PAKISTANI PHARMACEUTICAL INDUSTRY IN WTO REGIME- ISSUES AND PROSPECTS

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ABSTRACT

As a developing country Pakistan faces high challenges in health sector. Much of these challenges have emanated from the implementation of new WTO regime. Major health indicators compared with neighboring countries indicate that existing situation is worst (Table 4, Page 25) and has to be improved immediately. In addition Pakistan has to maintain a balance between its obligations as a signatory of World Trade Organization (WTO) and to provide essential protection to its local pharmaceutical manufacturers and patients. With in the framework of WTO, CL and Parallel import are important options for PPI and the Government against exploitive or anti competitive practices. The new regime may rejuvenate the dormant PPI and academic institutions by creating opportunity for Research & Development and facilitating transfer of technology. Manufacturing of off patented medicines is the strength of PPI and needs to be fortified in the new regime. This paper highlights some of the challenges and the opportunities for all stakeholders in the framework of WTO.

ABBREVIATIONS:

CL: Compulsory Licensing

CME: Continuing Medical Education

EMRs: Exclusive Marketing Rights

FJVs: Foreign Joint Ventures

IPRs: Intellectual Property Rights

LDCs: Least Developed Countries

MNCs: Multi National Companies

PPEA: Pakistan Pharmaceutical Exporters Association

PPI: Pakistani Pharmaceutical Industry

TRIPS: Trade Related Aspects of Intellectual Property Rights

UNCTAD: United Nations Commission for Trade and Development

USTRO: United States Trade Representative Office

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

1. INTRODUCTION:

In an era of cost containment and managed care, Pharmacoeconomics and outcomes research are increasingly used in both public and private sectors to improve the allocation of healthcare and pharmaceutical resources. While this trend has been well observed in developed nations, little is known about its status in developing countries (Liu 2003). The changing healthcare environment has presented new challenges to the pharmaceutical industry. Businesses have had to adapt to contend with new demands from their buyers while still striving to meet financial targets. Strategic plans need to take account of future developments as reorganised health systems evolve. (Anne et al 2005). Because of poor socio-economic situation of the country, the debate of WTO in Pakistani pharmaceutical sector has vital importance. WTO regime is today's ground reality so we must look to enhance the competitive advantage of Pakistani pharmaceutical business in WTO framework.

Looking at the history of pharmaceutical industry of Pakistan, it is obvious that the industry has passed through 03 main phases. First phase is from 1948 to 1971. After independence, Pakistan had no pharmaceutical industry and traders primarily based in India were importing most of the medicines. Recognizing the importance of this industry, the Government of Pakistan established two pharmaceutical units named "Khurram Chemicals limited" (near Islamabad) and "Antibiotics Private Limited" (in Mianwali) through the Pakistan Industrial Development Board (PIDB). The growth of pharmaceutical industry started from 1948 and continued till 1971. At that time, due to the conducive policy and the right entrepreneurial spirit, the pharmaceutical industry reached its peak and had a leadership position in Asia.

In the second phase (1972 to 1991) due to the discriminatory and restrictive registration policy (Drug Generic Act, 1972), national companies suffered a lot so that earlier created export markets were lost. In addition to that, completely manufactured drugs and medicines were imported largely with the permission of the government, which resulted in large scale flooding of imported drugs. Third Phase, is from 1991 to now. In this period, the government followed a policy of de-regulation in prices that resulted in free play where the national companies could fix the same price as multinational companies. Due to this policy

framework, the market share of national companies grew as compared to multinational companies. The national companies grew in size and also exploited possibilities in other regions (UNCTAD / WTO 2004).

Global sale of pharmaceuticals is US$317.2 billion and Pakistan's share in world pharmaceutical market is 0.31% only (Source: EPB). The PPI has flourished with the passage of time. Currently there are 379 companies (29 MNC's, 350 local) having valid drug manufacturing licenses. The share of top 50 players (29 MNC's and 21 local) is 83.74% of the total market volume (IMS data September 2004) and among top thirty players only twelve are local (Annexure 1).

National companies run their business mainly due to lower prices of medicines and by winning tenders and contracts for supplies of medicines to government institutes. Large companies mostly MNC's brag of their high quality medicines and run their business by the marketing strategy influencing the prescribing pattern of physicians in their favor through the use of incentives and other pay offs.

The price difference, of medicines of same active ingredient, among national and MNC's is significant and is sometimes manifold. The share of MNC's has gone down from 65% in 1992, to 55% in 2002. (Maqsood 2003).

National pharmaceutical companies manufacture mainly off patented medicines. The low prices of national pharmaceutical companies make them a prospective candidate in increasing the export of medicines in the new free trade regime. Currently the domestic pharmaceutical industry is operating with low production volumes, outdated and obsolete machinery and quality standards that are not comparable with that of MNC's. This bitter fact can effectively nullify the low priced advantageous effect of national companies.

In US and some parts of Europe, the pharmacists are authorised to dispense generic drugs in the place of prescription drugs, which will cost less than the prescription drug. Thus, the consumers have the option to choose between the generic and the branded drug. However, if the doctor writes it as "dispense as written" then the pharmacist cannot change the drug (Lalitha 2002). Thus, physician and governmental policies will play an important role in the selection of medicines in the post WTO regime.

Future growth in this sector depends on global business framework in addition to the domestic market. Innovation of Pharmaceutical processes is a long and time-

consuming process as compared to the much rapid speed of technology obsolescence. The future of the Pharmaceutical Industry lies with the genetically engineered medicines. Recombinant DNA technology & its improved descendants will also play an important role in tomorrow's medicines. The current, rather crude methods of deciding dosage based on your weight and age will be replaced by more sophisticated ways to tailor a drug regime to your genetically determined ability to process medicines (CME).

Unfortunately there is no infra structure for the biotechnology in Pakistan. Most of the biotech medicines are manufactured and marketed by MNC's. Situation is also quite pathetic at the educational institutions level. The advancement in biotechnology is not possible overnight, it takes decades to build an infra structure. So MNC's will enjoy their monopoly in the biotech medicines in the post WTO regime whereas local companies will try to secure their wicket by providing low priced off patented medicines. This is the broad scenario where PPI will operate in the post WTO regime.

This paper presents the various strategies to counter the pathetic situation in the context of WTO agreement.

2. ISSUES AND PROSPECTS

There is a genuine concern among many quarters that Pakistan Pharmaceutical Industry will not be able to compete with the giant sized well established competitors of China and India because they possess economies of scale, are endowed with superior technological and human resources.

Factors limiting the production output like inconsistent policy, lack of funds for upgrading the plants, high duties in formulation industry, poor policy framework, lack of research and development facilities, unavailability of sophisticated machinery , high costs of inputs, discriminatory policies and stringent price control are the generic factors which contribute to the poor performance of manufacturing in all sectors in Pakistan so the emphasis in this paper is mainly on TRIPS regulations and export opportunities

Among the various property rights systems, patents concerning pharmaceutical innovations, are one of the most widely and passionately debated issues all over the world, for their positive and negative impacts on welfare. (Lalitha, 2005).

One-third of the world's population lacks access to the most basic essential drugs. For the destitute sick in the developing world, the price of medicines can determine whether they will be treated. Patents drive drug prices up, the resultant monopoly status allowing the producer to charge whatever price the market will bear (Ford 2004). Drugs need to be provided for many people in the developing world but, on the other hand, adequate compensation needs to be given to pharmaceutical companies producing the medicine (Kobori 2002).

During the 1980s, the gradual erosion of the developed countries' supremacy in manufacturing and technology, due to the rise of the Asian countries as Competitors, was a cause for concern. The industrial lobbies convinced developed-country governments on the need to link trade with IPRs, in order to prevent imitation and to increase returns on research and development. Monopoly rights granted by IPRs were regarded as crucial to prevent the developing countries from further undergoing the "catching-up" process towards industrialization based on imitating and copying technologies, as the developed countries themselves had done. In other words, IPR protection was a tool to guarantee the comparative advantage that had so far ensured the developed countries' technological supremacy. Prior to the negotiation of the TRIPS agreement, over 50 countries (including developed countries) did not confer patent protection on pharmaceuticals. Many developing countries regarded the absence of protection as necessary to promote access to drugs at competitive prices. Implementation of the TRIPS Agreement may lead to high drug prices, low access and a weakening of national pharmaceutical industries (Cecilia 2000).

Pakistan being a member of WTO and WIPO is bound to conform its IPR laws in accordance with the requirements of TRIPS agreement. Before the agreement Pakistan had the following set of IP laws:

I) Merchandise Marks Act 1889.

ii) Patents & Designs Act, 1911.

iii) Trademarks Act.1940.

iv) Copyright ordinance, 1962.

v) Pakistan Panel Code, and

vi) Customs Act, 1969.

In order to fulfill our international obligations and to make our IP laws TRIPS compliant, the following new IPR laws have been promulgated as presidential

ordinances, which incorporate there in requisite amendments in the light of TRIPS agreement:

I) Copyright Amendment Ordinance, 2000.

ii) Registration of layout Designs of integrated Circuits Ordinance, 2000.

iii) Industrial Designs Ordinance, 2000.

iv) Patents Ordinance, 2000.

v) The trade marks ordinance, 2001.

Though the above ordinances have been promulgated but subordinate legislation in the shape of procedural rules, which can ensure effective implementation is still underway (Shafique, 2005).

Pakistan has been on the "Special 301" Watch List since 1989 due to widespread piracy, especially of copyrighted materials, and failure to implement its patent mailbox obligations under the TRIPS Agreement (United States Trade Representative Office, 2004). Violations of IPRs are one of negative impact on Pakistan's investment climate. The government has to provide better protection for IPRs by ensuring effective implementation of Patent Ordinance 2000.Under this law both the patent-owner and licensees can file a suit against an infringer. In 2003, Pakistan remained the fourth largest source of counterfeit and piratical goods seized by the U.S. Customs and Border Protection. The vast majority of these goods were either apparel or pharmaceuticals with counterfeit trademarks or, optical media products (USTR 2004)

In the new WTO regime, patent period has) been extended to twenty years and the scope of patent is extended to both products and processes (As per article 27 of TRIPS-Patentable subject matter). The extension in the patent period will fortify the monopoly of MNC’s because they will be producing these medicines without any competition. Since PPI is dependent mainly on the manufacture of off patented medicines, extension in the patent period and strict implementation of IPRs will decrease the number of options the domestic firms may go for. Furthermore they will have to wait longer before the raw materials appear in the market. This fortified monopoly will increase the prices of medicines to an extent where they will be inaccessible to common man.

Govt. of Pakistan can tackle this problem in any of the following ways.

Firstly by using CL option. According to the TRIPS regulations if a company fails to supply the medicines consistently or adopts anti competitive practices, then

government can grant CL to any third party without the consent of patent holder. Other reasons for granting the CL include emergency or unsuccessful negotiation to get the license for patented product. Going for this option is associated with paying some compensation to the patent holder; the compensation is decided by the government and the patent holder. Another stipulation in this regard is; person or company applying for a CL must have first attempted unsuccessfully to obtain a voluntary license from the right holder on reasonable commercial terms (article 31-b). However in case of national emergencies this clause can be safely bypassed. So national companies should keep themselves prepared for this option, if MNC's go for exploitive or anti competitive practices.

Developed countries have frequently used this option. On September 21, 2004, Government of Zambia issued a CL to allow for the local manufacture of antiretroviral medicines (lamivudine, stavudine and nevirapine) after declaring AIDS epidemic a national emergency (cptech). Therefore CL remains a live option for the government and national pharmaceutical industry in case of any malpractice or inability of MNC's to sufficiently produce any medicine.

Second option the government may use is parallel import, if a medicine is unavailable or available at a high price. When a company puts its product in the market; its rights of patents are lost. This is known as principle of exhaustion of rights. TRIPS leave the decision of exhaustion of rights to national laws so if any unscrupulous patent owner stops or limits the supply of medicine to any country, government can go for parallel import.

Although CL and parallel import are effective tools against exploitive practices of MNC's, but in fact it is not as easy as it looks like. The experience of CL and parallel import in the third world countries has been disappointing. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) opposes Compulsory Licensing, arguing that it would constrict incentives for research and development and slow down the research for new and better drugs. (Devraj Ranjit, 2001).

In South Africa efforts against AIDS were severely hampered by the political influence of MNC's and of USA. When the South African government opted for CL and parallel import to get access to cheaper AIDS medicines, South African government faced constant threats of trade sanctions from the USA (Oxfam 2001). When the South African Government sought to enact the medicines and

related substances control bill, the US government accused it of failing to adequately protect American drug patents. The US objection was directed at provisions in the law, which would allow for CL and parallel import. Despite the considerable pressure exerted on the government and parliament of South Africa, the bill was passed in 1997. It was only after intense campaigning by AIDS and health activists, successfully embarrassing then US presidential candidate Al Gore and marring his campaign efforts, that the US retreated from its position and eventually reached a resolution of the matter

(Cecilia 2000). Although South Africa resisted the pressure of MNC's and USA, many developing countries like Pakistan may not be able to resist due to fear of trade sanctions.

Kenya is another unfortunate example. In Kenya, one quarter of the adult population is HIV positive but fewer than 2% receive anti retroviral treatment. If Kenya could import medicines (Fluconazole) from the Thailand, it would reduce the cost of treatment from the $3000 to $104. But patent holder, the Pfizer Corporation, applied pressure to stop the import of cheaper medicines.

Similarly Glaxo Smith Kline challenged the import of its patented antiretroviral medicines to Ghana and Uganda from other countries. (Oxfam 2001)

A report from the Medicins Sans Frontiers (1999) says that US government put pressure on Thailand government to restrict the use of CL and parallel import. Thai government under a threat of high tariff on import of wood and jewelry passed a ministerial regulation in1998 to restrict the use of CL.

In Pakistan it is estimated that 70,000 to 80,000 persons, or 0.1 percent of the adult population is infected with the HIV virus, according to UNAIDS. However, by the end of December 2003, only 1,951 HIV-positive and 246 AIDS cases had been reported to the government's National AIDS Control Program (World Bank, 2004) and one year's worth of the standard treatment of anti-retroviral drugs costs between US$4000 - 6000. This puts it out of the reach of most of people in the developing world, where most HIV infections are recorded (Cecilia 2000). It is estimated that only when the average price of antiretroviral drugs is reduced by 95% or more will they be affordable to all those who need them (Panos 2000).

It is evident from the above examples that CL and parallel import may not be an easy option for many of the developing countries including Pakistan.

Another important aspect of TRIPS that might affect healthcare setup in the post WTO regime is EMR. Patents are country specific, if a medicine is patented in one country; separate application is required to get patent in other. EMR allows a patent holder to sell medicine in other country (where it is not patented) for a period of five years or till the patent is granted or refused which one achieved earlier. So a product that is under process for the grant or refusal of patent will enjoy status of a patented medicine. Many medicines patented in other countries can gain entry in Pakistan using this route and will be enjoying a "Safeguarded status". This problem can best be tackled by expediting the patent process. According to Pakistan Patent Ordinance 2000, the patent grant or refusal decision must be made with in eighteen months of filing the application.

2.1 STAGNANT DIRECT INVESTMENT

Pakistan's ranking according to the United Nations Commission for Trade and Development (UNCTAD 2004) foreign direct investment potential index is 128th. Political instability, lack of consistency of policies and poor law and order situation like other sectors has significantly reduced investment in pharmaceutical sector. Despite several trade liberalization measures like decontrolling the prices of several categories of drugs, opening up the sector for competition etc yet there is no significant increase in direct investment in this sector in recent years. Table 1(page 20), Figure 1 (page 21) indicates the investment increase in pharmaceutical sector in last 6 years.

3. OPPORTUNITIES:

Maximum benefits can be reaped if low priced medicines are made available to the customers. This is the safe way to survive in a highly competitive regime. Although India and China may give a tough time, nevertheless manufacturing of low priced medicines remains an important option for many of the domestic manufactures. Pharmaceutical industry must keep itself ready to take on the medicines whose patents are going to be expired sooner. With the expiry of patents, many of the raw materials will be available in open market. Even if no voice is raised at the consumer end, national companies must proactively campaign for CL of high priced MNCs products.

In fact high prices of branded medicines always provide a solid ground for the campaign of CL. There may be reasons other than the high prices as well. According to the Doha Declaration; each member has the right to determine ground for CL. Each country also has the right to determine what constitutes national emergency.

The costs associated with improving quality are of two types. First the cost which are due to improvement in design and feature of product and secondly those costs which are associated with reduction in waste. The former type of cost increases while later type of cost decreases in an attempt to improve the quality (Juran 1998).

National companies must go for high quality standards since it is a matter of survival and to stand firm in the cut throat competition. There are two different types of drug markets. Some diseases are prevalent worldwide, while others are confined to the poor countries and so is the R&D pattern. Western companies spend more on the R&D of diseases that are prevalent globally in both rich and poor countries without taking into consideration the diseases of poor counties. They are spending more on AIDS, breast cancer, leukemia, cardiovascular diseases, prostate cancer, ovarian cancer and other types of cancer without paying any attention to the malaria, chaga's disease, lymphatic Filariasis and Leishmaniasis which are typical to the poor countries. A 1996 World Health Organization (WHO) report says that of the $56 billion spent on health-related research and development worldwide, only 0.2 percent is spent on Pneumonia, Diarrhoeal diseases and Tuberculosis – which together represent 18 % of the global disease burden (Lalitha 2002). In Pakistan infectious and Childhood diseases are responsible for 2/3rd of burden of disease (Table 2 page22**)**.

The new regime may draw resources into the creation of drugs to prevent and treat diseases specific to the poor countries (Lanjouw 2001). An effective patent system will help in complete reimbursement of costs incurred in R&D of diseases specific to poor countries. If the markets of developing countries are not very lucrative, dedicated funds and/or subsidized purchases of specified products could be used to promote R&D in these areas. Such projects may stimulate the R&D efforts going at the level of developing countries like Pakistan. There will also be a chance for the PPI and the academic institutes to avail from R&D boost that will be induced in this region.

One of the possible outcomes of the new TRIPS regime is transfer of technology, from the rich countries to Pakistan. The argument in its favor is that since strong protection to patents will be available; so rich countries won't hesitate to introduce their technology in Pakistan. In the past, weak patent system has been the largest deterrent in the transfer of technology from rich countries to the poor countries. Article 7 of TRIPS declares that IPRs should be used for mutual benefit of producers and users and in a manner that would promote technological knowledge dissemination and social and economic welfare. Article 8 of TRIPS permits WTO members to induce suitable changes in their laws against the anti-competitive practices, which discourage transfer of technology or make prices of medicines inaccessible.

Another emerging concept in pharmaceutical manufacturing is contract manufacturing. Contract manufacturing costs cheaper since it decreases overheads and the costs associated with fixed assets. Globally the trend of contract manufacturing has increased during last few years. Local companies may work as subsidiaries of MNC's as a large number of these have yet to appear in Pakistan. Table 5 (Page 26) shows a list of world's top thirty pharmaceutical companies. Although a list of only thirty, yet it contains many unfamiliar names. In nutshell, there are many companies, which are yet to be attracted.

China is the most aggressive player among the Developing Countries to penetrate global markets and become the fifth largest exporter of the world. Our share in China's market is less than 0.2 percent. As close ally and friend there is no reason as to why we cannot increase this share.

China is encouraging foreign direct investment and Joint Ventures for establishing a commercial presence. The direct import content of exports by FJV's in China is high (Hussain 2003). The ownership structure of these enterprises and the high import content of their manufacturing have contributed significantly to strengthening the trade links between China and the East Asian economies. Foreign direct investment (FDI) from investors in East Asia uses China as an export platform for the western markets and that their home countries provide the inputs needed in such operations. Pakistan Pharmaceutical companies can create a window of opportunity by establishing joint ventures with these Chinese enterprises.

3.1 EXPORTS

Out of 350 local pharmaceutical manufacturers only 35 are EPB registered exporter (Annexure 2). The total export volume of Pakistan for the fiscal year 2003-2004 was $12.1 billion. The share of Pharmaceutical exports in this total export volume is only $50.46 million (4.16%). Table 3 (page 23) and Figure 2 (page 24) describes the pharmaceutical export volume of Pakistan during the fiscal year 1997-2004. Recent trend in pharmaceutical exports is positive. In recent 4 years the net increase is 24.17% which is significant. Keeping in view of this pace and improvement in quality of products, export promotion bureau government of Pakistan and PPEA must focus on the new markets especially the potential market of LDC's. France is a dominant player in the later markets. Following Trade barriers have to be kept in mind during this export enhance drive Each country's government strictly monitors pharmaceutical products. Testing, quality checks, authorization are required before selling pharmaceuticals in these countries.

All countries are engaged in some kind of bilateral treaty with other countries.

Relatively developed African countries like, South Africa, Tunisia, Morocco, etc take the advantage of selling their medicines in these countries. Due to Free Trade Agreement with EU (in most cases effective from later this decade). European countries will be able to sell their products without facing any tariff in some countries.

Following are the suggestions to counter these barriers

Looking at the disease profile in these countries, Pakistani companies may give stress on selling specific medicines in specific market. For example selling tetanus vaccine in Gabon, South Africa, Tanzania, etc. Medicines for Anemia might have a market in Tanzania, Morocco, Algeria, Cameroon, etc. In Tanzania child malnutrition is highest followed by Ivory Coast Cameroon etc. These countries may need medicines for child health care. Countries like Zimbabwe, South Africa, Tanzania, Ivory Coast have highest incidence of TB and thus have a market for TB medicines (FICCI 2004)

Earlier this year a group of local drug makers put forward a plan, entitled PharmaVision 2010, to the export promotion bureau, which sought to increase domestic pharmaceutical exports to $1bn by 2010. (drugResearcher.com)

3.2 INDUSTRY – ACADEMIA COOPERATION

The universities of Pakistan were established by the colonial British government in 1858 so as to produce educated Indians to serve in the expanding bureaucracy. As government and security were the major concerns of the colonial government they made the bureaucracy and the military prestigious and efficient institutions while higher education remained subordinate, government-controlled and poor. Being unattractive, the universities could not attract the most competent students and remained medieval teaching institutions with almost no research. (Rahman 1998). Pakistan has a low proportion of well-trained University graduates and even a lower proportion of technician per million populations relative to neighboring giants as China and India. There are 10 academic institutions recognized by Pakistan Pharmacy Council for Pharmacy education in Pakistan and at present the academia-pharmaceutical industry collaboration is at its inchoate stages in Pakistan. None of the pharmacy educational institutes has ever filed any patent application in Pakistan. Increased collaboration between academia and pharmaceutical industry may play a synergistic role for both parties.

Management and organizational issues have mark able impact on academia-university Collaboration and unfortunately the expectations and objectives of the people working in academia and industry are not aligned.

Disincentives for academics to undertake academia-industry collaboration includes the lack of recognition given to such activities and some times such collaborations are not likely to yield significant publication data. Industrial partners complain about the ‘unbusiness-like approach’ of people working in universities. It is bitter reality that in most of the collaboration efforts, universities have difficulty in meeting the timelines agreed. Industry and university partners must be sufficiently flexible as university regulations and corporate priorities and procedure can have a restrictive influence on collaborations. The key individuals need to have the freedom to take the necessary risks and bold decisions so that the collaboration objectives may be achieved.

Industry must respond to the uncertainties regarding the supply of pharmacy graduates by taking a more active role in universities, contributing to the design of relevant courses by influencing the course content, in this manner the industry

can ensure that students are equipped with skills that meet their requirements. Furthermore, the positive presence of the company within the university, coupled with direct links made with students, enhances the company's ability to recruit high caliber graduates.

4. CONCLUSION

After implementation of WTO regime since Jan 1st 2005, poor countries like Pakistan have to look out of local healthcare needs and their obligations as the signatory of the WTO. The WTO regime may fortify the monopolies of MNCs and make the access of medicines difficult to the poor patients; governments can tackle such problems by using CL and parallel import. On one hand PPI needs to strengthen it's ever strong point of "low priced medicines" and on the other hand it could draw more technology, research & development and foreign direct investment by providing better protection to the patents. In an era of cut throat competition PPI needs to go for unusual options such as FJV's, contract manufacturing and a proactive approach towards acquisition of CL of patented medicines which are unavailable or are available at unaffordable prices to the masses.

REFERENCES:

Cecilia Oh (2000) TRIPS and pharmaceuticals: A case of corporate profits over public health. The Guardian, Retrieved June 03,2005 from http://www.zip.com.au/~cpa/garchve3/1023twn.html

CME, Medicines by Design: The Biological Revolution in Pharmacology, National Institute of General Medical Sciences, National Institutes of Health, Maryland, USA, Retrieved May 16 2005 from http://www.healthieryou.com/rxdrugs.html

Consumer project on technology, (CPTECH) retrieved on June 10, 2005 from http://www.cptech.org/ip/health/cl/

Devraj Ranjit, (2001, October 25) India caught in drug patent trap, Asia Times on Line. Retrieved June 08, 2005 from www.atimes.com/ind-pak/CJ25Df01.html

DrugResearcher.com, Government actions hindering Pakistan's drug industry (2005) Retrieved May15, 2005 from http://www.drugresearcher.com/news/ng.asp?id=58755

FICCI, (2004) India's export potential of pharmaceutical products in selected African countries. Retrieved June 06, 2005 from http://www.ficci.com/ficci/publications/african-countries.pdf

Ford. Nathan, Patents, access to medicines and the role of non-governmental organizations, retrieved June 01, 2005 from http://www.accessmed-msf.org/documents/FordJGM.pdf

Hussain Ishrat (2003), Pakistan's export competitiveness in global markets, Export Promotion Bureau, Government of Pakistan.

Jolly, Anne; Nicol, Lindi; Waters, janet; Wight, Colin; (2005) Drivers affecting the pharmaceutical industry: How much is changing: Journal of medical marketing, Vol.5, no.2, pp.146-157 (12) Henry Stewart publications ISSN1745-7912.

Lanjouw Jean O; (2001) A patent policy proposal for global diseases The Brookings Institution. Retrieved March 11, 2005 from http://www.brookings.org/views/papers/lanjouw/20010611.htm

Juran, Joseph, A Blanton Godfrey, (1998) Juran's quality handbook; the quality improvement process; Mc Graw Hill pp5.11.

Kobori S. TRIPS and the Primacy of Public Health, Asia-Pacific Review, 1 May 2002, vol. 9, no. 1, pp. 10-19(10)

Lalitha, N (2002) "Indian Pharmaceutical Industry in the WTO Regime: A SWOT Analysis." Economic and Political Weekly 37(34): 3542-55

Lalitha, N (2002) Trips and Pharmaceutical Industry: Issues and Prospects, Retrieved May 02, 2005 from http://www.iprsonline.org/resources/health.htm

Lalitha N, A Review of the Pharmaceutical Industry of Canada', *Economic and Political Weekly*, 13(40), March 26, 2005

Liu G.G; (2003) Potential Expanded Use of Pharmacoeconomics and Outcomes Research in China: Pharmaceutical Development and Regulation, volume 1, no. 3, pp. 169-177(9) Adis International.

Maqsood, Azra and Sattar, Irfan. (2003) a marketing mix model for Pharmaceutical Industry – A Pakistani Perspective: Journal of Independent Studies and Research (SZABIST Karachi - Pakistan).Volume 1 No.2.

Medicins Sans Frontiers (1999): Access to HIV/AIDS medicines in Thailand. MSF Report to the National AIDS Committee of Thailand - August 1999, Retrieved May 29, 2005 from http://www.accessmed-msf.org/prod/publications.asp?scntid=492001236322&contenttype=PARA&

Medicines by Design: The Biological Revolution in Pharmacology National Institute of General Medical Sciences, National Institutes of Health http://www.healthieryou.com/rxdrugs.html

Oxfam, (2001) Cutting the cost of global health, Oxfam parliamentary briefing paper, retrieved May 23, 2005 from http://www.oxfam.org.uk

Panos (2000), Beyond our means, providing comprehensive information about access to antiretroviral treatment in the developing world, Retrieved May 07,2005 from http://www.panos.org.uk/Docs/reports/beyondourmeans.doc

Preventing HIV/AIDS in Pakistan(2004).World bank report, Retrieved on May 31,2005 from http://www.worldbank.org.pk/WBSITE/EXTERNAL/COUNTRIES/SOUTHASIAEXT/PAKISTANEXTN/0,,contentMDK:20154303~pagePK:141137~piPK:217854~theSitePK:293052,00.html

Rahman T, Transforming the Colonial Legacy: the Future of the Pakistani University', Futures, [U.K] Vol.30:No. 7 (1998), 669-680

Shafique, Muhammad: TRIPS agreement and its implications for Pakistan. (2005, April26) The business recorder.

UNCTAD, (2004) Pakistan country fact sheet: World Investment report, Division of Investment, Technology and Enterprise Development; United Nations Conference on Trade and Development.

UNCTAD / WTO (2004) Supply Survey on Pharmaceutical Products –Pakistan. South -South Trade Promotion Programme. International Trade Centre Nov. 2004

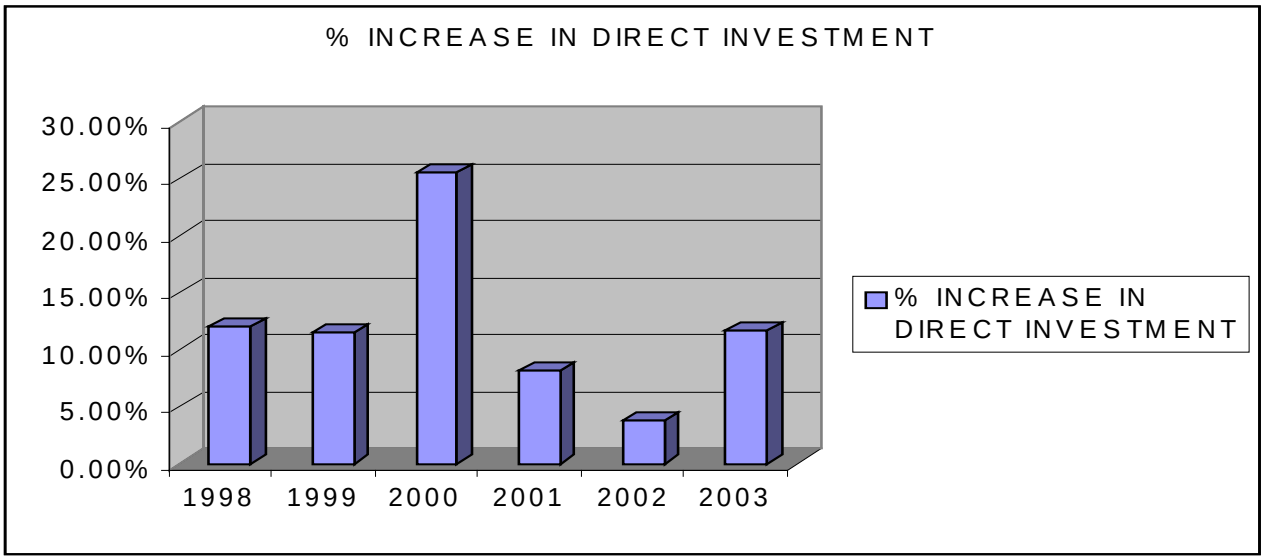
United States trade representative office (USTR), (2004) Special 301 watch list. http://www.ustr.gov/index.html

TABLE 1

YEAR	% INCREASE IN DIRECT INVESTMENT
1998	12.00%
1999	11.50%
2000	25.50%
2001	8.20%
2002	3.70%
2003	11.60%

Source: Board of Investment Government of Pakistan (www.boi.gov.pk)

FIGURE 1


% INCREASE IN DIRECT INVESTMENT
30.00%
25.00%
20.00%
15.00%
10.00%
5.00%
0.00%
1998
1999
2000
2001
2002
2003
% INCREASE IN DIRECT INVESTMENT

(TABLE 2)

BURDEN OF DISEASE IN PAKISTAN (as according to World Bank report 1998)

Communicable diseases	38.4%
Rh disorders	12.5%
Nutritional deficiencies	5.8%
Accidents / Injuries	11.40%
Diabetes / Cardiovascular diseases	10.60%
Neuro / Psychiatric diseases	2.60%
Other non communicable diseases	18.9%

(TABLE 3)

FISCAL YEAR	EXPORT VOLUME IN MILLION $
1997-1998	40.40
1998-1999	31.48
1999-2000	40.57
2000-2001	37.76
2001-2002	43.00
2002-2003	50.03
2003-2004	50.46

Source: Export Promotion Bureau Government of Pakistan

FIGURE 2

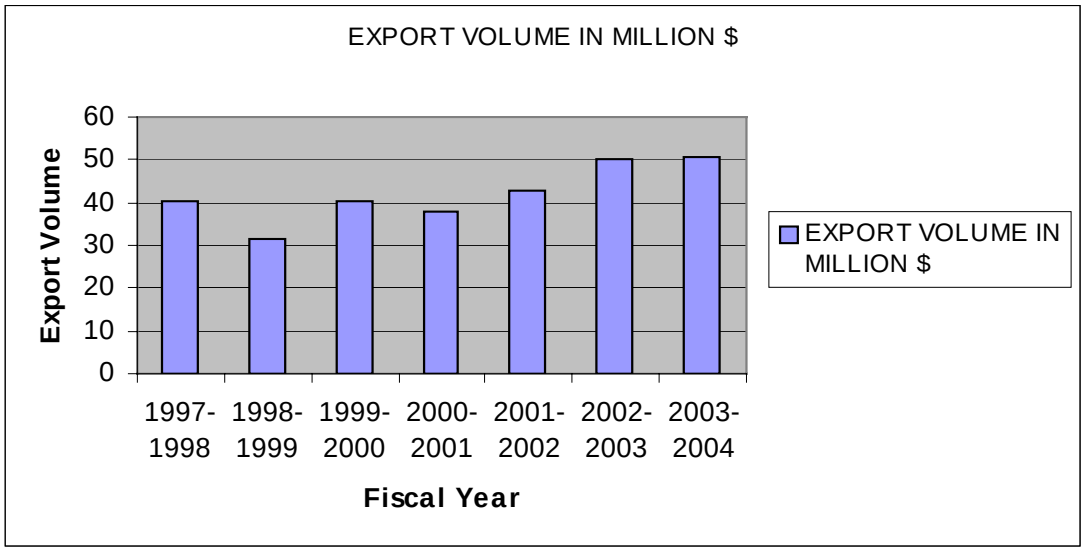

EXPORT VOLUME IN MILLION $
Export Volume
60
50
40
30
20
10
0
1997-1998
1998-1999
1999-2000
2000-2001
2001-2002
2002-2003
2003-2004
Fiscal Year
EXPORT VOLUME IN MILLION $

TABLE 4

CHALLENGES IN HEALTH SECTOR

Country	Population Growth Rate	Contraceptive Prevalence Rate	Total Fertility Rate	Life Expectancy	Infant Mortality rate	<5 Mortality rate	Maternal Mortality rate
Pakistan	1.96	32.0	4.0	63.0	77.1	103	350
India	1.8	48.2	2.9	-	-	-	-
Sri Lanka	1.3	66.2	2.0	73.0	15.0	18.0	60
Bangladesh	1.8	49.0	3.3	61.0	60.0	83.0	600
Nepal	2.4	34.5	4.1	59.0	73.6	105.0	415
Indonesia	1.6	66.4	2.6	-	-	-	-
Malaysia	-	-	-	73.0	7.9	11.0	20

Source: Health Situation in the South East Asia Region, National Estimates & world development report 2002-03, National Surveys

TABLE 5

THE WORLD'S TOP 30 PHARMACEUTICAL COMPANIES

No.	Company	No.	Company
1.	Pfizer	16.	Takeda
2.	Glaxo Smith Kline	17.	Schering AG
3.	Merck	18.	Bayer
4.	AstraZeneca	19.	Amgen
5.	Aventis	20.	Sankyo
6.	Johnson & Johnson	21.	Akzo Nobel
7.	Novartis	22.	Eisai
8.	Bristol-Myers Squibb	23.	Yamanouchi
9.	Wyeth	24.	Merck KGaA
10.	Eli Lilly	25.	Novo Nordisk
11.	Roche	26.	Baxter
12	Abbott Labs	27.	Shionogi
13.	Schering-Plough	28.	Daiichi
14.	Sanofi-Synthelabo	29.	Teva
15.	Boehringer Ingelheim	30.	Fujisawa

Source: Pharmaceutical Executive magazine - May 2003.

ANNEXURE 1:

TOP 30 COMPANIES OPERATING IN PAKISTAN

1 Glaxo Smith Kline	16 Werrick
2 Abbot+Knoll	17 Wilson
3 Pfizer	18 Getz
4 Aventis	19 Highnoon
5 Novartis	20 Barret Hodgson
6 Merck Marker	21 ICI
7 Searle	22 Reckitt Benkiser
8 Wyeth	23 Platinum
9 Roche	24 Macter
10 Bristol Myers Squibb	25 Janssen
11 Hilton	26 Eli Lilly
12 Sami	27 Schering AG
13 Ali Gohar	28 CCL
14 Merck Sharp Dohme	29 Bosch
15 Nestle	30 Himont

ANNEXURE 2

LIST OF EXPORTERS OF PHARMACEUTICAL PRODUCTS

S.NO.	NAME Of COMPANY & ADDRESS	CONTACT PERSON	PHONE#	FAX#
1	AM SON FORMACO BIOLOG1CO 154-INDUSTRiAL TRIANGLE, KAHUTA ROAD, ISLAMABAD	MR.SHAMIM A. KHAN, CHIEF EXECUTIVE	92-51-5584551, 5581067	92-51-5586291-92
2	CIRIN PHARMACEUTICALS 322-A PHASE-III, INDUSTRIAL ESTATE, DISTT. HARIPUR	MR.MUNIM S. MIR CHIEF EXECUTIVE	92-51-5519940	92-51-5523342
3	CONSOLIDATED CHEMICAL LABS (PVT) LIMITED, JAVAID HOUSE, 22-A, GULBERG-II, LAHORE.	MR.KASHIF SAJJAD SHEIKH, DEPUTY MANAGING DIRECTOR,	92-42-5713625-28 DIR, 92-42-5714104	92-42-5713624
4	DONVELLEY PHARMACEUTICAL (PRIVATE) LIMITED, 207-A, 2nd FLOOOR, EDEN HYTES, ZAFARALIROAD, LAHORE.	DR. SHEHLA JAVAID, Chief Executive.	92-42-5753994-95	92-42-5751488
5	ETHICAL LABORATORIES (PVT) LTD, 26- SH AHRAH-E-QUAID-E-AZAM, LAHORE.	MR. HAFERZ-UDUIN SHEIKH, CHIEF EXECUTIVE,	S2-42-7237100 7353446 FAC. 92-42-5421460	92-42-7235655
6	FEROZESONS LABORATORIES LTD, 197-A,THHMALL, RAWALPINDI	MRS.AKHTAR KHALID CHIEF EXECUTIVE,	92-51-5502155 - 5562138	92-51-584195
7	HIGHNOON LABORATORIES (PVT)LTD, 19.5 KM MULTAN ROAD, LAHAORE	MR. TAUSEEF AUMAD KHAN, MANAGING DIRECTOR	.92-42-7510023-5 7510026-7	92-42-7510037
8	IRZA PHARMA (PVT) LTD, 109-COLLEGE ROAD, G-O.R.-I, SHAHRAHE-QUAID-E- AZAM, LAHORE.	MR.NAJAM-ULFIASSAN, DIRECTOR,	OFF. 92-42-6371532-33 FAC. 92-42-7924942 7924842	92-42-6365632
9	MEDlPAK (PVT) LTD, 132/1, INDUSTRIAL ESTATE, KOT LAK.HPAT, LAHORE.	DR. KHALID JAVAID CH. MANAGING DIRECTOR,	92-42-5116612-1 DIP-51165524	92-42-5116522
10	PACIFIC PHARMACUTICALS 30 KM, MULTAN ROAD, LAHORE	MR.1RFANOMARCH IEF EXECUTIVE	92-42-7540491-3	92-42-7541354

S.NO.	**NAME Of COMPANY & ADDRESS**	**CONTACT PERSON**	**PHONE#**	**FAX#**
11	P.D.H. LABORATORIES (PVT) LIMITED, 9.5 K.M, SHEIKHUPURA ROAD, LAHORE.	MIAN MUHMMAD ILYAS. MANAGING DIRECTOR	FAC. 92-42-7931495 7920668 OFF. 92-42-5824496	92-42-7925789
12	PHARMAGEN BEXIMCO (PVT) LTD, 6-E. BLOCK-H, GULBERG-II, LAHORE.	MR. PERVAIZ SUFI, MANAGING DIRECTOR	92-42-5750170 5761434 5751093 FAC, 92-42-527092-30	92-42-5754972 FAC, 92-42-5270931
13	PHARMA WISE (PVT) LTD, 25-MAIN INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE	CH. NADIR KHAN, MANAGING DIRECTOR,	92-42-5120719-21 840900	92-42-5116574
14	PHARMEDIC LABORATORIES (PVT) LTD, 16-K.M. MULTAN ROAD, LAHORE.	MR. IFTIKHARA SHEIKH, MANAGING DIRECTOR,	92-42-7510497-8 7511861 7510798	92-42-7511396
15	POPULAR CHEMICAL WORK (PVT) LTD, 9-K.M. SHEKHUPURA ROAD, LAHORE.	MIAN MISBAH-URREHMAN, CHIEF EXECUTIVE,	92-42-7928423 7933035 273473 271493	92-42-7924044
16	REMINGTON PHARMACHUTICAL INDUSTRIES [PVT] LTD 117-ALLAMA IQBAL ROAD, LAHORE.	MR. ABDUL QADIR KOKHAR, M-D,	92-42-6369411 6363H40	92-42-63663990
17	SCHAZOO LABORATORIES (FVT) LTD, SCHAZOO HOUSE, 45-GRAND TRUNK ROAD, LAHORE.	MIAN M. ZAKAUR-REIIMAN, MANAGING DIRECTOR,	92-42-6818450-54	92-42-6856631
18	SHAIGAN PHARMACEUTICAL (PVT), ROOM# 02, 2nd FLOOR, MALL PLAZA, THE MALL, RAWALPINDI	MR. WAHEED AHMAD, CHIEF EXECUTIVE,	92-51-5571441-2 5573436	92-51-5573437
19	SHIFA LABORATORIES (PVT) LTD, 39- INDUSTRIAL ESTATE, GULBERG- 3, LAHORE.	MALIK MUHAMMAD YOUNAS, MANAGING DIRECTOR,	92-42-5697981-4 5713460	92-42-5715402

S.NO.	**NAME Of COMPANY & ADDRESS**	**CONTACT PERSON**	**PHONE#**	**FAX#**
20	SIZA IN'T'ERNATIONAL (PVT) LTD, FAC: 18/1 K.M, FEROZEPUR ROAD, LAHORE. OFF: 65/2-SYEDMURATAB ALI ROAD, F.C.C., GULBERG-IV, LAHORE.	MR. KHAWAJA M, ZAHID, CHIEF EXECUTIVE, MR. G HA LIB RAZEE, DIRECTOR EXP.,	92-42-5811-72-73-5810388-89 5763431-32 DIR:5755532	FAC:92-42-5812052 5751250 5711369 5763431 5715331
21	STAR LABORATOR1ES 23 KM MULTAN ROAD LAHORE	MALIK MOHAMMAD ISRAR HUSSAIN, DIRECTOR	92-42-7511331 7510690	9 2-42-7510163
22	WILSHIRE LABORATORIES (PVT) LTD, 124/1, INDUSTRIAL ESTATE, KOT LAKHPAT, LAHORE.	MR. AMJAD ALI JAWA, MANAGING DIRECTOR,	92-42-5116685 5116579	92-42-5151721
23	WILSONS'S PHARMACEUTICALS, 387-388, SECTOR-1/9, INDUSTRIAL ESTATE, ISLAMABAD.	MR. TAH1R HAMID, PARTNER,	92-51-5584475 5584141	92-51-5568606
24	ATCO LABORATORIES (PVT) LTD, F/423 S.I.T.E., KARACHI.	MR. SAEED ALLAHWALA MANAGING DIRECTOR	92-21-2577930-33	92-21-2563974
25	BROOKES PHARMACEUTICAL LABORATORIES (PAK) LTD, 58/15 KORANGI INDUSTRIAL AREA, KARACHI.	MR, ABDUL HASEEB KHAN PRESIDENT	92-21-5066281-2 5064469 5063596	92-21-5060505
26	BOSCH PHARMACEUTICALS (PVT) LTD, 8-MODERN HOUSING SOCIETY, TIPU SULTAN ROAD, KARACHI.	MR.S. MOHIUDD!N CHAW LA DIRECTOR	92-21-4547033 4547344 5153106-8 4543641-9 4541876	92-21-4545915
27	FEROZE CHEMICAL INDUSTRIES (PVT) LTD, 12-B/C, BLOCK-6, P.E.C.H.S, KARACHI,	MR. SHAFIUDDIN FEROZE MANAGING DIRECTOR	92-21-4524077 4545960 4536391	92-21-4545266
28	EPLA LABORATORIES (PVT) LTD, D-12 ESTATE AVENUE, S.I.T.E-, KARACHI.	DR. M. TARIQ SIDDIQI MANAGING DIRECTOR	92-21-2577965-6 2578826	

S.NO.	**NAME Of COMPANY & ADDRESS**	**CONTACT PERSON**	**PHONE#**	**FAX#**
29	GEOF'MAN PHARMACEUTICALS, 20/23, KORANGI INDUSTRIAL AREA, KARACHI.	MR, S.M. SABOOR MANAGING DIRECTOR	92-21-5215936-9 5211783	92-21-3681315 5681341
30	HAKIMSONS CHEMICAL INDUSTRIES (PVT) LTD, A/56-S.I.T.E. MANGHOPIR ROAD, P.O. BOX # 4789, KARACHI.	MR. NAWAZISH ALI HAKIM MANAGING DIRECTOR	92-21-2562507 2563772	92-21-2564393
31	HILTON PHARMA (PVT) LTD, 412-419, MUHAMMADI HOUSE, 11-CHUNDRIGAR ROAD, KARACHI.	MR. M- YASIN MAL1K CHAIRMAN	92-21-242529S 2412601-3	92-21-2414322 2422937
32	MACTER INTERNATIONAL (PVT) LTD, F-216 S.I.T.E., KARACHI.	MR. MISBAHUDDIN KHAN CHAIRMAN	92-21-2575311-2	92-21-2564236
33	SAMI PHARMACEUTICALS (PVT) LTD, 34-C, BLOCK-6, P.E.C.H.S., KARACHI.	MR. SHAMIM AHMAD DIRECTOR	92-21-4527490-2	92-21-2563934
34	SEALE PAKISTAN LTD, IST FLOOR, N.I.C. BUILDING. OFF SHAHRAH-EFAISAL, P.O.BOX H 5696, KARACHI.	MR.TARIQISMAIL MANAGING DIRECTOR	92-21-5674321-8	92-21-5687693
35	ZAFA PHARMACEUTICALS LABORATORIES (PVT) LTD, L-4/1, A &B, BLOCK-21, FEDERAL B INDUSTRIAL AREA, KARACHI.	MR. MUHAMMAD AMIN KHAN MANAGING DIRECTOR	92-21-6322051 C.324122	92-21-6312814

Source: Export Promotion Bureau, Government of Pakistan