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## Government Removes Price Cap on Innovative Drugs

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The government has removed price restrictions on new and innovative drugs developed by foreign pharmaceutical companies under the **Indian Patent Act, 1970**.

- The restrictions have been removed for the **first five years** from the date of first commercial marketing undertaken by the manufacturer in the country.
- This will give Indian patients access to drugs that are currently only available abroad. These also include **orphan drugs** that are used for treating rare medical conditions.

### Orphan drugs

- Orphan drugs are medicinal products intended for diagnosis, prevention or treatment of life-threatening or very serious diseases or disorders **that are rare**.
- These drugs are called “orphan” because under normal market conditions the pharmaceutical **industry has little interest in developing and marketing products** intended for only a small number of patients.

### Patent

- Patents provide the **patent owner with the legal means** to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.
- A patent only gives an inventor the right to prevent others from using the patented invention. It says nothing about whether the product is safe for consumers and whether it can be supplied.
- Patented pharmaceuticals still have to go through rigorous testing and approval before they can be put on the market.

### Section 3(d) of Indian Patent Act, 1970

- Section 3(d) of Indian Patent Act **prevents the “ever-greening” of patents**.

- It means that the following inventions are **not patentable**:
  - mere discovery of a new form of a known substance and which **does not result in increased efficacy** of that substance.
  - mere **discovery of any new property**.
  - **new use** for a known substance.
  - mere use of a known process, machine or apparatus unless such process results in a new product.
- This, in other words meant that India did not support inventions which were **minor modifications** and thus prevented undue monopoly during the extended period of patent protection by the inventor/company.

### Compulsory Licensing (CL)

- **Compulsory Licensing (CL)** allows governments to **license third parties** (that is, parties other than the patent holders) to produce and market a patented product or process without the consent of patent owners.
- Any time after three years from date of sealing of a patent, application for compulsory license can be made, provided:
  - reasonable requirements of public have not been satisfied;
  - patented invention is not available to public at a reasonably affordable price;
  - Patented invention is not worked in India.
- The Union government issued this Order under **section 3 of the Essential Commodities Act, 1955**, to provide essential and life-saving medicines at a reasonable price to the general public.
- **Drug Price Control Orders (DPCO) (Ministry of Chemicals and Fertilizers)** lays down the rules for regulating the prices of medicines through a National List of Essential Medicines, known as **Schedule-I of DPCO** which is amended by the government from time to time.

### National List of Essential Medicines (NLEM)

- The first National List of Essential Medicines (NLEM) of India was **prepared and released in 1996**. This list was subsequently **revised in 2003 and 2011**.
- The list is prepared by the **Union Ministry of Health and Family Welfare**.
- Essential medicines are those that satisfy the priority health care needs of the population. These are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

## Background

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- Earlier the US raised concerns about the Indian price controls on **coronary stents and knee replacement implants**, prices of which had been slashed by as much as 85% and 70%, respectively.
- The US announced that it was reviewing the **Generalized System of Preferences (GSP)** eligibility of India after the US dairy industry and the US medical device industry requested a **review of India's GSP benefits, complaining that Indian trade barriers affected US exports in these sectors.**