

**GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA**

UNSTARRED QUESTION NO:706
ANSWERED ON:05.12.2003
PRODUCT PATENT REGIME FOR DRUGS
RENUKA CHOWDHURY

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

- (a) the reasons for accepting the Product Patent regime;
- (b) the details of our gains and losses due to this change;
- (c) the possible effect on drug prices when product Patent comes into force;
- (d) the plans of the Government to control medical costs; and
- (e) the number of product patents have been filed by the Indian companies?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (SHRI CH. VIDYASAGAR RAO)

(a) to (d): India is a signatory to the agreement establishing the World Trade Organisation (WTO). The WTO agreement, inter-alia, contains an Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) which requires member countries to align their laws on intellectual property in conformity with their obligations under the TRIPs Agreement. Patent law is one of the elements of the TRIPs Agreement. In respect of India, this agreement, inter-alia, provides for a three-stage time frame to comply with patent-related obligations. India has already complied with the obligations that came into force from January 01, 1995 and January 01, 2000. The next stage of obligations, which require the introduction of a product patent regime in the fields of inventions relating to drugs is due from January 01, 2005.

The Patents Act, 1970 provides for a comprehensive set of safeguards to deal with the issues relating to availability and pricing of medicines. The provisions were comprehensively and recently reviewed by the Joint Committee of Parliament which examined the Patents (Second Amendment) Bill, 1999 and provided effective flexibilities to enable an appropriate, timely and efficient response to national and public interest requirements/concerns, especially those relating to public health and nutrition. The amendments were notified on June 26, 2002 as the Patents (Amendment) Act, 2002. The safeguards in the Indian Patent law to deal with public health concerns are: compulsory licensing, Government use, parallel imports and assumption and revocation of patent rights. These measures are intended to ensure availability of products covered by patents, including medicines, at reasonably affordable prices. Apart from the measures contained in the patents law, India also has a drug price control mechanism to ensure availability of drugs at reasonable prices. Further, almost all essential drugs are outside patent protection and for essential drugs under patent protection, alternatives are available in most cases.

(e): In order to meet transitional obligations effective from January 01, 1995 under the TRIPs Agreement, India has provided for receipt and storage of product patent applications in the field of medicines till the introduction of the product patent regime. These applications have been kept in a 'mailbox' and are to be taken up for examination only with effect from January 01, 2005.