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Contents

Research and development

Proposed overhaul of drug regulatory system (India)

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India's Health Ministry has released a draft of the proposed amendments to the Drugs and Cosmetics Act 1940 (Act) for public consultation. The Act is the primary legislative instrument which lays down the regulatory framework for drugs that are manufactured or imported for marketing in India.

The draft proposes to vest the powers to approve the manufacture of certain drugs in India exclusively with a single central authority appointed by the Health Ministry of the Union Government. Until now, the approval powers were vested with authorities appointed by the respective State Governments. The drugs sought to be centrally regulated include drug products comprising fixed dose combinations, monoclonal antibodies, stem cells, gene therapeutic products and xenografts.

The draft also lays down liabilities of sponsors and ethics committees conducting clinical research in India and clarifies the meaning of 'sponsor' by defining it as a person responsible for initiation, financing and management of a clinical trial. The draft, once finalised by the Health Ministry, is expected to be tabled before the Indian Parliament for debate in its budget session starting on 25 February 2015.

Source: *The Drugs and Cosmetics (Amendment) Bill 2015, 31 December 2014*.

Commercialisation

Pharma marketing practices code released (India)

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The Department of Pharmaceuticals (DoP) has published an amended form of the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for adoption by the Indian pharmaceutical industry on a voluntary basis, beginning 1 January 2015.

The UCPMP seeks to counter unethical promotional practices, with the code as now amended, placing

restrictions on:

- The number of drug samples that can be handed over to Healthcare Professionals (HCPs).
- Giving of gifts for the personal benefit of HCPs.
- Extending travel facilities to HCPs for attending conferences and seminars as delegates.
- Extending hospitality under any pretext to any HCP.

The UCPMP was first published in 2011 as a voluntary code. Following the release of the amended code, the DoP will monitor compliance with the UCPMP for six months. It will then consider whether compliance should be made mandatory. Pharmaceutical companies have in general indicated an intent to comply with the UCPMP.

Source: *UCPMP voluntary code, December 2014*.

Disputes

Novartis obtains interim injunction against Cipla for patent infringement (India)

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Novartis has successfully obtained a temporary injunction against Cipla, restraining Cipla from selling its generic equivalent (Unibrez) of Novartis' patented drug (Onbrez). The order will remain in force until the parties enter into a licence agreement or until Cipla is able to procure a compulsory licence from the Indian Controller of Patents.

Cipla announced the launch of its generic drug in October 2014. It had also filed an application before the Indian Department of Industrial Policy & Promotion to revoke Novartis' patent for Onbrez. The application was filed under Section 66 of the Patents Act 1970, which permits revocation of a patent if the patent is prejudicial to public interest.

In December 2014, Novartis filed a patent infringement action against Cipla before the Delhi High Court, together with a separate urgent application for interim relief. On 9 January 2015, Novartis was granted the interim relief. The case is important as it showcases the urgency and seriousness with which the courts in India have started treating patent infringement cases.

Case: *In the High Court of Delhi at New Delhi, I.A. No.24863/2014 IN CS(OS) 3812/2014, Novartis v Cipla, 9 January 2015*.