The Pharmaceutical Sector in Pakistan

—Export performance and potential
—Implications of the WTO Agreements

August 2007
ITC: The Partner in Export Development

ITC Mission

ITC enables small business export success in developing countries by providing, with partners, trade development solutions to the private sector, trade support institutions and policy-makers.

ITC strategic objectives

- **Enterprises** – Strengthen the international competitiveness of enterprises.
- **Trade support institutions** – Develop the capacity of trade service providers to support businesses.
- **Policy-makers** – Support policy-makers in integrating the business sector into the global economy.
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The report was prepared by:

- Morten Scholer, Senior Market Development Adviser, International Trade Centre (ITC), Geneva, Switzerland
- Javeed Lodhi, Consultant, Solutions Unlimited, Karachi, Pakistan
- Dr. Ward Roofthooft, Consultant, ERI – X Marketing Consultants, Belgium
- Bastiaan Bijl, Trade Data Analyst, Independent Consultant, New Delhi, India
- Madiha Butt, Research Executive, Aftab Associates (Pvt.) Ltd, Lahore, Pakistan
- Inaam ul Haque, WTO Adviser, WTO Cell, Planning and Development Department, Government of the Punjab, Pakistan

Inputs and support were provided by:

- H. Aftab Ahmad, CEO, Aftab Associates (Pvt.) Ltd., Lahore, Pakistan
- Quratulain Ibrahim, Executive Director, Aftab Associates (Pvt.) Ltd., Karachi, Pakistan
- Arif Ahmed Khan, ITC National Programme Coordinator, Islamabad, Pakistan
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- Zahid Saeed (Vice Chairman PPMA 2005-06), Karachi, Pakistan
- Muhammad Ali Majid (Chairman Export Committee PPMA 2005-06), Karachi, Pakistan
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- Gelcaps Pakistan Ltd
- Highnoon Laboratories
- Indus Pharma (Pvt.) Ltd
- Macter International
- Nabiqasim Industries (Pvt.) Ltd
- Pharmatec Pakistan (Pvt.) Ltd
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADC</td>
<td>Assistant Drug Controller</td>
</tr>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
</tr>
<tr>
<td>BA</td>
<td>Bio-availability</td>
</tr>
<tr>
<td>BE</td>
<td>Bio-equivalence</td>
</tr>
<tr>
<td>BP</td>
<td>British Pharmacopoeia</td>
</tr>
<tr>
<td>CBR</td>
<td>Central Board of Revenue</td>
</tr>
<tr>
<td>cGMP</td>
<td>Current Good Manufacturing Practices</td>
</tr>
<tr>
<td>CIS</td>
<td>Commonwealth of Independent States</td>
</tr>
<tr>
<td>CMI</td>
<td>Census of Manufacturing Industries</td>
</tr>
<tr>
<td>CPI</td>
<td>Consumer Price Index</td>
</tr>
<tr>
<td>DDA</td>
<td>Doha Development Agenda</td>
</tr>
<tr>
<td>DRA</td>
<td>Drug Regulatory Authority</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EDF</td>
<td>Export Development Fund</td>
</tr>
<tr>
<td>EDL</td>
<td>Essential Drug List</td>
</tr>
<tr>
<td>EMR</td>
<td>Exclusive Marketing Right</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FBS</td>
<td>Federal Bureau of Statistics</td>
</tr>
<tr>
<td>FDA</td>
<td>Federal Drug Authority</td>
</tr>
<tr>
<td>FPCCI</td>
<td>Federation of Pakistan Chambers of Commerce and Industries</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>GSP</td>
<td>Generalized System of Preferences</td>
</tr>
<tr>
<td>GST</td>
<td>General Sales Tax</td>
</tr>
<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>HVAC</td>
<td>Heating, Ventilation and Air Conditioning Systems</td>
</tr>
<tr>
<td>IMS</td>
<td>Intercontinental Marketing Services</td>
</tr>
<tr>
<td>IPO</td>
<td>Intellectual Property Organization</td>
</tr>
<tr>
<td>IPR</td>
<td>Intellectual Property Right</td>
</tr>
<tr>
<td>ITC</td>
<td>International Trade Centre</td>
</tr>
<tr>
<td>LDC</td>
<td>Least Developed Country</td>
</tr>
<tr>
<td>MFN</td>
<td>Most Favoured Nation</td>
</tr>
<tr>
<td>MNC</td>
<td>Multi National Companies</td>
</tr>
<tr>
<td>MoC</td>
<td>Ministry of Commerce</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MTN</td>
<td>Multilateral Trade Negotiations</td>
</tr>
<tr>
<td>NAMA</td>
<td>Non-Agriculture Market Access</td>
</tr>
<tr>
<td>NOC</td>
<td>No Objection Certificate</td>
</tr>
<tr>
<td>NTC</td>
<td>National Tariff Commission</td>
</tr>
<tr>
<td>OICCI</td>
<td>Overseas Investors Chamber of Commerce and Industry</td>
</tr>
<tr>
<td>PB</td>
<td>Pharma Bureau (Overseas Investors Chamber of Comm. and Industry)</td>
</tr>
<tr>
<td>PPMA</td>
<td>Pakistan Pharmaceutical Manufacturers’ Association</td>
</tr>
<tr>
<td>PPO</td>
<td>Pakistan Patent Office</td>
</tr>
<tr>
<td>PRC</td>
<td>Price Recommendatory Committee</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>RTA</td>
<td>Regional Trade Agreement</td>
</tr>
<tr>
<td>SBP</td>
<td>State Bank of Pakistan</td>
</tr>
</tbody>
</table>
SMEDA         Small and Medium Enterprise Development Authority
SOP           Standard Operating Procedures
SRO           State Regulatory Ordinance
TBT           Technical Barrier to Trade
TDAP          Trade Development Authority of Pakistan
TRTA          Trade-Related Technical Assistance
TRIMs         Trade-Related Investment Measures
TRIPs         Trade-Related Aspects of Intellectual Property Rights
UNCTAD        United Nations Conference on Trade and Development
USP           US Pharmacopoeia
WTO           World Trade Organization
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Executive summary

As part of the European Union (EU) Trade-related Technical Assistance (TRTA) programme for Pakistan, a study has been undertaken of the Pakistan pharmaceuticals sector to identify the export opportunities and threats, to examine the implications of the WTO Agreements on the sector and to make recommendations on how the industry could make a better use of the international trading conditions created by the WTO.

The primary purpose of the study was to make an inventory of the sector, looking at its relevance to Pakistan, including production processes, pricing and turnover performance, and export performance. The study also looks at the regulatory environment affecting the pharmaceutical industry.

The study presents a number of suggestions for projects that could be implemented if the required funding was made available.

Findings

Industry outlook

Pakistan counts close to 430 pharmaceutical companies, over 90% of which are national companies. Almost all of these companies manufacture finished products: there is very little manufacturing of raw materials in Pakistan.

The Pakistani market represents only one-third of 1% of the total world pharmaceutical market but its annual growth rate is twice as fast. The market is evenly split between national and multinational companies.

It is pertinent to mention here that Pakistan imports around three times more pharmaceuticals than it exports. While imports come from all over the world, exports mainly go to a small number of African countries.

The Pakistani pharmaceutical industry has not yet attained a satisfactory share of the national market when compared to other Asian markets. In several Asian countries, national companies take prominent places among the top 10 companies, whereas in Pakistan only two national companies could enter into the top 10 positions recently.

Also, Pakistan has not yet taken a position in the international market that would be commensurate with the size of the country and the undeniable professionalism of its pharmaceutical industrial personnel.

Government policies

The Government demonstrates clearly its understanding of the importance of the pharmaceutical industry for public health and for the overall economy by securing the quality of medicines, e.g. by constantly improving the regulation of the industry and by taking initiatives to assist companies in their efforts to export medicines.
The industry feels that certain price regulations on the domestic market are not favourable to the national industry. While on the one hand the assistance for exporting is much appreciated, it is felt that some import restrictions on productive items, such as machinery and packaging materials, are hampering the growth of exports.

At the company level

The Pakistani pharmaceutical industry shows a healthy appetite for investments, even though capital is not always easy to acquire.

The level of professionalism of executives and labour is undeniably of an adequate level and is further supported by quality education offered by the universities.

WTO rules are not sufficiently known and their impact on the international trade of pharmaceuticals not adequately recognized. This is particularly the case for the application of TRIPs, i.e. the Agreement on Trade Related Aspects of Intellectual Property Rights. A related shortcoming is the absence of an early warning system about the expiry of patents, which is delaying Pakistani companies from joining the international competition for generic medicines.

Markets are not adequately explored for their potential and accessibility. Tenders are not brought to the attention of potential participants in a timely fashion.

There is still a lingering fear for associations e.g. by working together with “competitors” at home or in strategic alliances with partners abroad for saving costs or for improving product portfolio.

Recommendations

Industry and government: shared opportunities and shared responsibilities

Material infrastructure

There is a need for a bio-availability and bio-equivalence laboratory. A few countries, to which Pakistan could export, will no longer accept generic medicines that cannot present BA and BE certificates. Such a laboratory could be attached to the pharmacy faculty of a university. It is likely that private capital for such a project can be found if needed.

Intellectual infrastructure

In spite of what is often said, a developing country such as Pakistan could engage in pharmaceutical research and development (R&D). The search for conventional allopathic medicines is out of reach for Pakistani companies because of the lack of capital and sufficient scientific personnel. But R&D is possible in at least two interesting fields: the galenic improvement of generic medicines and the scientific underpinning of traditional medicines, such as plant medicines. It is suggested that the Government in collaboration with the industry establish such an R&D centre and perhaps announce an R&D prize to motivate young scientists to apply their acquired skills and creativity to R&D.
Changing paradigms

From re-active to pro-active policies

The pharmaceutical industry needs to develop an understanding of WTO rules, procedures and policies. Rather than waiting for WTO decisions to start affecting the industry (often negatively), the industry and the Government should work hand in hand to influence and shape the WTO policies in favour of the industry. It will soon become desirable to extend these strategic alliances to other countries as well. Because of the idiosyncratic nature of the pharmaceutical industry, and in particular the very stringent regulatory policies in highly industrialized markets, this process can probably best start in other developing countries. In any case, the industry should take advantage of the WTO policies whenever an opportunity arises (such as the “mailbox agreement”) and optimally utilize it in the field of operation within the parameters of WTO membership.

A bigger picture

There are probably few industries that need such a large playing field as the pharmaceutical industry. The pharmaceutical market is a global market by definition and, consequently, there is no chance for the Pakistani pharmaceutical industry to achieve its full potential for development without actively participating on a global scale. Therefore, it is imperative to shift the industry’s focus from import substitution to export orientation.

The inevitability of alliances

Alliances in the country

Within Pakistan, the industry must seek alliances with universities to explore common projects for R&D.

In addition, companies should form partnerships with each other to rationalize product portfolios, to save costs in overheads that have no bearing on individual company strategy and to achieve economies of scale. This can be done in almost every discipline of business: purchasing raw materials and intermediates, participation in international events, the common exploration and exploitation of international markets, negotiating the purchase of machinery and equipment, etc.

International alliances

It will soon become desirable to extend these strategic alliances to other countries. Because of the idiosyncratic nature of the pharmaceutical industry, and in particular the very stringent regulatory policies in highly industrialized markets, this process can probably best start in other developing countries. In the industrial world, alliances should be sought with "second tier" companies, i.e. the giants of the future, who will still allow their Pakistani partner a large degree of independence.
Conclusions

The Pakistani pharmaceutical industry has come to a crossroads. It is fast outgrowing its capacity to live and thrive on the scale of Pakistan alone. It has to re-orientate its focus from inside-looking to outside-looking. A number of Critical Success Factors will ensure the success of that endeavour:

- An unlimited commitment to quality,
- The organization of a learning and information system for the industry,
- The mobilisation of the young intellectuals of the country for adapted and appropriate pharmaceutical R&D,
- And above all, the willingness to do things together with colleagues in Pakistan and abroad.

The Government has shown its eagerness to support the industry, by easing or eliminating policies that may hamper the internationalization of the industry, by supporting the search for high quality, and by defending the interests of the industry in international organizations, in particular at the WTO.

The future looks promising but also full of challenges that will require diligence, hard work and initiative.
1 Background and objectives

1.1 EC TRTA Programme for Pakistan

The International Trade Centre (ITC) is implementing, on behalf of the European Union (EU), a Trade-related Technical Assistance (TRTA) programme in Pakistan. The overall objective of the programme is to assist Pakistan to foster its integration into the world economy and, ultimately, to contribute to poverty alleviation through the achievement of trade-related conditions for sustained and stable economic growth.

More specifically, the programme aims to enhance awareness among government officials, the business sector and civil society about the implications of the World Trade Organization (WTO) Agreements on the economy of the country, and to assist Pakistan in building the necessary capacity to address issues resulting from its participation in the WTO.

1.2 Five sector studies

Within this framework, the programme has undertaken five studies on sectors selected by the Ministry of Commerce in Pakistan: automotive parts, footwear, furniture, pharmaceuticals and sports goods.

The studies have been undertaken by national consultants, working in collaboration with the respective business associations, national and international experts and ITC.

The studies identify export opportunities and threats in each sector and examine the implications of the WTO Agreements on these sectors. Specifically they include:

- An overview of the sector and its relevance to Pakistan, including production processes, pricing and turnover performance, regulatory environment and export performance.
- A summary of other studies, reports, policy papers, strategies, etc developed in recent years for the sector.
- An overview of the sector’s trading performance for key products, including the sector’s global trade position, national sector data, imports and exports over the last 5 years, and the global position of key Pakistani companies.
- Identification of the WTO Agreements relevant to the sector and analysis of their implications for the sector globally and in Pakistan, both currently and in the future. This includes analysis of changed or new market threats or opportunities arising out of the emerging multilateral trading environment.
- An assessment of the availability and accessibility of relevant information on WTO, including the information flows between the Government and the business community.
- Identification of the key obstacles or shortcomings for improving the sector’s export performance and provision of proposals for improvement or rectification.
- An assessment of the current export support services provided by the Government and suggestions on how these could improve the export performance in the relevant sector.
• Recommendations aimed at individual companies, business associations and relevant government authorities – including some hands-on suggestions in the form of scenarios with proposed partners and estimates of costs.

1.3 Methodology

A number of methods were used to gather and validate information for the study.

Mr. Javeed Lodhi (national consultant) had a series of discussions with several senior staff members of manufacturers and exporters in the pharmaceutical sector of Pakistan.

In addition, a questionnaire was sent to over 80 manufacturers and exporters after obtaining their contact details from the Pakistan Pharmaceutical Manufacturers Association (PPMA) and the Pharma Bureau (OICCI). The companies were a complete cross-section of the industry — large, medium and small — and were selected on the basis of their share in pharmaceutical exports. At least 40% of the companies selected were exclusive exporters of pharmaceutical products. These companies are either members of PPMA or the Pharma Bureau (OICCI). Only 9 companies responded to the questionnaire despite continuous follow-up.

Other inputs were collected directly from PPMA and the Pharma Bureau.

A workshop was conducted on 19 June 2006 at the Pearl Continental Hotel, Karachi, at which the first draft of this study, largely comprising unprocessed information, was debated extensively and areas of concern were noted. Participating in the workshop were nominees of the PPMA (South and North), Pharma Bureau and the Trade Development Authority of Pakistan (TDAP), and representatives of ITC, Mr. Morten Scholer, Dr. Ward Rooftooft and Mr. Arif Ahmed Khan, respectively, in addition to the local consultants and representatives of Aftab Associates.

The document presented herewith has been rewritten to take account of feedback from the workshop and also includes changes in recent legislation, formation of TDAP and current issues.
2 Pharmaceutical sector in Pakistan

2.1 Global scenario

The pharmaceutical industry in any country is considered as the mainstay of public health. Looking at the global scenario, the importance given by developing nations to the pharmaceutical sector can be clearly identified by including healthcare and pharmaceutical industry in their health and welfare strategy. The global pharmaceutical market is valued at no less than US$440 billion, with annual growth of 6%.

As the following graph indicates, the developed countries of North America, Europe and Japan have the largest share of the global pharmaceutical market.

![Figure 2.1 Global sales - Pharmaceuticals (%)](image)

Source: IMS

2.2 Pakistan overview

The pharmaceutical industry is considered the backbone of public health services in Pakistan. This is strategically important both for the well being of the population in general and for the provision of good yet affordable healthcare in particular. The low cost of production and the huge potential of this sector has attracted major multinationals to establish their operations and production facilities in Pakistan.

Local (Pakistani) pharmaceutical companies started in the 1960s but their growth increased in the 1980s. During the last decade, they made substantial investments in production facilities and introduced the latest technology along with many new high quality products that were previously either unavailable or available on a limited scale at very expensive prices. By providing quality medicines at economical rates in this fashion, Pakistani pharmaceutical companies have contributed substantially towards public health.

The key to the success of Pakistani pharmaceutical companies is based on a simple formula, i.e. the production of high quality products at current Good Manufacturing Practices (cGMP)-compliant facilities and offering them at the most economical rates. Nearly all of Pakistan’s leading pharmaceutical companies has maintained high standards to ensure compliance of all
operations of production and quality control under the cGMP guidelines. As a result, they are now successfully exporting their products to various international territories.

### 2.2.1 Key statistics

A quantitative overview of the pharmaceuticals sector is presented in the following table.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total market size (includes prescriptions, sales to institutions, vaccines, etc)</td>
<td>US$1.5 billion (Q2, 2006)</td>
</tr>
<tr>
<td>Growth rate</td>
<td>12% to 13% per annum (Q2, 2006)</td>
</tr>
<tr>
<td>Total number of companies</td>
<td>430 approx.</td>
</tr>
<tr>
<td>National companies (manufacturers)</td>
<td>406</td>
</tr>
<tr>
<td>Multinational companies</td>
<td>24</td>
</tr>
<tr>
<td>Average growth rate of national companies</td>
<td>27% (2004-06)</td>
</tr>
<tr>
<td>Average growth rate of multinational companies</td>
<td>6.5% (2004-06)</td>
</tr>
<tr>
<td>Pharmaceutical export revenues</td>
<td>US$80 million (2005-06)</td>
</tr>
<tr>
<td>Export growth rate</td>
<td>35% (Q2, 2006)</td>
</tr>
</tbody>
</table>

Source: PPMA/Pharma Bureau (OCCI)

Various studies are conducted each year on the pharmaceutical sector. The International Medical Services (IMS) also carries out quarterly surveys to assess the developments in the pharmaceutical sector. The results of these surveys are presented in the following graphs and tables.

**Figure 2.2 Inflation rate from 2000-01 to 2004-05 (%)**
Figure 2.3 Growth in pharmaceutical sector in Pakistan, 2003-2006 (%)

![Graph showing growth in pharmaceutical sector in Pakistan from 2003 to 2006.]

Source: IMS, Quarter ended 2006

Table 2.2 Top 25 national pharmaceutical companies

<table>
<thead>
<tr>
<th>No.</th>
<th>Company</th>
<th>No.</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Sami Pharmaceutical (Pvt.) Ltd</td>
<td>15.</td>
<td>Brookes Pharmaceuticals Labs (Pakistan) Ltd</td>
</tr>
<tr>
<td>4.</td>
<td>Werrick Pharmaceuticals</td>
<td>17.</td>
<td>Ferozesons Laboratories Ltd</td>
</tr>
<tr>
<td>5.</td>
<td>Hilton Pharma (Pvt.) Ltd</td>
<td>18.</td>
<td>Indus Pharma (Pvt.) Ltd</td>
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<tr>
<td>7.</td>
<td>Wilsons Pharmaceuticals</td>
<td>20.</td>
<td>Schazoo Laboratories (Pvt.) Ltd</td>
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<tr>
<td>8.</td>
<td>Bosch Pharmaceuticals (Pvt.) Ltd</td>
<td>21.</td>
<td>Highnoon Laboratories Ltd</td>
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<td>11.</td>
<td>Platinum Pharmaceuticals (Pvt.) Ltd</td>
<td>24.</td>
<td>PharmEvo (Pvt.) Ltd</td>
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<tr>
<td>12.</td>
<td>CCL Pharmaceuticals (Pvt.) Ltd</td>
<td>25.</td>
<td>Amson Vaccines and Pharma (Pvt.) Ltd</td>
</tr>
<tr>
<td>13.</td>
<td>Nabiqasim Industries (Pvt.) Ltd</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Included in IMS as a national company, although they have foreign shareholding and are a member of OCCI.

Source: IMS, Q2, 2006
Table 2.3 Top 10 multinational pharmaceutical companies

<table>
<thead>
<tr>
<th>No.</th>
<th>Company</th>
<th>No.</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>GSK</td>
<td>6.</td>
<td>Novartis Pharma (Pakistan) Ltd</td>
</tr>
<tr>
<td>2.</td>
<td>Sanofi Aventis</td>
<td>7.</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>3.</td>
<td>Abbott Laboratories (Pakistan) Ltd</td>
<td>8.</td>
<td>Pharmacia and Upjohn (Pvt.) Ltd</td>
</tr>
<tr>
<td>4.</td>
<td>Merck Marker (Pvt.) Ltd</td>
<td>9.</td>
<td>Parke-Davis</td>
</tr>
<tr>
<td>5.</td>
<td>Roche Pharmaceuticals</td>
<td>10.</td>
<td>Wyeth Pakistan Ltd</td>
</tr>
</tbody>
</table>

Source: IMS, Q2, 2006

2.3 The pharmaceutical sector in selected Asian countries

2.3.1 Key indicators

The tables below summarise key indicators of the pharmaceutical sector in selected Asian countries.

Table 2.4 China pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Js. Yangzijiang Fly*</td>
<td>Zuo Ke</td>
<td>Simulect</td>
</tr>
<tr>
<td>Pfizer Group</td>
<td>Kai Luo Xin</td>
<td>Fa Duo Lin</td>
</tr>
<tr>
<td>Astra Zeneca Group</td>
<td>Kai Shi</td>
<td>Voluven</td>
</tr>
<tr>
<td>Roche Group*</td>
<td>Glucobay</td>
<td>Ambolcol</td>
</tr>
<tr>
<td>ZhuHai LiZhu Group</td>
<td>Ceftazidim</td>
<td>Ou Kai</td>
</tr>
<tr>
<td>Novartis Group</td>
<td>Tienam</td>
<td>Starlix</td>
</tr>
<tr>
<td>GlaxosmithKline Group</td>
<td>Cellcept</td>
<td>Iressa</td>
</tr>
<tr>
<td>Guangzhou Tiantian*</td>
<td>Losec</td>
<td>Duphaston</td>
</tr>
<tr>
<td>Bayer Group</td>
<td>Rocephin</td>
<td>Trieptal</td>
</tr>
<tr>
<td>HLJ. Haerbin Pharm*</td>
<td>Sulbactam/Cefopera</td>
<td>Levitra</td>
</tr>
</tbody>
</table>

Total pharmaceutical market (Moving Average Total - MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 61.55 billion</td>
<td>Figures not available</td>
<td>LC: 79.03 billion</td>
<td>Figures not available</td>
</tr>
<tr>
<td>US$7.44 billion</td>
<td>Figures not available</td>
<td>US$9.55 billion</td>
<td>Figures not available</td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005
### Table 2.5 Hong Kong pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations*</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaxosmith Kline Group</td>
<td>Lipitor</td>
<td>Iressa</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Norvasc</td>
<td>Hepsera</td>
</tr>
<tr>
<td>Sanofi-Aventis GP</td>
<td>Zocor</td>
<td>Cialis</td>
</tr>
<tr>
<td>AstraZeneca Group</td>
<td>Iressa</td>
<td>Arcoxia</td>
</tr>
<tr>
<td>Merck Sharp and Dohme</td>
<td>Hepsera</td>
<td>Crestor</td>
</tr>
<tr>
<td>Novartis Group</td>
<td>Nexium</td>
<td>Lexapro</td>
</tr>
<tr>
<td>Roche Group</td>
<td>Plavix</td>
<td>Bextra</td>
</tr>
<tr>
<td>Abbott</td>
<td>Augmentin</td>
<td>Levitra</td>
</tr>
<tr>
<td>Wyeth Group</td>
<td>Risperdal</td>
<td>Ezetrol</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>Propecia</td>
<td>Invanz</td>
</tr>
</tbody>
</table>

**Total pharmaceutical market (Moving Average Total - MAT)**

<table>
<thead>
<tr>
<th></th>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 3,162 m</td>
<td>LC: 3,446 m</td>
<td>LC: 3,675 m</td>
<td>LC: 3,956 m</td>
<td></td>
</tr>
<tr>
<td>US$406 m</td>
<td>US$442 m</td>
<td>US$471 m</td>
<td>US$507 m</td>
<td></td>
</tr>
</tbody>
</table>

* No national companies included in top 10.

Source: IMS, Q2, 2005

### Table 2.6 Indonesia pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations*</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kalbe Group*</td>
<td>Norvask</td>
<td>Crestor</td>
</tr>
<tr>
<td>Sanbe*</td>
<td>Lipitor</td>
<td>Procoid Reformul</td>
</tr>
<tr>
<td>Dexa-Medica Group*</td>
<td>Amoxsan</td>
<td>Fatigon Spirit</td>
</tr>
<tr>
<td>Pfizer Group</td>
<td>Neurobin</td>
<td>Reductil</td>
</tr>
<tr>
<td>Aventis Group</td>
<td>Promag</td>
<td>Mucosta</td>
</tr>
<tr>
<td>Novartis B/C Group</td>
<td>Calcium-D-Redoxon</td>
<td>Herbesser CD</td>
</tr>
<tr>
<td>GlaxosmithKline Group</td>
<td>Amaryl</td>
<td>Lipanthyl Supra</td>
</tr>
<tr>
<td>Darya-Varia Group*</td>
<td>Cefat</td>
<td>Levcin</td>
</tr>
<tr>
<td>Roche</td>
<td>Plavix</td>
<td>Levitra</td>
</tr>
<tr>
<td>Merck Indonesia GP</td>
<td>Broadced</td>
<td>Aerius</td>
</tr>
</tbody>
</table>

**Total pharmaceutical market (Moving Average Total - MAT)**

<table>
<thead>
<tr>
<th></th>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 14,490 billion</td>
<td>Figures not available</td>
<td>LC: 17,325 billion</td>
<td>Figures not available</td>
<td></td>
</tr>
<tr>
<td>US$1,692 m</td>
<td>Figures not available</td>
<td>US$1,940 m</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005
Table 2.7 Korea pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations *</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Korea*</td>
<td>Norvasc</td>
<td>Cialis</td>
</tr>
<tr>
<td>Dong A</td>
<td>Plavix</td>
<td>Bacchus-D</td>
</tr>
<tr>
<td>Dae Woong*</td>
<td>Bacchus-F</td>
<td>Ammodipin</td>
</tr>
<tr>
<td>GlaxosmithKline*</td>
<td>Lipitor</td>
<td>Hepsera</td>
</tr>
<tr>
<td>Han Mi</td>
<td>Amaryl</td>
<td>Prevenar</td>
</tr>
<tr>
<td>Handok Aventis*</td>
<td>Viagra</td>
<td>Pridorplus</td>
</tr>
<tr>
<td>Yuhan Co.*</td>
<td>Aprovel</td>
<td>Physioneal</td>
</tr>
<tr>
<td>Choong Wae</td>
<td>Albumin KGC</td>
<td>Levitra</td>
</tr>
<tr>
<td>MSD Korea*</td>
<td>Zeffix</td>
<td>Crestor</td>
</tr>
<tr>
<td>Il Dong*</td>
<td>Zanidip</td>
<td>Micardis Plus</td>
</tr>
</tbody>
</table>

**Total pharmaceutical market (Moving Average Total - MAT)**

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 6,072,445 m</td>
<td>LC: 6,441,405 m</td>
<td>LC: 6,892,295 m</td>
<td>LC: 7,409,104 m</td>
</tr>
<tr>
<td>US$5,520.4 m</td>
<td>US$5,494.7 m</td>
<td>US$6,265.7 m</td>
<td>US$6,964.8 m</td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005

Table 2.8 Malaysia pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations *</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>Norvasc</td>
<td>Arcoxia</td>
</tr>
<tr>
<td>GlaxosmithKline Group</td>
<td>Subutex</td>
<td>Reductil</td>
</tr>
<tr>
<td>Sanofi-Aventis Group</td>
<td>Lipitor</td>
<td>Cialis</td>
</tr>
<tr>
<td>Merck Sharp and Dohme</td>
<td>Plavix</td>
<td>Vytorin</td>
</tr>
<tr>
<td>Astra Zeneca</td>
<td>Viagra</td>
<td>Iressa</td>
</tr>
<tr>
<td>Schering Plough</td>
<td>Fosamax</td>
<td>Yasmin</td>
</tr>
<tr>
<td>Roche Group</td>
<td>Avandia</td>
<td>Pediacel</td>
</tr>
<tr>
<td>Novartis Group</td>
<td>Diamicron</td>
<td>Crestor</td>
</tr>
<tr>
<td>Abbott Group</td>
<td>Eprex</td>
<td>Ezetrol</td>
</tr>
<tr>
<td>Servier</td>
<td>Augmentin</td>
<td>Lantus</td>
</tr>
</tbody>
</table>

**Total pharmaceutical market (Moving Average Total - MAT)**

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 1,198.3 m</td>
<td>LC: 1,309 m</td>
<td>LC: 1,424.7 m</td>
<td>LC: 1,424.7 m</td>
</tr>
<tr>
<td>US$315.4 m</td>
<td>US$348 m</td>
<td>US$374.9 m</td>
<td>US$394 m</td>
</tr>
</tbody>
</table>

* No national companies included in top 10.

Source: IMS, Q2, 2005
### Table 2.9 Philippines pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Lab*</td>
<td>Ventolin</td>
<td>Zegen</td>
</tr>
<tr>
<td>GlaxosmithKline Group</td>
<td>Norvasc</td>
<td>Crestor</td>
</tr>
<tr>
<td>Pfizer Inc</td>
<td>Ceelin</td>
<td>Myra E</td>
</tr>
<tr>
<td>Wyeth Philippines</td>
<td>Enervon C</td>
<td>Lifezar</td>
</tr>
<tr>
<td>Astra Zeneca</td>
<td>Bioqesic</td>
<td>Glucovance</td>
</tr>
<tr>
<td>Sanofi-Aventis</td>
<td>Solmux</td>
<td>Avandamet</td>
</tr>
<tr>
<td>Abbott Lab.</td>
<td>Neozep</td>
<td>Natravox</td>
</tr>
<tr>
<td>Boehringer Ingelheim</td>
<td>Augmentin</td>
<td>Revicon Ion</td>
</tr>
<tr>
<td>Novartis</td>
<td>Plavix</td>
<td>Revicon Max</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>Plandi Er</td>
<td>Quadtab</td>
</tr>
</tbody>
</table>

#### Total pharmaceutical market (Moving Average Total - MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 1,198.3 m</td>
<td>LC: 84,734.0 m</td>
<td>LC: 82,152.6 m</td>
<td>LC: 76,308.0 m</td>
</tr>
<tr>
<td>US$1,217.5 m</td>
<td>US$1,512.3 m</td>
<td>US$1,465.6 m</td>
<td>US$1,362.6 m</td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005

### Table 2.10 Singapore pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations*</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche Group</td>
<td>Tamiflu</td>
<td>Avastin</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Norvasc</td>
<td>Crestor</td>
</tr>
<tr>
<td>GlaxoSmithKline Group</td>
<td>Plavix</td>
<td>Erbitux</td>
</tr>
<tr>
<td>Sanofi-Aventis Group</td>
<td>Subutex</td>
<td>Ezetrol</td>
</tr>
<tr>
<td>Merck Sharp and Dohme</td>
<td>Lipitor</td>
<td>Alimta</td>
</tr>
<tr>
<td>Astrazeneca</td>
<td>Rosamax</td>
<td>Levitra</td>
</tr>
<tr>
<td>Novartis Group</td>
<td>Recormon</td>
<td>Vytorin</td>
</tr>
<tr>
<td>Schering Plough Group</td>
<td>Augmentin</td>
<td>Infanrix Hexa</td>
</tr>
<tr>
<td>J and J Group</td>
<td>Gemzar</td>
<td>Avodart</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>Neupogen</td>
<td>Enbrel</td>
</tr>
</tbody>
</table>

#### Total pharmaceutical market (Moving Average Total - MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 415.2 m</td>
<td>LC: 469 m</td>
<td>LC: 489.9 m</td>
<td>LC: 516 m</td>
</tr>
<tr>
<td>US$238.5 m</td>
<td>US$280 m</td>
<td>US$290.0 m</td>
<td>US$308 m</td>
</tr>
</tbody>
</table>

* No national companies included in top 10.

Source: IMS, Q2, 2005
Table 2.11 Taiwan pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>Norvasc</td>
<td>Lescol XL</td>
</tr>
<tr>
<td>Sanofi Aventis</td>
<td>Diovon</td>
<td>Cialis</td>
</tr>
<tr>
<td>Glaxosmithkline</td>
<td>Lipitor</td>
<td>Iressa</td>
</tr>
<tr>
<td>Novartis</td>
<td>Cozaar</td>
<td>Enbrel</td>
</tr>
<tr>
<td>Merck Sharp and Dohme</td>
<td>Plavix</td>
<td>Mevalotin Protect</td>
</tr>
<tr>
<td>Roche</td>
<td>Avandia</td>
<td>Deglu</td>
</tr>
<tr>
<td>AstraZenecie</td>
<td>Celebrex</td>
<td>Diamicron MR</td>
</tr>
<tr>
<td>Bayer Group</td>
<td>Viagra</td>
<td>Pegasys</td>
</tr>
<tr>
<td>Yung Shin*</td>
<td>Taxotere</td>
<td>Zolotin</td>
</tr>
<tr>
<td>C.C.P.C.*</td>
<td>Ciproxin</td>
<td>Daxoben XL</td>
</tr>
</tbody>
</table>

Total pharmaceutical market (Moving Average Total - MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 88,343.5 m</td>
<td>Figures not available</td>
<td>LC: 94,527.5 m</td>
<td>Figures not available</td>
</tr>
<tr>
<td>US$2,568.4 m</td>
<td>Figures not available</td>
<td>US$2,748.2 m</td>
<td>Figures not available</td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005

Table 2.12 Thailand pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Inter.Corp</td>
<td>Lipitor</td>
<td>Arcoxia</td>
</tr>
<tr>
<td>Sanofi Aventis</td>
<td>Plavix</td>
<td>Crestor</td>
</tr>
<tr>
<td>Glaxosmithkline</td>
<td>Meronem</td>
<td>Iressa</td>
</tr>
<tr>
<td>AstraZenecie</td>
<td>Eprex</td>
<td>GPO Curmin</td>
</tr>
<tr>
<td>Novartis Corp</td>
<td>Celebrex</td>
<td>Risperdal Quicklet</td>
</tr>
<tr>
<td>Slam Pharm*</td>
<td>Cef-3</td>
<td>Lexapro</td>
</tr>
<tr>
<td>GPO*</td>
<td>Augmentin</td>
<td>Flebogamma</td>
</tr>
<tr>
<td>Merck and Co*</td>
<td>Sulperazon</td>
<td>Ezetrol</td>
</tr>
<tr>
<td>Roche Group*</td>
<td>Tienam</td>
<td>Hepsera</td>
</tr>
<tr>
<td>BMS Group</td>
<td>Neurontin</td>
<td>Omezol Lyo</td>
</tr>
</tbody>
</table>

Total pharmaceutical market (Moving Average Total - MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 43.3 m</td>
<td>LC: 49,295 m</td>
<td>LC: 50.7 billion</td>
<td>LC: 58,143 m</td>
</tr>
<tr>
<td>US$1,046.5 m</td>
<td>US$1,199 m</td>
<td>US$1,260.3 m</td>
<td>US$1,415 m</td>
</tr>
</tbody>
</table>

* National companies included in top 10.

Source: IMS, Q2, 2005
Table 2.13 Viet Nam pharmaceutical sector overview

<table>
<thead>
<tr>
<th>Top 10 corporations*</th>
<th>Top 10 products</th>
<th>Top 10 new products</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline Group</td>
<td>Augmentin</td>
<td>Biobaby</td>
</tr>
<tr>
<td>Sanofi Aventis Corp</td>
<td>Zinnat</td>
<td>Neo-Terygyn</td>
</tr>
<tr>
<td>BMS Group</td>
<td>Vastarel</td>
<td>Panadol Extra</td>
</tr>
<tr>
<td>Novartis Group</td>
<td>Efferalgan</td>
<td>Vastarel</td>
</tr>
<tr>
<td>Servier Group</td>
<td>Salonpas</td>
<td>Imdur</td>
</tr>
<tr>
<td>Pfizer Group</td>
<td>Panadol</td>
<td>Mobic</td>
</tr>
<tr>
<td>JandJ Group</td>
<td>Diamicron</td>
<td>Daflon</td>
</tr>
<tr>
<td>Fournier Group</td>
<td>V-Rohto</td>
<td>Maxipime</td>
</tr>
<tr>
<td>AstraZeneca Group</td>
<td>Lipanthyl</td>
<td>Zinnat</td>
</tr>
<tr>
<td>United Pharma</td>
<td>Marvelon</td>
<td>Acnes</td>
</tr>
</tbody>
</table>

Total pharmaceutical market (Moving Average Total – MAT)

<table>
<thead>
<tr>
<th>MAT Q4 2003</th>
<th>MAT Q2 2004</th>
<th>MAT Q4 2004</th>
<th>MAT Q2 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC: 5,431,242 m</td>
<td>LC: 5,966,158 m</td>
<td>LC: 6,383,045 m</td>
<td>LC: 6,677,811 m</td>
</tr>
<tr>
<td>US$350 m</td>
<td>US$381 m</td>
<td>US$406 m</td>
<td>US$422 m</td>
</tr>
</tbody>
</table>

* No national companies included in top 10.

Source: IMS, Q2, 2005

2.4 National companies in the domestic market

As can be seen in Tables 2.4 to 2.13, the prominence of national companies in their home markets varies considerably. In Korea, seven out of the top 10 companies are national, four each in Indonesia and Thailand, two in Taiwan, and one in the Philippines. Eight of the top 10 companies in India are national. Hong Kong, Malaysia, Singapore, Viet Nam and Pakistan have no national companies in their top 10.

While there is a good explanation for Hong Kong and Singapore (the Asian operational centre of multinational companies) and Viet Nam (only recent liberation of the market), there is no excuse for Malaysia and Pakistan not capturing and increasing existing market share in this sector. In Pakistan, national companies hold 47% of the home market: for India the figure stands at 75%. If there is a trend, it is that the more a country is "export oriented", the better its national companies perform on the home market (or vice versa).

The trend is changing though: two national companies, Getz Pharma Pakistan (Pvt.) Ltd and Hilton Pharma (Pvt.) Ltd, are ranked No. 8 and 10 in terms of value and their growth rate in the IMS Q3 2006 report.

Sri Lanka is possibly the strongest alternative medicine market in Asia. The allopathic market is of special interest to the Pakistani pharmaceutical companies, which are mostly exporting allopathic products to Sri Lanka.

Companies namely Beximco (No. 2) in Bangladesh, Aristo (No. 8) and Alkem (No. 10) in India, participated in the Asia HealthCare Buyers-Sellers’ meetings held in Singapore. The first

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1 IMS Q4 2005.
Pakistani participant was Nabiqasim at No. 17. A more intensive participation of Pakistani companies in the future may be helpful in increasing the exports of the industry (See further details on Asia HealthCare in 4.2.1 and 5.5.6)

2.5 Production/manufacturing process

2.5.1 Manufacturing facilities

Pakistan produces various dosage forms, including tablets, capsules, syrup, suspension, drops, cream, gel, ointment, ophthalmic/optic drops, infusions, insulin, suppositories, vaccines, liquid and powder injections, inhalers, vitamin sachets, disposable enemas and modified release dosages. The national pharmaceutical industry is currently catering to more than 60% of the country’s needs in terms of volume. (If we were to add the volume being produced for multinational companies (MNCs) on contract, the figure rises to approx. 75%.) As a result, the heavy dependency on imported products has decreased and the local industry has experienced a great boost.

In accordance with cGMP, most of the leading national pharmaceutical companies invested heavily in the latest technology to produce cost-effective and quality products. Hence, the production facilities now include state-of-the-art equipment imported from leading European, US and Chinese manufacturers. The smaller units are understandably struggling.

The leading national pharmaceutical manufacturers claim that their products have an edge over Southeast Asian products. One of the reasons is that the active pharmaceutical ingredients (APIs) of most local products manufactured in Pakistan are imported from quality manufacturers in Europe, Japan, Korea, South America and Southeast Asia.

The reliability of the quality of local products is evident from the fact that leading multinational companies are having their products manufactured by the national companies under contract manufacturing arrangements. The national companies have been quite successful in introducing various innovative products by using technology transfers and licensing arrangements. If the amount of manufacturing done for the MNCs were to be added to the direct brand sales of the local manufacturers, this would exceed the 75% requirement of pharmaceutical products of the country.

Local companies have also acquired latest technologies and entered the field of micro-encapsulation of bitter molecules for taste masking and enteric coatings of various products.

The leading companies have acquired ISO quality certifications. There are about 15 new production facilities currently under construction that aspire to obtain FDA credentials. This clearly indicates that the local pharmaceutical companies are preparing to enter the highly regulated markets, such as the United States and Europe through achieving high quality on priority.

The quality of national pharmaceutical products has been acknowledged and accepted by many international countries and quality certification authorities, which include quality accreditation from:

- European Union (German GMP)
- Uganda (NDA)
The leading companies are also inclined to improve their systems and documentation requirements by complying with various quality management standards in their organisations, including ISO 9001, 2000 and ISO 14001.

Most of the essential drugs outlined in the WHO list are manufactured by national and international companies operating in Pakistan.

The industry employs over half a million people—directly and indirectly. Considering the complexity of operations and introduction of new technologies, highly educated, competent, and committed human resources of the country are working in the pharmaceutical sector. This should ideally result in the pharmaceutical sector stepping in the research operations where they have considerable potential to earn substantial revenues in the form of contract research arrangements.

The Ministry of Health, Government of Pakistan, controls all aspects of the industry and has played a vital role in improving the quality standards of manufacturers. This has been possible by ensuring that product registrations are only given on the basis of ability to manufacture quality products. In a number of new product registrations, an exclusive inspection of the applicant’s production facilities is also carried out, thus ensuring compliance with cGMP in accordance with the need of that particular molecule. Moreover, certain new regulations are under discussion and it is expected that their enforcement shall further strengthen their objective i.e. compliance with cGMP in pharmaceutical manufacturing as well as marketing.

For detailed information about the manufacturing process of each type of dosage, refer to Annex A.

### 2.6 Availability, quality and price of raw materials

Only a few companies are manufacturing quality APIs in Pakistan. There are only few small-scale API manufacturers operating, but they neither have technical commercial-scale expertise nor resources to operate as per Good Manufacturing Practices (GMPs). However, the Government of Pakistan is inclined to promote API manufacturing and has a positive attitude towards this particular category. The Government has often supported quality API manufacturers by granting various tariff protections.

The majority of pharmaceutical companies are dependent on European, Japanese, Korean, South American and Southeast Asian manufacturers for the requirements for their API raw materials requirements of their products hence have little control over the cost of APIs. The problem is further aggravated as the national manufacturers of APIs misuse the tariff
protection and sell APIs at higher than international prices. This makes finished products for the exporters uncompetitive at the international market.

The pharmaceutical industry imports approximately 91% of all raw materials. The local availability of raw materials is restricted to the following actives

- Amoxicillin
- Ampicillin
- Aspirin
- Cefixime
- Cefadroxil
- Cephalexin
- Cefradine
- Ciprofloxacin
- Cloxacillin
- Ephedrine
- Ephedrine Sulphate
- Fluoxacin
- Furazolidone
- Ibuprofen
- Magnesium Stearate
- Norflucacin
- Paracetamol
- Parabinez
- Piperazine
- Pseudoephedrine
- Pyrazinamide
- Santonin

The raw materials mentioned in the above list do not necessarily meet the entire need of the industry and a major portion of special grades is still imported.

There are numerous factors restricting the entry of national companies manufacturing APIs to the international market. A few of them have been mentioned below:

- Substantial cost of setting up R&D facility
- Continuous cost of test runs to achieve
- Required yields
- Required stability
- Required purities
- Required characteristics
- Continued technical support
- Salaries and perks to qualified scientists
- Cost of indirect inputs

Because of the limited manufacturing of quality APIs, uncontrolled API prices as well as various tariff protections meant to support the indigenous industry, the exports of certain molecules is affected and substantial opportunities are lost.

Another fact, worth considering, is that currently the national pharmaceutical products are registered and exported not only to the developing countries of Africa, but they are also doing
quite well in quality-conscious markets like Canada, the European Union, Central Asia, Middle East, South Africa and the Far East.

Raw and packaging material is easily available from international sources such as India and China. Their quality varies from one source to another. Yet in most of the cases, the materials are subjected to stability testing to conform to the standard of US Pharmacopeias and British Pharmacopeias. In exceptional cases, raw/packaging is not available off the rack and has to be manufactured to conform to the user’s specific needs. This entails longer planning horizon and lead times. The shortage of some raw packaging material occurs occasionally due to exceptional increase in demand. Cipro, for example, affected the local industry a couple of years ago no differently from the rest of the world. The prices of raw packaging have been on the decline for the last few years. The European prices are slightly higher followed by the lower prices of India and China.

The prices of Europe are usually higher to the extent of 20% as compared to other countries. Raw and packaging material from India and China conform to BP/USP standards thus prompt the local industry to switch to these sources.

2.7 Other production inputs

Following are the production inputs used in plant/machinery:

- **Plant/machinery** (should be according to cGMP regulations)
  - HVAC systems
  - Mixer
  - Blender
  - Granulation suits
  - Packing area machinery
  - Molding
  - Water treatment plant
  - Quality control equipment
  - HPLCs
  - GC etc

- **Energy**
  - Generator
  - Electricity connection

- **Documentation**
  - SOPs
  - Registrations
  - Regulatory compliance
  - Quality/standard certification

- **Building**
  - Drainage waste system
  - Raw material temperature control
  - Dispensary area
  - Laboratory
  - Stores
- Packaging material stores
- Finished goods stores
- Quarantine area

- Personal
  - Management
  - Executives
  - Regulatory
  - Distribution and supply chain
  - Marketing
  - Import and export
  - Engineering
  - Technical staff
  - Labour

2.8 Growth in the sector

Based on IMS figures\(^2\) (Q4, 2005), growth in the pharmaceutical sector of Pakistan in percentage was:

Market growth in volume → 14% per year

Market growth in value → 10% per year

2.9 Fluctuations in exports and imports

2.9.1 Reasons for fluctuations in exports

Exports have registered an increase from 2002 to 2006. The increase is attributable to the entrepreneurship of local manufacturers, supported by TDAP (formerly Export Promotion Bureau) and the desire to expand business as competition gets tougher in the home market.

The TDAP has been actively promoting exports in general and has allowed additional incentives in particular.

Exports have been recognised at various levels by the Government —this has prompted many to get on the bandwagon to get noticed.

2.9.2 Reasons for fluctuations in imports

Imports of active and finished goods remained at the same level between 2002 and 2005. As per 2005 figures, imports stood at US$275 million.

Imports include active ingredients, packaging material for the pharmaceutical industry and finished goods (the details of these have been provided earlier in the Customs Notification SRO 1147 and 1146); other items are either covered under chemicals or separate heads.

\(^2\) IMS monitors 79% of the total pharmaceutical market and these figures are considered authentic.
The demand for imported materials should have gone up in value alongside the 10% growth in value/volume year after year (growth in industry volume). However, imports have been restricted to their current level as the prices of raw materials and packaging materials have been on a downward trend. Additionally, there has been a major shift to import from India and China instead of European and other sources.

The volume of imported materials has gone up, yet the total import bill remains stable due to price reduction and the change of source from Europe to India and China.

2.10 Pricing structure

The Pakistan Pharmaceutical Manufacturer’s Association (PPMA) believes that the pricing policy of leader prices, adopted during 1992, should be reinstated and the price of drugs be linked to the annual Consumer Price Index (CPI) to take into account inflation and high cost of production.

2.10.1 Pricing structure strategy

The Ministry of Health (MoH) controls, assigns and decides the drug prices in Pakistan. Retail price determinations are made by the Price Recommendatory Committee (PRC), which regularly monitors the drug prices in the country and decides the ceiling price of a product referred to them by the MoH’s Registration Board during monthly meetings. It is important to note that the PRC have not allowed any across-the-board price increases in the last 5 years.

The practice adopted in 1992 of pricing based on leader prices or the CPI is no longer applicable. Hence, the classification of controlled and uncontrolled drugs remains invalid.

However, in the exercise of powers conferred by section 10 (I) of the Drug Act, 1976, the Federal Government has constituted a price review committee for price evaluation and reviews. This committee comprises the Director General Health, a Cost Accountant, a Drug Controller, a representative of PPMA and a representative of the Pharma Bureau.

The main concerns of the price review committee for the determination of retail price are as follows:

- For a drug already on the market:
  - Need of the product
  - Import price
  - Product registration price in other countries
  - Prevailing price in neighbouring countries
  - Price demanded by the applicant and justification thereof
  - New molecules - available internationally

Other concerns

- Cost of raw materials
- Demand of the product
- Analysing competitors
- Marketing concessions
Other factors

The Government of Pakistan and the Ministry of Health issue instructions from time to time through notifications, orders, circulars, state regulatory orders or legislative amendments for the formation of a pricing strategy that jointly or severally affect the pricing structure in Pakistan.

Such instructions are restricted to the consumption of policy-makers, the executors and the pharmaceutical industry.

2.11 Annual turnover

The growth in the industry is recognised as between 12% - 13% on an annual basis. Following are this cumulative 12 months growth figures reported in the last four quarters:

<table>
<thead>
<tr>
<th>Quarter (2005)</th>
<th>Turnover (PKR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>January to March</td>
<td>66 million (ca US$1.1 million)</td>
</tr>
<tr>
<td>April to June</td>
<td>69 million</td>
</tr>
<tr>
<td>July to September</td>
<td>71 million</td>
</tr>
<tr>
<td>October to December</td>
<td>73 million</td>
</tr>
</tbody>
</table>

Source: IMS

2.12 Rules and regulations

2.12.1 Industry regulation

Given below are the rules and regulations affecting the pharmaceutical industry in Pakistan:\footnote{3}{All above-mentioned laws are available in the Drug Manual at all law book houses. Additionally, they are also posted at the MoH website \(\text{www.dcomoh.gov.pk}\).}

- Drug Act, 1976
- The Drugs (Licensing, Registering and Advertising) Rules, 1976 (updated)
- The Drugs (Appellate Board) Rules, 1976
- The Drugs (Imports and Exports) Rules, 1976
- The Drugs (Generic Names) Rules, 1973
- The Drugs (Labelling and Packing) Rules, 1986
- The Pharmacy Act, 1967
- Control of Narcotic Substances Act, 1997
- Allopathic System (Prevention of Misuse) Ordinance, 1962
• The Drugs (Research) Rules, 1978
• The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts’ Rules, 1976
• The Drugs (Specifications) Rules, 1978
• The Northern Areas Drugs Rules, 1996
• West Pakistan Dangerous Drugs Rules 1976
• The North West Frontier Dangerous Drugs (Confiscation and Rewards) Rules, 1954
• The Poisons Act, 1919
• Pakistan Penal Code, 1860 (provisions aimed at prevention of adulteration of drugs - sections 274, 275 and 276)
• Punjab Drug Rules, 1945
• Sindh Drug Rules, 1945
• Anti Narcotic Force Act, 1997

As stated above, the Government of Pakistan and the MoH from time to time introduce amendments to the basic legislation that also forms part of the drug laws after coming into force. An example is the recent amendment to The Drugs (Licensing, Registering and Advertising) Rules, 1976, via Special Regulation Ordinance (SRO) 662 of 2005.

In addition, the drug policy and the essential drug list have a legislative effect on the pharmaceutical industry.

2.12.2 Export planning process

• ISO/IEC DIS 17025 (1998), International Organisation for Standardisation, Geneva, Switzerland. (The ISO/IEC guide is still used as a basis for accreditation. However, it is expected that it will be replaced by ISO/IEC DIS 17025. Therefore, laboratories are advised to consult the ISO/IEC DIS 17025).

They may develop an active plan on ways to implement ISO/IEC DIS 17025. The plan should include:

• Steps for implementation
• A time schedule with checkpoints
• Resources needed for implementation
The ISO requirements are related to enhancing the capability of units in the industry, as these facilitate approvals, especially when registering products with other nations and to use a quality substantiation tool for local/regional/global marketing.

References: For FDA guidelines, please refer to the FDA official website www.fda.gov/oc/gcp/guidance.html WHO Guidelines

2.12.3 Product registration, order processing and export procedure

Export profile of Pakistani pharmaceuticals

Exports are given priority by all departments of the Government of Pakistan. Unlike the textile sector, the country’s major export revenue resource, pharmaceutical exports, is not dependent on the weather or other uncontrollable factors. Pharmaceutical exports are based on the manufacturing process and operations to convert APIs and raw material into finished medicines.

The Government has generally extended its support to the pharmaceutical sector, resulting in continuous growth in pharmaceutical exports. PPMA, the registered representative association of the pharmaceutical industry, now forecasts that by 2010 pharmaceutical exports will achieve the target of US$1 billion.

Given that pharmaceutical exports amounted to US$80 million in financial year 2005-06, this target might seem too optimistic. However, it is based on the fact that the leading Pakistani pharmaceutical companies have been investing heavily to obtain export registrations in various new export territories and these registrations are nearing completion. Concurrently, the pharmaceutical exporters have been focusing on equipping themselves with modern machinery, latest quality-control equipment, and research and other development techniques in addition to acquiring quality certification to improve their competitiveness in the international market.

The national pharmaceutical manufacturers who successfully registered their products in the Commonwealth of Independent States (CIS) region recently are likely to get a substantial business share because of their competitive edge through high quality products.

Considering the huge market potential and the enormity of the task, the national companies require additional facilities, incentives and support from the relevant departments of the Government of Pakistan for their support in their endeavours.

Regulatory authorities of certain CIS countries have recently introduced various additional requirements regarding product registration, such as Bio-Equivalence and Bio-Availability Studies and other clinical profiles. These are expected to delay several pending registration applications.

The leading manufacturers of Pakistan are of the opinion that, with adequate support, national pharmaceutical products have the potential to develop a sustainable export business and get a respectable market share in Eastern Europe as well as Latin America. The support desired from the MoH and the Ministry of Commerce (MoC) is discussed later in this report.
Leading export companies

A majority of Pakistan’s leading pharmaceutical companies have acquired ISO quality certifications, demonstrating their quality standards and vision. Around 15 new production facilities are being established to comply with FDA standards. All this reflects that the national pharmaceutical companies are aiming at highly regulated markets, such as the United States and Europe.

The top 25 national pharmaceutical companies are provided in Table 2.2.

Export procedures

For narcotics and other controlled drugs, the Ministry of Health requires an exporter to submit not only an import licence for the raw material, but also a licence for the finished drugs from the regulatory authority of the importing country.

Due to this strict check and control system, Pakistani medicines are registered in and exported to many developed countries of the world, including Singapore, Russia and Canada.

Every exporter has to obtain a No Objection Certificate (NOC) from the Ministry of Health, which is issued after submission of the batch quality certificate and other details of every consignment.

Order processing for exports

The procedure of order processing is given below.

Table 2.15 Order processing for exports

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Order negotiation, acknowledgement and finalisation.</td>
</tr>
<tr>
<td>2.</td>
<td>Issue proforma invoice / sales contract.</td>
</tr>
<tr>
<td>3.</td>
<td>Order receipt includes the following:</td>
</tr>
<tr>
<td></td>
<td>• Contract</td>
</tr>
<tr>
<td></td>
<td>• Letter of Credit</td>
</tr>
<tr>
<td>4.</td>
<td>Prepare order requisition with calculation sheet i.e. invoice amount, wt/m³ calculation/freight.</td>
</tr>
<tr>
<td>5.</td>
<td>Internal order communicated to supply chain for production.</td>
</tr>
<tr>
<td>6.</td>
<td>Supply chain prepare order compilation and provides the following:</td>
</tr>
<tr>
<td></td>
<td>• Packing list</td>
</tr>
<tr>
<td></td>
<td>• Analysis report</td>
</tr>
<tr>
<td>7.</td>
<td>Export department prepares and issues the following:</td>
</tr>
<tr>
<td></td>
<td>• Final proforma invoice</td>
</tr>
<tr>
<td></td>
<td>• Final customs invoice</td>
</tr>
<tr>
<td></td>
<td>• Freight and volume calculation</td>
</tr>
<tr>
<td></td>
<td>• Shipment break-up into commercial and bonus</td>
</tr>
<tr>
<td></td>
<td>• Promotional item dispatch detail</td>
</tr>
<tr>
<td></td>
<td>• Promotion item packing list</td>
</tr>
<tr>
<td></td>
<td>• Import declaration form</td>
</tr>
<tr>
<td>Step</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
</tbody>
</table>
| 8.   | **Export department:**  
|      | • Completes inspection formalities (if applicable)  
|      | • Books cargo through cargo agent  
|      | • Arranges NOC from ADC office:  
|      |   - Commercial invoice  
|      |   - NOC print (5) copies  
|      |   - Bond paper for NOC affidavit  
|      |   - Analysis report  
|      |   - Any other document that may be required from time to time  
|      | • Obtains Form E endorsement from bank as per L/C or contract  
|      | • Completes other documents  
|      |   - Certificate of origin  
|      |   - Certification of various documents by the relevant embassy and chamber of commerce  
|      |   - Commercial invoice (if required)  
|      |   - Other documents |
| 9.   | **Export department / supply chain:**  
|      | • Facilitate lifting of stocks by clearing agent  
|      |   - Form E  
|      |   - Commercial invoice  
|      |   - Packing list  
|      |   - NOC  
|      | • Obtains following documents from clearing agent:  
|      |   - Customs invoice (for rebate)  
|      |   - Packing list  
|      |   - Shipping bill (for rebate)  
|      |   - Form E  
|      | • All documents attested by Customs are submitted to Customs House for rebate claim  
|      | • Bill of exchange obtained from city court  
|      | • Copy of documents sent to the customer:  
|      |   - Commercial invoice  
|      |   - Packing list  
|      |   - AWB/BL  
|      |   - Certificate of analysis  
|      |   - Certificate of origin  
|      |   - Weight certificate  
|      |   - Others (if any)  
|      | • Completes/verifies all documents with L/C requirements and presents to bank for negotiation:  
|      |   - Covering letter  
|      |   - Form E (duplicate and triplicate)  
|      |   - AWB/BL  
|      |   - Copy of Letter of Credit  
|      |   - Bill of exchange  
|      |   - Packing list (original)  
|      |   - Invoice (original)  
|      |   - Certificate of analysis |

**Product registration - MoH**

The steps involved in product registration are given below:
Table 2.16 Ministry of Health product registration procedure

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Develop business plan.</td>
</tr>
<tr>
<td>2.</td>
<td>Obtain business approvals.</td>
</tr>
<tr>
<td>3.</td>
<td>Sharing with materials / production / QA management.</td>
</tr>
<tr>
<td>4.</td>
<td>Coordination to obtain trial raw material / packaging material.</td>
</tr>
<tr>
<td>5.</td>
<td>Development of product, samples, packaging etc.</td>
</tr>
<tr>
<td>6.</td>
<td>Development of country specific “Registration File”.</td>
</tr>
<tr>
<td>7.</td>
<td>Submit regulatory application, documents, dossiers and samples.</td>
</tr>
<tr>
<td>8.</td>
<td>Obtain registration from MoH.</td>
</tr>
</tbody>
</table>

Table 2.17 provides easy comparison of requirements in Pakistan and other Asian countries.

2.13 Existing studies, strategies and policy papers

2.13.1 South-South trade promotion programme, Pakistan - Supply survey on pharmaceutical products. Geneva: ITC, July 2005

This survey covers the complete Essential Drug List (EDL) and describes the overall pharmaceutical industry in detail.

Pharmaceutical products in Pakistan range from all kinds of vitamins, anti-allergics, and alkaloids to ointments and cough syrups. Around 125 categories of medicines produced in Pakistan.

The main objective of the supply survey was to provide export information to potential buyers of pharmaceuticals from Asian countries participating in an ITC-organised buyers/sellers meeting in Singapore in 2005. The supply survey aimed at:

- Describing the characteristics and structure of the pharmaceutical market in Pakistan.
- Assessing the potential for increasing demand and/or changing to new sources of supply.
- Identifying impediments to exports.
- Determining areas in which specific measures are required, with reference to customs procedures, payment arrangements, licensing and other rules and regulations.

Significance of the pharmaceutical industry to Pakistan economy

- Local production – US$1 billion
- Local consumption – US$1 billion
- Number of manufacturing units – 316
- Share of MNCs in the pharmaceutical industry – 47%
- Share of local companies – 53%
• Global sales of pharmaceuticals – US$317 billion
• Pakistan’s share in the global pharmaceutical market – 0.31%
• Increase in exports of pharmaceuticals – 17% per year

Profile of pharmaceutical industries
• Number of units – 316
• Investment – PKR 21 billion (US$350m)
• Import of pharmaceuticals – US$275m (2003-04)
• Export of pharmaceuticals – US$50m (2003-04)
<table>
<thead>
<tr>
<th>No</th>
<th>Required information</th>
<th>Bangladesh</th>
<th>Cambodia</th>
<th>India</th>
<th>Indonesia</th>
<th>Laos</th>
<th>Malaysia</th>
<th>Nepal</th>
<th>Pakistan</th>
<th>Philippines</th>
<th>Sri Lanka</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A certificate from the health authorities in the country showing that: (a) The product is produced and marketed under the same commercial name. (b) Date and number of registration. (c) In case of different commercial name for the same product this should be explained by the health authorities.</td>
<td>X</td>
<td>X</td>
<td>X (1)</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>2</td>
<td>Name and concentrations of active ingredients.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>3</td>
<td>Names and concentrations of inactive ingredients.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>4</td>
<td>Names and origin of ingredients from animal origin.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>5</td>
<td>Quantity of alcohol concentration.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>6</td>
<td>Product certificate of analysis.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>7</td>
<td>Method followed in the product analysis.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>8</td>
<td>Description of the finished product.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>9</td>
<td>Method of production for the same batch to be registered.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>10</td>
<td>Stability study expiry date and storage conditions.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
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<tr>
<td>11</td>
<td>Bio-equivalence studies</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (3)</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
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<tr>
<td>12</td>
<td>Bio-availability studies</td>
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<td>X</td>
<td>X</td>
<td>X (3)</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>13</td>
<td>A brief on the clinical pharmacological and toxicological studies.</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>14</td>
<td>Samples of the finished product with the leaflet and final package</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>15</td>
<td>Samples from the active ingredients to be used as standards</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
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<tr>
<td>16</td>
<td>Scientific references used in analyzing the product</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
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<tr>
<td>17</td>
<td>Public price certificate in the country of origin</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>18</td>
<td>C &amp; F price from the mother company</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X (6)</td>
<td>X</td>
<td>X (7)</td>
<td>X (8)</td>
<td>X (9)</td>
<td>X (10)</td>
</tr>
<tr>
<td>No</td>
<td>Required information</td>
<td>Bangladesh</td>
<td>Cambodia</td>
<td>India</td>
<td>Indonesia</td>
<td>Laos</td>
<td>Malaysia</td>
<td>Nepal</td>
<td>Pakistan</td>
<td>Philippines</td>
<td>Sri Lanka</td>
<td>Thailand</td>
</tr>
<tr>
<td>-----</td>
<td>--------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>19</td>
<td>Export prices of the product in neighbouring Asian countries</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>List of other countries where the products have been registered and marketed</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Input from industry gathered by consultants

**Footnotes**

1. Only the generic name.
2. India: Plus several additional requirements that can be summarised as follows:
   - Toxicological, clinical and bio-equivalence studies performed in India
   - Post marketing studies according to approved protocol
   - Re-registration 4 years after obtaining initial registration for a new product.
3. Only for some products.
4. Only for slow release products.
5. Malaysia, No. 15: only on request
6. Nepal, No. 13: only for new products and vaccines
7. Philippines, Nos. 11 to 12: only for products in the National Formulation
8. Thailand, Nos. 11 to 12: only for selected drugs
9. Thailand, No. 13: only for new drugs

**Important note**

The information in this table was gathered by Dr Ward Roofthoof during the ITC-organised Buyers-Sellers Meeting on pharmaceuticals at the United Nations Conference on Trade and Development (UNCTAD X) in 2000 in Bangkok. Most of the information is based on interviews of representatives in the pharmaceutical sector from the countries mentioned.

It is important to note that the table is NOT endorsed by the relevant authorities in the countries mentioned.

It cannot be excluded that the table contains some information that was unintentionally incorrect at source.

Some regulations may have changed since 2000.

The information on Pakistan was collected in the first half of 2005 from the relevant authorities in Pakistan.
Quality standards followed by pharmaceutical manufacturers

Most of the leading pharmaceutical manufacturing units are ISO certified. These units strictly adhere to the British and US Pharmacopoeia, which provide manufacturing-specific guidelines. The GMPs are also followed, providing an in-depth analysis of the rules that are product-specific.

Raw materials

Almost 95% of the basic raw materials used for the manufacturing of medicines are imported from various countries such as China, India, Japan, the United Kingdom, Germany and the Netherlands among others. However, a few firms are now producing some of the raw material locally. Details come later in the report.

Other production inputs

Major production inputs such as technology, labour, packaging materials, power and raw materials are easily available. The government gives incentives for importing raw materials and technology to the industry / exporters.

Research and development

Research on pharmaceuticals requires a huge capital. It is, therefore, not applicable to local companies and it is only suitable for MNCs in the corporate sector that can incur such huge expense.

Exports of pharmaceuticals

Table 2.18 Exports of pharmaceuticals, 1990 to 2005 (US$ million)

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1999-2000</td>
<td>38</td>
<td>38</td>
<td>40</td>
<td>43</td>
<td>50</td>
<td>63</td>
</tr>
</tbody>
</table>

Source: FBS

Rules and regulations regarding export of pharmaceutical products

- Finished goods to be exported if the exporter has a licence to manufacture or sell by retail.
- The application for licence to export drugs shall be made to the licensing authority signed by the manufacturer.
- A licence to export drugs shall be valid for two years.
- All consignments of drugs to be exported shall have an invoice, having the number and address of the manufacturer and the name and quantity of drugs.
If the collector of customs finds that the drug is in some way not complying with the provisions of the act, he will take samples and give them to the laboratory for testing.

If the manufacturer fails to comply with any of the conditions of the licence to export drugs, the licensing authority will cancel the licence.

Factors affecting production output

- Inconsistent policy
- Lack of funds for upgrading the plants
- High duties in formulation industry
- Poor policy framework
- Lack of R & D facilities
- Non-availability of sophisticated machinery
- High cost of inputs
- Discriminatory policies
- Stringent price control

Tariffs/custom duty and other charges regarding pharmaceutical industry

- Sales tax on import supply: 15%
- Customs duty: 10% of additional value
- Assessable rates on account of exemption or regulatory duty: 15% of tariff

Export channels

The first step relates to identification of a local distributor willing to do business with the company referred to as the local distributor, agent or partner. The export of pharmaceutical products takes place through local distributors/agents/partners at destination. They assume responsibility to get the product registered in their country, import and establish the selling network through wholesalers and distributors.

Export credit and finance facilities

Firstly, the general scheme of financing is 8% (SBP Circular) interest rate on the loans. Secondly, freight subsidy given is 25%. Thirdly, TDAP repays 50% of the registration fee to the local manufacturers who have applied for approval to export medicines to the United States through FDA.

Trade promotion

Basis trade promotion activities conducted by trade promotion organisations are seminars, delegations, buyers/sellers meetings and international trade fairs.

Recommendations

The representative of TDAP and marketing managers suggested the following recommendations:
• Financial help to the sector to get consultancy for research and development to develop new formulas.

• Establishment of a WHO-recognised lab by TDAP in association with PPMA.

• Ease in acquiring funds to install FDA-approved plants i.e. subsidised interest rates, government subsidy and tax holiday, etc.

• Long-term policy measures to establish raw material industry in Pakistan such as giving financial aids to small manufacturers.

• The government should change the pricing policy; there should be no disparity between the prices given to MNCs and local companies. These should be based on the cost incurred rather than meeting price control compulsions.

• Introduce/develop easy and early registration procedure for generic products and new molecules. The process in place takes too much time.

• Improvement in the quality of documents and certificates.

• Gearing up to the upcoming challenges of WTO such as setting up accredited laboratories by TDAP.

• Altering the duty drawback procedures for the pharmaceutical industry.

• Reviewing the Patent Ordinance to change the duty structure of the pharmaceutical industry.


This guide introduces key issues facing the pharmaceutical industry, responding to frequently asked questions by the manufacturers of pharmaceutical products in an export-related step-by-step manner. It covers the fundamentals of exporting, looks at export competitiveness, addresses market research and analysis, contracting, licensing, technology transfer, quality management, packaging and labelling, e-commerce, and sector-related intellectual property issues. Appendices contain an ITC survey in the pharmaceutical industry and a list of survey respondents, a list of respondents as well as a list of pharmaceutical associations worldwide, with their contact details and URLs where available.

The guide covers the following subjects:

• Introductory issues
• Making the decision to export
• Drawing up a business strategy
• Export competitiveness
• Market research and analysis
• Licensing and contracting issues
• Payment and delivery
• Managing quality in the company
• Technical regulations and registration
• Technology in the pharmaceutical companies
• E-Commerce and the use of information technology
2.14 Overview of exiting policies —National drug policy

2.14.1 Introduction

Pakistan is committed to its Health for All programme, inspired by the principle of social equity. To achieve this, the government is taking all possible measures in the field of health services at large and for drugs in particular. The national drug policy forms an integral component of its national health policy.

The purpose of the drug policy is to ensure the regular availability of essential drugs of acceptable efficacy, safety and quality at affordable prices to all, irrespective of their socio-economic status or place of living. Essential drugs are those that meet the health care needs of the majority of the population. This will help in combating disease and maintaining and improving the health of the population. The ultimate goal is to develop potent within the resources of the country and ensure its availability to control common diseases and alleviate pain and sufferings.

Towards achieving this goal, Pakistan though has drug legislation, quality control system in addition to certain other elements of the drug policy in a fragmented form, a more comprehensive drug policy is necessary to meet the challenges of the day.

This document outlines the national drug policy encompassing all aspects of drugs formulated for the first time in Pakistan to serve as a future guide.

2.14.2 The specific objective of the national drug policy

- Develop and promote the concept of essential drugs and ensure regular, uninterrupted and adequate availability of such drugs of acceptable quality at reasonable rates.
- Inculcate in all related sectors and personnel the concept of rational use of drugs with a view to safeguarding public health from overuse, misuse or inappropriate use of drugs.
- Encourage the availability and accessibility of drugs in all parts of the country, with emphasis on those areas that are included in the national essential drugs list.
- Attain self-sufficiency in the formulation of finished drugs and encourage the production of pharmaceutical raw materials by manufacturing active ingredients.
- Protect the public from the hazards of substandard, counterfeit and unsafe drugs.
- Develop adequately trained manpower in all fields related to drugs management.
- Develop a research base, particularly for operational and applied research, with a view to achieving the above-mentioned objectives.
- Develop the Pharmaceutical industry in Pakistan, with a view to meeting the requirement of drugs within the country and to promote their exports.
2.15 Overview of pharmaceuticals trade

2.15.1 SWOT analysis of Pakistani pharmaceutical companies

The following SWOT analysis has been done after interviewing manufacturers, exporters, PPMA and Pharma Bureau. It also includes the consultants’ views and observations.

Strengths

- Pakistan has a fairly large prevalence and continuous supply of well-trained, English speaking pharmaceutical technicians and professionals. The colleges and universities all over Pakistan produce 1,500 pharmacists and 3,500 chemists every year.

- Approximately 430 pharmaceutical manufacturing units are working in the country. These include 24 multinational pharmaceutical plants, manufacturing and marketing more than 100 molecules, which results in the transfer and dissemination of technology and information from these innovators to the Pakistani industry. Each year about 13 to 15 new manufacturing licences are issued.

- There is still a huge potential existing for pharmaceutical products to penetrate into the Pakistani market because they are still not reaching each consumer in Pakistan. No data is available for Pakistan, but a Pharmbiz report for India indicates that pharmaceuticals reach only 30% of the total Indian population, the rest of whom still rely on traditional medicines and faith healers.

Additional strengths mentioned include:

- Flexibility

- Because of the recent global political and economic changes, there is a reverse-drain of skilled Pakistani pharmaceutical professionals and technicians from developed countries to Pakistan.

- The Pakistani pharmaceutical industry is growing at a rate of 12-13% each year. The growth is phenomenal both in terms of value and volume.

- Pakistani pharmaceutical professionals have developed good skills in making the generic copies of innovative molecules through reverse engineering and process development.

- The pharmaceutical exports of Pakistan are growing: from US$37 million in 1997 to US$63 million in 2005. More and more Pakistani companies are now inclining towards exports. This surge of exports is well supported by enabling government policies.

- There is a 50% subsidy on the registration of pharmaceutical products in export countries. Also, the Government gives a freight subsidy for exports to some countries.

- Opening and liberalising trade with India is resulting in the inflow of useful and affordable capital goods and raw materials for the Pakistani pharmaceutical industry.
The availability of rich and promising knowledge base in the field of Unani Tibb can be helpful in developing Pakistan as a major supplier of herbal raw material, herbal products and Neutraceuticals.

Weaknesses

The main weaknesses identified were as follows:

- The low perception of quality – by customers and consumers.
- The Pakistani pharmaceutical industry is 100% dependant on copying of innovative drugs. Not much innovation takes place in processing and developing products.
- Hardly any Pakistani pharmaceutical manufacturing plant has a license or approval from renowned international regulatory authorities. (India has 74 US FDA-approved plants.)

Others mentioned the following weaknesses:

- Scarce management know-how, especially in international marketing.
- Auto-financing.
- No world-class reference labs are available for drug evaluation and testing.
- National companies, despite being very large in number (406 national against 24 multinational companies), have only 47% of the total market share, which indicates the low level of national capacity development.
- Pakistan is largely dependant on imports for raw materials and hi-tech finished products. At least 91% of raw materials consumed by the Pakistani pharmaceutical industry is imported.
- Approximately 24% of pharmaceuticals sold in Pakistan are imported.
- The price of pharmaceuticals in Pakistan is fixed, which restricts competitions.
- R&D efforts and expenditure in the pharmaceutical industry are very low.
- The size of the Pakistani pharmaceutical market is small. Pakistan’s population is 2.5% of the total world population; however the Pakistan pharmaceutical market is only 0.325% of the total world pharmaceutical market.
- Entry barriers for the Pakistani pharmaceutical market are very low. For this reason, competition is ever increasing and it is further complicated by tight price regulations.

Opportunities

The main opportunities identified were:
• A well-developed regulatory network compliant with WHO standards that regulates the pharmaceutical market all over Pakistan, combined with the recent modernisation in drug regulations in Pakistan:

• A drug regulatory authority is being developed and will be an independent body under the federal cabinet.

• Herbal drugs will soon be regulated: the draft has been submitted to national parliament for debate.

• The Supreme Court has been vigilant in modulating regulatory practices through instructions on various issues to the Ministry of Health.

• Migration to a patent product regime is likely to transform industry fortunes in the long term. The new patent product regime will bring with it new innovative drugs. This will increase the profitability of multinational pharmaceutical companies and will force domestic pharmaceutical companies to focus more on R&D.

• Being low-cost producers, Pakistani companies can become a global outsourcing hub for pharmaceutical products, provided they obtain regulatory approvals and upgrade their plants.

Others mentioned the following opportunities

• Knowledge of local/regional markets.

• Motivation.

• The positive development of the natural products market.

• The rapid development of the generics market.

• Pakistan’s economy has taken a positive turn. The per capita income is increasing.

• The increasing penetration of the media and the growing rate of literacy have increased health awareness.

• Recent trends stressing primary healthcare are opening new horizons for exploration.

• The saturation point of the market is still far away.

• Recent trade pacts with neighbouring countries, for example Sri Lanka, and expected regional agreements (ASEAN) are likely to give bigger market opportunities for the exports of Pakistani pharmaceuticals.

This migration could result in consolidation as well. Companies operating at small-scale may not be able to cope with the challenging environment and may succumb to bigger companies.

The large number of drugs going off-patent in Europe and in the United States between 2005 and 2009 offers big opportunities for the Pakistani companies to develop modern generics.

Opening up of the health insurance sector and the expected growth in per capita income are key growth drivers from a long-term perspective. This leads to the expansion of the healthcare industry, of which the pharmaceutical industry is an integral part.
Threats

Following are the main threats identified:

- Trade barriers, especially regulatory difficulties.
- The existence of very strong pharmaceutical manufacturing and marketing industries in neighbouring countries that would speedily penetrate the Pakistani market in case of trade liberalisation.
- The increasing vigilance of international regulations and the hi-tech demands of the regulators have significantly increased the cost of quality compliance.

Others mentioned the following additional threats:

- Poor access to finance.
- The Internet, enabling customers/consumers to access competitive information and seeking other options.
- Globalisation, new entrants in the home market and in export markets.
- The industries of these countries also give a tough competition to Pakistani exporters in export markets.
- There is also a rise in the cost of entry into the new export markets.
- Pakistan has entered a product patent regime that expels Pakistani products from competing into the more modern molecules’ markets.

2.15.2 The role of pharmaceutical associations

The Pakistan Pharmaceutical Manufacturers’ Association (PPMA) and the Pharma Bureau (PB) of the Overseas Investors Chamber of Commerce and Industry (OICCI) are the only two government-recognised associations within the industry. The Pharma Bureau represents multinational companies engaged in producing pharmaceutical products. Both organisations are over three decades old. They are represented on the Registration Board and the Price Review Committee. The collective industry-related issues are covered through these associations. The contact details of both associations are given below.

<table>
<thead>
<tr>
<th>Pakistan Pharmaceutical Manufacturers’ Association</th>
<th>Pharma Bureau of Information and Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>130-131 Hotel Metropole Club Road Karachi Tel: 00 92 (0)21 5211773 Email: <a href="mailto:ppma@cyber.net.pk">ppma@cyber.net.pk</a></td>
<td>Overseas Investors Chamber of Commerce and Industry Chamber of Commerce Building Talpur Road P.O. Box 4833 Karachi Tel: 00 92 (0)21 2410815 Email: <a href="mailto:riazhussain@oicci.org">riazhussain@oicci.org</a></td>
</tr>
</tbody>
</table>
3 Implications of the WTO Agreements

3.1 Background

3.1.1 Multilateral discipline of trade rules

For nearly six decades, international trade has been subjected to the discipline of multilaterally agreed rules “by which the countries are required to conduct their trade relations with one another”\(^4\). The institution responsible for overseeing this rules-based system is the World Trade Organisation (www.wto.org) established on January 01, 1995. WTO is a successor to the General Agreement on Tariffs and Trade (GATT), which had been performing a similar role since January 01, 1948. The box given below explains the multilateral discipline of trade rules in the WTO system:

<table>
<thead>
<tr>
<th>Box 3.1 Multilateral discipline of trade rules - the WTO system</th>
</tr>
</thead>
<tbody>
<tr>
<td>International trade is subject to the discipline of multilaterally agreed rules by which countries are required to comply within their trade relations with one another.</td>
</tr>
<tr>
<td>• The World Trade Organisation (WTO) oversees this multilateral system. Its agreements aim to help international trade flow smoothly, freely, fairly and predictably.</td>
</tr>
<tr>
<td>• Under the WTO trade regime there are both opportunities and challenges for Pakistan.</td>
</tr>
<tr>
<td>• It is for the business community supported by the government to convert tariff reductions and liberalisation commitments into opportunities for trade.</td>
</tr>
<tr>
<td>• Likewise concerted action needs to be taken by both the public and private sectors to adequately meet challenges.</td>
</tr>
</tbody>
</table>

Source: WTO Cell, Planning & Development Department, Government of the Punjab

The chapter is divided into four main sections:

• General background
• Information on the WTO issues
• Implications of the WTO agreements
• Trade conditions as a result of the WTO agreements

3.1.2 Purview of the WTO

WTO’s purview encompasses agreements, relating to trade in: (1) Goods; (2) Services; and (3) Trade-related intellectual property rights. In addition, there are 12 associate agreements relevant for trade in goods.

3.1.3 Functional scope

The functional scope of WTO is depicted in the diagram below:

Figure 3.1 Functional scope of WTO

These Agreements seek to establish a trading system which is: non-discriminatory, freer, predictable, more competitive and arguably more beneficial to developing countries.

Source: WTO Cell, Planning & Development Department, Government of the Punjab
3.1.4 Dispute-resolution

For disputes arising under GATT 94, GATS and TRIPs, there is a common dispute-resolution mechanism embodied in WTO’s Disputes Settlement Understanding (DSU).

3.1.5 Focus on trade in goods

In this report focus is on trade in goods. Hence, further reference will not be made to the GATS while TRIPs will be referred to wherever it is relevant.

3.1.6 Obligation of conformity

Each member country of WTO is obliged to ensure conformity of its laws, regulations and administrative procedures with the agreements of the Organisation (Article XVI (4) of the Marrakech Agreement Establishing the WTO).

3.1.7 Opportunities and challenges under the WTO regime

Overview

The central objective of the WTO is to help international trade flow smoothly, freely, fairly and predictably. The WTO rules with their trade liberalisation orientation, have led to a rapid expansion of the world trade.

In ranking many achievements of the GATT-WTO system, among the most significant is the deep reduction in developed-country tariffs from high double-digit figures in 1947 to low single-digit numbers today. There has been also a significant reduction in other barriers to trade.

Under this liberal international trade regime there are both opportunities and challenges for Pakistan. No doubt Pakistan faces many challenges. At the same time, the multilateral trade dispensation has created many opportunities. If a proper strategy is adopted and the government plays a supportive and facilitative role it can lead to a significant increase in international trade and substantially contribute to the economic growth. Hopefully, the ongoing trade negotiations would add to these opportunities. However, the WTO is “about providing opportunities — it does not provide guarantees nor does it provide all the conditions for participation in the global economy”. In short, Pakistan has to get its act together to realise the potential that has become available due to the trade liberalisation. Action is to be taken by the government agencies, trade bodies and, above all, by entrepreneurs themselves. As it has been aptly observed, “the business community has the primary responsibility for converting tariff reductions and liberalisation commitments into opportunities for trade by adopting appropriate export promotion and development strategies.”

6 See supra note 1 at 23
Current status of efforts to liberalise trade

Currently (mid 2007), the ninth (and the first under the WTO) Multilateral Round of Negotiations (MTN) called the Doha Development Agenda (DDA) is in progress (more correctly in a state of suspended animation). Earlier rounds have given a great impetus to the growth of international trade by slashing tariffs, mostly in industrial countries, as well as by eliminating non-tariff barriers such as quantitative restrictions. Following the Uruguay Round (the most important MTN held so far), average tariff rates in developed countries on manufactures stand at an average of 3% on imports, down from the 5.5% pre-Uruguay Round average, a 45% reduction. Tariffs, however, on goods of export interest to the developing countries still remain relatively high, for example, on clothing and footwear. DDA has been launched to improve the situation of the developing countries in the multilateral trading system through focusing on the issues of principal concern to them. The progress of negotiations has been very slow so far and the deadlines for reaching agreements have been repeatedly missed. Meetings to take forward the DDA process held 2006 and 2007 turned out to be inconclusive and negotiations have been suspended. One comment from an influential periodical graphically describes the situation – “the Doha round lying comatose after five years of fruitless negotiations”.

Ongoing negotiations under the DDA on the Non-Agriculture Market Access (NAMA) cover the sector under study. Modalities are yet to be finalised on a Swiss formula (i.e. envisaging the rate of reduction for a higher tariff to be greater than that for a lower one. For further details see: www.wto.org)

3.2. Information on the WTO issues

Information flows, both upwards and downwards, on the WTO is depicted in Figure 3.2 below.

The present arrangements leave a lot to be desired in terms of their content, sources, destination, user friendliness and nature of information i.e. optional or compulsory. There are markedly divergent perceptions among the Pakistani entrepreneurs of pharmaceuticals about the nature and frequency of such flows. Despite contrary claims made by individual entrepreneurs, one cannot help reaching the conclusion that flows are erratic in both directions.

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7 See Hong Kong Ministerial Declaration, WT/Min (05), Dec 22, 2005 and for update on the latest development and pending issue visit www.wto.org


9 The Economist, November 4, 2006, p.40
Figure 3.2 Upward and downward information flow on the WTO

Source: WTO Cell, Planning & Development Department, Government of the Punjab
3.2.2 Information flows-upwards —from companies via government to WTO

Government-driven flows —upwards

**There is no problem with respect to information transmitted by the Government of Pakistan to WTO** as an obligation of the membership of the organisation. Regularly, the Ministry of Commerce sends necessary information about notifications to WTO as agreed in the Ministerial Decision on Notification Procedure\(^{10}\). Some of the items that are notifiable are: tariffs, GSP provisions, custom valuation, rules of origin, safeguard actions, details regarding exports subsidies and concessional export financing.

**Trade statistics**

As regards trade statistics, the Government of Pakistan is obliged to furnish data for the integrated database of WTO. These figures are based on the data of custom stations and are reliable. There has been, however, a lag in furnishing these statistics. The problem is being sorted out.

Another compulsory upward information flow is generated from the Census of Manufacturing Industries (CMI) —conducted every five years\(^{11}\). Results of CMI suffer from the problems of coverage, research design and lack of adequate response from the industry. Further, these at best are historical data.

**Information through consultative meetings**

The Government of Pakistan gets itself informed about the problems facing the industry and the suggestions made by the private sector at meetings preceding the formulation of each year’s trade policy. Apart from the Federation of Chambers of Commerce and Industries (FCCI), the regional chambers of commerce and sectoral associations, which are registered with the government, are invited. However, as regards associations, some selection is made to ensure that representation is adequate in terms of both sectors and regions.

**Information flow - Upwards: Exporters’ opinion**

**Semi voluntary and sporadic**

**Claimed perception as to the obligatory nature of information:** Most exporters claimed that they regarded it as an obligation to provide information about their company, including that pertaining to sales record, nationality of clients, number of employees, etc. Any additional information deemed in the interest of the industry was also provided. Such information included statistics about total exports sales by year, region, country, product, turnover, certifications, sales targets, achievements, markets and production record, selected materials’ consumption record and distributors’ sales data.

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\(^{10}\) WTO: Decision on Notification Procedures, Ministerial Decisions and Declaration adopted by the Trade Negotiations Committee on December 15, 1993.

\(^{11}\) The census is undertaken under the Industrial Statistics Act, 1942 for industrial units employing 10 and above workers registered or qualifying for registration. Information furnished is treated confidential.
Information, either voluntary or perceived as an obligation, was provided, among others, to TDAP, the Central Board of Revenue, PPMA, FPCCI, Customs, State Bank, Ministry of Health, Ministry of Labour and Manpower, Ministry of Production and Regulatory Authorities and the Securities and Exchange Commission. The content of information was determined as per requirements of the situation. Obligatory information is provided per specific requirements when it is deemed necessary. One of the respondents said that he provided information about his company to TDAP and Ministry of Health frequently, while information to PPMA was being provided on demand. One gets the impression that the flow of information in many cases was sporadic.

Information about the concerned government agencies/departments

Most entrepreneurs said they were aware that complaints and suggestions regarding WTO could be made to PPMA, Ministry of Health and TDAP. Others said that they would be able to provide information to various government bodies like TDAP, FPCCI, Ministry of Commerce, Ministry of Industries and their representative bodies. A majority had been conveying their suggestions and complaints about WTO to PPMA, which handled such issues on behalf of Pakistani companies.

3.2.3 Information flow – downwards —from WTO via government to companies

Complaints about the lack of information about WTO

According to some entrepreneurs, information flow was inadequate. They received information only by chance as there was no specific source, which was providing such information. Others looked for information themselves, when required. Only one exporter said information was provided to him on a quarterly basis, however, he did not specify the source in his interview.

Knowledge about the implications of the WTO agreements

More than 50% of the exporters, however, were of the opinion that information regarding WTO was available in some form. They have been getting information about the WTO agreements from PPMA, WTO Websites, TDAP and Ministry of Health. Other organisations, which were providing such information, were the Centre for Global Development and Commission on Macro Economics and Health, Oxfam UK, Scrip (PJB Publications) and European Intellectual Review. The pharmaceutical industry in Pakistan appears to be knowledgeable about the WTO regime. As compared to several other sectors, the level of information about WTO is high.

A large number of companies confirmed that adequate information was available about challenges and effects of the WTO agreements, opportunities for the pharmaceutical industry and the impact of the new patents regime on drug prices. Some published material was also available. A few seminars were also organised which proved quite helpful. Further information was gathered from the WTO legal texts, websites, discussion meetings, courses, seminars, circulars and magazines. However, only a few books related to the WTO trade agreements (in general) were available at bookstores. However, they were dissatisfaction that information in the form of articles, reports, features, handouts, courses, reading material, magazines or newsletters was also not readily available. No specialised trainings were being organised. Most
of the information was not user-friendly in terms of accessibility, comprehension and interpretation. Some of the entrepreneurs were unhappy that the federal government had not been systematically undertaking awareness campaigns.

More than 43% said that though necessary information about WTO was available, neither pharmaceutical industry nor the government had made plans as yet to meet challenges. A few also thought that pharmaceutical companies themselves did not seem to be serious in creating awareness about the new patent regime and WTO-related issues among their employees.

**Downward flows**

With respect to downward flows, the website of Ministry of Commerce ([www.commerce.gov.pk](http://www.commerce.gov.pk)) and other ministries, TDAP ([www.tdap.gov.pk](http://www.tdap.gov.pk)) and WTO Cell of the Government of the Punjab ([www.wtopunjab.gov.pk](http://www.wtopunjab.gov.pk)) have been playing a useful role. However, here again it was found that various notifications issued by the WTO Secretariat, which were regularly sent to the Ministry of Commerce, were not put on the website. The plea taken in this regard was that this information was available at the WTO website. It is; however, felt that the Government of Pakistan and its export/trade development organisations must play a more proactive role. The WTO, in collaboration with ITC and EU, has also established reference centres in the Ministry of Commerce, TDAP, FPCCI, selected Chambers of Commerce and Industries and the Planning and Development Department of the Government of the Punjab.

**Demand for proactively supportive role of the government**

The exporters thought that the government, Ministry of Commerce, Ministry of Health, Ministry of Industries, the association of each sector, TDAP, entrepreneurs, training institutes, PPMA, business leaders/managers and the intellectual property organisation of Pakistan should play a more proactive role in further increasing awareness about the WTO agreements and advise the industry how to maximise opportunities, resolve the problem of compliances and respond to challenges to set up information and counselling networks. In view of majority of exporters, funding should be made through government grants.

Some of them, however, suggested that instead of funding the proposed facility through grants, contribution should be made by the industry itself. In any event they thought that the pharmaceutical industry, through its association and all stakeholders, should contribute some amount in addition to that coming from government sources.

**Recommendations**

The situation as to information flows is not satisfactory. A proactive role is indicated on the part of the Ministry of Commerce and TDAP. This organisation should provide leadership and collaborate efforts with other relevant agencies e.g. chambers of commerce and trade associations, SMEDA, the provincial government’s WTO cells and trade associations. Funds are not an insurmountable problem because the Ministry of Commerce and TDAP have ample resources in the form of the Export Development Fund (EDF). The real challenge is to organise a system that is user-friendly and available in virtual real time. Technical assistance from ITC to set up and improve such an information system should be very much welcome. This should become one of the important tasks to be assigned to the National WTO consultant for TDAP appointed by ITC. TDAP should intensify its activities for capacity building, specifically for
the better use of opportunities and coping with challenges emanating from the WTO system among other things. The following measures are recommended:

- The present system of generalised information on WTO should be changed to regular, focused information on concrete issues.
- A comprehensive plan for the dissemination of sector-specific information may be prepared by TDAP in consultation with stakeholders.
- A helpline, professionally manned, should be established in TDAP. Sector-specific experts should be available to callers.
- Special meetings/workshops/seminars to educate entrepreneurs about the WTO issues should be organised by TDAP, preferably in partnership with the concerned trade associations, at least four times a year at different places.

(Action: Ministry of Commerce and TDAP)

3.3 Implications of the WTO Trade Agreements

3.3.1 Relevant WTO agreements for the global and Pakistani pharmaceutical sector

The WTO agreements in terms of their degree of relevance to the pharmaceutical sector can be divided into three categories: high intensity relevance, low intensity relevance and contingent relevance. The agreements of high intensity relevance are those that are most directly relevant to the pharmaceutical sector, while those described as of low intensity relevance are agreements that are less directly relevant. Agreements possessing contingent relevance refer to those that come into effect in certain situations only.

The degree of relevance of these agreements to the pharmaceutical sector is the same in Pakistan and elsewhere i.e. in other WTO member countries as well.

The agreements of direct relevance to the pharmaceutical sector are GATT 1994 as well as the one on the Trade Related Aspects of Intellectual Property Rights (TRIPs). Other agreements having high level of relevance are Technical Barriers to Trade (TBT), Application of Sanitary and Phytosanitary Measures (SPS), Rules of Origin and the Customs Valuation. The agreements of lesser relevance are on pre-shipment inspection, import licensing procedures and the agreement on TRIMs. Agreements on anti-dumping, subsidies, countervailing, safeguards and the DSU (Dispute Settlement Understanding) fall in the category of contingent relevance. The WTO agreements not only influence the volume of trade but also affect the operational space of a policy-maker and market access of an individual exporter.

A diagrammatic representation of the degree of relevance of the WTO agreements to the pharmaceutical sector is given in Figure 3.3 below.
**3.3.2 General Agreement on Tariffs and Trade 1994**

GATT 1994, the most relevant agreement for the pharmaceutical sector, lays down the framework within which the international trade of goods takes place. It rests upon five pillars that constitute the core of the legal obligations of the member countries.

**Unconditional Most-Favoured Nation (MFN) obligation (Article I)**

Every member of the WTO is required to treat imports from all other members “on an equal, non-discriminatory basis vis-à-vis all other members’ imports”. Thus if a country grants another a special favour (e.g. lower customs duty rates) the same treatment has to be extended to all other WTO member countries.
Implications for the pharmaceutical sector

Imports

- Pakistan or any other WTO member country while importing pharmaceutical products has to extend the same treatment to the same products of all the member countries. It is not allowed to give a differential treatment to any trading partner who is member of WTO. Specifically in the context of pharmaceuticals, insistence on the condition of registration will not be an infringement of the MFN principle as this condition is prescribed for all imports from all countries.

- This obligation leads to non-discriminatory trade and provides a level playing field to every member of the WTO.

Exports

- For Pakistani exports non-discriminatory market access to other markets is legally assured. This does not, however, indicate the rate of tariff which is leviable on pharmaceutical items. Thus the market access will be virtually blocked if tariff rates are excessively high. Likewise, exports will be adversely affected if non-tariff barriers are being used by importing countries.

Exception to the MFN principle

Some exceptions are permitted from this principle such as:

- Preferential tariff rates given to countries: (a) that are members of a free trade area/regional trading arrangement (RTAs) under Article XXIV of GATT, (b) Preferential tariff rate arrangements among developing countries permitted under Enabling Clause\(^\text{12}\) (see Box 3.2).

- Special access to markets of industrial countries at lower tariff rates granted to developing countries e.g. Generalised System of Preferences (GSP)\(^\text{13}\). Member countries are allowed to introduce trade restriction in case of balance of payment difficulties.

All these exceptions are, however, allowed under strict conditions.

Once foreign goods have entered a country’s market, these and locally produced goods are to be treated equally (as if foreign goods have acquired importing country’s nationality).

This article embodies the same principle of non-discrimination as set out in the MFN commitment. It also establishes the principle that no tax will be imposed on imports in excess of the amount of the indirect taxes levied on similar domestic products.

\(^{12}\) WTO, Guide to the Uruguay Round Agreements 1999, p.40

\(^{13}\) The GSP was proposed at UNCTAD II in 1968. It entered into force in 1971 and gives developing countries a margin of preference in the tariff rates their goods face in the markets of developed countries. In this way GSP increases their competitiveness vis-à-vis those countries’ products that get their entry on the payment of duties at the MFN rates.
In order to make trade predictable, WTO member countries have been generally binding their commitments (Article-XI) i.e. ceilings are imposed on tariff rates that can be charged by a country. Under the WTO system tariffs (i.e. customs duties) are the only form of the permissible measure for trade protection (Article II and Article XI). The bound tariffs cannot be increased above the bound rates unless compensation is paid to the other adversely affected WTO member.

In case of developing countries, imports often take place on lower than the bound rates. These lower rates are called “applied” rates. If necessary, the GOP can increase applied rates up to bound levels without consultation with anyone.

Reduction of tariffs is an important aspect of trade liberalisation. As a matter of fact rates of tariffs have been constantly coming down since GATT became operational in 1948. Industrial countries’ tariffs in most of the traded items, including pharmaceutical products, have fallen down to less than 4%. Such a significant reduction in tariff barriers has been very helpful in increasing trade. However, as stated earlier, on many items of interest to developing countries, tariff rates remain relatively high.

14 Pakistan has bound more than 99% of its tariff lines.
Elimination of quantitative restrictions (Article XI)

Member countries are required to eliminate quantitative restrictions on imports and exports. There are, however, a number of exceptions to this rule. For example, export restrictions can be applied to the export of goods to prevent or relieve critical shortages, Article XI-2 (a).

Implications for the pharmaceutical sector

Exports

- Pakistani pharmaceutical exports do not, by and large, face significant non-tariff barriers in industrial countries’ markets, though these products must comply with requirement of registration in the importing country\(^\text{15}\).

- Refusal to register a pharmaceutical product or an overly difficult process of registration can act as a significant non-tariff barrier.

- The pharmaceutical sector of Pakistan, with the proviso about registration, enjoys a fair “market access” in foreign markets. This indicates substantial scope for increasing export in this item provided we have the right products at right prices.

- Pakistan’s exports have in fact better opportunities in the markets of industrial countries on account of their comparatively lower tariffs. (However some of these countries have very high standards for registration e.g. the United States.)

Imports

- The effects of Articles-II and XI are that foreign pharmaceutical goods enjoy reasonable access to Pakistan’s market though our tariffs are relatively high (25%). However, they are obliged to get their products registered before these can be imported into the country\(^\text{16}\).

Transparency of government regulations affecting trade

Members are obliged to publish relevant laws, regulations, administrative rulings of general application, including those pertaining to the classification of the valuation of the products etc. Governments are also required to disclose their policies and practices publicly within the country as well as by notifying WTO. With a view to ensuring that members adhere to their obligations, their trade policies are periodically examined through a surveillance mechanism called the Trade Policy Review Mechanism. This examination of the trade policy and its results becoming a part of public domain also contribute to greater transparency.

Implications for the pharmaceutical sector

Transparency in government regulations, in Pakistan and abroad, helps in smoother flow of trade. It is “in essence a shield against arbitrary government action.”.

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\(^{15}\) In addition to the registration, countries may choose to prescribe unrealistic standards that may act as the NTB on pharmaceuticals exports.

\(^{16}\) Re: Registration of drugs see Box 3
Before marketing any drug in the Pakistani market, whether manufactured locally or imported from any other market, it requires to be registered with the Government of Pakistan. Registration of a drug is granted by the Registration Board, set up by the Federal Government under the Drugs Act, 1976. This Board, which comprises 21 experts in the field, before registering a drug, satisfies itself of its safety, efficacy, quality and economy. The Board also takes into consideration the public interest. In addition, with respect to the registration of a drug for local manufacture, it is ascertained that the manufacturer possesses matching facilities.

Registration is valid for a period of 5 years at a time, after which it is renewable by filing an application. Registration may be suspended or cancelled or renewal denied if the holder of the registration fails to comply with the conditions of registration.

The Federal Government has set up Expert Committees, including a committee on Biologicals and a committee on Veterinary Drugs for furnishing opinion after drug's evaluation. The Registration Board also considers these opinions while granting registration. 17

Source: WTO Cell, Planning & Development Department, Government of the Punjab

Trade Related Aspects of Intellectual Property Rights (TRIPS) 18

Many countries entered into international agreements (non-WTO) to protect creative ideas and new knowledge by giving the creators of these knowledge-based assets (called the intellectual property rights): (a) The right to prevent others from “using their inventions, designs or other creations” 19 and (b) The ability to negotiate payment for their intellectual property (IP) rights.

However, the protection given to IPRs (by several international agreements) was found to be inadequate. This was particularly true as to the level of protection, implementation and enforcement. It was, therefore, agreed to develop new internationally agreed rules. The result was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiated in the Uruguay Round of MTN, which sought to reduce distortions and impediments to international trade through promoting effective and adequate protection of intellectual property rights.

The agreement spells out the way the basic principles of trading order and other intellectual property agreements should be applied. The MFN and the national treatment requirement constitute key elements of TRIPS’ architecture. This agreement requires members to comply with pre-existing agreements governing IPRs. It is explicitly provided that nothing in the TRIPs agreement shall derogate from existing obligations as spelled out in the Paris Convention, the Berne Convention, the Rome Convention and the Treaty about Integrated Circuits.

The TRIPs agreement has markedly narrowed the gaps in the manner these rights were recognised, protected and enforced among trading nations. It also provides for settlement of

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17 Drug Control Organization, Ministry of Health, Pakistan, procedure of registration is also available at http://www.dcoMoH.gov.pk/registration/drugregistration.php

18 For detailed discussion, see WTO, TRIPS and Pharmaceutical Patents, September 2003(Fact Sheet)

19 This Agreement fixed minimum levels of protection that each member of the WTO is required to provide to intellectual property rights of other members.
disputes through the WTO dispute settlement system. In compliance with the TRIPS agreement, new legislation (IPO law) as well as amendments in the existing laws relating to patents, copyrights and trademarks have been made (see Box 3.4). Pakistan has also set up Intellectual Property Organisation (www.ipo.gov.pk), which is “an independent body, fully dedicated to preparing and implementing the IPR laws in line with the best international practices. Enforcement mechanism has also been strengthened and the country is moving towards complete enforcement of these laws”.

The box given below explains amendments made in the existing laws relating to patents, copyrights and trademarks:

<table>
<thead>
<tr>
<th>Box 3.4 IPR laws in Pakistan</th>
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<tbody>
<tr>
<td>Copyright</td>
</tr>
<tr>
<td>Patents</td>
</tr>
<tr>
<td>Trademarks</td>
</tr>
</tbody>
</table>

Source: WTO Cell, Planning & Development Department, Government of the Punjab

Relevance to the pharmaceuticals sector

Implications of the patent regime under the TRIPs for the pharmaceutical sector are:

- Patents are granted both for products and processes.
- The term of a patent is 20 years from the date of the application.
- Patents will be granted irrespective of the fact whether the drugs were produced locally or imported from another country.
- Though the grant of the patent excludes unauthorised use, sale or manufacture of the patented item, yet there are clauses that provide manufacturing or other exercise of such rights by a person other than the patent holder.
- In a dispute about infringement, the onus to prove that a process other than the one used in the patented product has actually been used in the disputed product lies on the accused (i.e. the person against whom proceedings have been initiated at the instance of the patent holder) rather than on the patent holder.

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20 The Prime Minister of Pakistan quoted in the World Trade Review, Issue No.17, Volume No. 6 (September 1-15, 2006).
Other relevant features

Certain other relevant features of the patent regime are as follows:

Transitional periods

Countries with different developmental status (i.e. developed, developing and LDCs) have been given different transitional periods to put into effect reforms and bring the laws in conformity with the TRIPs agreement. In Pakistan’s case (being a developing country), it is required to amend and enact laws (so that these fully comply with the TRIPs agreement). The latest date for compliance was by January 01, 2005. During the transitional period of 1995-2004, Pakistan started accepting applications for product patents and providing exclusive marketing rights (EMRs) for the products that had patent protection elsewhere.

Exclusion from patent ability

- Governments may exclude from patentability inventions to protect public order or morality or to protect human, animal or plant life or health — Article 27.2.
- Diagnostic, therapeutic and surgical methods for the treatment of humans or animals — Article 27.3a
- Certain plants and animals — Article 27.3b.

Research exception and Bolar provision

Countries can use this provision to advance science and technology by allowing researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow the manufacturers of generic drugs to use the patented invention to obtain marketing approval — for example from public health authorities — without the patent owner’s permission and before the patent protection expire. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the “regulatory exception” or “Bolar” provision. Article 30.

Anti-competitive practice

The TRIPS Agreement empowers governments (subject to certain conditions) to prevent patent owners and other holders of IPRs from abusing these rights, inter alia, by, “unreasonably” restraining trade, or hampering the international transfer of technology or creating public health related difficulties. Some of the measures that can by taken in this context are explained below.

Parallel imports, grey imports

This is another way to protect public interest. Products marketed by the patent owner (or trademark- or copyright-owner, etc) or with the patent owner’s permission in one country are imported into another country without the approval of the patent owner (See Box 3.5). It would be pertinent to note that parallel or grey-market imports are not imports of counterfeit products or illegal copies of a genuine product.

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21 In the case of LDCs, the period of exemption has been extended to 2016.
22 Articles 8.2 and 40 of the TRIPS Agreement.
Facilitating effective use of compulsory licensing

Compulsory licensing refers to permission by a government to someone other than the right holder to produce the patented product or process without the consent of the patent owner. This is, however, subject to a number of conditions (set out in Article 31 of TRIPS agreement) aimed at protecting the legitimate interests of the patent holder. Incidentally the term “compulsory licensing” did not appear in the TRIPS Agreement. Instead, the phrase “Other Use without Authorization of the right holder” appears in the caption of title of Article 31. This power is predicated on the provisions of law of member countries allowing for other uses by the government and others. This is the basis of doctrine of compulsory licensing (An explicit reference will be made to “Compulsory Licensing” after coming into effect of an amendment in TRIPS Agreement as explained below).

In the Doha Declaration (Article 17) it was emphasized that TRIPS agreement should be implemented and interpreted in a manner supportive of public health. A separate Declaration on the TRIPS and Public Health (WTO/MTN (01) /December/2 Dated 20/11/2001) was also adopted. It was agreed that the TRIPS agreement does not and should not prevent Members to protect public health. The right of Members to promote access to medicines for all was clearly recognized. The right to use flexibility under the TRIPS Agreement was reaffirmed. The TRIPS Council was instructed under Article 6 of the Declaration, to find an expeditious solution to the difficulties, encountered by countries having insufficient or no manufacturing capacity, in making effective use of compulsory licensing.

The WTO General Council resolved the issue vide its decision of 30 August 2003, allowing countries to import generics made under compulsory licensing if they are unable to manufacture the medicines themselves. Further, constraints on exports laid down under Article 31(f) of the TRIPS Agreement were relaxed for developing and least-developed countries. They could now export such medicines manufactured under compulsory licensing system within a regional trade agreement, when at least half of the members were categorized as least-developed countries. That way, these countries could make use of economies of scale.

Conditions were, however, imposed to ensure that beneficiary countries would do so without undermining the patent system. To make such imports possible waivers from the provisions of TRIPS Article 31 (f) had to be granted. Since, these waivers were interim it was agreed in 2005 to amend the TRIPS Agreement itself by inserting Article 31 bis in the TRIPS Agreement. Acceptance of the amendment is required to be notified by 1 December 2007 (the deadline can be extended, if necessary).

Opportunities for the pharmaceutical industry of Pakistan

Prior to charges in compulsory licensing regime through 2003 this flexibility could be used for meeting domestic demand. Now, domestic manufacturers producing under compulsory licensing can export to the countries that have insufficient or lack of manufacturing capacity. This opens a window of opportunities for Pakistan’s pharmaceutical industry. African countries in this context are the best export destinations. Pakistan’s industry should proactively explore this new avenue.

The box given below highlights the agreement made on TRIPs with particular reference to patents:
Box 3.5 Agreement on TRIPs with particular reference to patents

The TRIPs agreement negotiated in the Uruguay Round of MTN sought to reduce distortions and impediments to international trade through promoting effective and adequate protection of intellectual property rights.

**Patents**

Under the TRIPs agreement patents will be granted both for products and processes for all the inventions in all the fields of technology and will be valid for 20 years from the date of application.

**Anti-competitive practices**

Governments can also act, again subject to certain conditions, to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, “unreasonably” restraining trade, or hampering the international transfer of technology.

Articles 8.2 and 40

**Compulsory licensing**

When a government allows someone else to produce the patented product or process without the consent of the patent owner but under certain conditions.

**Parallel or grey-market imports**

Parallel or grey-market imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner (or trademark or copyright owner, etc) or with the patent owner’s permission in one country and imported into another country without the approval of the patent owner.

Source: WTO Cell, Planning & Development Department, Government of the Punjab

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**Agreement on Technical Barriers to Trade (TBT)**

Every WTO member, while allowing imports, has the right to adopt standards considered by it to be appropriate for human, animal or plant life or health or for the protection of the environment or for the prevention of deceptive practices. The TBT seeks to assure that regulations, standards, testing and certification procedures do not create unnecessary hurdles to trade. However, with a view to preventing excessive diversity, TBT encourages member countries to use international standards where these are appropriate but it does not oblige them to change their levels of protection in the process.

The TBT contains a code of good practice for the preparation, adoption and application of standards. It lays down that the procedures used to determine whether a product conforms with the national standards have to be fair and equitable. It does not approve of any methods that would give domestically produced products an unfair advantage. It also encourages countries to accord recognition to each other’s testing procedures. To help the stakeholders to know about the latest standards in the prospective markets, all WTO members are required to establish a national enquiry point.

The TBT gives decisive advantage to industrial countries as they have superior technologies and do follow more rigorous and higher standards as a matter of course. On the contrary, Pakistan being a developing country has yet to progress to those relatively sophisticated standards. In particular, there are not enough quality laboratories that may help to enforce required standards. Non-compliance is an expensive proposition that may result in refusal to grant permission to enter foreign markets. This puts Pakistan at a disadvantage.
Relevance to the pharmaceutical sector

Divergent and higher technical standards can become barriers to cross-border transactions, basically due to two reasons: first, incremental costs to be incurred to make the domestic product conform to foreign standards; second, the costs to be incurred for certification procedures and the difficulties in proving product conformity.

There is also a possibility that protectionist interests in importing countries may insist on laying down unrealistic standards that might have the effect of obstructing trade. In such cases, Pakistani exporters may be well advised to plead that the arbitrary standards have been creating unnecessary hurdles to trade and constitute a violation of the TBT agreement. They will have to approach the WTO wing of the Ministry of Commerce, Government of Pakistan, to take up this matter at the diplomatic level and if necessary through the dispute settlement mechanism of WTO.

(Action: Entrepreneurs/associations and Government of Pakistan.)

Agreement on the application of Sanitary and Phytosanitary Measures (SPS)

Member countries of WTO are allowed under Article XX of GATT 94 to regulate trade with a view to protecting human, animal or plant life or health. Under the agreement on Sanitary and Phytosanitary Measures (SPS), WTO has disciplined the exercise of discretion by member countries by disallowing them to discriminate or misuse this authority serving as a form of disguised protectionism.

Members of WTO are allowed to establish their own standards but it is stipulated that the relevant regulations must be based on science and applied only to the extent necessary to protect human, animal or plant life or health. They are not allowed to arbitrarily or unjustifiably discriminate between countries, where identical or similar conditions prevail. Member countries are encouraged to use international standards, guidelines and recommendations if these are available.

In order to make the process fair from the perspective of exporters, standards different from those already prescribed, can be applied. Similarly, different methods of inspecting products can be adopted. In order to ensure this, exporters demonstrate that the measures which exporting countries have applied are at the same level of “health protection” as adopted by importing countries. Once that is done, an importing country is expected to accept the exporting country’s standards and methods. The Agreement also lays down that governments must provide advance notice of new or changed SPS regulations. They are also required to set a national enquiry point to provide up-to-date information.

Relevance to the pharmaceutical sector

Apparently, this agreement should not be relevant to the pharmaceutical sector. However, protectionist interests can assume any garb and come up with objections to the imported pharmaceutical on the (false) ground of it being harmful to human or animal health. In such a situation, it would be open for our exporters to approach the Government of Pakistan (GOP) to press into service provisions in the SPS agreement against untenable standards.

23 Technology Exports, VOL. VI NO. 1 July-September 2003, Indian Institute of Foreign Trade, New Delhi.
(Action: Entrepreneurs/associations and Government of Pakistan.)

Customs valuation under GATT —Implementation of Art. VII of GATT

The provisions regarding customs valuation under GATT seek to establish a fair and uniform system for the valuation of goods and to provide protection to international traders from the fixation of arbitrary values by the customs authorities of importing countries. The agreement lays down that the customs value of the imported goods in the case of unrelated parties will be the “transaction value”, really means the price actually payable for the goods when sold for exports. Additional considerations apply where the importer and exporter are related entities. Some costs such as freight, packaging, commissions etc. may be added for the purpose of working out customs value. The agreement however excludes items that are regarded irrelevant for fixing custom value e.g. the price of goods on domestic market of the exporting country. If the custom authorities of a country have doubts about the declared value, they may determine the value by sequentially adopting one of the five options: (a) the value of identical goods, (b) the value of similar goods, (c) the imported price of identical or similar goods less applicable deductions for costs, (d) computed value and (e) if none of these methods work, reasonable means may be used for determining value.

Relevance to the pharmaceutical sector

Serious problems can arise if custom authorities of a country choose to fix arbitrary values. If values fixed are excessive, trade liberalisation policy can be effectively negated. In case values are on the low side the tariff protection given to domestic manufactures will cease to be effective. Pharmaceutical importers and domestic producers if they find this misuse of custom processes they can agitate the matter with the relevant revenue authority (Central Board of Revenue).

Rules of origin

The WTO agreement on the Rules of Origin contains a work-programme seeking to bring about harmonisation of these rules in the long term. The issue of Rules of Origin does not arise in cases where import and export take place on the MFN basis. This issue arises in cases where a country is to benefit from the lower tariff available through GSP or under a regional trading arrangement. Such a concessional arrangement rightly requires the scrutiny of imported goods to ensure that they are coming from the eligible sources.

Relevance to the pharmaceutical sector

Where pharmaceutical exports are destined for a country either granting GSP or for a member of a regional arrangement of which Pakistan is a member, the Rules of Origin acquire special importance. Exporters will be advised in these cases to obtain complete documentation, certifying the Pakistani origin of the concerned articles. Importers should likewise, in such cases, insist on getting proper documentation from the importing country. Certificate as to the origin are issued by the TDAP. Exporters are advised to approach the local office of the Bureau.

(Action: Entrepreneurs/Associations and Government of Pakistan.)
Agreement on Trade-Related Investment Measures (TRIMs)

At times, local content requirements and performance requirements have been, inter alia, employed by host countries as an instrument to promote development objectives, such as industrialisation, import-substitution and export growth. Such requirements can affect international trade. For example, a requirement of local content in a product may prevent or limit the use of imported inputs. Any investment-related measure of this type has been now prohibited as a trade distorting measure. As such, this agreement is irrelevant to the pharmaceutical sector.

Agreement on Antidumping

Article VI of GATT 94 finds objectionable the practice of sale of products of a foreign country at less than the normal value of the products in the exporting country (called dumping) if the price level causes or threatens material injury to an established industry in the importing country or materially retards the establishment of a domestic industry. Article VI (2) of the agreement permits a country to offset or prevent dumping by levying on the concerned product antidumping duty not greater in amount than the margin of dumping. The margin of the dumping is the price difference determined in accordance with Article VI (1).

Under the antidumping agreement, a country is allowed to act in a way that would normally infringe the GATT principles of binding a tariff on an MFN basis because antidumping action means “charging extra import duty” on a particular product from a particular exporting country.

Detailed procedures have been laid down on how antidumping cases are to be initiated, how their investigations are to be conducted and the conditions for ensuring that all interested parties get an opportunity to present evidence.

Normally, antidumping measures expire five years after the date of imposition, unless an investigation shows that ending the measures would lead to injury. Anti-dumping investigations are required to end immediately in cases where it is determined if the margin of dumping is insignificantly small (defined as less than 2% of the export price of the product). Likewise, proceedings must end if the volume of dumped imports is negligible. The agreement lays down that the member countries must inform WTO about all preliminary and final antidumping actions promptly as well as report on investigations twice a year.

Relevance to the pharmaceutical sector

This agreement is important both for importers and exporters of pharmaceutical products. If actionable dumping takes places in the Pakistani market, one can have recourse to the National Tariff Commission (www.ntc.gov.pk) to seek relief. If necessary, the Government of Pakistan also can, on the basis of the Antidumping Agreement, agitate the matter in the dispute settlement system of WTO. The Ministry of Commerce, Government of Pakistan, is the concerned agency.

(Action: Entrepreneurs/Association and Ministry of Commerce.)

In case, export of pharmaceutical from Pakistan faces anti-dumping proceeding in an importing country or in the dispute settlement system of the WTO the Government of Pakistan has to argue (and present evidence) that dumping has not taken place or the margin of dumping is
insignificantly small. However, given the extremely small quantum of pharmaceutical exports from Pakistan, there is little likelihood of antidumping action against us in the near future. Where action is called for it is to be taken at the instance of the industry by the Ministry of Commerce.

(Action: Entrepreneurs/Association and Ministry of Commerce.)

Agreement on subsidies and countervailing measures

This agreement disciplines the use of subsidies and also regulates the actions that can be taken by the countries to counter effects of subsidies. A country can have recourse to the WTO dispute settlement mechanism and seek the withdrawal of the subsidy or the removal of its adverse effects. Another alternative is to launch its own investigation and charge extra duty (known as countervailing duty) on the goods in question to nullify the effects of the subsidy given by our trading partners. The agreement defines a subsidy and also introduces a concept of a specific subsidy i.e. a subsidy available only to an enterprise/group of enterprises. The discipline applies only to specific domestic or exports subsidies.

The agreement deals with the following two types of subsidies:

- **Prohibited subsidies:** Requiring the recipients of subsidies to achieve certain export targets, or to use domestic goods instead of imported goods in their manufacture. Such subsidies (trade distorting) can be challenged in the WTO dispute settlement mechanism. In case, it is found that the prohibited subsidies have been given, the respondent country will be ordered to withdraw those immediately. In case the respondent fails to comply, the complaining country can levy countervailing duty on such subsidised products after following the prescribed procedure.

- **Actionable subsidies:** This category is less objectionable than prohibited subsidies. A complaining country has to demonstrate that the subsidy has an adverse effect on its interests. The agreement defines three types of damage that can be caused by this class of subsidies (i) The domestic industry of the importing country is being hurt (ii) Rival exporters from another country may be hurt when the two compete in third markets (iii) Domestic subsidies in one country can hurt exporters trying to compete in the subsidising countries’ domestic market.

**Exception**

- Subsidies given by LDCs/developing countries with GNPs of less than US$1,000 per capita per year are exempted from the subsidy regime.

**Relevance to the pharmaceutical sector**

**Imports**

- In case prohibited and actionable subsidies are given to promote the export of pharmaceutical products, the affected interests in Pakistan can request the National Tariff Commission to impose countervailing duties.
Exports

- On the other hand if allegations are made by an importing country, this agreement provides the exporter with the wherewithal facility to show that countervailing duty should not be imposed. Should the matter require referral to WTO, the Ministry of Commerce would have to be approached.

(Action: Entrepreneurs/association and Government of Pakistan.)

Agreement on safeguards

This agreement disciplines the initiation of emergency safeguard measures by laying down requirements for safeguard investigations. These have to be transparent as well as oblige the member countries to follow the established rules and practices. The criteria for serious injury caused or threatened to be caused has also been laid down. The agreement also sets a time limit on all safeguard actions (4 years) and addresses grey area measures by providing that the members must not take or maintain any voluntary export restraints, orderly marketing arrangements or any other similar measures. An import surge that triggers action under this agreement is defined to be a real increase in imports i.e. an absolute increase or an increase in the import share of a shrinking market (even if the import quantity has not increased).

Relevance to the pharmaceutical sector

Imports

This agreement can be used wherever any importing country finds that there has been a surge in imports, causing injury to the domestic industry. Affected parties are well advised to approach the Government of Pakistan for remedial steps if Pakistani exports are involved.

Exports

By the same token, the exporting country can always show that action under safeguard provisions is not transparent or does not meet the criteria of serious injury or threat of serious injury.

(Action: Entrepreneurs/association and Government of Pakistan.)
### Box 3.6 WTO Agreements in a nutshell

**General Agreement on Tariff and Trade** regulates international trade in goods and rests on five pillars: Most-Favoured Nation (MFN) Obligation, National Treatment Obligation, Elimination of Quantitative Restrictions, Transparency of Government Regulations Affecting Trade and Tariff Bindings.

**Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs)** seeks to reduce impediments to international trade through promoting adequate protection of intellectual property rights. The TRIPs agreement is especially relevant to pharmaceutical industry.

**Agreement on Technical Barriers to Trade (TBT)** contains a code of good practice for the preparation, adoption and application of standards.

**Agreement on Sanitary and Phytosanitary Measures (SPS)** disciplines the exercise of discretion when a country wishes to disallow the import of any item on the ground that it would be hazardous to life or health of human being, or wishes to disallow import to protect humans, animals or plants.

**Customs Valuation** under GATT — Implementation of Article VII. This agreement seeks to establish a fair and uniform system for the valuation of goods that provides protection to international traders from fixation of arbitrary values by the customs authorities of importing countries.

**Agreement on Rules of Origin** seeks to clarify and harmonise the rules of origin in member countries and in particular requires members to ensure that such rules do not create distorting or disruptive effects on trade. The rules of origin are of special relevance in cases where a country is to benefit from the lower tariff available through GSP or under a regional trading arrangement.

**Agreement on Implementation of Article VI of GATT 1994 (Antidumping)** regulates the practice of dumping i.e. the sale of products of a foreign country at less than the normal value of the products in the exporting country if the price level causes or threatens to cause material injury to an established industry in the importing country.

**Agreement on Trade-Related Investment Measures (TRIMs)** seeks to prohibit investment-related measures which are trade distorting e.g. local content requirements and performance requirements.

**Agreement on Subsidies and Countervailing Measures** disciplines the use of subsidies and also regulates the actions that can be taken by the countries to counter the effects of subsidies.

**Agreement on Safeguards** disciplines the initiation of emergency safeguard measures by laying down requirements for safeguard investigations.

Source: WTO Cell, Planning & Development Department, Government of the Punjab

### 3.4 Trade conditions of the Pakistani pharmaceutical sector as a result of the WTO Agreements

The box below indicates the exports and imports profile of pharmaceuticals of Pakistan.
Box 3.7 Exports and imports profile of pharmaceuticals of Pakistan

<table>
<thead>
<tr>
<th>Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2005-2006: US$ 80 million</td>
</tr>
<tr>
<td>• Ranking as an exporter in the world trade: 59th</td>
</tr>
<tr>
<td>• Major export destinations: Nigeria, Sri Lanka, Afghanistan, Singapore and the Philippines.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2005-2006: US$ 206 million</td>
</tr>
<tr>
<td>• Ranking as an importer in the world trade: 77th</td>
</tr>
<tr>
<td>• Major import sources: Switzerland, Germany, United Kingdom, China and France.</td>
</tr>
<tr>
<td>• Applied tariffs: 12.70%</td>
</tr>
</tbody>
</table>

Source: Trade Statistics, Trade Development Authority of Pakistan

3.4.1 General

Market access for Pakistani pharmaceutical products has improved. As a result of the WTO agreements, market access for the Pakistani pharmaceutical products in industrial countries’ market has improved as tariffs have come down. Furthermore, there is now protection available against any discriminatory treatment to our products in our trading partners’ markets. In addition to that, Article XI of GATT 1994 has eliminated quantitative restrictions that were the most significant non-tariff barriers to trade.

Pakistan has also opened its market substantially, among others, in respect of pharmaceutical products form abroad. Only those products are permitted to be imported which have been able to get registration with the health authorities in Pakistan. A price control system is also there. Since 1998 the import regime of Pakistan has been significantly liberalised through reduction in tariffs, rationalisation and removal of import quotas, import surcharges and regulatory duties. The un-weighted (i.e. simple) average statutory tariff has come down from 47.1% in 1997-98 to 14.4% in 2006-07.

The process in fact started in 1988 after the agreement on Structural Adjustment Programme was concluded with the International Monetary Fund (IMF). Unilateral, liberalisation has been, in the case of Pakistan, the principal avenue of liberalisation of trade. Pakistan has been complying with all its commitments under WTO. The net actual liberalisation on the part of Pakistan has been much more than multilaterally required in its WTO agreements. Some experts are of the view that Pakistan should not have unilaterally reduced tariffs to such a steep extent.

The WTO system is dynamically evolving. The WTO regime is not static, but is dynamically evolving. Currently, MTN are taking place on the Doha Development Agenda (DDA). The way these negotiations proceed and the ultimate agreement reached will influence the landscape of the international trade (though at the moment the prospects of a satisfactory outcome are bleak).
3.4.2 Other countries’ access to Pakistan (Threats)

The following table shows the share in Pakistan’s imports and the imported value of pharmaceutical products of top ten supplying countries.

<table>
<thead>
<tr>
<th>Exporters</th>
<th>Imported value 2004 (US$ million)</th>
<th>Share in Pakistan's imports (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>24.40</td>
<td>14</td>
</tr>
<tr>
<td>Germany</td>
<td>22.22</td>
<td>13</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>20.12</td>
<td>12</td>
</tr>
<tr>
<td>China</td>
<td>13.74</td>
<td>8</td>
</tr>
<tr>
<td>France</td>
<td>9.54</td>
<td>6</td>
</tr>
<tr>
<td>Belgium</td>
<td>8.89</td>
<td>5</td>
</tr>
<tr>
<td>United States of America</td>
<td>8.72</td>
<td>5</td>
</tr>
<tr>
<td>Netherlands</td>
<td>8.08</td>
<td>5</td>
</tr>
<tr>
<td>Italy</td>
<td>7.68</td>
<td>4</td>
</tr>
<tr>
<td>Japan</td>
<td>6.26</td>
<td>4</td>
</tr>
</tbody>
</table>

Source: ITC Trade Statistics

One cannot hope for a closed economy in a globalized world. In the world of liberalised trade one cannot expect a closed economy and should not be upset about the flow of imports. In 2004-05 Pakistan imported pharmaceuticals worth US$171.43 million, which have gradually increased to US$206.76 million in the year 2005-06.\(^{24}\)

The sustained rate of growth in imports should be a matter of some concern, as it constitutes a potential threat. It would be, however, relevant to note that the MFN duty levied by Pakistan on the import of different pharmaceutical products is 12.70%\(^{25}\), which is relatively high as compared to tariffs imposed by developed countries. This provides reasonable protection to the local industry.

Imports, though substantial, do not apparently constitute a threat to domestic manufactures at this point in time. Because of the population growth, the demand for pharmaceutical products is increasing, hence the raised volume of imports. Besides this, the entry in the market of greater number of foreign suppliers, who now enjoy more effective patent protection for their products, has resulted in greater competition for local manufacturers. They will have to make substantial investments in research and development to survive in the long run.

Both the domestic manufacturers and foreign suppliers face a common threat in the form of spurious and counterfeit drugs. This phenomenon does not only pose a commercial threat to the industry (imported products) but is extremely hazardous to the life and wellbeing of the people. Vigorous action by the government in this connection is called for to extirpate this menace.

\(^{24}\) Information obtained from TDAP

\(^{25}\) Source: Market Access Map, ITC.
3.4.3 Pakistan’s access to other/new markets (Opportunities)

The liberal trade regime of WTO has opened up new markets for Pakistani pharmaceuticals because relatively low tariffs are now levied on them in the developed countries. Moreover, Pakistani products do not face discriminatory tariffs or other trade impediments. As with all cases, there is the requirement of registration of drugs by the authorities of the importing countries.

The total exports of pharmaceutical products for 2004-05 amounted to US$64.03 and in the year 2005-06 it reached US$80.49 million.\(^{26}\) The positive feature of this trend is the sustained growth\(^ {27}\). The future holds good promise, though the local industry is not capable enough of competing in the field of patent drugs, yet there is huge potential in generic products. Fortunately for Pakistani exporters, the share of generics in the global market is constantly increasing.\(^ {28}\)

Presently TDAP is facilitating exporters by subsidising the cost of drug registration abroad. In addition, a subsidy is given for meeting a part of expenditure on freight as well as on the appointment of representatives in import markets. Delegations and participation in international exhibitions are also subsidised. Different new initiatives that are proposed include holding annual pharmaceutical/health care exhibitions, setting up accredited laboratories, establishment of centres for bio-availability and bio-equivalence studies.\(^ {29}\)

A table setting out tariff rates in various export destinations for Pakistan’s pharmaceutical products, exported value and share in exports is given below (the countries in the table are shown according to their share in Pakistan’s pharmaceutical exports).

<table>
<thead>
<tr>
<th>Importers</th>
<th>Tariff (Applied)</th>
<th>Exported value 2004 (US$ million)</th>
<th>Share in Pakistan’s exports (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nigeria</td>
<td>14.15%</td>
<td>10.55</td>
<td>18</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>0.21%</td>
<td>5.40</td>
<td>9</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>Not known</td>
<td>4.30</td>
<td>8</td>
</tr>
<tr>
<td>Singapore</td>
<td>0.00%</td>
<td>4.03</td>
<td>7</td>
</tr>
<tr>
<td>Philippines</td>
<td>4.00%</td>
<td>2.72</td>
<td>5</td>
</tr>
<tr>
<td>Sudan</td>
<td>10.00%</td>
<td>2.68</td>
<td>5</td>
</tr>
<tr>
<td>United Arab Emirates</td>
<td>0.00%</td>
<td>2.31</td>
<td>4</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0.00%</td>
<td>1.88</td>
<td>3</td>
</tr>
<tr>
<td>United States of America</td>
<td>0.00%</td>
<td>1.20</td>
<td>2</td>
</tr>
<tr>
<td>Italy</td>
<td>0.00%</td>
<td>1.12</td>
<td>2</td>
</tr>
</tbody>
</table>

\(^{26}\) Source: Trade Statistics, Trade Development Authority of Pakistan

\(^{27}\) In the fiscal year 2000-2001 the pharmaceutical exports of Pakistan amounted to US$ 38 million. The current level is indicative of progress made so far. (Source: Trade Development Authority Available at www.tdap.gov.pk.

\(^{28}\) In the year 1985 the share of generics in global market was 22% and by the year 2000, it increased to 45%. (Source: TDAP)

\(^{29}\) Dr. J. Akhtar, Presentation at the Seminar on Pharmaceutical Industry on 20th September 2006.
3.4.4 Third parties' /countries' access to other markets (threats/ competition)

In the post WTO regime Pakistan faces more competition than ever before. In such an environment countries having competitive advantage would reap the fruit of trade liberalisation. Further, Pakistani exporters will be well advised to bear in mind that the increase in exports does not depend only on lower tariffs in importing countries but also on several other factors such as consumer choices (In this case preference of prescribing physician), international standardization and market size. Currently Pakistan is exporting most of its pharmaceutical products to countries that have a nominal share in international imports, i.e. their capacity to demand is relatively limited. Very little exports are destined for bigger international markets.

A glance at the top ten markets in the world for pharmaceutical products and their share in Pakistan’s exports would be instructive.

<table>
<thead>
<tr>
<th>Importers</th>
<th>Tariff (Applied)</th>
<th>Exported value 2004 (US$ million)</th>
<th>Share in Pakistan’s exports (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States of America</td>
<td>0%</td>
<td>1.20</td>
<td>2</td>
</tr>
<tr>
<td>Belgium</td>
<td>0%</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Germany</td>
<td>0%</td>
<td>.70</td>
<td>1</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0%</td>
<td>1.88</td>
<td>3</td>
</tr>
<tr>
<td>France</td>
<td>0%</td>
<td>.72</td>
<td>1</td>
</tr>
<tr>
<td>Italy</td>
<td>0%</td>
<td>1.12</td>
<td>2</td>
</tr>
<tr>
<td>Switzerland</td>
<td>0%</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Netherlands</td>
<td>0%</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Spain</td>
<td>0%</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Canada</td>
<td>0%</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Source: ITC trade statistics

Pakistan needs to explore markets especially in the European Union and the United States. In the EU, the applied tariff is zero and the EU countries are nearer to Pakistan than the United States’. However, Pakistan should seriously explore the United States market, which is one of the biggest import markets in the world. Presently only 2% of Pakistani exports are destined for this market. The main obstacle to increasing exports to both these huge markets is that of getting registration (authorisation to sell any particular drug). Pakistani firms should be motivated by the government as well as facilitated in with respect to the time-consuming, complicated and expensive registration process. While exploiting opportunities provided by such big markets, Pakistan should not retreat from its traditional markets such as Nigeria, Sri Lanka and Afghanistan.
Identification of five export markets

Following is the list of five markets with good potential for the growth of Pakistani pharmaceutical exports.

**United States of America**

The world’s biggest pharmaceutical importer. However, as stated above, only 2% of Pakistani exports are destined for the US. Pakistan stands nowhere compared with other exporters. There is definite potential for growth in a market of this size.

**United Kingdom**

Pakistan’s fourth biggest import market (applied tariff is 0%). However, its share in Pakistan’s export market is only 3%. Here again, building on our presence (albeit very small) and utilising our knowledge of this market, there are good prospects of increasing our share.

**Nigeria**

The biggest export market for Pakistan, Nigeria still has untapped potential. Efforts should be made to further increase our share.

**Sri Lanka**

The second biggest export market for Pakistan, occupying third position. However, there is a huge difference between the volume of exports from Pakistan compared with those from India, which occupies first position. Pakistan has great potential to expand in this market and close the gap between Indian and Pakistani exports.

**Afghanistan**

Geographically contiguous to Pakistan, Afghanistan should be a natural market for our products. However, Pakistan has to face a strong competition from India. Though Pakistan is the second biggest exporter to Afghanistan, the volume of Indian exports is far bigger than that of Pakistan. Our effort should be to narrow this gap.
Box 3.8 At a glance: Impact of WTO Agreements on Pakistani pharmaceutical sector

**Exports**
- Better market access for Pakistani pharmaceutical products in developed countries’ markets. Tariff rates have been drastically reduced (very low or even zero) in those markets.
- Opportunity to intensify penetration in the European Union, United States, Nigeria, Sri Lanka and Afghanistan markets, provided our firms succeed in getting registration in the US and the EU.
- Great potential for increasing exports of generic drugs, but we have to tackle the supply side problem.
- Manufacturers must learn to tailor their products according to the market requirements and on competitive prices.

**Imports**
- Substantial opening of Pakistan’s market, albeit on relatively higher duty.
- Not much of threat at present from imported goods, but problem is caused by malpractice of under-invoicing, misdeclaration and smuggling.

Another threat to domestic industry as well as to imported products is the menace of spurious/counterfeit drugs.

Source: WTO Cell, Planning & Development Department, Government of the Punjab
4 Obstacles to export

4.1 Exporters’ opinions

4.1.1 Unavailability of bio-equivalence laboratories

Most regulatory authorities in export territories require the bio-equivalence and bio-availability studies of the product to be conducted under import registration from WHO-approved laboratories. The pharmaceutical exporters of Pakistan are unable to comply with this requirement due to the non-availability of a WHO-approved laboratory; hence substantial export opportunities are lost.

However, some companies manage to get their product’s bio-availability and bio-equivalence studies conducted from the relevant organisations in the export territory by paying substantial amounts. This is a temporary arrangement and is restricted to a few countries only —others do not recognise it.

Possible solution

Since all major hospitals are under the jurisdiction of the Ministry of Health, it is generally believed that independent WHO-approved laboratories may be developed in coordination with national pharmaceutical manufacturers to conduct various studies, including bio-availability and bio-equivalence, in Pakistan.

This project shall not only be utilised to seek export registration in the territory, but also shall act as a cradle towards the research and development of many new drugs and medical science in Pakistan.

4.1.2 Lack of financial support to carry out accreditations

In nearly all developed countries and even in some developing countries, Indian pharmaceutical companies have succeeded in exporting pharmaceutical products because of their WHO and other relevant certifications. Pakistan’s national pharmaceutical companies lack in this regard because of the substantial cost involved and unawareness, as there are a very few pharmaceutical companies in Pakistan that have undergone these audits and inspections.

Possible solution

Considering the increasing demand of the WHO certification in major export territories, the national industry believes that the Ministry of Health should enter into contacts with such organisations. These organisations should carry out WHO inspections at the request of the exporter having annual exports of US$250,000 or more, conduct WHO audits and share the cost of the audits with the exporter.

This practice will not only help the exporter but also act as a catalyst for the MoH objective that only quality medicines are manufactured in the country.
4.1.3 Restriction on import of pharmaceutical machinery, systems and equipment from India

The majority of European and American pharmaceutical machinery manufacturing companies have outsourced their production operations to Indian pharmaceutical machinery fabricators/manufacturers to avail the benefits of lower costs. Accordingly, a number of European machines are being manufactured under licence in India.

Through this contract manufacturing arrangement many Indian pharmaceutical machinery fabricators/manufacturers have gained sufficient technical expertise and are now offering cGMP-compliant production machinery, QC equipment and HVAC systems at significantly lower prices.

Possible solution

Pakistan’s national industry believes that the import ban on pharmaceutical machinery, QC equipment and HVAC systems from India should be lifted so that national pharmaceutical companies could acquire cGMP-compliant pharmaceutical machinery at economical rates and become competitive in the international market.

Furthermore, these steps should be a stepping-stone for national pharmaceutical manufacturers to take the initiative in the field of API manufacturing and R&D operations.

4.1.4 Restrictions on import of quality API from India and tariff protection to indigenous industry

The National Tariff Commission (NTC) is inclined to boost the indigenous industry, which constitutes only one or two companies in aggregate. Recently, the NTC has banned the imports from India of those APIs that are being manufactured in Pakistan. Moreover, Pakistani API manufacturers are charging higher than international rates for APIs from finished pharmaceutical manufacturers-cum-exporters, which has resulted in a cost increase.

Possible solution

The national companies advocate that the duty protection may still be provided to API manufacturers in Pakistan but the tariff protection of such APIs that are being manufactured in Pakistan should be limited to the increased import duty (i.e. 20% to 25%). Accordingly, the additional sales tax charged should also be withdrawn to facilitate the pharmaceutical manufacturers, and the import of the above-mentioned should be allowed from India.

This practice will complement API manufacturers in Pakistan through duty protection as well as the national pharmaceutical manufacturers/exporters, as they can control their cost through duty drawback claims. And the national companies can utilise the regulatory API documentation support from the approved API manufactures of India for product registration in the international market.
4.1.5 Import tariff on production machinery, HVAC systems and QC equipment

Production machinery

Most national pharmaceutical companies are currently in the process of upgrading production facilities to comply with various international requirements/certifications and regulatory approvals from numerous international territories. This is a revolutionary era for pharmaceutical manufacturing in Pakistan where substantial cGMP-compliant production machinery is being procured by the manufacturers on a regular basis, and any additional cost in form of duties should be withdrawn with an immediate effect.

HVAC systems

Heating, Ventilation and Air-Conditioning (HVAC) systems are the integral part of any pharmaceutical unit and the controlled environment of the manufacturing area is among the basic requirements of cGMP. It is also notable that a significant cost is required to procure and install the HVAC system that acts as a backbone for the approval of any pharmaceutical production area. Currently, the HVAC systems fabricated in Pakistan lack compliance with cGMP. Therefore, the import of cGMP-compliant HVAC systems and their installation is the only solution and is on the priority list of all pharmaceutical manufacturers. Currently, the import tariff structures/regulations regarding the HVAC are not supporting the pharmaceutical manufacturers.

Possible solution

The import duties on HVAC systems are withdrawn to lower the cost of procuring such equipment and encourage the industry to install it to promote quality manufacturing and increase exports in the pharmaceutical sector.

4.1.6 Quality control equipment

Quality control equipment, the most important components in any pharmaceutical production facility, is categorised under higher import tariff and is also subjected to 15% sales tax.

The quality unit of any pharmaceutical facility is considered the most important tool that not only analyses and assures the quality of the product, but also acts as a monitoring tool for the whole production process. The product quality is dependent on quality control instruments.

The importance of the validated QC equipment can be analysed from the fact that the majority of the inspection teams monitoring Pakistani pharmaceutical manufacturing units give significant importance to the Quality Control section and equipments thereof.

Possible solution

The industry believes that this important aspect should be encouraged through a downward revision of the existing import tariff for CFR21 / GLP-compliant QC equipment.
Further, to promote and improve the quality of pharmaceutical manufacturing, it is necessary that the trade policy for the import of all pharmaceutical machinery, HVAC systems and QC equipment be classified under exempted items or under minimal duty, and all the existing additional duties and sales tax should be exempted.

4.1.7 Import tariff and sales tax on packaging materials

The national pharmaceutical manufacturers are facing a fierce competition from Indian and Chinese companies in international markets because the cost of a product plays a vital role in making it competitive in international markets. Currently, nearly all packaging materials used for the manufacturing of the pharmaceutical products are subjected to sales tax, which forms part of the cost for manufacturers, as the finished pharmaceutical products are exempted from sales tax – this tax is not adjustable like GST.

Possible solution

The industry believes that all packaging material, whether imported or locally purchased, used by pharmaceutical manufacturers for their products, be exempted from the sales tax and the minimal import duties slab should be assigned to them.

4.1.8 Restrictions over contract manufacturing and marketing

There is a strong resistance at the level of Ministry of Health to the contractual manufacturing of pharmaceutical products. To discourage contract manufacturing, MoH has made strict rules, and even have limited the number of molecules that can be manufactured by a manufacturer. This limits the ability of the manufactures to utilise their full manufacturing capabilities though they may have customers in hand.

It is recognised that these steps have been taken by the Ministry of Health because of some unethical practices of a few, small-scale, shortsighted manufacturers. These rules for restricting the contract manufacturing and marketing have created substantial problems for the pharmaceutical marketing companies.

Possible solution

The industry believes that the current restrictions regarding the toll/contract manufacturing should be withdrawn.

4.1.9 Discrimination in awarding registrations by Ministry of Health

The pharmaceutical industry currently faces substantial difficulties at the time of product registration. In many instances products, which have already been registered by the Ministry of Health for another manufacturer, are denied registration. Difficulties are also experienced in some cases where a manufacturing company applies for registration of a new product which is already registered internationally. The product is referred to various committees, faces red tape and queries at each stage, which delays the registration as well as affects the manufacturer’s interest, as it usually can take more than 18 months for product registration.
Possible solution
The process of registration should be made transparent and a mechanism be adopted to expedite the registration process.

4.1.10 Inconsistent policies and rules
Apart from red tape, the regulations and policies are changed frequently. At the time of submission of the dossiers, these requirements are neither existent nor applicable to the said products, yet manufactures frequently receive queries.

Possible solution
The MoH clearly establish document requirements by product category and restrict the frequency of such changes.

4.1.11 Lack of industry representation in high-level delegations
In high-level delegations from Pakistan travelling with the Prime Minister or the President to potential export territories, the pharmaceutical sector is often ignored and opportunities remain unexplored.

Possible solution
Therefore, to boost pharmaceutical exports it is recommended that the trade agreements of any kind made between Pakistan and other countries should include the collaboration of the pharmaceutical sector.

This practice could fast-track registrations and increase pharmaceutical exports to new territories. This will provide an opportunity for Pakistani pharmaceutical exporters to present themselves and convince various health, commerce and foreign affair ministries of the prospective territories.

4.1.12 Import of pharmaceutical products already manufactured in Pakistan
The National Tariff Commission has provided substantial duty protection to the API manufacturers by imposing import duty at the rate of 25%, which qualifies the product to be subjected to 15% sales tax. However, it is worth mentioning that the import duty on finished formulations of similar molecules still continues at 10%, which has resulted in a tariff anomaly and has discouraged the pharmaceutical companies manufacturing such products in the country.

Possible solution
The industry recommends that the National Tariff Commission should impose maximum import tariff with sales tax on the following corresponding finished products whose APIs are already manufactured in Pakistan to remove the existing tariff anomaly. The table given below indicates the existing tariff:
Table 4.1 Existing tariffs

<table>
<thead>
<tr>
<th>Raw materials having 25% regulatory duty</th>
<th>Protective duty to be imposed by CBR on finished products import</th>
<th>Finished form having 10% duty + 15% sales tax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicillin Trihydrate/Anhydrous</td>
<td>Ampicillin Caps</td>
<td>PPMA proposed to impose 25% duty + 15% sales Tax</td>
</tr>
<tr>
<td>Amoxicillin Trihydrate/Anhydrous</td>
<td>Amoxicillin Caps</td>
<td></td>
</tr>
<tr>
<td>Cloxacillin Sodium for Caps</td>
<td>Ampicillin+Cloxacillin Caps</td>
<td></td>
</tr>
<tr>
<td>Cephradin Monohydrate</td>
<td>Cephradin Caps and Susp</td>
<td></td>
</tr>
<tr>
<td>Cephalexin Monohydrate</td>
<td>Cephalexin caps</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Paracetamol Tabs</td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Ibuprofen tabs</td>
<td></td>
</tr>
<tr>
<td>Sulphamethoxazole</td>
<td>Cotrimaxazole Tabs</td>
<td></td>
</tr>
</tbody>
</table>

Source: PPMA

### 4.1.13 Lack of financial support for incorporation of representative offices in export territories

In certain export territories products are mishandled by distributors despite better quality and presentation. As a result, the substantial market potential of the product remains unexploited. To cater to the demand of such territories it is necessary for the exporters to form their own representative/scientific office in such territories and register themselves with the concerned regulatory authorities of the export country. This will enable the manufacturers/exporters to register their products in their own name instead of the distributor’s name and could pave the way for further exports.

However, the cost of incorporating a representative office and registration of a company with the concerned regulatory authorities requires a substantial amount of funds, which restricts many exporters to rely on their distributors and do a limited business.

**Possible solution**

The national industry has long been lobbing for an additional subsidy of 50% for company incorporation and registration with the concerned regulatory authorities (based on the reimbursement of actual expenses) to promote and boost the pharmaceutical exports of Pakistan.

### 4.1.14 Lack of funding to acquire common warehouse/godown in export territory

In export territories like CIS states, Pakistani pharmaceuticals are compelled to limit their volume of business due to the non-availability of guaranteed banking channels and the absence of warehouse facilities. At the same time, various Indian pharmaceutical companies have succeeded due to their business setup and economies of scale. Hence, a substantial export opportunity remains unexploited due to cost constraints and risk factors.
**Possible solution**

It is generally believed that TDAP should provide the required initial funding for acquiring a common warehouse/store for the Pakistani pharmaceutical products.

It is recognised that such support is not possible on a continuous basis, but the industry is confident that initial support for the first two to three years from TDAP for a common warehouse will enable the Pakistani pharmaceutical companies to establish their sizeable business in CIS states.

Several Pakistani pharmaceutical products do have potential competitive advantages, in terms of quality and packaging, over Indian, Chinese and Bangladeshi products.

**4.1.15 Absence of revolving credit facilities to LDCs and CIS states**

The Ministry of Commerce introduced a revolving credit facility in one territory for the pharmaceutical sector and it resulted in substantial exports. Under this arrangement a credit facility was created with the respective ministry in the export territory and pharmaceutical exporters were facilitated by the award of fast track registrations by the relevant regulatory authorities in the export country. The products were procured by government agencies of the importing country and payments were made at ministerial level and finally reimbursed to the exporting pharmaceutical companies. All this arrangement helped establish Pakistani pharmaceutical products in the territory. However, the practice was limited to a single country.

**Possible solution**

The industry recommends that a similar revolving credit facility for the pharmaceutical sector be introduced in CIS states and African countries, where exports are limited due to payment risk factors and non-availability of guaranteed banking channels.

**4.1.16 Price fixation without taking into account the effect of inflation and the increasing requirements of regulators**

The MoH strictly regulates the price of pharmaceutical products in Pakistan. No price increase has been granted for five years.

It is also necessary to mention that potential inflation has been witnessed during the last five years and the cost of pharmaceutical manufacturing in Pakistan is constantly increasing, which includes:

- Increasing requirements of regulators (domestic and foreign)
- Cost of utilities (electricity etc.)
- Labour cost
- cGMP compliance cost
- Inflation

The figure below shows inflation from 2000-01 to 2004-05. Total inflation over this period was 27.3%.
Figure 4.1 Inflation in Pakistan from 2000-01 to 2004-05 (%)

Source: PPMA & PB

Figure 4.2 Petrol prices in Pakistan (PKR/litre)

Source: PPMA & PB
The above graphs clearly indicate that the cost of manufacturing has increased substantially.

**Possible solution**

The industry recommends that the pricing policy of leader prices (as adopted during 1992) be reinstated and the prices of drugs should be linked with the CPI (consumer price index) on an annual basis.

### 4.1.17 Lack of incentive schemes to motivate pharmaceutical manufacturers to enter into exports

It is also observed that various quality manufacturers from Pakistan have restricted their operations within the country and are hesitant to enter the export market. The main reason is that they feel not much incentives and opportunities are present for them to invest in new territories. Moreover, a majority of the exporters are also more focused on the local market, due to a lack of incentives from the government bodies.

**Possible solution**

The industry recommends that new incentive schemes should be introduced to motivate the exporters, which may include the following:

- Fast track registrations of five products on achieving annual exports of US$250,000 and 10 products on achieving annual exports of US$500,000 are awarded as an incentive to the exporters during a year.
- 10% price increase of one product as an incentive to the company on achieving exports target of US$500,000 or more.
4.1.18 Patent and IP matters

The national pharmaceutical industry has full regard for the new Patent regime and Intellectual Property Rights and would like to remain within the domain of the TRIPs agreement.

However, at the same time, the misuse or abuse of intellectual property laws by many multinational companies (which are detrimental to national interest) cannot be overlooked.

The Pakistan Patent Office, till date, is not fully equipped to cope with the challenges of the TRIPs agreement under the WTO regime. The examination reports and the quality of examinations at the Patent Office are questionable.

A majority of the patents previously awarded in Pakistan have frequently been challenged in the courts of law in terms of their validity. In most of the court cases relating to patents, it is now known that patents had been awarded in ignorance or disregard of the prevailing laws. Another reason was lack of technical capacity at the Pakistan Patent Office.

The PPO has commenced issuing examination reports in respect of the so-called black box applications. This has triggered serious concerns among the national pharmaceutical companies. They feel that improper, ineffective and non-comprehensive examination of the black box applications will only result in a large number of product patents, which will promote the concept of evergreen patents, or the patents that go beyond the stipulated 20 years. The main reason is that a large number of patent applications is believed to be mere repetition of old and expired patents.

Moreover, the perpetuation of patent monopoly beyond the stipulated 20 years by recycling the patent grants, derived by making small changes to the original/basic molecule, would cause a great damage to the national companies.

Possible solution

The national pharmaceutical companies believe the Pakistan’s Patent Office should put their house in order to provide expertise to cope with challenges of the TRIPS, WTO, and issues relating to validity of such reports and confirm these are in accordance with the prevailing laws.

4.2 Importers’ opinions

4.2.1 Obstacles for export (existing hindrances)

Obstacles at company level

Fear of association — fear of new entrants in the market

Small Pakistani pharmaceutical companies have a general fear of associating with other companies. Many such companies are family businesses and they do not like to show the lining of their jacket to anybody, believing that the entire business must “stay in the family”. As a result, their size is often too small to take care of obvious opportunities, to operate at a good economy of scale and to acquire the necessary know-how about production, quality assurance (QA), marketing and human resource management.
There is a widespread fear in the Pakistani pharmaceutical industry of being steam-rolled by the competition from China and India. This fear can have a paralysing effect i.e. the companies may abstain from venturing into international business despite the fact that they have the necessary assets and strength to compete in the international forum.

**Possible solution**

Pakistani pharmaceutical companies should seek strategic alliances to make up for their shortcomings in size, power, influence and networks.

They should seek strategic alliances with medium-sized multinationals. The big ones already have subsidiaries or distributorships in Pakistan. The Pakistani companies should seek out the giants of the future who are not already firmly committed in Pakistan. Such strategic alliances will bring with them a dearly needed transfer of technology i.e. in R & D, production, QA, marketing, and management in general. They will also constitute a base for future power and influence in the Pakistani market and possibly even in other markets, which these ‘big-to-be’ multinationals may entrust to their Pakistani partner.

Even more pressing is the need for strategic alliances within the Pakistani industry. Most probably not a single pharmaceutical company in Pakistan is able to face all the challenges of today and tomorrow. Strategic alliances are necessary to share costs and risks, to develop products and markets, to complement product portfolios and to stimulate each other in benchmarking.

In order to respond effectively to the perceived or real trouble from China and India (and from elsewhere), the companies should pay more attention to niche marketing. The more precisely they can define and exploit their best suited market segments, the sooner they will be able to achieve leadership in such segments, and the more difficult it will be for any intruder to become dangerous. (*Also refer to “The Boston Matrix”)*

**How to go about creating strategic alliances?**

An annual Buyers-Sellers meeting is organised by ITC, for Asia under the name of Asia HealthCare. Participants are matched for 30 minutes encounters in such a way that they offer the best chances to enter into common business ventures. It is the forum par excellence to start negotiations for all types of associations: distributorships, representation, licences, franchising, incorporated and non-incorporated joint ventures e.g. for common production, marketing, exploration and exploitation of foreign market, for mergers, and acquisitions. It is even possible that ITC will in the future organise this type of meeting trans-continentally for companies from Asia, Africa, and Latin America.

At Asia HealthCare 2005 in Singapore, out of 108 participants, eight companies were Pakistanis — a figure way below the degree of importance of the population, the pharmaceutical market and the pharmaceutical industry of Pakistan.

Several Pakistani companies also participated in Asia HealthCare 2004, which was also organised in Singapore. This is a proof of the fact that the participants were satisfied with the forum. However, some companies complained about too few buyers participating in the meeting. This in turn demonstrates two things. Firstly, the companies are mentally ready for exports. Secondly, they have not yet acquired the give-and-take attitude, which is necessary for a successful international business.
For updated information about ITC Buyers-Sellers meetings, refer to www.intracen.org.

Pakistani participation in conferences held in Singapore in 2004 and 2005 respectively is reflected in the below table.

<table>
<thead>
<tr>
<th>Table 4.2 Participation in Asia HealthCare conferences, 2004 and 2005</th>
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<tr>
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<tr>
<td><strong>Asia HealthCare 2004</strong></td>
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<tr>
<td><strong>Asia HealthCare 2005</strong></td>
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<tr>
<td><strong>Total number of participants</strong></td>
</tr>
<tr>
<td>103</td>
</tr>
<tr>
<td>108</td>
</tr>
<tr>
<td><strong>Pakistani participants</strong></td>
</tr>
<tr>
<td>Gelcaps</td>
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<tr>
<td>Irza</td>
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<tr>
<td>Medipak</td>
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<tr>
<td>Orta</td>
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<tr>
<td>Pacific</td>
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<td>Pakheim</td>
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<td>Schazoo</td>
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<td>Unison</td>
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<td>EPLA</td>
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<td>Helix</td>
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<td>Lahore Chemical</td>
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For the annual participation of Pakistani pharmaceutical companies in ITC-organised Buyers-Sellers meetings (Asia HealthCare), the total cost was US$30,000.

**Overcrowded product portfolios**

Among pharmaceutical companies, there exists a misconception that they must produce everything which leads to less investment in machinery, stocks of raw material and packaging material for products that may never reach an economical volume of sales. Even more detrimental to the health of the company is the lack of focus on a company’s core business. As there is a known saying, “Whoever wants to do too much will end up doing nothing well.”

**Possible solution**

Companies should enter into strategic alliances among one another in order to give the correct answer to the question, “Do we make this product or do we buy it?” More often than most companies would expect, the answer is going to be: “We do not make it. We do not buy it. We simply do not need it.” They should also be aware of the high cost of needless products. According to the Boston Consulting Group, dogs are lousy products in miserable market segments. Such products are literally sitting in the way of success of pharmaceutical companies.

“Companies should learn to do what they can do best and leave the rest to someone else.”

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The product portfolio: The Boston Matrix

How is a company going to decide which of its products should be supported and which ones should be eliminated in order to arrive at a profitable international product portfolio, the one that is going to secure the future of the company?

For the analysis of the product portfolio the Boston Matrix is used – see Figure 4.4. It is so called because it was devised by the Boston Consulting Group.

**The Boston Matrix**

**Thin, full-line arrows: the ideal career path of a product**

The ideal career path of a product depicted by thin, full-line arrows is firstly to be launched as a wildcat, which then grows into a star and when the market segment declines, maintains its strong position as a cash cow.

**Broad arrows: investment flow**

The broad arrows showing investment flow should start from cash cows and move mostly towards the wildcats, with a moderate investment in the stars as well.

**Dogs are to be killed!**
Notes on the x- and y-axes of the Boston Matrix: competitive position

**The x-axis**

For placing the participants of a market or market segment on the x-axis, the various numbers seen on the graph show a certain position of the market or market segment. No.1 represent the leader, No.2 the co-leader, No. 3 the competitor, No. 4 the participant and No. 5 the “also run”.

The leader and the co-leader are genuine stars and enjoy the benefits of leadership.

The competitor and the participant struggle hard to shift from wildcat to the status of a star. The “also run” should quickly make efforts to move up. Otherwise, they would always remain at that position and sink to the status of dogs. Products beyond position No. 5 are of no significance in the market, except if they have only been launched very recently and are moving strongly ahead.

**The y-axis**

In the original Boston Matrix, the y-axis expressed market segment growth i.e. above the x-axis or decline (below the x-axis). However, a market segment does not necessarily have to grow in order to be of interest to a company. Reasons for this are as follows:

- A segment may be of interest because of profitability.
- Products in that segment are complementary to other products of the company.
- This segment will be deserted by competition.
- The product is still in its development stage and holds very strong promises for the future.
- Better, more competitive, and more profitable products of the same family are in the pipeline.
- This product can create an economy of scale with other products of the company.
- This product is alone in this market.
- The product is creating a new market of which the interest is not yet known.

The home portfolio of a company is of course no model for its international portfolio. Products that are at home undisputed stars, may have a hard life as a fighting wildcat in other markets. Products that are at home generous cash cows, may be stars or wildcats or even dogs in other markets.

The rule is to look at each market for is own sake and to adapt the South-South marketing strategy if and when necessary. Some considerations about this adaptation of the international strategy are given below:

**Wildcats**

Some consider it unwise to launch wildcats anywhere else but in the home market or in a test market. Even very powerful multinational companies have failed in product launches abroad
when they did not have enough experience with that product at home or in well-chosen test markets.

Wild cats are very precious i.e. they are the future of the company. Their importance will depend on how hard it is to get a new product. In the pharmaceutical business a new product has usually cost a lot of money in development and health registration. No company wants to miss this kind of product launch. Also, “You don’t get a second chance to make the first, lasting impression.” That is certainly true for products in an export market and that is the reason why wildcats should be taken very seriously.

Feeding wildcats

An internationally very successful pharmaceutical company applies a very simple rule to judge a plan for a product launch in an export market. The responsible international product manager has to promise that the plan will lead to a leadership or a co-leadership of that product in its market segment within 3 years. If he/she cannot make that promise, the plan is sent back to the drawing board. If no better solution is found, the plan is cancelled altogether. That company only wants wildcats that eventually are going to be stars. “If you are going to think small, why think at all?”

Stars

Stardom at home does not guarantee that a product will be an instant star in foreign markets as well. But it helps a product tremendously to be a star at home before it wanders out into the wide world. Many international marketers only select home stars for international work. Their attitude is: “First show me how good you are on your home turf before we take you to play internationally”. Success at home is also a strong motivator for the international partners. They will obviously have more confidence in a product that has already shown its mettle at home before they have to launch it in their own market.

A company that has a strong star in a market segment should take care of it. It should strongly defend the product’s trademark and never allow that trademark to become a generic name for the product.

Shining stars

Successful international companies do not allow a product to be launched if it does not have a fair chance to become a leader in its market segment in a reasonably short time. (See the previous caption.) Market leadership — stardom — is a goal in itself, and rightfully so.

Most people will remember the name of the first man on the moon: Neil Armstrong. Some people will even know who the second man on the moon was: Buzz Aldrin. However, no one knows the name of the third man on the moon. Yet, it was an incredibly impressive scientific and technological performance to put him there and it cost the American taxpayers billions of dollars. Really, it does pay to be the star.

Cash cows

Every cash cow was at one time a wildcat and a star. Then, the market segment of which it was a star declined. No money in the world would suffice to maintain the stardom of that product. Another market segment grew faster e.g. because of new technology, and pushed the segment of which this product was the star into obsolescence. It would be utterly futile to continue investing in such a product. As a result, it should be milked as it has acquired the status of a cash cow. A product can be a confirmed cash cow at home and therefore receive no more marketing support. However, that same product may still have a brilliant wildcat and a star career ahead in other markets. This situation may lead to the decision to also support the product in the home market against all “home” logic, just for the sake of keeping the product in the spotlight internationally.

Milking cows…or not always?

A pharmaceutical company in Kenya has a genuine cash cow in the home market — a cough syrup that has been around ever since Kenya’s independence in 1962. The market segment of anti-cough products is absolutely stagnant and feared to decline in the future. The product is a clear case of a cash cow and should not any longer be promoted. However, the company launched it in one of its export markets for a better opportunity. Surprisingly, it is catching on! In order to support the product in this market the company continues to promote the product in the home market far beyond the level that would normally be expected for a cash cow. It looks unwise to support a cash cow but in the international context, it can make all the sense in the world.

Dogs

Dogs at home are almost certainly going to be dogs anywhere. There should be no mercy for dogs, not at home and even less on the international scene. Dogs usually become dogs because products and markets have not been followed carefully enough. One day somebody stops and sees that a product has sunk into nothingness in a Mickey Mouse market and calls it a dog. Hopefully, he will not meet with too much resistance when killing it. It is bad enough that such a situation can arise in the home market. It should never occur in international markets where the need for focusing on profitable priorities is even greater.

Killing dogs

A very successful company in South-South marketing of pharmaceuticals hates dogs with a vengeance. They apply the following rules of fist to eliminate dogs in time in international markets.

- Any product that does not represent at least 1% of total sales is eliminated.
- Any product form of a product — different galenic forms and strength or units per pack — that does not represent at least 10% of total sales of that product is eliminated.

Exception: These rules do not apply to a product or product form in the first year of its life, or to a product that has to be available on the market on moral grounds, or if it can be proven that it is a genuine “loss leader”, i.e. a product or product form that is indispensable to sell another profitable product.
An overall example of sound product portfolio management

An international area manager responsible for the Caribbean started his tenure with 90 different product forms in the 16 markets of his territory. In year one, he eliminated 45 products. As a result, sales dropped down to 10% in volume but profits went up by 30%.

In year two, he slashed another 19 product forms, bringing down the total number to 36. This resulted in another drop in sales to 10%. However, profits rose by another 40%.

In year three, he launched three new product forms and eliminated three old ones. The number stayed at 36. Because of the focus on products with a future (cats) and a present (stars), the market shares improved substantially. Sales then increased by 35% and profits doubled against the profits of the previous year. In addition, the leadership acquired by most products bode well for further increase in the market share and profits. Thus, by practicing portfolio management, the company benefited manifold.

Obstacles at government level

Complicated regulatory requirements, no international harmonisation

The most frequently pointed out obstacle by pharmaceutical companies is the lengthy and cumbersome regulatory procedures for registering a medicine in various international meetings.

Possible solution

The Government can greatly help the industry by adopting the following measures:

- Simplifying the procedures, especially for generic medicines and in particular for the medicines on the Essential Drugs’ List of WHO. Such medicines should be allowed on the market if the requesting company can prove its GMP (Good Manufacturing Practices) status, e.g. according to WHO regulations and/or an appropriate ISO certification, and/or a Quality Assurance statement form an EU or US pharmaceutical multinational.

- Weighing on friendly foreign governments to accept the Pakistani products lawfully registered in Pakistan according to the procedures described above without further administrative requirements or cost. The document internationally used for that purpose is the Free Sales Certificate.

In order to facilitate such procedures, the government should establish or help the industry to establish a Central Laboratory for the accreditation of bio-availability and bio-equivalence of such medicines. This accreditation means that the new generic product behaves in the human body exactly in the same way as the original product.

Going a step further, this laboratory should be established in close coordination with other countries in the region. The other option could be having strategic alliances with other developing countries, e.g. Mexico and Brazil, where such laboratories already exist. This would be more productive and more cost-effective because Pakistani companies would no longer have to entrust such studies to very expensive US or EU laboratories.
Estimated cost

- A Central Laboratory for issuing bioavailability and bio-equivalence certificates for generic medicines should best be attached to the faculty of pharmaceuticalcy of an important university. This Central Laboratory would be able to use the university’s laboratory infrastructure. If provided with competent leadership, most of the actual laboratory work could be performed by the students for whom this would be an excellent training method and would keep the cost of operation low.

- An effective Central Laboratory created in this fashion, using to the maximum the infrastructure of the university should not cost more than US$500 a year.

- A certificate would be priced on an average at US$1,000 to US$5,000 instead of the often claimed US$10,000 to US$100,000 in Western laboratories.

Export licensing

There is a general perception that export licensing procedures are very cumbersome. This slows down the export activities and may even discourage companies from starting exporting activities.

Possible solution

“If you cannot help me by putting ointment on my wounds, you can help me by not rubbing salt into them.”

The Government of Pakistan seems to have made too many irrelevant export licensing procedures, according to some.

The government should compare its procedures with the procedures of other successful countries e.g. India, Singapore and Thailand. These countries have done very well in the export of medicines. The government should adapt its export procedures accordingly in order to create a level playing field for the Pakistani exporters.

When asked, exporters generally point out “non-tradables” as the desired assistance from the government. Companies do not necessarily want the “promotional support” offered by trade support institutions. They rather want assistance with the straightforward chores of international business: simplification of customs documents, speedy, easy and inexpensive administration of certificates of origin and export licences, administrative assistance with letters of credit, guarantees or insurance for foreign payments, the creation of free zones and/or bonded warehouses, etc.

A good model of credit insurance can be found in Belgium’s Delcredere service (www.delcredere.be). Not all of Delcredere’s guarantees will be possible or needed for Pakistan, but the model can serve to devise a similar service adapted according to the requirements of the country.

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**Step by step, day by day**

For both Health Registration and Export Licensing, it would be ideal to have lists, which indicate the approval procedures in Pakistan — step by step i.e. the person from whom the product is to be approved/registered, from where does it have to be approved/registered, what will be the procedure, how much time would be involved, which type of documents would be required, how much cost would be involved and how many renewals would be required (if required), etc.

Ideally, these lists would be in short text, telegraphs style or bullet points, with references given where full text would be required. This format would be simpler and faster, allowing the study report to be directly used for discussions and for making amendments afterwards. It will also be a cheaper method. Once the lists have been established, it might be possible to trace similar kind of lists for other countries for comparison.

**The fiscal burden**

Another obstacle present at government level is that companies even have to pay duties on imported raw goods when these goods are used to manufacture export goods.

**Possible solution**

The government should allow the creation of a bonded warehouse in pharmaceutical companies and/or offer free zone facilities. In these warehouses/free zones, companies can keep tax-free raw materials, intermediate products, excipients (products added to the active substance in order to produce e.g. a tablet — starch, sugar, etc.), and packaging material to be used for the production of export batches.

**Estimated cost**

- The cost of a bonded warehouse is negligible. It will take a few square metres of fence to make a separated and closed warehouse area for goods to be exported. An agreement would be required between the company and the authorities for the Customs to make regular inspections each time the products enter or leave this separated area. Taxes, if any, will only be due at the time of release of these goods. The total cost will not be more than US$1,000.

- If Pakistan wants to establish a free zone, then it’s a different matter (if it does not already have one). A free zone requires the dedication of a sizable piece of land, usually close to a harbour, for the construction of warehouses and possibly even premises for the transformation and/or packaging of goods destined for export. The investment for a free zone runs easily in the millions of dollars.

**Pricing policy**

It appears that the Pakistani industry has grown over the last year by 13%. Of this, 10% comes from the growth in units and 3% from the growth in value. This may indicate an unfortunate evolution towards value depletion and therefore to profitability depletion.

**Possible solution**

Many countries allow imported products to be priced more or less at the level of the prices in their country of origin. A common yardstick is that the FOB price should not be higher than the
wholesale price in the country of origin. The level of these export prices is mostly controlled by an agency commissioned by the importing country against payment of a percentage commission on the exporter’s invoice. The Swiss company SGS turned this type of inspection into a specialty (www.sgs.com).

It is therefore recommended to have rather high prices in the home market for products that are going to be exported. The Belgian pharmaceutical industry which is a very active exporter, uses this argument to obtain high internal prices for its products.

This means a burden for the citizens of the exporting country, but on balance and in macro-economic terms, the higher prices are all to the advantage of the exporting country. With more successful exporting companies, more jobs will be created, more taxes will be paid and as a result more foreign currency would be earned.

**Other obstacles**

Important hindrances mentioned by foreign export managers are as follows:

- The pharmaceutical industry does not market itself adequately.
- Opportunities are lost due to delayed documentation to obtain registrations.
- Most national companies focus on push sales only i.e. do not have own marketing setup
- The lead-time between the placement of an order and the receipt of goods is long — this could be addressed through a bonded warehouse arrangement at destination.
- The national companies often delay shipment of goods — the commitments for delivery schedule made by export managers are generally not adhered to by the companies.
- Most national companies demand premium price over similar products from India and China.
- Communication and response time relating to scientific product information needs improvement.
- Samples/literature for the promotion of products needs to be evaluated on actual need rather than on the basis of percentage of the order.

These eight points show the need for improved professionalism in the national export teams — “willingness, ability and readiness”. It seems that there may still be a problem with being “ready”. Export requires an iron discipline and an extremely close attention to all the business functions involved. Export demands “immediacy” and spotless accuracy in administration.

**4.2.2 Shortcomings for export (things missing)**

**Shortcomings at company level**

**Lack of focus in the choice of export markets**

The Pakistani pharmaceutical industry possibly does not have the capacity to tackle the markets all over the world. Without adequate focus on priority markets, the international ambitions of Pakistani pharmaceutical companies are doomed to fail. Perhaps too much
attention goes to business between Pakistani companies and companies from the rich North. In this “South-North” or “North-South” business, Pakistani companies will often be in a non-competitive position.

**Possible solution**

The industry should clearly identify target markets for its export in full coordination with the government (TDAP). Among those target markets, each Pakistani pharmaceutical company can then choose the markets that are most accessible or offer the best chances for the export of its medicines. This would place the pharmaceutical industry in a more comfortable position where it would be able to make use of any kind of support offered by the government for its export business e.g. information, networking, financing services, legal assistance, logistics, local legislation on marketing and regulatory matters, etc.

Selecting the right market is not only important for export but also for the following reasons:

- Import of raw materials, intermediate products, excipients, packaging material and machinery. One can grow rich by selling high but also by buying low.
- Opportunities for various forms of strategic alliances: common purchasing, participation in tenders, product development, production and training, etc.

Having a close contact with ITC would be very useful ([www.intracen.org](http://www.intracen.org)). The reasons why it will be useful are given:

- ITC provides trade flows showing the way to the most promising markets, whether it is for export or for import.
- ITC has a very extensive database of pharmaceutical companies practically in all developing countries, many of which have exactly the same needs of focus and association as the Pakistani companies.
- ITC has a long experience of stimulating South-South trade and is probably the No. 1 powerhouse when it comes to defining international business strategies for developing nations.\(^{35}\)

See also below under “Lack of information”.

**Note:** It appears that over the years 2003-04, no less than 53% of the Pakistani export of pharmaceuticals went to four African countries. This can indicate an unexpected strength of market share in these countries. Observations such as this can be very useful for selecting the most promising export markets.

It would be interesting to analyse these exports to Africa.

- To which countries are the exports going?
- Is there any one country to which exports are particularly strong? (And why?)
- What is the product mix? Is it indicative of strength or is it just coincidental?

---

\(^{35}\) ITC, Redefining Trade Promotion - The Need for a Strategic Response. (Geneva: ITC, 2000).
How dependent is this strong export on personalities, or events e.g. specific promotional activities or organisations such as United Nations agencies or NGOs?

It would in any case be advisable to focus much more on South-South trade because of much better chances for success.\textsuperscript{36,37}

The export priorities for each individual company would be different because of differences in product portfolio, type of business, financial strength and organisation, etc.

Here is a hypothetical scheme for arriving at such a priority decision. The crux of the matter is to:

- Choose the criteria that really matter to the exporting company
- Have the possibility and take the time to find out what the situation of these criteria really is in the target markets.
- Be extremely honest in the appraisal of the company’s own strengths and weaknesses.

What is the process — how to go about it?

- Rank the importance of each country for each item from 1 to X, with 1 being least favourable and X being most favourable.
- If one item is more important than another, it can be given a heavier weight e.g. from 2 to 2 times X.
- It may be necessary to add more criteria or to revise the score because of unexpected difficulties or opportunities. It is better to have a plan and change it when needed than to work without any system.

“A plan is something you make so that you know what you are deviating from.”

<table>
<thead>
<tr>
<th></th>
<th>Viet Nam</th>
<th>Thailand</th>
<th>Myanmar</th>
<th>Indonesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market volume</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Weakness of competition</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Logistics\textsuperscript{*}</td>
<td>4</td>
<td>8</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Cultural affinity</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Convertible currency</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>14</strong></td>
<td><strong>15</strong></td>
<td><strong>16</strong></td>
<td><strong>13</strong></td>
</tr>
</tbody>
</table>

* Given double weight because of its importance.


\textsuperscript{37} South Centre, Enhancing South-South Trade. (Geneva: South Centre 1996) 71-72.
From the above total scores, Myanmar is the right place to select. However, the difference between Myanmar with the others is so narrow that it will be necessary to add a couple of criteria in an attempt to make a priority choice that offers more confidence.

Lack of information in companies

“Knowledge is power.”

- Most pharmaceutical companies never get useful information about the happenings in the world’s pharmaceutical markets. The various types of information to which companies have no access are given below:
- Market size and market potential in export markets
- International meetings with an impact on the industry e.g. ITC Buyers-Sellers’ meetings
- The issuance of tenders
- New products that may constitute a threat to any company’s business

The running out of patent protection and, therefore, the opportunity for adding interesting new products to a company’s portfolio

New regulatory and administrative requirements, new legislation affecting the pharmaceutical business in export markets

Possible solution

The first, most effective and least expensive source of international market information for Pakistani pharmaceutical companies is the Buyers-Sellers’ meeting Asia HealthCare (see above ‘Lack of focus in the choice of export markets’)

At the Asia HealthCare participating companies receive detailed information about all Southeast Asian markets i.e. market size and evolution, regulatory requirements, imports and exports and major companies. In addition, experts give lectures on business issues specific to the industry.

The establishment of a Pharmaceutical Info Centre is hereby strongly recommended. Various tasks of this Centre are listed below:

- Capturing international initiatives in favour of the pharmaceutical industry and organising participation in them. (For example, the Buyers-Sellers’ meetings of ITC for which ITC now relies mainly on the assistance of the Chambers of Commerce, which cannot possibly have the same depth of knowledge of the pharmaceutical business as a specialised bureau may have).
- Syndicated participation of ambitious pharmaceutical companies in international events such as those organised by the Dutch CBI (www.cbi.nl). CBI supports companies from developing countries in their participation in European Union trade fairs in order to enable them to export to the European Union. CBI typically pays for travel expenses, and/or for the rental of a booth, and/or the renting of a national booth in which all the companies from a given country can participate. CBI has done this repeatedly for the annual exhibition of the German pharmaceutical association.
• Negotiate the syndicated purchase of market intelligence on behalf of the entire Pakistani pharmaceutical industry. This could be the case for e.g. IMS (International Medical Statistics) and SCRIP, services that are far too expensive for any individual pharmaceutical company.

• Capture early notification of tenders issued in the countries of interest to the Pakistani pharmaceutical industry. The bureau could do this by developing a network of informing agencies in export countries, obviously against the willingness to provide similar information about Pakistan.

• Become the one-stop office for a pharmaceutical company that has to fulfil official requirement. Coordinating and executing these obligations with the relevant administration:
  - For the registration of a new product,
  - For matters of compliance with GMP requirements,
  - For obtaining import or export licences,
  - For Free Sales certificates,
  - For Proof or Origin certificates,
  - For building permissions for plants or extension of plants,
  - For environmental matters.

• Be the coordinating office to submit promising products, researched or developed by Pakistani companies, to a body of consulting scientists and marketing experts who can gauge the chances of such products in the world markets.

Ideally, the Pharmaceutical Centre should be a joint initiative of PPMA and the relevant branches of the government.

**Estimated cost**

• The Pharmaceutical Info Centre can do very effective work with 5-10 people, provided these people are chosen from the ranks of the relevant administration e.g. the Ministries of Health, Economy, Industry and Environment, etc. There should also be one or two people who know the pharmaceutical industry very well e.g. retired or pre-retired managers from the industry.

• According to the contemplated size and basket of duties, the Pharmaceutical Info Centre should be able to function on a budget between US$200,000 and US$500,000 annually.

ITC has huge volumes of data containing general as well as specific information for countries or sectors of the economy on business in the developing world. This information can be found at [www.intracen.org](http://www.intracen.org), “e-shop publications and products”.

Much of this information is available free of charge. For some, a nominal price has to be paid, which can be substantially lower or even cancelled altogether for purchases from the developing world.

Below are chapters listing various types of information offered. Each one contains a wealth of useful facts, figures and advice.
Information sources

ITC publications and products

Box 4.1 ITC e-shop/publications and products

Looking for:
Market overviews,
Trade development insights,
Exporter success stories, or
‘Best practices’ in developing and transition economies?

These topics and more are covered by ITC, which produces a wide range of information materials as part of its technical cooperation programme.

What's available:

Books and CDs
ITC produces a number of trade promotion handbooks, market surveys and commodity handbooks each year.

Technical materials
Directories, bibliographies, short market studies and trade support studies are available.

ITC's magazine
ITC’s flagship publication, the International Trade Forum, is available quarterly in print and on the Internet.

International trade bulletins:
ITC regularly issues newsletters, bulletins and technical announcements on a range of specific trade topics.

Source: www.intracen.org

At the same website (www.intracen.org) there is another chapter that contains numerous useful items, mostly with a direct reference to the relevant web site and the e-mail addresses of people to be contacted. Here are excerpts from the chapter “Books and CDs:

Country market analysis profiles (Country map)

The profiles of 184 countries and territories, with benchmarks of their national and sectoral trade performance and competitiveness.

Cyber-Cafes

CD-ROMs with business information for specific products and regions, including trade-related internet sites, market studies and supporting information. Information includes pharmaceuticals in Latin America and South and South-East Asia.

Database of importers' associations

An interactive database available in print and online, including profiles of over 500 associations, mainly from developed countries. Searchable by sectors and/or products, it aims at assisting exporters and export promotion bodies from developing countries in identifying potential trade partners.
Database of trade promotion organisations

An interactive database available in print, CD-ROM and online, which includes profiles of over 1,200 trade support institutions worldwide.

Internet: www.intracen.org/tradinst

E-shop

An online publications site for buying ITC books, CDs, technical papers, tools and bulletins faster and easier via the internet using credit cards. Full prices for books and technical papers range from US$11 to 70, plus shipping and handling. Customers in developing and transition countries benefit from a 60% discount.

Internet: www.intracen.org/eshop

E-Trade bridge website

Information about the ITC programme to develop the e-trade capability of SMEs, including national strategy formulation, the creation of a network of stakeholders, design and delivery of e-readiness assistance programmes for SMEs and capacity building for training and counselling.

Internet: www.intracen.org/etradebridge

Executive forum website

To facilitate the development of global and regional networks for information exchange and sharing of best practices in national export strategy design and management. Interactive web page and e-discussions to complement the Executive forum meetings.

Internet: www.intracen.org/execforum

Export packaging bulletins

Bulletins covering topics of interest to export packaging trade professionals, trade support institutions and SMEs interested in packaging for exports. Published bi-monthly in English and French.

Internet: www.intracen.org/ep
Contact: packaging@intracen.org

Export quality bulletins

Bulletins focusing on specific export quality topics, such as ISO 9000:2000, Hazard Analysis and Critical Control Point (HACCP) and Information Retrieval on Standards, Technical Regulations and Conformity Assessment Procedures, issued in English, French and Spanish.

Internet: www.intracen.org/eqm
ITC's online trade information reference system

Online access to the ITC bibliographical databases, providing references and, where applicable, direct links to over 16,000 selected trade information sources.

Internet: www.intracen.org/tirc

JURIS International

A multi-language collection of trade-related information on international law (including legal agreements, model contracts and networks of business lawyers) aimed at business lawyers and SMEs. Provides affordable legal information and strengthens the user’s position in contract negotiations. JURIS International is also available on CD-Rom.

Internet: www.jurisint.org

Lega Carta

An online database showing ratification and adherence to major treaties, trade-related legal instruments, and trade agreements by country.

Internet: www.legacarta.net

Market Access Map (MAC Map)

An interactive database containing the tariffs and market access conditions applied at the bilateral level by 167 importing countries to the products exported by over 200 countries and territories. It allows users to simulate the impact of tariff reductions as well as analyse protection at different levels of sectoral and regional aggregation.

Contact: macmap@intracen.org

Market access through standards and conformity assessment

A modular information pack for the export-oriented business community on how to improve/maintain market access using the benefits resulting from the WTO agreements on TBT and SPS.

Market News Service

Weekly/monthly reports, provided through Product Map (www.p-maps.org), containing market intelligence on selected primary and semi-processed products. Information is gathered directly from manufacturers and traders. Sectors include: fresh fruit and vegetables, cut flowers and ornamental plants, fruit juices, spices, pharmaceutical starting materials/essential drugs, and medicinal plants and extracts.

Internet: www.p-maps.org/mns
Contact: mns@intracen.org

PC-TAS — Trade Analysis System

A CD-ROM published annually by ITC and the United Nations Statistics Division (UNSD) providing five-year time-series and trends on international trade flows. It is suitable for
researchers wishing to perform technical analysis. PC-TAS is available either at the SITC 5-digit or the HS 6-digit level.

Internet: www.intracen.org/mas
Contact: pctas@intracen.org

Product Market Analysis Portal (Product Map)

A Web portal presenting business information and intelligence in a product context for 72 product clusters. Product Map includes market studies, price indicators in certain sectors, links to product information, trade data and over 20,000 companies and organisations. Companies can also create their own basic web site, which is hosted on the portal.

Internet: www.p-maps.org
Contact: pmaps@intracen.org

South-South trade promotion website

The site provides information gathered from ITC’s work on the promotion of south-south trade, including the methodology, the tools, the calendar of events, publications, business links and cyber-cafes.

Internet: www.intracen.org/ssstp
Contact: south-south@intracen.org

Trade finance press abstracts

Finance-related press abstracts, contact information for export credit agencies and information about ITC trade financing activities. Issued quarterly. Available in printed format or online.

Internet: www.intracen.org/tfs

TradeMap

An online database of global trade flows and market access barriers for international business development and trade promotion, providing detailed export and import profiles and trends for over 5,300 products in 200 countries and territories. It supports the analysis of market and product diversification opportunities.

Contact: trademap@intracen.org

World Trade Net newsletter

News on important WTO meetings and their business implications, dispute settlement cases, relevant ITC publications and events of interest to partners in the ITC World Trade Net programme. Available monthly, by e-mail and on the World Trade Net site.

Internet: www.intracen.org/worldtradenet
Contact: worldtradenet@intracen.org
World Trade Net website


Internet: www.intracen.org/worldtradenet
Contact: worldtradenet@intracen.org

Specific pharmaceutical information

International Medical Statistics (IMS)

IMS can be found on www.imshealth.com. This is the website of IMS (International Medical Statistics). IMS offers unbelievably complete information about the pharmaceutical industry of major markets:

- For each pharmaceutical presentation on the market:
  - Monthly and annual (moving annual total) sales in units and in value (US$)
  - Evaluation of the same.

- Prescription data:
  - Indications for which each medicine is prescribed
  - Expected results
  - Which type of patients this medicine is prescribed for: women, men, children
  - Which other medicines this medicine is co-prescribed with

SCRIP reports

SCRIP reports can be found on www.scripreports.com. SCRIP reports offers literally all types of information about the pharmaceutical industry i.e. new products, status of development of new products, regulatory matters in major markets, products accepted and rejected by regulatory authorities, business news: mergers, acquisitions, strategic alliances and even gossip such as which CEO has to go and who is going to replace him/her.

Both IMS and SCRIP reports are almost indispensable tools for the international pharmaceutical marketer. However, the problem is that both are expensive and therefore probably inaccessible to individual companies in the developing world. Hence, the solution is to create a Pharmaceutical Bureau that can try to acquire the most indispensable information on a syndicate basis.

Estimated cost

- The ITC library with publications relevant to the pharmaceutical industry will cost US$5,000
- Regular subscription to ITC publications will be US$1,000 annually
- The minimum subscription to IMS and SCRIP - prescription costs for individual companies are too high. Hence, the suggestion is to have a centre in Pakistan that can
negotiate such prescriptions with IMS and SCRIP on behalf of the entire pharmaceutical industry.

- CBI usually carries the cost of travel, board and lodging of selected companies. (Selection is done by CBI inspection on the spot.) CBI also arranges national booths at exhibitions at its expense. There are, therefore, no other costs than meals and other out-of-pocket expenses.

Lack of supply chain knowledge

Many companies for several years buy certain products and services from the same supplier without ever looking elsewhere or pressuring that supplier for better trade conditions.

Possible solution

ITC publishes a monthly paper listing the lowest supply prices for the raw materials required for the production of Essential Drugs. Apart from showing the way to lower cost supplies, this paper can be used to convince the existing suppliers on more advantageous prices and/or supply conditions. Whether Pakistani pharmaceutical manufacturers are aware of this source of information is a question mark.

The box given below provides links for acquiring information on MNS.

Box 4.2 ITC Market News Service for pharmaceutical starting material and essential drugs

(Starting Material is synonymous with ‘active ingredients’ or ‘raw material’)

The Market News Service (MNS) works in collaboration with the WHO Essential Drugs and Medicine Policy (EDM). MNS issues a monthly report providing up-to-date prices and supporting commercial data on active ingredients used in the production of essential drugs. The report covers the main trading centres in Europe and Asia. It is aimed at organisations that wish to stay informed about worldwide prices and need a guide for the comparison of market prices. This is not a brokerage service, but strictly an information service with the goal of improving market transparency, which will lead to increased price and quality competition for the benefit of all market players.

Full information can be found at www.p-maps.org under pharmaceuticals and medicaments. On the same website and under the same heading, similar information is available about natural medicines.

Lack of adequate laboratory support

Invariably, export countries will require proof of bio-equivalence and bio-availability for generic products entering its market. Unfortunately, laboratories offering such services are not available in Pakistan, though companies can acquire these services in the EU or in the US but the cost is often prohibitive.

Possible solution

The Pakistani pharmaceutical industry should urgently provide itself with such services.

For a detailed description and an estimation of cost: see above “Complicated administrative requirements”.
Lack of professional consulting support

Not even the biggest giants in the pharmaceutical industry make all their decisions just based on their internal competencies. They all make frequent and effective use of consultancy services. This has three advantages: (1) they are better served by the advanced know-how of consultants than by their own know-how, (2) they do not incur extra social charges by hiring such specialists as employees (3) they use the contribution of the consultants as a benchmark for the contribution of their own staff.

It is highly probable that Pakistani pharmaceutical companies lack expert advice in at least three crucial fields of management i.e. finance, packaging (in particular branding and house style), and legal issues (contracts). For a start, each of these fields’ publications can be found at the ITC website www.intracen.org.

Possible solution

- Consulting: Sources of finance

Frequently, SMEs in developing countries are not aware of alternative sources of financing. UNDP organises seminars where this subject is dealt with. It should not be too difficult to enlist the advice of experts in this field.

- Consulting: Packaging

It should be possible to save money and to turn packaging into an instrument of marketing. This too could be a subject of specific coaching and consulting for which competent consultants are already available in the UN programmes.

- Consulting: Legal

Legal advice with respect to the negotiation and signing of memorandums of understanding, letters of intent, distributorship agreements and strategic alliances with foreign partners is also available via the UN system. A special case where legal advice is needed is for companies that want to get seriously involved in Internet business.

Lack of size

In pharmaceutical business, possibly more than in any other business, company size is of the essence. There are many things in the pharmaceutical business that are simply inaccessible to a company that is too small. Also, the risks involved in conducting a pharmaceutical business are huge, from the high cost of machinery, clinical trials, product launches, the training of medical representatives, the participation in congresses, to the heavy responsibility coming from product liability.

Possible solution

Pakistani pharmaceutical companies should seek strategic alliances to make up for their shortcomings in size, power, influence and networks.

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As mentioned before, they should seek strategic alliances with medium-sized multinationals. The big ones already have subsidiaries or distributorships in Pakistan. The Pakistani companies should seek out the giants of the future who are not already firmly committed in Pakistan. Such strategic alliances will bring with them a dearly needed transfer of technology (in R & D, production, QA, marketing, and management in general). They will also constitute a base for future power and influence in the Pakistani market and possibly even in other markets, which these ‘big-to-be’ multinationals may entrust to their Pakistani partner.

Even more pressing is the need for strategic alliances within the Pakistani industry. Most probably not a single pharmaceutical company in Pakistan is able to face all the challenges of today and tomorrow. Strategic alliances are necessary to share costs and risks, to develop products and markets together, to complement product portfolios and to stimulate each other in benchmarking.

A way to find good candidates for strategic alliances is the ITC Buyers-Sellers’ meeting and, in the case of Asia, the Asia HealthCare. There, a company executive gets the opportunity to meet 25 pre-selected candidates in two days at the cost of one air ticket and a couple of days in a hotel and accomplishment that would otherwise take him/her weeks of travel and huge travel costs (see above).

**Shortcomings at government level**

**Quality assurance**

In many countries one can notice an - “eat your cake and keep it too” attitude with respect to quality.

On one hand, companies want their government to assist them in projecting a high quality image for their products in other countries, but on the other, they complain about governments being “too demanding and too expensive” when it comes to assuring quality.

Yet, governments should adopt the attitude of total intransigence when it comes to the quality of medicines because of its responsibility towards its own citizens and the citizens of export countries, and because there can be no success in international business without the highest degree of quality.

Quality constitutes a double challenge for Pakistan. Firstly, in a large country such as Pakistan, sub-standard medicines entering the market are almost unavoidable. If authorities in the Ministry of Health are occupied with many other usual chores, there is a little chance that they can go out and chase criminal drug peddlers.

Secondly, even the most quality-conscious Pakistani pharmaceutical companies will have trouble making its quality accepted for what it is. Too many customers, including people in Pakistan, believe that a medicine ‘made in Switzerland’ or ‘made in the USA’ is by definition better than a medicine produced at home.

**Possible solution**

The quality image of the Pakistani pharmaceutical industry could be greatly improved if:

- The government would do its utmost to keep sub-standard medicines out of the country
The government would step up its quality requirements for pharmaceutical manufacturing to the level of the industrialised world. It is hoped that some industrialised countries would delegate some of their own GMP inspectors to Pakistani companies desiring to attain such a high level of quality.

The government should in all its promotion of the Pakistani industry abroad always include the pharmaceutical industry and highlight its quality especially.

The government can open its embassies for institutional promotion and image building for any Pakistani pharmaceutical company that has demonstrated a flawless GMP.

The government should buy its pharmaceuticals preferably from Pakistani companies and encourage all UN agencies and NGOs to do likewise. This is going to convey confidence to the Pakistani industry. Remember the common premise: “If it is good enough for my government, for the UN and for the Red Crescent, it is good enough for me!”

Economic development of SMEs

Undoubtedly, any SME with sufficient dedication and competencies can one day become a big company. However, with some help this process can be greatly accelerated and painful accidents or bankruptcies can be avoided to a large extent.

Pakistan already makes a strong effort in favour of the development of SMEs through SMEDA. It would be worthwhile to wonder whether these efforts are the most adequate for the rather peculiar pharmaceutical SMEs, which, apart from the problems usual with all SMEs, are facing the complications of the TRIPs agreements.

Possible solution

Most, if not all, pharmaceutical companies in Pakistan can be labelled as SMEs. Some countries and international organisations (e.g. ILO www.iло.org) have acquired very advanced know-how in the economic development of SMEs. This involves, among others, techniques of clustering, external economy of scale, the organisation of support from large companies, ‘incubating’ services for starting companies and coaching, etc. It might be wise for the government to draw on this know-how and launch a sustainable economic development programme for the pharmaceutical industry. Pakistan already has the organisational infrastructure for the support of SMEs in the form of SMEDA. It could be useful for SMEDA to approach ILO for inspiration and assistance in its efforts to develop SMEs. ILO already has, for example, run for more than seven years a very successful programme in Chile, in collaboration with SERCOTEC41,42, the Chilean counterpart of SMEDA.

41 SERCOTEC, Guía de Programas e Instrumentos de Apoyo a la Micro, Pequena y Mediana Empresa (Santiago: SERCOTEC, 1999). 
Limited impact on international trade regulation issues

In spite of admirable efforts, the voice of the Pakistani government may not sufficiently be heard at the forums of international trade. If this is the case, nobody should be surprised: until the Fifth Ministerial Conference in Cancun in 2003, the developing world was altogether not sufficiently heard.\textsuperscript{43,44}

**Suggested solution**

In its future dealings with international organisations, the government should do well to heed the advice of, e.g. the World Bank\textsuperscript{45} and the former director of WTO, Supachai Panitchpakdi.\textsuperscript{46}

In short, these recommendations amount to the following:

**Table 4.4 Recommendations from the World Bank and WTO**

<table>
<thead>
<tr>
<th>From the World Bank</th>
<th>From WTO</th>
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<tbody>
<tr>
<td>• Export orientation should be anchored in competitive and stable currencies.</td>
<td>• Strive for a tariff- and quota-free market access to the 48 least developed countries.</td>
</tr>
<tr>
<td>• Red tape should be cut. Customs clearance practices should be improved.</td>
<td>• Challenge the current penalties system for countries that do not have the ability to implement certain WTO rules.</td>
</tr>
<tr>
<td>• Export promotion should be part of a balanced national plan, including infrastructure, human resource development, exchange rates and investment policies.</td>
<td>• Challenge the excessive anti-dumping investigation for the same countries.</td>
</tr>
<tr>
<td>• Take advantage of regionalism to introduce macroeconomic, regulatory and infrastructure reforms.</td>
<td>• Resist linkage between social and trade issues.</td>
</tr>
<tr>
<td>• Participate actively in multinational forums.</td>
<td></td>
</tr>
<tr>
<td>• Base all the preceding in a consultative process involving all stakeholders.</td>
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</tbody>
</table>


\textsuperscript{45} Graham Hancock, Lords of Poverty (n.p.: Mandarin 1994).

\textsuperscript{46} IBRD, Can Africa Claim the 21\textsuperscript{st} Century? (New York, N.Y.: The World Bank, 2000), x-xi, 208-34.

5 Export services in Pakistan

5.1 Export strategy

The Trade Development Authority of Pakistan (TDAP, formerly EPB) is based on an evaluation of the world demand of goods and services. Its strategy aims to prioritise those areas where Pakistan has or can achieve a competitive edge, sourced from within or outside Pakistan, and facilitate the achievement of the desired levels of profitable exports via a 'demand-led' strategy, as opposed to the previous 'supply-led' efforts.

TDAP’s strategy is as follows:

Whilst retaining undivided focus on increase in the share of world imports of Pakistan’s Core Product categories, achieve earliest and maximum Product and Geographic Diversification.

- Adoption of the concept of world-class supply chain management or facilitation for comprehensive dealing with the production efficiencies and on-time delivering capabilities (as opposed to just ‘manufacturing capacity’, ‘warehousing’ or ‘coordination with Pakistan Council for Scientific and Industrial Research (PCSIR))’.

- Active excellence in communication capability both to promote products and services and the overall business image of Pakistan and the understanding and appreciation of the services of TDAP.

- Prioritisation and focus will govern the allocation of available personnel and financial resources for optimising efficiency.

- Achieve maximum market access to enable exporters to maximum returns of their efforts.

- Ensure an export-enabling environment in the country and amongst the country’s missions abroad.

- Training of manpower and incentives to the levels appropriate to the commercial and business profile of the organisation.

More details are available from the Trade Development Authority of Pakistan website www.tdap.gov.pk.

Pharmaceuticals not a core export category

Using national alignments and a focussed application of resources, TDAP’s role is to pursue selected developmental export opportunities where Pakistan currently enjoys, or can achieve, a strong competitive edge. The categories that have been identified for attention are:

- Fruit, vegetables and wheat
- Marble and granite
- Engineering goods
- Healthcare
- IT - Software and services
- Gems and jewellery
• Chemicals
• General services.

5.2 Available export services

5.2.1 Central Board of Revenue (CBR)
• Export rebate to cover off duties paid on the imported components used
• Export refinance facility

5.2.2 Trade Development Authority of Pakistan (TDAP)
• 50% subsidy on product registration
• 25% freight subsidy
• Trade delegation travel subsidy: 50% airfare and US$100 per day TA/DA when visiting with trade delegations
• Hiring of 3 medical reps in an exporting country (US$500)
• International exhibition subsidy
• Organisation of yearly Healthcare Expo exhibition in Karachi
• Currently providing warehousing facility in Kenya.

5.3 Desired export services
• TDAP classify pharmaceuticals as a core category.
• Develop understanding within TDAP and its commercial officers stationed in various countries.
• Reduce or eliminate the paperwork and bureaucracy involved in claiming various facilities offered by TDAP.

5.4 Changes required to achieve desired services
• Development and provision of facilities for bio-equivalence and bio-availability study and validation of international standard.
• Provision of financial support to carry out WHO/FDA/MCA/EU/TGA accreditations.
• Removal of restrictions on the import of pharmaceutical production machinery, HVAC systems and QC equipments from quality and economical suppliers in India.
• Removal of restrictions on the import of quality APIs from India and restricting tariff protection to the indigenous industry.
• Exemption of import tariff on production machinery, HVAC systems and QC equipments.
• Removal of import tariff and sales tax on packaging materials.
• Establishing a clear policy on contract manufacturing and marketing.
• Making a level playing field for all in awarding registrations by the Ministry of Health.
• Making clear and consistent policies and rules.
• Increasing industrial representation in high-level delegations.
• Restrict import of Chinese pharmaceutical products already manufactured in Pakistan
• Provide financial support for incorporation of representative office in export territory
• Provide funding for acquiring a common warehouse in the export territory.
• Allow revolving credit facilities for pharmaceuticals to the least developed nations and CIS states.
• The price of pharmaceuticals is fixed after taking into effect inflation and cost of manufacturing.
• Develop incentive schemes to motivate pharmaceutical manufacturers to enter in exports.
• Formal training of exporters on the best practices to export pharmaceuticals.

5.5 Export services offered by others (examples)

5.5.1 Chile (1998 onwards)

In Chile, a government organisation for the development of SMEs is operating in collaboration with ILO and the Flemish SME organisation UNIZO, in the SERCOTE programme financed by the Flemish Government. Its major objective is to increase the number of official SME consultants from 16 to 308 by training the natural consultants of the SME, i.e. their accountants, with the help of the 16 trained consultants.

5.5.2 Comes (1995-1999)

The Commonwealth of South-East African states invited ITC to set up a programme for the intra-COMESA trade of pharmaceuticals. The initiative gave rise to the creation of PHARMESA, the Pharmaceutical Manufacturers’ Association of COMESA, an organisation that, while probably formally asleep, is still very much alive in practice in the exchange of products among members (LPC of Lesotho from CAPS of Zimbabwe). It also helped in successful selling by GAMMA of Zambia to the US missionary organisation AMFA (Affordable Medicines for Africa). Some sources say that these sales go into millions of US Dollars.

5.5.3 AABF-II (2000 - 01)

Africa-Asia Business Forum-II is a result of an initiative taken by UNDP and financed by Japan to promote Asian investments in Africa and African trade in Asia. Pharmaceutical
companies were also involved in this forum: a Pakistani company got together with a Tanzanian company. Unfortunately, this project did not come to fruition, but other alliances were successful.

5.5.4 Mexico (1995-2000)
ICB is a Dutch organisation for the promotion of import of products from the developing world into the developed world – an export stimulation for developing countries. ICB has repeatedly invited pharmaceutical industries to participate at their own expense, e.g. in the annual German pharmaceutical exhibition. As such, five Mexican companies have already participated three times with a common booth, organised and paid for by ICB.

5.5.5 India
India has at times subsidised the export of pharmaceuticals, a policy that is divergent from WTO rules.

5.5.6 ITC (2000 to date)
An important and very effective export promotion of pharmaceuticals comes from ITC’s Buyers-Sellers meetings, including those arranged as follows:

- 2000 Bangkok, Thailand
- 2002 LatinPharmaceutical, San Salvador, El Salvador
- 2003 LatinPharmaceutical, Lima, Peru
- 2004 LatinPharmaceutical, Rio, Brazil
- 2004 Asia HealthCare, Singapore
- 2004 ECO, Central Asia, Istanbul, Turkey
- 2005 LatinPharmaceutical, Santiago, Chile
- 2005 Asia HealthCare, Singapore
- 2006 LatinPharmaceutical, Cartagena, Colombia
- 2008 AsiaHealthCare, -

At these meetings around 800 companies have been matched for negotiating international pharmaceutical alliances of all kinds, such as trade, strategic alliances on technology, marketing, R&D, registration issues, purchase of machinery, packaging and exchange of market intelligence.

5.5.7 General
Most countries have some kind of export promotion institution. However, the problem is that many of these agencies do not have the means to provide much assistance to pharmaceutical exporters and are not knowledgeable enough about the complexities of the international pharmaceutical business. They may also be misguided because they are only allowed to support export, thereby forgetting that if everybody only wants to export, there will be nobody left over to import. As a result the possibility for integrating import smartly into the value chain is often overlooked.
6 Conclusion and recommendations

6.1 General

6.1.1 Awareness

Even before the first step has been taken to implement some of the recommendations from this report, it has already yielded a positive impact on everybody involved in the creation of this report. The report has indeed created a higher level of awareness of the present status and the future needs of the Pakistani pharmaceutical industry, which is an unprecedented achievement.

6.1.2 Strengths – Weaknesses – Opportunities – Threats

Challenging the executives of pharmaceutical companies has revealed such a wealth of perceived SWOT elements, both in the industry and in government policies that it will be difficult but necessary to focus on just the few elements that are really going to make a difference for the future of the industry. The authors of the report have done their best to identify these overruling elements. Obviously it will be up to the industry and to the government to decide on the priority with which they will be tackled.

6.1.3 A wake-up call for the industry and for the government

The real speed of change

Change in the pharmaceutical universe is taking place at a speed much faster than hitherto realised.

- New ‘Centres of Excellence’ are surfacing up all over the world, but most prominently in the immediate vicinity of Pakistan, namely in India and China.

- In these new centres products are manufactured of a quality that is acceptable to the whole world, including to the highly industrialised regions, at highly competitive prices.

- In some of these centres, R& D has reached a level of genuine innovation, allowing some of them to rightfully dream of joining the club of the creative multinationals.

- That same surge for excellence is rapidly leading to an explosive growth of some pharmaceutical markets. This means an easier access of ever-larger populations to medicines, hence an opportunity for competent pharmaceutical companies to take a slide of the ever-growing pie.

- To WTO the pharmaceutical industry is a primary target of concern. WTO continuous to promote free world trade. WTO endeavours to protect intellectual property rights (TRIPs), in particular patent rights on innovative pharmaceutical products, while at the same time ensuring the right of poor populations to the best possible medicine. The difficulties to bring the Doha Round to a successful conclusion are proof of the fact that this task comes closer to an attempt for squaring the circle.
Pro-active policies rather than re-active ones

It should be clear that nothing good can come out of the Doha Round or any future Round if the developing nations do not take a more active or a pro-active role in international discussions. It is therefore strongly recommended that the Pakistani pharmaceutical industry and the Government of Pakistan should work hand in glove to elaborate the most promising policies that should then be defended with utmost vigour in international organisations such as WTO.

6.2 Highlights of conclusions and recommendations

6.2.1 Internationalisation

It seems utterly futile to consider the Pakistani pharmaceutical industry without taking into account the context of internationalisation of the pharmaceutical universe.

• If the Pakistani industry were not to take an active role in the world markets, there would be a very real risk that it is going to be swept aside by the new and old international players. ‘Not going international’ would mean that the Pakistani pharmaceutical industry would be relegated to the status of provincial businesses which would have to accept the full impact of all the competitive winds blowing over it without even so much as a chance for survival. Industry initiatives and government rules and legislation will always have to take the international nature of the pharmaceutical business into account.

• It has now been established beyond any doubt the world over that export orientation is by far more beneficial to the pharmaceutical industry of a country than import substitution. Hence, protective measures from the government should be replaced by export promotion measures or at least export facilitation measures, and the mentality of the industrialists should be changed from defence to attack.

• Internationalisation means exports and imports.

• Smart imports of high quality goods, services, and equipment at well-negotiated prices and conditions should make Pakistani companies more competitive in the world markets.

• Smart imports should allow Pakistani companies to clean up their overcrowded product portfolios so as to free money, time and energy for their product lines where they are really competitive.

6.2.2 Obsession with quality

Quality will be the indispensable prerequisite to remain competitive, at home against the invaders from the new centres of excellence and obviously even more so in the export markets. The reason: governments around the world are becoming ever more demanding about quality for the protection of their citizens and for safeguarding the competitiveness of their own pharmaceutical companies. This will require a number of steps from the Pakistani industry and from the government.
• A solid, world-level regulatory system is already being installed. It now behoves the industry to wholeheartedly embrace it and the government to strictly reinforce it.

• There is an urgent need for a Bio-availability/Bio-equivalence (BA-BE) laboratory. Indeed, it is to be expected that very soon no country in the world will accept on its territory generic medicines that cannot produce BA-BE certificates. If Pakistan is not able to create such a laboratory, the industry and the government should most urgently conclude agreements for out-farming BA-BE certification to another country. This should preferably be a developing country in order to evade the often forbiddingly high costs for such services when offered by laboratories from the industrialise countries.

6.2.3 The creation of intellectual infrastructure

Apart from all the hardware needed for the successful participation in international pharmaceutical business such as better equipped production facilities, a better transportation infrastructure, adequate warehouses, a free zone and a BA-BE laboratory, there is a need for investment in the intangibles of the international business.

Information

Knowledge is power.

The efficient collection and speedy distribution of relevant information about the world’s pharmaceutical industry is a must. This information should comprise at least the following items but is by no means limited to these items alone:

• The appearance of new medicines on the world markets
• Medicines running out of patent protection
• Laws governing the admission and the marketing of pharmaceuticals in target markets for the Pakistani pharmaceutical industry
• The publication of tenders
• Companies seeking various ways of collaboration in R&D, product development, market penetration, product launches, production improvement, training of technical and commercial personnel, etc.

Innovation

The industry and the government should come together to devise a common policy and procedures to increase the level of innovation in which the pharmaceutical industry can engage. For example, this could be for:

• The development of new galenic forms for existing medicines
• The discovery of or the scientific justification for alternative medicines such as natural medicines.
• The creation of expertise in clinical research
• The practice of original marketing methods, in Pakistan and abroad
6.3 The three magic points: focus - standards - alliance

6.3.1 Focus

Focus for the industry

The industry should focus on:

- **Product portfolio:** Stop trying to make and sell everything. Companies should concentrate on product lines in which they are strong, effective and efficient, and for which they have a high degree of market expertise and credibility. If they absolutely need other products, they should buy them instead of making them.

- **Sourcing:** Companies should review their purchases of literally everything: machinery, services, raw material, packaging material, and negotiate more favourable conditions with their suppliers.

- **Exports:** Companies should identify the export markets where their products stand the best chances of success.

Focus for the government

The government too should concentrate its efforts where they really matter:

- Choose the best suited foreign markets and concentrate on whatever support services available for these markets. Study and, where appropriate, apply successful industry supporting measures from other countries.

- Simplify all administrative obligations for exporting companies and keep only the ones that are really important.

- Always have the pharmaceutical industry prominently present in international discussions. The pharmaceutical industry happens to be a very important industry for the Pakistani economy.

6.3.2 Standards

‘Good enough’ is not good enough everywhere all the time, and it is especially true for the pharmaceutical industry.

For the industry and for the government alike, all the standards presently in use should be elevated by at least a couple of points. This applies to:

- Quality (see above)

- Simplification and speed of administrative chores imposed by the government (see above) and increased smoothness and expediency of international operations in the companies.

- Professional competencies of international executives in the companies: insight in international marketing principles, language proficiency, negotiation skills and diplomacy.
6.3.3 Alliances

At a time when the international giants of the pharmaceutical business are getting together in ever more intricate associations — strategic alliances, mergers, acquisitions — it cannot be that the relatively small Pakistani pharmaceutical companies could meet all of today’s formidable challenges on their own. Alliances are therefore called for:

- Between Pakistani pharmaceutical companies
- Between Pakistani pharmaceutical companies and companies from other (developing) countries
- Between Pakistani pharmaceutical companies and multinational companies, in particular the so-called medium-tier companies
- And last but not least, between the Pakistani pharmaceutical companies and the government of Pakistan

6.4 A case of opportunity for Pakistan: The African pharmaceutical market

According to the World Health Organization (WHO), two-thirds of the world's population - and 80% of Africans do not have adequate access to drugs. Despite this alarming statistic Pakistan is doing its bit in serving the continent with needed pharmaceuticals. A significant share of Pakistan’s pharmaceutical exports is destined for Africa. ITC’s TradeMap allows us to look at Pakistan’s exports by region and we see that in 2005 Africa had a share of around 30 % of Pakistan’s exports. If we were to take into account what ends up in Africa after re-distribution from Dubai, Africa’s share of Pakistan’s pharmaceutical exports may well be even higher.

Trade data acquired from recordings of customs declarations is a powerful means by which to study trade opportunities, especially in Africa where other sources of market information are limited. Whilst the classification of the World Customs Organization is not ideal for the pharmaceutical sector, it is unique in the sense that a tool like ITC’s TradeMap can easily group data together for cross-reference analysis. Using the same classification, we see in table 6.1 that an important portion of Pakistan’s exports fall under the clearly defined categories: bandage and suture materials, antibiotics, vitamins and veterinary vaccines.

<table>
<thead>
<tr>
<th>Export category</th>
<th>Quantity</th>
<th>Value</th>
<th>Main destinations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kgs</td>
<td>US$</td>
<td>%</td>
</tr>
<tr>
<td>Other</td>
<td>4,741,163</td>
<td>40,469,133</td>
<td>Nigeria, Afghanistan, Sri Lanka</td>
</tr>
<tr>
<td>Raw material</td>
<td>n.c. units</td>
<td>17,662,483</td>
<td>USA, Tanzania, Singapore</td>
</tr>
<tr>
<td>Bandage and suture</td>
<td>4,318,483</td>
<td>11,460,600</td>
<td>UK, Italy, Nigeria</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>502,749</td>
<td>3,134,317</td>
<td>Syria, Sri Lanka, Singapore</td>
</tr>
<tr>
<td>Vitamins</td>
<td>490,618</td>
<td>2,646,333</td>
<td>USA, UAE, Mauritius</td>
</tr>
<tr>
<td>Veterinary</td>
<td>247,873</td>
<td>2,202,233</td>
<td>Sudan, Nigeria, Ethiopia</td>
</tr>
<tr>
<td>Herbal</td>
<td>443,303</td>
<td>2,054,733</td>
<td>Sudan, Japan, Ethiopia</td>
</tr>
</tbody>
</table>

Table 6.1 Pakistan's exports by broad categories, 2004-05
<table>
<thead>
<tr>
<th><strong>Export category</strong></th>
<th><strong>Quantity</strong></th>
<th><strong>Value</strong></th>
<th><strong>Main destinations</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Kgs</td>
<td>US$</td>
<td>%</td>
</tr>
<tr>
<td>Homeopathic</td>
<td>60,628</td>
<td>420,800</td>
<td>0.5 Singapore, Afghanistan, SLK</td>
</tr>
<tr>
<td>Volume supplement</td>
<td>33,790</td>
<td>234,000</td>
<td>0.3 Nigeria, Sri Lanka, Kenya</td>
</tr>
<tr>
<td>Blood</td>
<td>187,723</td>
<td>164,667</td>
<td>0.2 Sudan, Ethiopia, Afghanistan</td>
</tr>
<tr>
<td>Dental</td>
<td>6,692</td>
<td>126,617</td>
<td>0.2 Italy, Singapore Malaysia</td>
</tr>
<tr>
<td>Eye preparation</td>
<td>12,953</td>
<td>117,967</td>
<td>0.1 Sudan, Nigeria, Ethiopia</td>
</tr>
<tr>
<td>Contraceptives</td>
<td>18,591</td>
<td>113,250</td>
<td>0.1 Iraq, Thailand, Vietnam</td>
</tr>
<tr>
<td>Anti anxiety/Insomnia</td>
<td>119,776</td>
<td>110,417</td>
<td>0.1 UAE</td>
</tr>
<tr>
<td>Human vaccine</td>
<td>900</td>
<td>7,933</td>
<td>0.0 Sudan, Singapore, Ethiopia</td>
</tr>
<tr>
<td>Food supplement</td>
<td>100</td>
<td>950</td>
<td>0.0 Sri Lanka, Somalia, Kazakhstan</td>
</tr>
<tr>
<td>Steroids</td>
<td>2</td>
<td>283</td>
<td>0.0 India</td>
</tr>
<tr>
<td>First aid</td>
<td>58</td>
<td>233</td>
<td>0.0 UK, Nigeria, Germany</td>
</tr>
</tbody>
</table>

Source: FBS

If we select a table to review Africa’s imports and dig deeper into the pharmaceutical group represented by group HS 30, we see that the continent does not have a well established pharmaceutical industry by the fact that most of the imports are final formulations in dosage form in group HS3004. Included in this group are products such as penicillins, antibiotics, hormones and a larger unknown group. Further pharmaceutical import categories (outside HS3004) of significance include bandage and suture materials; human and veterinary vaccines; and vitamins.

The two key markets for pharmaceuticals in Africa are South Africa (US$1.17bn in 2005) and Algeria (US$907m est.47) along with Nigeria (US$300m est.), Tunisia (US$245m est.) and Morocco (US$205m est.).

France is a key supplier to Africa, taking up 40 % market share. Looking a bit closer at France’s pharmaceutical product exports, though, reveals that these exports to Africa are very concentrated around a few countries. TradeMap also allows us to look at France’s exports of HS30 separately showing the list of countries French pharmaceutical goods are exported to. We see that the lion’s share (US$672m) of the French pharmaceutical exports to Africa are in fact destined for Algeria and a significant amount (but much less) to Nigeria, South Africa, Morocco (c. US$130m) and Senegal, Egypt, Cote d’Ivoire (US$50m-100m).

It is understandable that Pakistan’s pharmaceutical export sector will have a tougher time breaking the French umbilical cord in North Africa (e.g. France’s market share of Magreb countries’ pharmaceutical imports is 67% and as high as 72% in Algeria) and therefore focuses more on its trading ties with Nigeria (12% share of Pakistan’s exports), Sudan and Kenya. Despite problems with counterfeit pharmaceuticals, unsafe and fake medicines continuing to plague the sector, Nigeria remains an important market in Africa. The Chinese are well aware of this fact evidenced by their latest move to build a pharmaceutical production facility in Nigeria’s south-western state of Osun.

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47 Estimation based on partner trading country information.
<table>
<thead>
<tr>
<th>HS code</th>
<th>Label</th>
<th>Pakistan's exports to South Africa</th>
<th>South Africa's imports</th>
<th>Pakistan's exports</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Value (US$'000)</td>
<td>Value (US$'000)</td>
<td>Qty. (Mt)</td>
</tr>
<tr>
<td>30</td>
<td>Pharmaceuticals</td>
<td>449</td>
<td>1,168,572</td>
<td>19</td>
</tr>
<tr>
<td>300410</td>
<td>Penicillins or streptomycins and their derivatives, in dosage</td>
<td>0</td>
<td>12,419</td>
<td>375</td>
</tr>
<tr>
<td>300420</td>
<td>Antibiotics nes, in dosage</td>
<td>0</td>
<td>51,588</td>
<td>1,363</td>
</tr>
<tr>
<td>300431</td>
<td>Insulin, in dosage</td>
<td>0</td>
<td>21,696</td>
<td>89</td>
</tr>
<tr>
<td>300439</td>
<td>Hormones nes, not containing antibiotics, in dosage, o/t contraceptive</td>
<td>0</td>
<td>33,048</td>
<td>174</td>
</tr>
<tr>
<td>300450</td>
<td>Vitamins and their derivatives, in dosage</td>
<td>0</td>
<td>4,506</td>
<td>77</td>
</tr>
<tr>
<td>300490</td>
<td>Medicaments nes, in dosage</td>
<td>230</td>
<td>800,910</td>
<td>10,747</td>
</tr>
</tbody>
</table>

Source: ITC calculations based on COMTRADE statistics
<table>
<thead>
<tr>
<th>Product code</th>
<th>Product label</th>
<th>Pakistan’s exports</th>
<th>Africa’s imports</th>
<th>Pakistan’s exports to Africa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Value US$’000</td>
<td>Qty (Tons)</td>
<td>Value US$’000</td>
<td>Qty (Tons)</td>
</tr>
<tr>
<td>300450</td>
<td>Vitamins and their derivatives, in dosage</td>
<td>2,074 307</td>
<td>126016 10</td>
<td>7926 ALG, NIG FRA, IND</td>
</tr>
<tr>
<td>300230</td>
<td>Vaccines, veterinary use</td>
<td>2,602 302</td>
<td>93029 11</td>
<td>2959 EGY, RSA NL, FRA</td>
</tr>
<tr>
<td>294190</td>
<td>Antibiotics, not formulated, in bulk</td>
<td>77 4</td>
<td>100201 12</td>
<td>1560 EGY, MOR CHN, ITA</td>
</tr>
<tr>
<td>300310</td>
<td>Penicillins or streptomycins and their derivs, formulated in bulk</td>
<td>40 3</td>
<td>100401 36</td>
<td>2092 SDN, RSA FRA, JDN</td>
</tr>
<tr>
<td>300320</td>
<td>Antibiotics nes, formulated, in bulk</td>
<td>46 4</td>
<td>26062 11</td>
<td>0 TZA, SEN USA, IND</td>
</tr>
<tr>
<td>300410</td>
<td>penicillins or streptomycins and their derivs, in dosage</td>
<td>114 24</td>
<td>197030 16</td>
<td>11317 ALF, SDN FRA, IND</td>
</tr>
<tr>
<td>300420</td>
<td>Antibiotics, in dosage</td>
<td>1,745 262</td>
<td>329080 11</td>
<td>12141 SDN, RSA FRA, USA</td>
</tr>
<tr>
<td>3005</td>
<td>Dressing packaged for medical use</td>
<td>9269 3549</td>
<td>87279 15</td>
<td>12766 RSA, ALG CHN, FRA</td>
</tr>
<tr>
<td>300610</td>
<td>Suture laminaria, sterile; haemostatics, sterile, surg/ dentl</td>
<td>7322 2588</td>
<td>60631 11</td>
<td>0 RSA, EGY FRA, UK</td>
</tr>
</tbody>
</table>

Source: ITC calculations based on COMTRADE statistics
Pakistan’s very small position in the South African market is curious. Trade Map allows us to do a bilateral analysis between the two countries for HS30 as shown in table 6.2. We see that in 2005 Pakistan’s pharmaceutical exports to South Africa were a mere US$450,000 whilst Pakistan can supply much more and South Africa has a solid billion dollar demand. Looking at more specific examples, we see for a product like HS 300420 antibiotics in dosage that Pakistan does not supply a single drop of antibiotics to South Africa whilst the country bought US$51.6m worth in 2005 and Pakistan has a proven capacity to export this product.

Returning to current and potential trade between Pakistan and the African continent as a whole, we see for the selected categories in table 6.3 that Africa offers a sizeable market to absorb increases in Pakistani production for export. For these selected categories, Pakistan’s exports are rarely destined for the continents largest buyers of that product category even when Pakistan’s exports of that category are almost entirely destined for Africa.

This brief analysis concentrating on clearly classified products alone already merits further investigation into the feasibility of expansion of production and exploring the African market. This observation is of course limited to an identified trade gap, that could be explained by many reasons but these opportunities cannot be taken lightly.

It is obvious that Pakistan already has a foothold in African pharmaceutical markets through substantial exports. It is also clear however that these exports do not reflect the general profile of African pharmaceutical imports meaning that there may still be lots of hitherto unexploited opportunities for expanding Pakistan’s exports to Africa. It is recommended that the industry form a small ad hoc “think tank team” to identify which product groups would offer the best chances for expanding the exports to which countries. The conclusions from that team should go to the government with the request to concentrate whatever support the government can offer in terms of export promotion to these specific opportunities.

For trade data case stories refer to Annex B.

6.5 The way forward - if we had a million

Here is a list of hands-on projects that could improve the conditions for production and trade in the sector. It is a wish list based on meetings with parties who assisted in the preparation of the study. Most of the project proposals are related to some of the conclusions and suggestions in the study.

All costs are early-stage estimates inserted as magnitudes for the ease of discussion of follow-up from the study. The project proposals are independent of each other (unless otherwise indicated) and are listed in no order of priority.

The study does not speculate on possible funding for the implementation of the projects proposed. Funding could be from the Government of Pakistan, a trade promotion organisation, the sector associations and their members, an external donor or in some cases from self-generated funds (selling services).

6.5.1 Pharmaceutical information bureau

The pharmaceutical industry in Pakistan would benefit from an easily accessible common centre of information. A Pharmaceutical Information Bureau would remedy this shortcoming
as a neutral, continuously updated source of useful information available to all parties in the sector in Pakistan.

**Proposal in detail**

A databank of useful addresses, procedures, events etc.

Collecting and disseminating information to pharmaceutical companies (by way of examples):

- Laboratories for Bio-Equivalence and Bio-Availability studies
- Government agencies regulating the business
  - Ministry of Health: registration, regulation of pharmaceutical promotion
  - Ministry of Labour: regulations on employment, work safety, hiring and firing
  - Ministry of Economy: incentives, international agreements
- Agencies for quality certification
- Shippers, forwarders, customs agents
- Agencies for marketing and sales training: An estimate of cost
- Roster with trustworthy consultants
- Early warning of fairs and events
- Suppliers of:
  - Active principle ingredients,
  - Intermediates,
  - Natural products,
  - Finished formulations and raw materials
  - Packaging materials
  - Machinery
- Purchasing procedures of UN agencies (IAPSO) and important NGOs (IFCR - MSF).
- Import promotion fairs (type: CBI of the Netherlands and SIPPO or Switzerland).
- ITC Buyers-Sellers meetings.
- Latest on WTO issues relevant for the pharmaceutical industry in Pakistan

**Parties**

Initiative and responsible for organising and control:
- PPMA and Pharmaceutical Bureau.

Execution:
1. One senior secretary familiar with the pharmaceutical sector in Pakistan.
2. Ad hoc support/advice/guidance from professionals in the industry (at no cost).

**Needs**

1. One office room with furniture, phone etc.
2. One laptop with Internet connection etc.
3. Some subscriptions (e.g. KOMPASS for suppliers, the official gazette, ITC publications)
4. Up-front publicity (folders, presentations)

**Costs**

Salary, rental, equipment, communication expenses, ad hoc domestic travel costs, printing, insurance etc.

1. Establishment (only): US$20,000
2. Establishment ($20,000) + Year 1 ($20,000) US$40,000
3. Establishment + Years 1, 2, 3 and 4 ($20,000 pa) US$100,000

A subscription/fee arrangement could be considered if experience is positive after the first few years or payments for special requests and services.
Similar projects
SERCOTEC, Chile with the help of Carl Duisberg Gesellschaf, Germany, ILO and UNIZO of Flanders.
ITC Buyers-Sellers meetings on personal products in Nairobi, Dakar and Pretoria.

6.5.2 An early warning system

The pharmaceutical industry in Pakistan would benefit from an easily accessible common centre of information. An early warning system would remedy this shortcoming as a neutral, continuously updated source of useful information available to all parties in the sector in Pakistan. The system would also actively investigate risks and opportunities for the industry. It would on its own initiative contact individual producers with warnings and suggestions.

Proposal in detail
1. An early warning system on issues affecting the pharmaceutical industry in Pakistan. Market and product information
2. Trade flows, which countries need which products: opportunity for export.
3. Trade flows, which countries have excess capacity for which products: opportunity for import.
4. Identifying ‘medium tier’ companies: opportunity for in-licensing or for distribution.

Legal information
3. Providing standard agreements for MOU, licences, distribution and joint ventures
4. Providing explanation and cover for the correct use of INCOTREMS.
5. Latest information on WTO issues relevant for the pharmaceutical industry in Pakistan.

Parties
Initiative and responsible for organising and control:
- PPMA and Pharmaceutical Bureau.

Execution:
1. Two professionals, preferably (but not necessarily) with experience from the sector:
2. One commercial executive: e.g. MBA or master in Applied Economics or Marketing.
3. One lawyer conversant with international law.

Needs
1. Two office rooms with furniture, phone, etc.
2. Two laptops with Internet connection, etc.
3. Some subscriptions (e.g. IMS, SCRP, ITC publications, classical business papers)
4. Up-front publicity (folders, presentations)
Costs

Salary, rental, equipment, subscriptions, communication expenses, travel costs, printing, insurance etc.

1. Establishment (only): US$50,000
2. Establishment ($50,000) + 6 months operation ($50,000) US$100,000
3. Establishment ($50,000) + Years 1 and 2 ($100,000 pa) US$250,000

A subscription/fee arrangement could be considered if experience is positive after the first few years or payments for special requests and services.

Similar projects

Every multinational pharmaceutical company organises the collection and dissemination of this kind of information throughout the organisation on one way or the other.

6.5.3 Proposal for a Bio-equivalence/Bio-availability laboratory

The pharmaceutical industry in Pakistan would benefit from a Bio-Equivalence/Bio-Availability laboratory. Such a facility would remedy this shortcoming, as this is now a perquisite to gain registrations in most international markets. The industry is currently relying on getting these studies conducted in other countries at a considerable cost in terms of finance and time.

Proposal in detail

Set up a free standing facility - approved by WHO. This would include the right skills, equipment and validation processes.

Parties

MoH initiative and responsible for organising and control:
- PPMA and Pharmaceutical Bureau as stakeholders.

Execution:

1. Two professionals, preferably with experience from the sector
2. Two bio technicians/analysts
3. One commercial executive: e.g. MBA or MA in Applied Economics or Marketing.

Needs

1. Fully equipped lab
2. Two office rooms with furniture, phone, etc.
3. Two laptops with Internet connection, etc.
4. Some subscriptions and technical reference books
5. Up-front publicity (folders, presentations)

Costs

1. Set up US$5,000,000
2. Annual running costs US$500,000
3. Establishment ($50,000) + Years 1 and 2 ($100,000 pa) US$250,000

Investment and running costs can be recovered from proceeds, including from orders from other countries.

Initial set up costs from donors and the research fund maintained by MoH.
6.5.4 A quality label for the Pakistani pharmaceutical industry

Estimated costs
1. Creation and promotion of label by advertising company  US$100,000
2. Inspection costs for awarding the label  US$50,000

6.5.5 A scientific award for R&D of natural medicines in Pakistan

Estimated costs
Award and costs related to ceremony and news coverage  US$20,000

6.5.6 Sponsoring R&D for natural medicines via doctorates

Estimated costs
Annual salary and laboratory expenses for 5 researchers  US$500,000

6.5.7 Annual ‘Pakistani pharmaceutical industry fair’

Estimated costs
Organising and promoting the fair  US$500,000
# Annexes

## Annex A — Production processes for various dosage forms

<table>
<thead>
<tr>
<th>Asr. #</th>
<th>Dosage form</th>
<th>Process No. 1</th>
<th>Process No. 2</th>
<th>Process No. 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tablet</td>
<td>Mixing</td>
<td>Granulation and compression</td>
<td>Primary packing in blister packing and vial filling secondary packing cartons</td>
</tr>
<tr>
<td>2</td>
<td>Syrup</td>
<td>Heating</td>
<td>Mixing</td>
<td>Primary packing in bottles and secondary packing in cartons</td>
</tr>
<tr>
<td>3</td>
<td>Capsule</td>
<td>Issuance of materials</td>
<td>Dry mixing</td>
<td>Primary filing in capsules and secondary packing in cartons</td>
</tr>
<tr>
<td>4</td>
<td>Sachets</td>
<td>Issuance of materials</td>
<td>Dry mixing</td>
<td>Primary packing in sachet and secondary packing in cartons</td>
</tr>
<tr>
<td>5</td>
<td>Creams/ointments</td>
<td>Heating</td>
<td>Mixing</td>
<td>Primary packing in tubes and secondary packing in cartons</td>
</tr>
<tr>
<td>6</td>
<td>Gels</td>
<td>Issuance of materials</td>
<td>Mixing</td>
<td>Primary packing in tubes and secondary packing in cartons</td>
</tr>
<tr>
<td>7</td>
<td>Eye/ear drops</td>
<td>Heating</td>
<td>Mixing</td>
<td>Primary packing in vial and secondary packing in cartons</td>
</tr>
<tr>
<td>8</td>
<td>Inhaler</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Injections (powder)</td>
<td>Issuance of materials</td>
<td></td>
<td>Primary packing in vial and secondary packing in cartons</td>
</tr>
<tr>
<td>10</td>
<td>Injections (liquid)</td>
<td>Issuance of materials</td>
<td>Preparation of formulation</td>
<td>Primary packing in ampoules/protective packaging and secondary in cartons</td>
</tr>
<tr>
<td>11</td>
<td>Enema</td>
<td>Heating</td>
<td>Mixing</td>
<td>Primary packing in bottles and secondary packing in cartons</td>
</tr>
<tr>
<td>12</td>
<td>Dry suspension</td>
<td>Issuance of materials</td>
<td>Dry mixing</td>
<td>Primary packing in bottles and secondary packing cartons</td>
</tr>
<tr>
<td>13</td>
<td>Infusion</td>
<td>Issuance of materials</td>
<td>Preparation of formulation</td>
<td>Primary packing in glass, plastic dispensers/protective packaging and secondary in cartons</td>
</tr>
<tr>
<td>14</td>
<td>Suppositories</td>
<td>Issuance of materials</td>
<td>Preparation of formulation</td>
<td>Formation/ Protective packaging and secondary in cartons</td>
</tr>
</tbody>
</table>
Annex B — Trade data case stories

**Antibiotics**

Antibiotics fall under various categories in the international trade classification. Excluding penicillins and streptomycins, the following categories represent antibiotics:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>294190</td>
<td>Antibiotics in bulk</td>
</tr>
<tr>
<td>300320</td>
<td>Antibiotics formulated in bulk</td>
</tr>
<tr>
<td>300420</td>
<td>Antibiotics in dosage</td>
</tr>
</tbody>
</table>

Pakistan has records of exports of all of these categories, but the main form of export is in dosage (HS300420). Exports in 2005 amounted to US$1.7 million or 262 tons, a small piece of the pie considering world imports of antibiotics in dosage were worth US$10 billion. Most of Pakistan’s exports went to Asia – Singapore, Afghanistan, Philippines and Sri Lanka – and also to various other African countries. On average, the FOB return on these exports US$6,600 per ton. There is considerable variation per country with the highest return from exports to the Philippines at US$10,000 per ton.

TradeMap identifies untapped markets – Belgium, Canada, France, Germany, Italy, Netherlands, Spain, and Switzerland. These are all markets of significant size having at least 3% share of world imports that are currently not being supplied by Pakistan. However, Pakistani exporters may not be seeking the largest markets especially if they are highly regulated. He or she may wish to explore other smaller markets showing high growth rates, such as Tanzania, Cote d’Ivoire and Ghana. Imports of pharmaceuticals in these countries need to be analysed with care, as the imports can be aid or relief related destined for the country itself or a neighbouring country in crisis. For example, 87% of Tanzania’s imports in 2005 were from USA, while in 2004 imports from USA were a mere 4%. This would suggest that the imports in 2005 were tied to an aid programme of USA.

**Dental cement and fillings**

The market for dental cements and fillings (HS 300640) looks bright: around US$1 billion worth is imported around the world and this figure is currently growing at a rate of 14% per year. Markets are very concentrated around North American and Europe. The major buyers are USA and Germany, making up 17% and 11% of world imports, respectively. Medium sized markets include other European countries, Japan, Republic of Korea and Australia. People in emerging markets, like Russian Federation, Mexico, and Ukraine, also seem to be taking dental care more seriously and are these countries are becoming markets over the US$10 million mark.

Like international demand, supply is also very concentrated in the West. The largest developing country supplier, China, only has a 1% share of total world exports. However, it is making headway and gaining market share along with South Africa, Brazil and India. The international trade classification of this product leaves something to be desired as we see that the major buyers are each other’s major supplier (e.g. Germany has 24% share of USA’s
imports and USA has 16% market share of Germany’s imports.) The countries would less likely be buying and selling the same product from each other (although this is not impossible) but rather one is likely to be supplying cements and the other fillings, for example.

Pakistan currently exports 6 tons of dental cement and fillings worth a FOB value of US$137,000. This is a very small amount from a global perspective, compared for example to the thousands of tons that Germany and USA export. Nevertheless, there is ample room for expansion. Interestingly 46% of Pakistan’s exports went to Ecuador, a market well identified by the Pakistani exporters, showing growing demand reflected by 26% annual average growth over 2001-05. Similar cases could be explored in other fast growing markets, such as Turkey (34%), Romania (31%), and Lebanon (40%).

Governments do not seem to want to restrict the trade of this product, as most markets do not apply any tariff duty. Therefore, this is one less headache for Pakistani exporters.
European Commission (EC) Trade-Related Technical Assistance Programme (TRTA) for Pakistan

The European Commission Trade Related Technical Assistance Programme for Pakistan commenced in September 2004 with the objective of assisting Pakistan to foster its integration into the world economy and, ultimately, to contribute to poverty alleviation through the achievement of trade-related conditions for sustained and stable economic growth.

The programme is designed to enhance awareness among government officials, the business sector and civil society about the implications of World Trade Organisation (WTO) Agreements on the economy of the country, and to assist Pakistan in building the necessary capacity to address issues resulting from its participation in the WTO.

The programme has three components:

**Component 1 – implemented by ITC** – focuses on creating awareness and building the necessary capacity for Pakistan to benefit fully from its participation in the WTO Agreements.

**Component 2 – implemented by the United Nations Industrial Development Office (UNIDO)** – focuses on improving the quality, standards, metrology and accreditation systems in the country. This will enable Pakistan to address challenges and requirements brought by WTO Agreements in this field, as well as to increase the competitiveness of Pakistan’s export industry.

**Component 3 – implemented by the World Intellectual Property Organisation (WIPO)** – focuses on strengthening the intellectual property (IP) system in Pakistan and enhancing Pakistan’s capacity to use the IP system for developmental goals, where necessary by examining international obligations in the IP field.

The expected results of the programme are as follows:

- Pakistan's officials, business sector and civil society organisations are more aware and knowledgeable about WTO issues, and able to take full advantage of rational WTO trade policies.
- The Ministry of Commerce, and other government departments and institutions involved in WTO negotiations, are more able to formulate trade policy and actively participate in multilateral trade negotiations.
- Dialogue is strengthened between government services, the business sector and civil society on WTO negotiations and other trade matters.
- A full assessment is made of the constraints faced by Pakistan’s exporters in relation to technical barriers to trade (TBTs) and sanitary and phytosanitary standards (SPS).
- Pakistan’s export industry is more able to comply with standards and certificate requirements, because of improved accreditation and conformity assessment processes, and metrology and testing laboratory services.
- Policy formulation, administration and enforcement of intellectual property rights (IPR) are improved, by modernising the IPR legislation, creating more awareness of the role of IPR for economic growth and trade development, and supporting the establishment of a Pakistan IPR organisation.

For further information and contact details, visit: [www.accesspakistan.org](http://www.accesspakistan.org)