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# Pharmaceutical regulation in Pakistan

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In Pakistan the pharmaceutical industry is highly regulated. The Drugs Act, 1976 and the rules framed thereunder (collectively 'the Drugs Law') provides a comprehensive framework regulating various aspects of the pharmaceutical industry relating to licensing, manufacture, packaging and sale of products, clinical trials and marketing authorisations, product registration, labelling and advertising and product pricing.

Pharmaceutical products are registered with the Central Licensing and Registration Board of the Ministry of Health (MOH), Government of Pakistan which also renews drug registrations and approves proposed pharmaceutical brand names. Registrations are granted for a period of five years and may be renewed for further periods of up to five years each. The Central Licensing and Registration Board also grants licenses for formulation, basic manufacture, semi-basic manufacture and repacking of pharmaceutical products. No pharmaceutical product may be manufactured in, imported into or sold or offered for sale in, Pakistan unless it is registered. Quality Control is ensured through inspection and laboratory services. Further, all packaging and labelling material must provide information consistent with that approved by the Central Licensing and Registration Board. Each province also has a Provincial Health Authority which oversees a Quality Control Board and drug inspectors.

Product registrations are granted to manufacturers and importers. However, once a product is registered it may be sold in Pakistan by licensed wholesalers and retailers. Separate registrations are granted for each product sold under each brand. There is no provision for the transfer of product registration. When the right to manufacture or sell a product is sold, the usual practice is that the seller surrenders the product registration with a request to the MOH that the registration may be granted to the buyer. In such cases, the buyer's application is treated as a fresh application and the buyer may get involved into a price negotiation with the MOH as the MOH views this as an opportunity to review the maximum retail selling price for the particular product.

Local manufacturers are required to comply with Good Manufacturing Practice and the pharmaceutical industry is required to follow the Ethical Criteria for Medical Drug Promotion developed on the basis of the guidelines issued by the World Health Organization.

MOH also determines the maximum retail selling prices at which pharmaceutical products may be sold. Since the year 2001, the MOH has not granted any price increases, despite the increase in costs and inflation except on an ad hoc and a case by case basis. For a short while prior to 2001 the MOH had prepared a list of controlled and decontrolled products (principally essential and non-essential products) and had allowed manufacturers and importers to determine prices of decontrolled products. However, due to informal pressures, effectively all products are now considered as controlled products for the purposes of pricing. MOH does have the power to determine and notify maximum prices and has in the past exercised such powers.

While MOH has in the past granted toll manufacturing permission for a period of two years (with renewal on a yearly basis), more recently toll manufacturing permission is only being granted to those applicants who have a manufacturing license, and in such cases toll manufacturing permissions are being granted only until 30 June 2010. It is possible that MOH may in future decline to grant toll manufacturing permission. This effectively means that product registration has to be transferred into the name of the manufacturer.

All local manufacturers of pharmaceutical products, which essentially comprise of formulation and repacking, are required to contribute 1 percent of their profit to a Drug Research Fund established by MOH for conducting researches on the development of new drugs and encouraging rational drug therapy. While such contribution has been and continues to be made, there is no effective utilisation of the funds for the purposes of research.

Pakistan has for several years been following the policy of encouraging local manufacture of pharmaceutical products. Consequently whereas there was virtually no pharmaceutical manufacturing in Pakistan at the time of its independence in 1947, today about 80 percent of the drugs market is from local production. However the industry still depends largely on imported raw materials to meet its production needs.

The Government of Pakistan has been taking steps to encourage the growth of pharmaceutical companies by providing exemption from customs duty (in excess of 10 percent ad valorem) and sales tax for pharmaceutical raw materials. Packing materials also enjoy the benefit of exemptions from customs duty. However, sales tax is leviable on the packing material. In order to promote exports of pharmaceutical products, under the current Trade Policy, certain relief is granted to pharmaceutical companies which is linked to efficiency standards and productivity targets.

As regards payment of royalty and technical assistance fees for the use of trademarks and patents and for the provision of technical assistance, the State Bank of Pakistan has permitted such payments under the Foreign Exchange Regulations subject to the relevant agreement being ▸▸

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registered with the State Bank of Pakistan. Application for registration must be made within 30 days of the execution of the agreement. Royalty and technical assistance fee is payable only in respect of products manufactured/formulated in Pakistan (repacking is for this purpose not considered as manufacture), and has to be a percentage of net sales/ex-factory price. Generally a royalty and technical assistance fee of up to 4-5 percent of net sales has been permitted.

Since 2005 it is possible to secure patents for products per se. Previously, patents for pharmaceutical products were required to be process dependent. However, following certain amendments made in 2002, the Patents Ordinance 2000 in the view of many professionals, does not comply with the requirement of the TRIPs Agreement. Also as a result of these amendments, separate applications have to be made for each salt, solvate, optical isomer, recimate, enantiomer, diastereomer, tautomer, ester, pro drug and intermediates. Patent rights are now granted for a term of 20 years. Recently a number of local manufacturers have filed oppositions to the grant of patents per se, which oppositions are still pending adjudication by the Patent Office.

Patents may be granted for products consisting of or containing biological material and processes by which such materials are produced. However, no patents may be granted for plants and animals other than micro-organisms and essentially biological processes for production of plants and animals.

Biotech pharmaceutical products are not locally manufactured and are currently being imported in the finished form. At present there is no specific legislation in the field of biotech. However, in 2001 the Ministry of Science and Technology established the National Commission on Biotechnology to monitor new developments in the field of biotechnology at national and international levels and to recommend appropriate measures for the benefit of the country. The Commission has been working in partnership with the government, biotechnology institutes and professionals to provide a technical assistance, technology sharing, and information resources. Recently the Pakistan Biotechnology Information Center (PABIC) has been established to initiate multidisciplinary research and enhance the awareness in the field of biotechnology in the public, education and industrial sector. The PABIC has had some success in the areas of medicine, molecular genetics, biomedical and genetic engineering. ■

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Ferzeen has been involved in corporate, commercial, finance and taxation matters, including mergers and acquisitions, incorporation of companies, foreign direct investment, joint ventures, anti-trust, project financing, winding up of companies, development of standards for the petroleum industry, the setting up and operation of manufacturing facilities, public floatation and tender offers for listed securities, banking and financing transactions, privatisation. She also represents clients before the High Court and assists senior counsels in the Supreme Court on litigation involving taxation and commercial matters.
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