GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. **4650**
TO BE ANSWERED ON THE **20TH MARCH 2026**

Affordability of Medicines

4650. Shri Adhikari Deepak Dev:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the initiatives taken by the National Pharmaceutical Pricing Authority to ensure the affordability of medicine;
(b) the steps taken by the Government to end Intellectual Property Rights issues arising between branded pharma companies and generic pharma companies; and
(c) the steps taken by the Government to reduce revenue loss caused by Compulsory Licensing?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): The National Pharmaceutical Pricing Authority (NPPA) regulates the prices of medicines as per extant provisions of DPCO, 2013. NPPA fixes the ceiling prices of formulations specified in Schedule-I to DPCO, 2013. All manufacturers, marketers and importers of scheduled medicines are required to sell their products within such ceiling price (plus applicable local taxes). As on 18.3.2026, Ceiling prices of 935 formulations are effective.

NPPA also fixes retail prices of new drugs as defined in para 2(1)(u) of DPCO, 2013. As on 18.3.2026, Retail prices of 3,702 new drugs are fixed. Further, in case of non-scheduled formulations, manufacturers are required to not increase their maximum retail price (MRP) of a formulation by more than ten percent of the MRP of that formulation during the preceding 12 months. In addition, NPPA also fixes the prices of drugs under Para 19 of the DPCO, 2013 in case of extra-ordinary circumstances and in public interest to ensure the availability of drugs at affordable prices which, inter alia, include the following:

(i) MRP of 106 non-scheduled anti-diabetic and cardiovascular drugs were capped in 2014.
(ii) Ceiling prices of coronary stents were fixed and notified on 13th February, 2017 for the first time.
(iii) Ceiling price of knee implants, which is one of the components under 'Orthopaedic Implants', was notified on 16th August, 2017.
(iv) A cap on Trade Margin of 42 selected non-scheduled anti-cancer medicines was put under 'Trade Margin Rationalization' approach, which brought down prices of 526 brands of anti-cancer medicines.
(v) During COVID-19, the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer were regulated under "Trade Margin Rationalisation" approach in June/July 2021.

Details of prices fixed or revised by NPPA are available on NPPA's website (www.nppa.gov.in). NPPA monitors the prices of drugs and instances of overcharging are dealt with as per the relevant provisions of DPCO, 2013.

(b): As informed by Department Promotion of Industry & Internal Trade (DPIIT), the Government has incorporated several safeguards under the provisions of the Patents Act, 1970 to maintain a balance between the interests of innovator pharmaceutical companies and generic manufacturers, while ensuring access to affordable medicines. The key measures are as under: -

(i) Patent rights granted under Section 48 are private rights, providing the patent holder exclusive authority to prevent others from making, using, selling or importing the patented product without consent. Disputes arising from such rights are adjudicated by competent courts, thereby providing a structured legal framework for resolving conflicts between innovators and generic manufacturers.

(ii) Patent applications undergo a robust two-stage scrutiny in the Indian Patent Office. Under Sections 12 and 14, applications are first examined by a Patent Examiner for technical and legal compliance, including patentability criteria. The findings are subsequently reviewed by the Controller of Patents, and patents are granted under Section 43 only after due consideration, thereby ensuring quality and preventing grant of weak or frivolous patents.

(iii) The Act provides a comprehensive opposition framework to safeguard public interest. Pre-grant opposition under Section 25(1) allows any person to challenge a patent before grant, while post-grant opposition under Section 25(2) enables interested parties to contest a granted patent within one year. These provisions allow generic manufacturers and other stakeholders to challenge patents not meeting statutory requirements of novelty, inventive step and industrial applicability, thereby reducing potential disputes.

(iv) To prevent unjustified extension of patent monopoly, Section 3(d) restricts patentability of new forms of known pharmaceutical substances unless they demonstrate enhanced therapeutic efficacy. This ensures that minor or incremental modifications cannot be used to prolong patent protection.

(c): As informed by DPIIT, the Patents Act, 1970 contains carefully designed safeguards to ensure that Compulsory Licensing (CL) is invoked only in exceptional circumstances, while protecting the legitimate interests of patent holders. The key provisions are as under:

(i) Under Section 84, compulsory licences may be granted only when specific conditions are fulfilled, such as non-availability of the patented invention at a reasonably affordable price, failure to meet the reasonable requirements of the public, or non-working of the patent in India. This ensures that CL is not granted arbitrarily.

(ii) Under Section 90, the Controller of Patents determines the terms and conditions of the licence, including payment of reasonable royalty and remuneration to the patent holder. This balances public interest with the commercial interests of innovators.

(iii) Compulsory licences are granted only after detailed examination, hearing, and adherence to due process by the Indian Patent Office, ensuring transparency and fairness.

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