

## **Chapter 1**

### **Introduction**

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At the beginning of the 21st century, too many people still lack access to essential drugs. WHO estimates that more than one third of world's population lacks regular access to the medicines they need. In the developing countries, 10.3 million children under five years of age died last year; 8.6 million of these deaths could have been prevented if those at risk would have had access to essential drugs. Today, in 32 countries, more than half the population lacks regular access to basic, essential drugs.

The four most important reasons for this situation are:

- Public spending for healthcare in general and for drugs in particular is insufficient, and decreasing.
- Health insurance is non-existent or has very limited coverage; most people, especially in the developing countries, have to pay for drugs out-of-pocket.
- New essential drugs are costly.
- Supply systems are often unreliable and poorly managed, leading to wastage and shortages.

Ensuring access to essential drugs depends on several factors, such as rational selection of the drugs allowed on the market, affordable prices, sufficient and sustainable financing for drugs and a reliable health care and drug supply system. Price is only one of the factors in ensuring access to essential medicines; however, especially for countries and populations with limited resources, it is an important factor. One of the most effective strategies for promoting affordable prices is to increase competition. Previously, many developing countries did not, or only to a limited extent, grant patents for pharmaceutical products, in order to encourage (generic) competition.

Though incentives to innovate are important in the field of pharmaceuticals, rapid diffusion of products of innovation is even more critical for social and public health. Patent protection for pharmaceutical products has raised concerns in developing countries because it is widely believed that their introduction would result in higher prices for essential medicines. Pharmaceutical product patents usually cover well-defined chemical-molecules, substitution around which can require expensive clinical

trials. Thus, the pharmaceutical product patents are particularly effective in limiting competitive entry into the production of specific new drugs and hence in permitting the producer to hold prices well above production costs.

The implications of TRIPS for the pharmaceutical sector are that (a) patents will be granted both for products and processes for all the inventions in all fields of technology; (b) the patent term will be twenty years from the date of the application (compared to the seven years under the 1970 Act), which is applicable to all the member countries and thus rules out all the differences in the protection terms which earlier was the case in different countries; (c) patents will be granted irrespective of the fact whether the drugs were produced locally or imported from another country; and (d) though the grant of the patent excludes unauthorized use, sale or manufacture of the patented item, yet there are clauses which provide manufacturing or other such rights of the patented item to a person other than the patent holder. In the case of a dispute on infringement, the responsibility (to prove that a process other than the one used in the patented product has actually been used in the disputed product) lies with the accused rather than with the patent holder (in the 1970 Act, the responsibility was with the patent holder). This is the broad framework which will guide the pharmaceutical industry of India in the WTO regime. The universal TRIPS regime is expected to result in free flow of trade, investment and technical know-how among the member countries by resolving the barriers that exist in the form of differences in the standards of intellectual property.

Under the workplan of WHO Biennium 2004-2005, the Ministry of Health and Family Welfare, (government of India) had commissioned the National Institute of Pharmaceutical Education & Research to conduct a study entitled "Impact of TRIPS on Pharmaceutical Prices".

The objectives of this study were:

- a) To review the current drug pricing mechanism in the country
- b) To review the drug procurement and purchase (including the process of such procurement and purchase) at all the levels of health care system in India
- c) To perform an analysis of variation, if any, in the prices of drugs in the post TRIPS scenario by reviewing similar studies, if any, performed within the country or by other countries.

- d) To provide suggestions on the options for the public health care system in the globalizing India.

Under the terms of reference of the project, a workshop was held on Feb. 14<sup>th</sup>, 2005 with the objective of eliciting the inputs from various stakeholders in the healthcare system. The summary of the points that emerged from the workshop are a part of this report. Another workshop for the dissemination of the results of these findings will be held at a subsequent date.

This report is divided into following subsections:

1. Introduction
2. Overview of the TRIPS agreement (including the summary of the inputs received in the first workshop)
3. Drug Pricing Mechanisms
4. Drug procurement and purchase process
5. Study on Drug Prices
6. Experiences from other countries
7. Results and Discussion
8. Concluding Remarks and Recommendations