Agreements - A significant investment in R&D is needed to develop innovative pharmaceutical products. For small or medium sized companies it is highly recommended to develop licence or technology transfer agreements with companies as a way to obtain technical capabilities in manufacturing, quality control and marketing of high value products. This study found a significant variation between the performances of the companies in this area. Further analysis showed that larger companies were in a better situation while small companies did not have a strategic approach towards licensed and technology transferred products due to their lack of appropriate infrastructures. However licensed and technology transferred products do not make a major contribution to the total sales of the respective companies. The pharmaceutical industry had a high score of performance in this category that subsequently made it a priority for the industry while focusing on the gap in one of the suggested scenarios (see chapter 6).

2. Sales and Marketing - The performance of the industry in this category was identified as unsatisfactory mainly due to the limited funds for marketing activities. It should be also noted that most of the companies do not have differentiated products with the competition being mainly limited to local companies. Reviewing the Iranian pharmaceutical market shows that there is considerable price oriented competition which underlines the lack of differentiated products. However this situation will be changed by the gradual decreasing of importation tariffs. There were variations in the performance of different companies in their contribution to marketing expenditures in order to gain a higher market share and increasing customer loyalty which would endanger the sustainability of the local industry in the competitive environment that is anticipated in the post-WTO situation. The industry should learn how to target the right customers and how to efficiently allocate its limited marketing funds to ensure obtaining acceptable results such as increased market share or customer satisfaction. Sales and marketing would be a top priority in the scenarios for improving weaknesses, closing the gap and increasing the industry readiness.

4. GMP & QA - This category can be considered as one of the main functions of the industry to compete in the post-WTO situation and enabling it to export their products and obtain agreements with reputable companies as licensors or co-development partners. It was expected that the industry would show a varied performance in this area due to their different financial and technological capabilities. However, the whole industry unanimously considered this category as one of their strategic goals. The industry also identified 'having a documentation system' as satisfactory that reflected the primary steps in GMP improvement. GMP and QA are major topics for the industry to address if the focus on importance or improvement opportunities is to be the selected scenario.

5. Research and development – One of the key advantages of pharmaceutical companies in the competitive environment resulting from implementing the WTO/TRIPS agreement will be their ability to develop new products which for generic companies mainly means new formulations. In general this category was recognised with high variations between the companies mainly due to different performances to allocate R&D funds and its role in creating competitiveness and developing exclusive products.

However, the results were unsatisfactory in measuring the effectiveness of R&D expenditures and developing new formulations. This means the importance of this area has not been recognised by the industry and it was expected that they would be more willing to invest in new formulations. Research and development can be considered as one of the choice strategies for improving weaknesses, bridging the gap and increasing the readiness of the industry.

6. Product Packaging - It was a major surprise from the early stages of this study that product packaging was a major concern for the industry experts and managers. Attractiveness, proper sealing, ease of reading and understanding, child proofing and durability of the pharmaceutical packaging are some of the unmet characteristics in this area. Improving the packaging of pharmaceutical products requires less technological and financial resources in comparison with other product development aspects such as developing new molecules from chemical or biological sources. This study showed that the industry has failed to design packages as attractive and appropriate as their international rivals and this was identified as a result of constraints in modern packaging lines. The study showed that some companies are allocating resources to improve their packaging but the results have not been realised as yet or the attempts have not been successful. Product packaging was identified as an important area for improving the weaknesses, closing the gap and increasing the readiness of the industry.

7. Manufacturing technology - Companies differed with regard to this category as expected because of their inherent differences in their technological experience. The only parameter that was satisfactory in this group was documentation of the manufacturing procedures but all respondents considered that their automation level was unsatisfactory. These results show that the industry has started to do the paper work that is required for modern technology implementation but the automation level that presents on important aspects of the GMP complied technologies are not deployed yet. The automation level is affected by both financial capabilities and the legal environment but the current labour law does not permit the firms to cut jobs in order to replace automated systems and manual work is frequently used especially in transporting the material in the process of manufacturing and also in packaging the finished goods. However the companies need to upgrade their automation level in order

to comply with rigorous current GMP regulations that are required by both local and international regulatory bodies. For instance, closed systems are more and more common for transferring in-process material to prevent the susceptibility of the employees from the harmful effects of pharmaceutical materials and at the same time to protect the product from human sourced contamination. The industry has identified the manufacturing technology category as one of its strengths and this would be one of the top priorities focusing on strengths and importance scenarios.

8. Mergers and Strategic Alliances - The performance of the Iranian pharmaceutical industry in evaluating possible mergers was recognised as unsatisfactory by the participants in this study. The largest pharmaceutical companies in Iran have annual sales of 100-150 million US dollars but this is considered as small or medium sized even on a regional scale. Optimum size is one of the important factors affecting the success of the pharmaceutical companies in the international environment. This lack of evaluation shows the industry is not taking serious steps towards international competition. Merging between companies with complementary product portfolios, merging with manufacturers of the key raw materials or with owners of well-established R&D facilities are suggestions that have been rehearsed with local and even international companies, especially in China and India. Involvement of the Iranian pharmaceutical companies in strategic alliances was also recognised as unsatisfactory. Strategic alliances can be formed for co-development of innovative products with significant marketing efforts or procurement of the key raw materials leading to increase sales or the reduction of costs. Unsatisfactory performance in this area is a clear sign of the lack of readiness of the industry to face these future challenges.

9. Pricing Policies - The respondents did not show any agreement to indicate that the pricing policy of the local industry was either satisfactory or unsatisfactory. However, with the current high importation tariff for imported products, it is expected that the industry is not sufficiently motivated to reassess its pricing strategies. With the challenges that will appear in the post-WTO situation, especially by considering the inexpensive generics from India and China, it is crucial for the industry's sustainability to ensure the competitiveness of the local industry particularly in the case of price sensitive generic products. It is important that many companies claim even higher prices

to cover their cost without sufficient attempts to demonstrate the efficiency of their cost control policies such as enhancing productivity, strategic alliances or deploying more efficient technologies. In general, pricing was recognised as one of the strengths of the industry and can be considered as an important strategy in the scenario of focusing on strengths.

10. Training for Employees - This was the only category that was identified as satisfactory in this study although the results varied for single statements. This result was not surprising with regards to the increasing importance of human resources in the success of companies especially in a knowledge-based industry such as pharmaceuticals. Providing necessary training for employees is also required by the Iranian inspectors from the Iranian Ministry of Health. This is why the average performance of the industry in this category reached a satisfactory level although better results were expected for some of the parameters such as having training programmes for employees. This shows a gradual increase in local regulatory standards that would allow the industry to cope with the requirements and improve results. It is important that future competition will not only deploy new technologies or own differentiated products, but that talented and well trained staff will play a crucial role in the sustainability of the firms. Development of progressive training programmes for employees will be a preferred strategy in the scenarios dedicated to focusing on strengths and importance.

11. Skills of R&D Staff - Not surprisingly, this category was identified as unsatisfactory. The results varied for the regular improvement of the skills of the R&D staff, but developing innovative products and their contribution to company revenues or competitive advantage remained unsatisfactory. This result may indicate the lack of either sufficient funds or equipment to allocate to skills improvement in R&D departments. It may also be the result of poor protection of intellectual property rights. Highly skilled personnel can easily move to competitor companies and share acquired expertise. It is obvious that one of the key requirements for developing innovative products is having skilled staff in R&D departments. The overall results specified this category as important in all proposed scenarios.

12. Management Knowledge - The level of management knowledge was differently evaluated by individuals participating in this study. The study also revealed the fact that

there are not adequate numbers of management graduates in pharmaceutical companies and the availability of qualified persons in managerial positions is a controversy. In general, pharmacists and accountants or finance graduates are key decision-makers in Iranian pharmaceutical companies, while the need for management graduates such as MBAs and human resource experts was frequently identified in this study. The consequences of management decisions are also not followed according to findings from this study. An appropriate way for management can only be realised by competent and qualified managers leading the company toward sustainability in a competitive environment. This fact is very important and noted by investors and boards of companies in appointing the right people in managerial positions. Reviewing the proposed scenarios showed that management knowledge was not considered as the preferred strategy either if the industry wants to focus on its strengths or to bridge the gap, but is a priority in improving weaknesses, focusing on importance, improving opportunities and increasing the industry readiness.

13. Customer Satisfaction - Being customer oriented was not a characteristic of this study and the results showed a major variation between the companies. The constraints of the organisational resources dictate rational resource allocation based on customer needs and requirements. Categorising the customers, identifying their needs and evaluating the level of their satisfaction are preliminary steps for being a customer-oriented company. In the pharmaceutical environment, customers are patients, physicians and pharmacists. It is important to categorise the priorities and concerns of each of these customer groups. Physicians are more concerned about the onset of action, side effects and efficacy of the prescribed medicines. Pharmacists are more involved in product stability, interactions, route of administration, accompanying information (labels and leaflets) and logistical issues while patients are affected by all the above factors. Finally price, insurance coverage and reimbursement are important for all of the stakeholders. The companies, in a competitive environment, should have the ability to monitor the performance of their products in the marketplace and in meeting these important aspects. Even in the current situation there is a degree of competition between local companies and it was surprising that the companies have such a poor performance even in easier tasks such as categorisation of the different

groups of customers. Apart from the scenario of improving weaknesses, all other proposed scenarios considered customer satisfaction as an important area.

14. Creativity of the Employees - The performance of the companies to encourage innovation among its employees and its further utilisation for value creation was not satisfactory, despite the fact that this category will have an essential role in driving the industry towards sustainability in the post-WTO era. It should also be noted that reaching a satisfactory level in this category is not a quick fix as there are many pre requisites such as proper cultural dimensions for being successful in these areas. Focusing on future importance of the identified parameters would place this category as one of the top priorities as well as playing an important part in the noted scenarios of improving weaknesses and opportunities.

15. Qualifications for jobs - It was interesting to note that the minimum qualification requirement for jobs has been increased and therefore the industry performance in this area was satisfactory. This means the industry has realised the importance of having qualified staff to face future challenges. Giving scholarship to potential applicants is a popular way to ensure access to qualified persons, but here the industry performance was unsatisfactory. Having access to qualified staff and the ability to compensate their services remained a controversy among the participants of this study. These findings show that industry considers this category as one of its strengths.

It is believed that there are some areas that are underestimated by the participants of this study. For instance two parameters, related to the role of the payers, were ranked low by the expert panel as well as the policies of paying subsidies and bargaining power of the payers. It should be noted that in recent years, with increasing importance of health technology assessments, economic evaluation of medicines by governments and insurance companies has become a major barrier for market access. Nowadays, time to reimbursement, and not time to licensing, as was in the past, is the main barrier to products being marketed. This argument can also be used to explain the role of the patients' associations. Increased knowledge sharing in society, especially with regards to the role of the internet, has made ample information, including benefit-risk assessment outcomes, available to many patients and their relatives. This has created an unprecedented bargaining power for patients' associations. For an economically

superior product, regardless of being more expensive or cheaper, this can be an advantage. Therefore, patients may push the regulators to support a more expensive imported product as a result of its health technology assessment outcome. The findings presented in chapter four demonstrate the lack of sufficient awareness with respect to these topics and the importance of these parameters for the pharmaceutical community in influencing their sustainability in the competitive environment of post-WTO.

In summary approaching the deadlines of WTO in 2016 highlights the importance of such a study and its timely nature. The findings of this study have demonstrated that the industry as a whole is ill prepared in many areas and this underlines the need for a reliable roadmap such as the strategy map proposed earlier in chapter 8 .The case of Singapore, explained earlier in this chapter, highlights the role of government to support the industry for a competitive global economy. Conversely, a lack of readiness strategies as mentioned in the case of Turkey would result in increased importation, decreased exportation leading to a deterioration of the domestic pharmaceutical industry. Thus, the proposed strategy map provides a strong base for starting from a most efficient and effective position. The causal effects and the lead and lag indicators, applied for the development of this strategy map, provides the necessary tool for enabling rational and efficient resource allocation.

LIMITATIONS OF THE STUDY

There were a number of limitations to this study and these are as follows:

- **Methodology:** in an ideal world, the panel experts would have been randomly selected from a much larger pool including academics, the pharmaceutical industry, physicians, patients and government officials. However this was not possible because of the limited availability of appropriate experts who are known and available with appropriate knowledge and experience of this particular topic.
- **Patients:** the main group of stakeholders who will be affected by the introduction of the TRIPS agreement are the patients. If time had allowed, an appropriate questionnaire would have been developed and piloted in a sample population, which would have provided a different perspective from what has been given in this study.

- **Physicians:** prescribing physicians and the practicing pharmacists are significantly affected by the introduction of the WTO/TRIPS agreement. The availability of innovative medicines in the post-WTO period will significantly affect the armamentarium of the practicing prescriber. Their perspective on this issue would have been considered valuable.
- **Government:** the local industry is responsible for the production of 95% of the prescribed medicines in Iran of which the majority are the generics. However, innovative medicines are a key to the future of medical practice. Therefore, it is the responsibility of the government including payers and regulators to secure the patients' access to appropriate medicines. The government perspective of the impact of WTO is considered essential to define the appropriate strategies.

RECOMMENDATIONS

As result of this study there are a number of key recommendations that would contribute to the sustainability of the pharmaceutical industry in the post-WTO era.

- **Policy makers:** It is recommended in preparation for joining WTO that the government consider the country's pharmaceutical industry as a partner in the development of appropriate strategies. In addition they should be willing to support and motivate the industry in this respect. It is essential that in facing these challenges the government should put in place contingency funds that would allow pharmaceutical companies that get into difficulties in the new situation to be rescued as they could well in turn contribute both to the GDP and an improved healthcare environment. It is considered vital for the government work with industry to ensure the implementation of a current international standard to enable the industry to be a significant player in the competitive environment of the post-WTO era including the creation of local patent protection. Setting up joint government and industry task forces can facilitate this process as there are similar experiences even in developed countries such as UK (PICTF, 2001; PICTF, 2005).
- **Industry and investors:** in view of the importance of the TRIPS agreement for the pharmaceutical industry, it is recommended every company's first priority is to carry out a situational analysis of their own organisation using such tools as:

SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, PEST (Political, Economic, Social and Technological) analysis and using PITI (Pharmaceutical Industry Transition Instrument). This should be followed by an awareness programme for employers and employees, which would include a comprehensive review of the WTO/TRIPS agreement and its implications for their own company. It is recommended that they prepare an appropriate strategy map and allocate sufficient resources for its implementation. In addition, the industry should align their strategy with government policies to protect public health and work closely with patient advocate groups in order to remove their concerns and reassure them of the industry's commitment to patients access to medicines.

- **Patients' associations:** the patients' advocate groups should communicate their expectations to the industry and seek a clear understanding as to how and to what extent their members need to adjust their expectations in preparing for a potential short and long term shortage of medicines in the post-WTO situation and hope to overcome such difficulties. In this quest the patient groups should collaborate with the industry in an attempt to understand their difficulties and become involved in the industry's strategic direction in preparing for the competitive environment of the post-WTO era.
- **Medical and pharmacy practitioners:** Physicians and pharmacists have a central role in delivering effective healthcare to patients. In the post-WTO situation, the pharmaceutical industry may have to be innovative in order to produce new medicines which will need to be evaluated in Iran for quality, safety and efficacy prior to marketing. This will require appropriate systems to be in place for the approval of clinical research i.e. clinical research certificates. It is recommended that government consider financing appropriate clinical research centres in hospital and academia and in addition physicians and pharmacists (in government and private practice) would need to be trained in Good Clinical Practice. As these new products may initially only be marketed in Iran, an effective post marketing surveillance system would also need to be in place and this again will require the cooperation and collaboration of all relevant

stakeholders. It is hoped that these initiatives will evolve to the development of Centres of Excellence for clinical research.

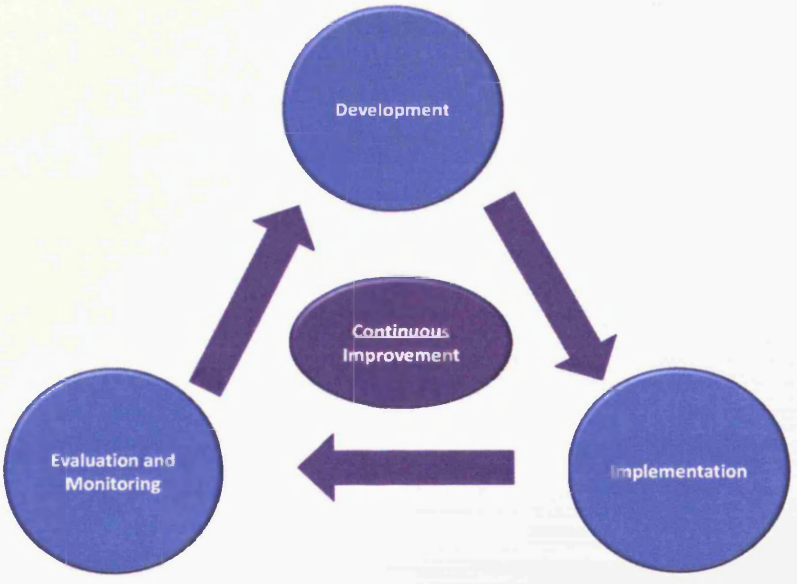
FUTURE WORK

This study is the first of its kind to evaluate the sustainability of the pharmaceutical industry in Iran in the post-WTO environment. Once it is realised that this research has resulted in the development of instruments to measure the impact of the TRIPS agreement on the pharmaceutical industry. Further work is now required in the five years that remain before this TRIPS agreement is implemented in 2016.

- Initially, as a follow up study it would be critical to develop appropriate questionnaires in order to assess the impact of the WTO/TRIPS agreement on other stakeholders such as patients, physicians and payers
- The strategy map that has been successfully developed from this research for the pharmaceutical industry should now be adopted or adapted to individual companies' requirements. This may require a different approach for small, medium or large companies. Once a company has a roadmap and relevant strategies in place it would be essential to develop a methodology in order to monitor its implementation
- In view of the limited time available, there was no opportunity to look at the economic impact of the WTO/TRIPS in Iran. In view of the significant financial implications of these initiatives, it is essential that future work should include an economic evaluation of the impact of the WTO/TRIPS agreement on individual companies, as well as the country at large.
- Finally it is important that the government should develop a critical evaluation of the changes or modifications with respect to the regulations that need to be in place in order to comply with the WTO/TRIPS agreement in the field of trade agreements in Iran. It would be an advantage if this could be carried out in association with a review of what regulatory changes were required in other countries that have gone through this accession procedure.

An overarching framework, that would be apply to all of the above suggestions for future work to ensure its long term success and relevance, would be the continuous improvement underpinned by development, implementation and evaluation and monitoring cycle (Figure 9.1).

Figure 9.1 Continuous improvement cycle



CONCLUSION

This study, for the first time, provides a detailed insight into the current situation of the pharmaceutical industry in Iran covering the whole spectrum of activities from molecule to market place and their future importance to WTO accession. The findings can help the government and the industry to shape their strategy in fostering a harmonised approach, involving all stakeholders, to embrace the paradigm shift of the pre and post-WTO/ TRIPS agreement.

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Publications

Poster presentation

Farzandi, Gh., Salek, S and Walker,S (2008). The sustainability of the Iranian Pharmaceutical Industry post-WTO/TRIPS Agreement. 44th DIA Annual Meetining, Monday June 23, Boston USA. Published in Drug Information Journal, 2008: 398.Appendix 5.

Publications and Oral Presentations

Farzandi, Gh., Saffarinejad, M,. "A Successful Implementation of the Strategy-Focused Excellence In DarouPakhsh Holding (DPH) by Combination of EFQM and BSC." 13th Toulon Verona Conference. Cuimbra, Portugal: University of Cuimbra, 3 September 2010.

Farzandi, Gh., (2010). "The Challenges of the Policy Making in the Pharmaceutical Industry and Proposed Solutions." Daroudarman, 2010: 42-43.

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Farzandi Gh., (2009). The post-WTO sustainability of the pharmaceutical industry in Iran. Presentation in the Applied Research Council, Ministry of Health, 3 May 2008 Tehran Iran.

Farzandi, Gh., (2008). Innovation Management in Pharmaceutical Industry. Presented in the 8th conference on Creativity and Innovation. Social Security Organisation, 15 December 2009,Tehran, Iran.

Appendix 1

The cover pages of the WTO, PI Impact Rating Scale

Dear .....

I would like to take the opportunity to thank you for accepting to take part in this study with the purpose of identifying the impact of WTO/TRIPS on pharmaceutical industry in Iran. This represents round 2 of the Delphi technique which has been formulated from the responses to round 1. As you will see, a divergence of opinions has been expressed by experts who took part in round 1, underlining the need for such a study.

Your responses will be treated in the strictest confidence and will be analysed without identifying individual respondents. Any responses that are used in the subsequent rounds or in publications will be anonymised.

Please read each statement and rate your agreement by selecting a figure from 1 to 9. Selecting 1 means that you strongly disagree with the meaning of the statement while selecting 9, shows your strong agreement. The other figures are in between the two extremes.

It is estimated that the questionnaire will take 15-20 minutes to complete. Your continued input in this process is highly appreciated. Our deadline to collect all responses is **30th of October 2009**.

May I remind you of the ground rules of the Delphi method:

- The questionnaire should be completed independently by the respondent.
- The proceeding of the study should not be discussed with colleagues or co-workers until the final round is completed. This is to ensure anonymity and independent generation of ideas.
- A list of experts taking part in this study is attached for your information.

Following completion of the project, you will receive a copy of the final report.

Thank you very much for your help and time

Yours Sincerely,

Gholamhossein Farzandi, Pharm. D

PhD Research Fellow

Background

Iran has planned to join the World Trade Organisation (WTO). This organisation aims to minimize trade barriers between the member states, this means the high importation tariffs are mostly hard to maintain, which for instance is now 90% for importation of medicines. An essential part of accession procedure to WTO is enforcing trade related intellectual property rights (TRIPS). This can be considered as granting protection to patents for a period of 20 years from the date of filing the patent. These consequences including low importation tariffs and high degree of patent protection have been considered as major challenges for the pharmaceutical industry in all the countries that have joined the WTO so far. This will be a real challenge for Iran as well.

Objectives

This study aims to identify the impact of WTO/TRIPS on the sustainability of the pharmaceutical industry. These impacts can be on internal aspects of the industry as well as on the regulatory environment.

Methodology

This study has been designed to identify the most vulnerable aspects of the industry by using a Delphi method, which is characterized by interviewing a panel of experts independently until they reach a consensus. This method normally consists of three rounds.

Round 1: This involves extracting the experts' opinions by asking them a number of open-ended questions (sometimes using some background information on the subject).

Round 2: This involves generating a series of statements based on the results of round 1. All participants will be asked to rate their agreement with each statement.

Round 3: The summarised results of round 2 are fed back and participants have the opportunity to change the rating of their agreement. (There may be a need to repeat the final round to reach better consensus).

We have categorised the statements under three main headings:

Structure Parameters: Tangible resources (technology/ procedures, methods, information technology system, financial strength, GMP and R&D resources)

Context Parameters: Background variables such as: physicians' behaviour; consumer culture, regulation (patent protection & tariffs), market structure, international situation

Content Parameters: Intangible resources, human resource, culture and behaviour of the industry, management, training, etc.

Appendix 2

The cover pages of the PITI

Introduction

The pharmaceutical industry in the Islamic Republic of Iran has seen tremendous growth in recent decades; however, unless it adopts a new strategy in the coming years, it could face a bleak future once the country joins the World Trade Organisation (WTO). Iran must join the WTO in order to compete in the international market and contribute to the decision-making process of the international economy. The WTO aims to minimise trade barriers between its member states and this means that high importation tariffs are mostly hard to maintain, which, for instance, exceed 60% in the case of imported medicines. We are currently faced with various views on the pros and cons of joining or not joining the WTO, in both the government and private sectors, but it is essential that Iran's pharmaceutical industry learn to deal with the important issue of how to react to and cope with the effects of joining the WTO.

Background

An essential part of the accession procedure to WTO is enforcing trade-related intellectual property rights (TRIPS). This can be regarded as granting protection to patents for a period of 20 years from the date of filing the patent. The consequences, which include low importation tariffs and a high degree of patent protection, have been regarded as major challenges for the pharmaceutical industries of all the countries that have joined the WTO so far. Coping with this situation is likely to be a real challenge for Iran as well.

Study rationale

This study aims to identify the impact of WTO/TRIPS on the sustainability of the pharmaceutical industry in Iran. These impacts can be on internal aspects of the industry as well as on the regulatory environment. The rationale for this study is based on not only the vital role played by this industry in maintaining and improving the

healthcare standards of society but also the direct impacts of the WTO/TRIPS ascension on the economic aspects of the pharmaceutical industry. In other words, a sustainable pharmaceutical industry plays an important role in the healthcare and economy of the country.

Objectives

The objectives of this study are to:

- Identify the most vulnerable aspects of the pharmaceutical industry and propose relevant strategies to address them
- Identify the current situation of the industry and its desirable situation
- Compare the current and desirable situations and identify the gap between them
- rank and prioritise the actions required to meet this gap
- explore the readiness and fitness of Iran's pharmaceutical industry to join the WTO

Methodology

The first step of the study used the Delphi technique to identify the variables. This technique was characterised by selecting a group of experts and collecting their opinions through an interview and two subsequent questionnaires until a consensus was reached. The group was selected from the three major areas of the pharmaceutical industry, regulatory authorities and academia to cover a wide range of opinions regarding the topic of this study. Based on this step, we obtained a list of ranked variables indicating the most important impacts of the WTO/TRIPS on the pharmaceutical industry.

At this stage of the study, you are requested to rate your evaluation of each statement in terms of both the current situation (the extent of the work which is currently being done) and its future importance (the extent of the work that will be done in a competitive environment after WTO/TRIPS).

For example, a high score for the current situation implies that the industry is paying high attention to the subject of the statement, while a high score for future importance

indicates that the subject of the statement will have a high priority in the post-WTO/TRIPS situation.

If a subject with high future importance receives a low score in the current situation, it will indicate a low level of readiness of the industry for WTO/TRIPS implementation. This difference can be referred to as a gap analysis.

Study participants

This questionnaire is being sent to people employed at managerial levels in pharmaceutical companies. The responses from each company will be collected separately, thus giving us the opportunity to analyse the situation of every single company. It is emphasised here that the names of the companies will not be disclosed in any published material and are only used to map the company situation with respect to other companies (the other companies will be denoted by letters of the alphabet in the final report that you will receive).

How to complete the questionnaire

Please complete the questionnaire on your own and do not share your ideas with other colleagues to maintain the accuracy of the responses. ***The average time needed for reading the instructions and completing the questionnaire is 30 minutes.*** You are requested to answer all questions, but if any question is outside your area of expertise, you may leave it blank. The scoring of the statements is as follows:

For the current situation:

A score of 0 means 'no compliance' and indicates that the company has not done anything with regard to the subject of the statement.

A score of 10 means 'absolute compliance' and indicates that the company has completely and satisfactorily dealt with that subject matter; the other figures (i.e. 1–9) indicate levels of compliance between 0 and 10.

For the future importance:

A score of 0 means, this item will be of no importance at all after WTO/TRIPS implementation.

A score of 10, means, this item is likely to be extremely important after WTO/TRIPS implementation.

Please first provide answers for the 'current situation' and then consider the 'future importance' of each statement.

Confidentiality policy:

This is an academic research project, and all names and addresses of the respondents will be protected as confidential information and will not be reported in any published form of material. If the top management of a company wishes to receive an individual report, the diagrams will show 'your company', while the other companies will be represented by coded figures.

This questionnaire has been tested for reliability and validity before being sent to you to ensure that it is clear and easy to answer. Nevertheless, your comments are highly welcome and will be used for further analysis.

Contents of the Questionnaire

1. ***General questions***
2. ***Patent review***
3. ***Licensing and technology transfer agreements***
4. ***Marketing expenditure***
5. ***GMP expenditure***
6. ***R&D expenditure***
7. ***Product packaging***

8. *Manufacturing technology*

9. *Mergers and strategic alliances*

10. *Pricing policy*

11. *Training for employees*

12. *Skills of R&D staff*

13. *Management knowledge*

14. *Customer satisfaction*

15. *Creativity of the employees*

16. *Qualifications for jobs*

Appendix 3

The website for the Web-based PITI


Pharm
Economics
Welcome to PharmEconomics.com
CURRENT PROJECTS:
The Impact of WTO/TRIPS on the Pharmaceutical Industry in Iran
By:
Dr. Gholamhossein Farzandi
An Evaluation of Review Process in Iran and Its Impact on Patients' Access to Medicines
By:
Dr. Seyed Hamid Mostafavi
Pharmacoeconomics refers to the application of economic evaluations for analyzing the impact of pharmacy services, pharmaceutical processes and products on health care systems and healthcare organizations with the aim of effective resource allocation.
Health expenses have grown dramatically during recent decades and due to the premise of scarcity of resources, considering economic impact (as well as health impact) of different health related products application and different medical interventions is vital and inevitable for each healthcare system. In this regard, pharmaceutical companies , specially in developing countries, have an essential role in controling and minimizing the costs of health provision by applying efficient and effective drug development and delivery process to improve the affordability and accessibility of essential medications.
In Iran, pharmacoeconomics is growing and certainly many challenges and opportunities lie ahead as the field continues to grow and respond to unforeseeable future events. It is our hope that pharmeconomics.com can become a useful reference for students of pharmacoeconomics and those are learning in "the real world" who will respond to the challenges to discuss the problems and share information and experiences with each other. We are always students of our own discipline and looking forward to receiving your comments to improve this resource. We hope that this website will be educational for all of us.
Dr. Gholamhossein Farzandi
Dr. Seyed Hamid Mostafavi
CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Welsh School of Pharmacy
CENTRE FOR SOCIOECONOMIC RESEARCH
CMR International
DIA
User Name:
Password:
Log In
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Appendix 4

Friedman Ranking for All Statements of the PITI

Current situation: all statements

ID	Statements	Mean Rank
F5.7	GMP improvement is a strategic goal for us.	51.71
F8.4	Our manufacturing procedures are well documented and well executed.	47.73
F3.1	Having licensed products is a strategic goal for our company.	47.22
F16.1	The minimum qualifications have been increased in our organisation in recent years.	46.31
F8.5	We regularly update the manufacturing procedures for our products.	45.25
F16.2	We have access to people with the required qualifications.	44.61
F11.1	Qualifications are considered very important while recruiting people in our company.	43.71
F5.4	We have an appropriate documentation system for GMP.	43.61
F11.3	We are increasing our training hours per capita.	42.92
F8.3	Our manufacturing technology is in compliance with environmental standards.	42.19
F6.4	A major part of our revenue comes from exclusive products.	41.57
F13.1	We have qualified persons in all managerial positions.	39.09
F11.2	We have training programmes for every job.	38.76
F5.1	We allocate sufficient funds to improve our GMP.	38.38
F3.2	The infrastructure of our company satisfies the requirements of reputable licensors.	38.20
F14.1	We have internal programmes to meet the customers' requirements.	37.88
F6.3	R&D investment plays a major role in our competitiveness.	37.55
F14.3	We know the needs of our target customers.	37.51
F11.5	The capabilities of our employees are comparable with those of our international rivals.	37.09
F4.4	Our marketing activities contribute to capturing the market share.	36.85
F4.5	Our marketing activities have increased our customer loyalty.	36.70
F14.4	We measure the satisfaction levels of our customers.	36.63
F5.6	Our manufacturing areas are updated regularly.	36.59
F10.1	We have competitive pricing in comparison with our international rivals.	36.56
F11.4	We measure the effectiveness of our training programmes.	36.36
F8.1	We regularly improve our production lines.	36.35
F7.2	We invest in improving our product packaging.	36.12
F9.3	Being a subsidiary of a holding company facilitates strategic alliances.	35.72
F6.1	We allocate sufficient funds for our R&D department.	35.53
F7.1	The attractiveness of the packaging is a strong point of our products.	34.45

ID	Statements	Mean Rank
F15.3	Innovation plays an important role in maintaining our competitiveness.	34.28
F15.2	We have utilised the innovativeness of our employees to create value.	34.27
F14.2	We have categorised our customers into different groups and have communication programmes for each group.	34.23
F16.3	Our company can afford to employ highly qualified people.	34.10
F5.3	We have a well-planned validation master plan for GMP.	33.90
F13.3	There are adequate numbers of management graduates in our managerial team.	33.85
F9.2	We are evaluating possible mergers and acquisitions.	33.78
F3.4	We have technology transfer agreements with technology owners.	33.72
F10.2	We have price flexibility in comparison with our rivals.	33.71
F3.3	We have license agreements with innovator companies.	33.52
F15.1	Our organisation encourages innovation.	32.97
F12.1	We regularly improve the skills of our R&D staff.	32.78
F13.2	We measure the efficiency of the decisions taken by our managers.	32.02
F9.1	We have strategic alliances with some of our partners.	31.54
F7.5	The quality of our packaging is comparable with that of our international competitors.	31.43
F5.5	We have a change control system for all related departments.	30.72
F3.5	Licensed or technology transferred products constitute an important part of our total sales.	29.45
F7.3	Our packaging lines are comparable with those of our international rivals.	29.28
F12.2	Our R&D team can develop innovative products.	29.09
F5.8	We measure the effectiveness of our GMP expenditure.	28.56
F8.2	The automation level in our plant is comparable with that of our international rivals.	27.78
F6.5	We have close relations with R&D institutions outside our company.	27.57
F16.4	We have offered scholarships to obtain employees with the required qualifications.	27.41
F2.2	Intellectual property right is a key issue in the selection of a new product.	26.79
F7.4	We measure the role of our packaging in creating customer satisfaction.	26.50
F6.6	We have innovative new formulations.	25.39
F12.4	The skills of our R&D staff have created advantages for us against our rivals.	25.15
F4.3	We measure the effectiveness of our marketing expenditure.	24.89
F6.2	We measure the effectiveness of our R&D expenditure.	24.20
F4.2	We regularly increase the percentage of marketing expenditure to total sales.	24.06
F12.3	A considerable part of our revenue is the result of innovation in R&D.	22.98
F2.3	We review intellectual property rights when exporting products.	22.60
F5.2	We have the GMP approval of international inspectors.	22.07
F2.1	Our company has dedicated personnel for reviewing intellectual property rights to prevent	13.62

ID	Statements	Mean Rank
	patent infringements.	
F4.1	Our marketing expenditure is comparable to that of our international rivals.	13.17
F2.4	We know the financial impact of enforcing patent protection on our company.	10.49

Future Importance: all statements

ID	Statements	Mean Rank
F5.4	We have an appropriate documentation system for GMP.	46.26
F5.7	GMP improvement is a strategic goal for us.	45.42
F5.3	We have a well-planned validation master plan for GMP.	43.73
F5.1	We allocate sufficient funds to improve our GMP.	41.89
F8.4	Our manufacturing procedures are well documented and well executed.	41.64
F3.2	The infrastructure of our company satisfies the requirements of reputable licensors.	41.45
F5.2	We have the GMP approval of international inspectors.	40.17
F8.5	We regularly update the manufacturing procedures for our products.	39.94
F6.3	R&D investment plays a major role in our competitiveness.	39.81
F6.1	We allocate sufficient funds for our R&D department.	39.61
F11.1	Qualifications are considered very important while recruiting people in the company.	39.61
F5.5	We have a change control system for all related departments.	38.76
F5.8	We measure the effectiveness of our GMP expenditure.	38.39
F13.1	We have qualified persons in all managerial positions.	38.30
F3.4	We have technology transfer agreements with technology owners.	37.17
F3.1	Having licensed products is a strategic goal for our company.	37.12
F5.6	Our manufacturing areas are updated regularly.	37.05
F14.4	We measure the satisfaction levels of our customers.	36.98
F15.3	Innovation plays an important role in maintaining our competitiveness.	36.95
F14.1	We have internal programmes to meet the customers' requirements.	36.62
F4.4	Our marketing activities contribute to capturing the market share.	36.34
F15.1	Our organisation encourages innovation.	36.24
F12.2	Our R&D team can develop innovative products.	35.92
F11.2	We have training programmes for every job.	35.89
F8.3	Our manufacturing technology is in compliance with environmental standards.	35.36

ID	Statements	Mean Rank
F3.3	We have licence agreements with innovator companies.	35.21
F13.2	We measure the efficiency of the decisions taken by our managers.	34.39
F16.3	Our company can afford to employ highly qualified people.	34.31
F16.1	The minimum qualifications have been increased in our organisation in recent years.	34.14
F16.2	We have access to people with the required qualifications.	33.90
F15.2	We have utilised the innovativeness of our employees to create value.	33.64
F14.3	We know the needs of our target customers.	33.60
F11.4	We measure the effectiveness of our training programmes.	33.35
F12.1	We regularly improve the skills of our R&D staff.	33.35
F6.6	We have innovative new formulations.	33.01
F11.5	The capabilities of our employees are comparable with those of our international rivals.	32.92
F4.5	Our marketing activities have increased our customer loyalty.	32.30
F4.3	We measure the effectiveness of our marketing expenditure.	32.20
F8.1	We regularly improve our production lines.	32.14
F6.4	A major part of our revenue comes from exclusive products.	32.13
F2.2	Intellectual property right is a key issue in the selection of a new product.	31.91
F12.3	A considerable part of our revenue is the result of innovation in R&D.	31.77
F11.3	We are increasing our training hours per capita.	31.58
F7.3	Our packaging lines are comparable with those of our international rivals.	31.07
F7.1	The attractiveness of the packaging is a strong point of our products.	31.01
F6.2	We measure the effectiveness of our R&D expenditure.	30.73
F14.2	We have categorised our customers into different groups and have communication programmes for each group.	30.70
F7.5	The quality of our packaging is comparable with that of our international competitors.	30.62
F13.3	There are adequate numbers of management graduates in our managerial team.	30.40
F9.1	We have strategic alliances with some of our partners.	29.65
F12.4	The skills of our R&D staff have created advantages for us against our rivals.	29.55
F7.2	We invest in improving our product packaging.	29.37
F7.4	We measure the role of our packaging in creating customer satisfaction.	28.91
F10.1	We have competitive pricing in comparison with our international rivals.	27.76
F2.3	We review intellectual property rights when exporting products.	27.74
F8.2	The automation level in our plant is comparable with that of our international rivals.	27.58
F16.4	We have offered scholarships to obtain employees with the required qualifications.	26.95
F2.1	Our company has dedicated personnel for reviewing intellectual property rights to prevent patent infringements.	26.90

ID	Statements	Mean Rank
F2.4	We know the financial impact of enforcing patent protection on our company.	26.43
F6.5	We have close relations with R&D institutions outside our company.	25.80
F9.3	Being a subsidiary of a holding company facilitates strategic alliances.	25.64
F3.5	Licensed or technology transferred products constitute an important part of our total sales.	25.41
F4.2	We regularly increase the percentage of marketing expenditure to total sales.	24.90
F10.2	We have price flexibility in comparison with our rivals.	24.41
F9.2	We are evaluating possible mergers and acquisitions.	24.27
F4.1	Our marketing expenditure is comparable to that of our international rivals.	22.77