Elective Proposal, Fall 2025, JGLS

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Drugs and Pharmaceuticals Regulation in India

The drugs and pharmaceutical sector has been one of the most robust sectors of the Indian economy. Globally, the Indian pharma industry occupies an important position as the 3rd largest pharmaceutical market in the world in terms of volume,[1] and 14th in terms of value of production.[2] The Indian pharmaceutical industry which includes a network of approximately 3000 drug companies and 10,000 manufacturing units,[3] is estimated to reach a value of US$ 100 billion by 2025 with a 10%-12% growth rate.[4] In addition to its vital contribution to economic growth, the pharma industry also ensures the health security of the country through its innovation and supply of both novel and generic drugs. This becomes even more crucial given the high disease burden in India. The outbreak of COVID-19 realigned the spotlight on the importance of drug innovation and drug regulation in a country like India with its teeming millions. Unfortunately, while drug innovation is necessary for human survival, it is often at the cost of de-humanising processes which undermine the virtue of innovation itself. Over the past decades, a spate of deaths and serious adverse events (SAEs) during clinical trials conducted in India have invited both Parliamentary and judicial scrutiny on the underlying processes involved in medical/clinical research which pave the way for creation of new drugs and medical devices. Such adverse events have led to targetted reforms in the rules governing clinical trials in India. Another major problem plaguing the pharma sector in India is the issue of manufacture and distribution of sub-standard drugs in the market which has jeopardised availability of safe and efficacious drugs to patients and consumers both in India and in the overseas markets. This warrants a major transformation in the way India's national drug regulator – the CDSCO, conducts regulatory surveillance on drugmakers in the country as weak regulatory vigilance poses a serious threat to public health and safety. Additionally, the existence of a thriving traditional systems of medicines creates a unique situation in India where drug regulators have to also engage in regulatory oversight of AYUSH drugs to ensure

[1] *See*, https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=152038 (Ministry of Commerce and Industry, Government of India, 22 May 2024).
[2] *See*, https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2085345 (Ministry of Commerce and Industry, Government of India, 17 December 2024).
[3] *See*, https://pib.gov.in/PressReleasePage.aspx?PRID=1924204 (Ministry of Health & Family Welfare, Government of India, 15 May 2023).
[4] *See*, https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=152038 (Ministry of Commerce and Industry, Government of India, 22 May 2024).

such drugs and cosmetics comply with regulatory standards otherwise applied to the allopathic drugs. Together these issues have now culminated into discussions to overhaul India's 85-year-old Drugs and Cosmetics Act of 1940 to make it more aligned with advancements in the medical sector as well as recalibrate it with global best regulatory practices.

In this Course, we will undertake a study of the regulatory regime for drugs and pharmaceuticals in India from the stage of drug discovery (pre-clinical phase) to drug development (clinical phase), and finally to the post-clinical phase which includes aspects such as product safety, drug pricing, sale and distribution of drugs, drug advertisements, product liability and pharmacovigilance. Besides, this Course will also explore other allied issues such as medical ethics, access to medicines, and regulatory reforms in the pharmaceutical sector in India.

This is a standalone course and is recommended for students who are interested in medical ethics, drug innovation and pharma policy. This elective course has been designed in a way to enable students to develop at least a working understanding of regulatory issues related to pharma law and practice in India. While the focus of this Course will remain on drug regulation in India, however, it is inevitable that reference will also be made to global pharmaceutical standards in other robust drug regulatory regimes like U.S.A, EU and so on.

[N.B.: This Course does not deal with regulation of narcotic drugs and psychotropic substances which may fall within the purview of other electives offered at JGLS addressing the NDPS Act, 1985]

Select Readings:

Conventions and Agreements:

1. The Nuremburg Code, 1947
2. The Declaration of Helsinki (World Medical Association, 1964)

Statutes:

3. The Drugs and Cosmetics Act of 1940 (Act 23 of 1940)
4. The Drug and Magic Remedies (Objectionable Advertisements) Act, 1954 (Act 21 of 1954)

Regulations:

5. National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR, 2017).

Bill(s):

6. The Drugs, Medical Devices, and Cosmetics Bill 2023

Reports:

7. Fifty Ninth Report on Functioning of Central Drugs Standard Control Organisation (Department-Related Standing Committee on Health and Family Welfare, Parliament of India, May 2012)

8. Seventy Second Report on Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India (Department-Related Standing Committee on Health and Family Welfare, Parliament of India, August 2013)

Books:

9. Dinesh Thakur and Prashant Reddy T., The Truth Pill *The Myth of Drug Regulation in India* (S&S, 2022)
10. Katherine Eban, Bottle of Lies Ranbaxy and the Dark Side of Indian Pharma (Juggernaut, July 2019)