Pharma & Healthcare Update

March 09, 2015

PHARMA ALERTS

- Proposed overhaul of drug regulatory system
- Pharma marketing practices code released
- Novartis obtains interim injunction against Cipla for patent infringement

PROPOSED OVERHAUL OF DRUG REGULATORY SYSTEM (INDIA)

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.

PHARMA MARKETING PRACTICES CODE RELEASED (INDIA)

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.

NOVARTIS OBTAINS INTERIM INJUNCTION AGAINST CIPLA FOR PATENT INFRINGEMENT (INDIA)

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.

**** Reproduced from Practical Law with the permission of the publishers.***

– Anay Shukla & Khushboo Baxi
You can direct your queries or comments to the authors

Research Papers

Medical Device Industry in India
April 28, 2025

Clinical Trials and Biomedical Research in India
April 22, 2025

Structuring Platform Investments in India For Foreign Investors
March 31, 2025

Research Articles

2025 Watchlist: Life Sciences Sector India
April 04, 2025

Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?
February 04, 2025

INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals
January 15, 2025

Audio

CCI's Deal Value Test
February 22, 2025

Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice
December 18, 2024

Digital Lending - Part 1 - What's New with NBFC P2Ps
November 19, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

Click here to view Hotline archives.

Video

Vyapak Desai speaking on the danger of deepfakes | Legally Speaking with Tarun Nangia | NewsX

DISCLAIMER

The contents of this hotline should not be construed as legal opinion. View detailed disclaimer.

April 01, 2025

Vaibhav Parikh, Partner, Nishith Desai Associate on Tech, M&A, and Ease of Doing Business

March 19, 2025

SIAC 2025 Rules: Key changes & Implications

February 18, 2025