

**IPR and Innovation**

1. [NATIONAL IPR POLICY – Pharmabiz.com](#)

**Medical & Regulatory**

1. [Drug ban: EU 'ready' to fast-track clearances for fresh clinical trials](#) – The Hindu Business Line
2. [Govt plans a slew of policy measures to give critical push to medical technology sector: DoP secretary](#) – Pharmabiz.com
3. [D&C Rules to be amended to make only registered pharmacists eligible to become wholesalers](#) – Pharmabiz.com

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Implementation of India's amended Patent Act allowing grant of product patent in pharmaceutical industry has been facing major hurdles ever since 2005 with the long drawn litigations in the patent offices and various courts in the country. Granting such an absolute marketing right to companies with freedom to sell the patented drug at any price is a serious matter considering the essentiality and life saving nature of these products. The Act, however, provided for certain key provisions relating to patentability of a product and opportunities for pre grant and post grant opposition to the affected parties.

The government's decision to frame a national intellectual property rights policy is in the context of these ongoing disputes and challenges of the Patent Act. The final draft of this IPR policy has been circulated for inter-ministerial consultation and will be sent to the Cabinet for approval after receiving comments.

**Medical & Regulatory**

1. [Drug ban: EU 'ready' to fast-track clearances for fresh clinical trials](#) – The Hindu Business Line  
The Commerce Ministry may not have been able to get the EU ban on 700 medicines revoked, but it has managed to convince the European Commission to speed up clearances for new bio-equivalence studies of the affected drugs. Miffed by the ban, the Commerce Ministry deferred Free Trade Agreement discussions with the EU. Simultaneously, it also tried to get the ban revoked, with ministry officials meeting teams of the European Medical Agency and other regulatory bodies.

However, according to sources, the Commerce Ministry's efforts had resulted in only "limited" success, with the European regulators saying that any dilution of their order would only set a "bad precedent".

2. [Govt plans a slew of policy measures to give critical push to medical technology sector: DoP secretary](#) – Pharmabiz.com  
The central government will soon come up with a slew of policy decisions to give critical push to the medical technology sector as a part of the 'Make in India' programme. The measures will include evolving a regulatory mechanism for the sector through a separate legislation, overhauling tax structure to make the domestic production of medical equipment more competitive through introducing purchase preference for boosting local manufacture and stress on research & development, said Dr VK Subburaj, secretary, department of pharmaceuticals (DoP).
3. [D&C Rules to be amended to make only registered pharmacists eligible to become wholesalers](#) – Pharmabiz.com  
The Union health ministry will soon amend Rule 64 of the Drugs and Cosmetics Rules, 1945 to make only registered pharmacists eligible to become wholesalers dealing with pharmaceutical products in the country. However, the new rule will not be applicable to the persons already registered prior to the date of final notification in this regard by the ministry.

## **Others**

1. [Things that Influence Pharma Growth Story – The Economic Times](#)  
Rupee has depreciated 9% over the past one year, turning brighter the growth prospects of Indian pharmaceutical industry. There are fundamental factors, besides rupee, influencing the industry's growth in the short- to medium-term. Drug companies' performance stands impacted by these factors in the coming quarters - Price Control in the domestic market remains a sore point, especially if prices of more drugs are brought under the control regime. MNCs in India have become aggressive in launching products in the domestic market. The growth of MNCs have outpaced that of the Indian companies in the last two months.