



# PRICING RULES FOR DRUG IMPORTS RELAXED

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The National Pharmaceutical Pricing Authority has eased the norms for pricing of imported drugs in India allowing companies to seek approval once in six (6) months. This is a shift from the previous practice wherein the pharmaceutical companies in India were required to submit report to the NPPA on every imported consignment of drugs and seek their approval for pricing in the domestic market. The eased norms will also be applicable to bulk drugs and other intermediate chemicals.

**PSA view** – With a single approval for six months, pharmaceutical companies will be able to import any number of consignments and sell it in India without seeking any fresh approvals. This change will definitely reduce the procedural delays associated with pricing of imported medicines. The retail price of formulation is calculated per the formula provided in Order 7 of the Drugs (Prices Control) Order, 1995. Accordingly, in the case of an imported formulation, the landed cost is the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit.

## National public health boards at Centre and States proposed

The Central government is all set to create National Public Health Board ("Board") to streamline the entire healthcare delivery in India apart from formulating a national policy on health and laying down and monitoring the standards in the sector. The proposed Board shall comprise of Health secretary (Chairman), Director General of Health Services (Co-chairman), Secretaries/nominees from Ministries of Women and Child Welfare, Rural and Urban Development, Social Justice and Empowerment, Environment, Industry, Food and Agriculture, Panchayati Raj, Finance, Information & Broadcasting apart from nominee of Planning Commission, 5 representatives from National Directorate of Health Services, 5 representatives from the State Governments, and 5 representatives of recognized professional associations and statutory councils relating to health at national level. It will also have 5 experts, and 5 representatives from NGOs.

Board will have state units and will ensure a national health policy revision every five (5) years. Given the dynamic scientific knowledge the Board will also formulate, negotiate, and adopt review strategies for all national health programmes every five (5) years. Regulation of public and private clinical establishments and other health service providers regarding other related matters, regulation of clinical research and field trials, health technology assessment, regulation of health impact assessment, and regulation of healthcare insurance companies will also be under the Board.

**PSA view** – Establishing a national level health service regulatory body to ensure compliance with the aforementioned functions is a welcome step as it will help in streamlining the sector in a major way. Among other functions, it is also mooted that the Board will lay down minimum standards for food, water, sanitation and housing, personal health care and well being, formulate, and implement the national strategies and

plans of action for the determinants of health. It shall also cover the standards and protocols for prevention and control of communicable diseases or vectors affecting humans, registration of births, deaths and other vital statistics for health, food safety, access to safe drugs, labor safety and welfare, including maternity benefits; social security and employment, population stabilization and family planning, health related social and economic planning- in toto the functions will encompass the entire aspects that the New Health Bill contains.

### **Cabinet approves Clinical Establishments (Registration & Regulation) Bill**

The Centre has approved the Clinical Establishments (Registration & Regulation) Bill proposed by the Health Ministry, which has been pending for several years. Once the Bill is approved by the Parliament, all clinical establishments in the country will be required to follow the mandatory registration stipulated in the legislation. Such establishments will include hospitals, nursing homes, clinics, pathological laboratories. It would result in categorization and classification of different clinical establishments depending on their geographical location as well as services offered.

**PSA view** – The Bill aims to bring in uniformity in the healthcare delivery sector by making registration of clinical establishments mandatory, enhancing punishment for offenders and improving the overall quality of health services by prescribing minimum standards of facilities and services. Given that the healthcare sector has remained largely unregulated and uncontrolled in India, the law, if implemented effectively, will attempt to regulate the health care sector.

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