



NATIONAL LAW UNIVERSITY ODISHA



CENTRE FOR DISABILITY LAW AND ADVOCACY



TRIPLE CREDIT COURSE ON HEALTH LAWS AND PHARMACEUTICAL REGULATION: POLICY, ETHICS AND GOVERNANCE

REGISTRATION DEADLINE:
10TH AUGUST 2026

MODE OF LECTURE:
ONLINE (GOOGLE MEET)

ABOUT THE CREDIT COURSE:

This course examines the legal, regulatory and ethical frameworks governing pharmaceuticals within national and international contexts. It explores drug approval systems, pricing control, intellectual property, access to medicines, clinical trials regulation, public health emergencies, and the role of global institutions. The course integrates public health perspectives with regulatory governance and human rights approaches.

COURSE OBJECTIVES:

- 1.To introduce students to the legal and regulatory framework governing pharmaceuticals.
- 2.To critically examine the relationship between intellectual property and access to medicines.
- 3.To analyse regulatory mechanisms relating to drug approval, pricing, marketing and safety.
- 4.To explore ethical and human rights dimensions of pharmaceutical governance.
- 5.To evaluate India's pharmaceutical regulatory regime in a global context.

COURSE LEARNING OUTCOMES:

By the end of the course, students will be able to:

- 1.Explain the structure and function of pharmaceutical regulatory systems.
- 2.Critically analyse drug approval and safety mechanisms in India.
- 3.Assess the impact of patent law on access to medicines.
- 4.Evaluate pharmaceutical governance from a public health and human rights perspective.
- 5.Engage with contemporary debates on vaccine equity, compulsory licensing and drug pricing.

BRIEF OVERVIEW OF THE COURSE:

TOTAL DURATION:

- 48 Hours

DAYS:

- Friday, Saturday, and Sunday (**Tentative**)

TIME:

- **Friday to Sunday:** 6:30 PM – 8:30 PM (**Tentative**)
- **Saturday and Sunday:** 11:00 am - 1:00 pm (**Tentative**)

IMPORTANT DATES:

- **Course Commencement:** 14th August 2026
- **Course Conclusion & Exam:** 26th September 2026 (**Tentative**)
- **Score Sheet Declaration:** 05th October 2026 (**Tentative**)
- **Certificate Circulation:** 10th October 2026 (**Tentative**)
- **Mode of Learning:** Hybrid (Online sessions with an optional 1-day in-person expert lecture series at NLUO, Cuttack)

ASSESSMENT STRUCTURE:

- **Mode:** Online
- **Format:** 50 Marks MCQ + 50 Marks Descriptive

ATTENDANCE REQUIREMENT:

- **Minimum:** 75% attendance is mandatory to be eligible for the examination.

MODULE STRUCTURE (48 HOURS):

MODULE I: INTRODUCTION TO HEALTH LAW AND PHARMACEUTICAL GOVERNANCE

- Concept and scope of Health Law
- Evolution of pharmaceutical regulation
- Public health governance and State responsibility
- Regulatory authorities in India (CDSCO, DCGI)
- Pharmaceutical industry and third world
- Role of global institutions like World Health Organization

Key Indian Law:

- Drugs and Cosmetics Act, 1940
- National Pharmaceutical Pricing Policy

MODULE II: DRUG APPROVAL, CLINICAL TRIALS AND SAFETY REGULATION

- Drug development lifecycle
- Clinical trials regulation in India
- Ethical approval and informed consent
- Pharmacovigilance and post-marketing surveillance
- Regulation of vaccines and emergency use authorisation
- Case study: COVID-19 vaccine approvals

Important Case:

- Swami Achyutanand Tirth v. Union of India (Clinical Trials Regulation)

MODULE STRUCTURE :

MODULE III: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

- State of access to medicine and health system approach
- TRIPS Agreement and pharmaceutical patents
- Compulsory licensing
- Patent evergreening
- Data exclusivity
- Access to medicines as a human right

Important Cases:

- Novartis AG v. Union of India (2013) 6 SCC 1
- Bayer Corporation v. Natco Pharma Ltd. 2013 (56) PTC (IPAB)

International Framework:

- World Trade Organization
- TRIPS Agreement
- Doha Declaration on TRIPS and Public Health

MODULE IV: DRUG PRICING, COMPETITION AND CONSUMER PROTECTION

- National Pharmaceutical Pricing Authority (NPPA)
- Essential Medicines List
- Competition law and pharmaceutical markets

MODULE STRUCTURE :

- Excessive Pricing (Roche Holding, CDCA- Laediant)
- Misleading advertisements and regulatory control
- Role of Competition Commission of India

Important Case:

- Samir Agarwal v. Competition Commission of India (2020 SC)
- Biocon v. Hoffmann La Roche (2017 CCI)
- Vivek Sharma v. Becton Dickinson India Pvt. Ltd. & Max Super Speciality Hospital (2018)

MODULE V: ETHICS, HUMAN RIGHTS AND EMERGING ISSUES IN HEALTHCARE

- Right to health under Article 21 (Indian Constitution)
- Pharmaceutical ethics and corporate accountability
- Vaccine equity and global justice
- Regulation of biologics and biosimilars
- AI in drug discovery and regulatory challenges

MODULE VI: PSYCHOLOGICAL DIMENSIONS OF HEALTH LAWS AND PHARMACEUTICAL REGULATION

- Foundations of Health Psychology and Legal Decision-Making
- Cognitive Bias and Patient Choice in Healthcare
- Psychology of Prescribing and Professional Ethics

MODULE STRUCTURE :

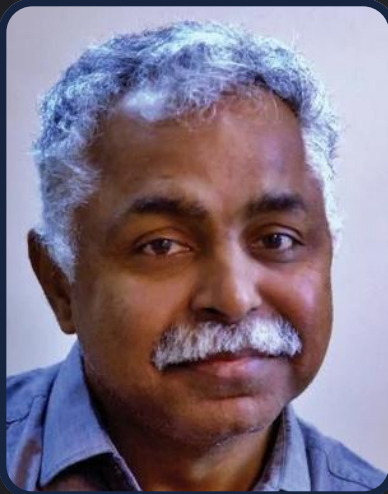
- Behavioural Manipulation and Pharmaceutical Marketing
- Behavioural Governance, Public Trust and Regulatory Legitimacy

CHAPTER VII : RARE DISEASES AND DRUG REGULATION IN INDIA

- Introduction to Rare Diseases - Definition, prevalence, and public health burden in India.
- National Policy for Rare Diseases (2021) - Objectives, funding mechanisms, and Centers of Excellence.
- Orphan Drug Regulation – Drug approval processes, clinical trials, and regulatory oversight by the Central - Drugs Standard Control Organisation.
- Health Laws and Legal Framework - Drugs and Cosmetics Act, 1940; New Drugs and Clinical Trials Rules, 2019; Rights of Persons with Disabilities Act, 2016; and Article 21 (Right to Health).
- Ethics, Access, and Affordability - Equity, patient rights, access to treatment, and governance challenges.
- Future Directions - Gene therapies, personalized medicine, and policy reforms for rare diseases.

ABOUT RESOURCE PERSONS:

K M GOPAKUMAR, SENIOR RESEARCHER & LEGAL ADVISOR, TWN



K.M. Gopakumar is a Senior Researcher and Legal Advisor, Third World Network (TWN) based in New Delhi, India. TWN is an independent, not-for-profit organization that carries out policy research and advocacy on issues around trade and development, with a focus on third-world countries. His work in TWN focuses on the global IP regime and its implications on development.

PROF.(DR.)DEBASIS PODDAR, NLUJAA



Dr. Debasis Poddar is a Professor of Law and Coordinator for the Centre for Law, Public Policy and Governance (CLPPG) at NLUJA, Assam. NLUJA is a premier National Law University dedicated to advancing legal education, research, and policy advocacy in India. His work focuses on bridging legal history, contemporary legal philosophy, and public policy research methodologies.

ABOUT RESOURCE PERSONS:

DR. TOPI BASAR, DEPT. OF LAW, RAJIV GANDHI UNIVERSITY, AP



Prof. Topi Basar is the Associate Professor and HoD of Law at Rajiv Gandhi University in Arunachal Pradesh. Rajiv Gandhi University is a premier central university committed to fostering higher education, research, and sustainable development in Northeast India. Her work focuses on the legal protection of traditional knowledge, intellectual property rights (IPR), and the advancement of tribal customary laws.

DR. GARGEYA TELAKAPALLI, PUBLIC HEALTH CONSULTANT, TWN



Dr. Gargeya Telakapalli is a Public Health Consultant at the Third World Network (TWN) based in New Delhi, India. TWN is an independent, not-for-profit organization that carries out policy research and advocacy on trade and development issues for third-world countries. His work focuses on legal and policy interventions to ensure global access to medicines and treatments.

ABOUT RESOURCE PERSONS:

DR. SWATHI KRISHNA N., ASSISTANT PROFESSOR, DVVPF'S MEDICAL COLLEGE



Dr. Swathi Krishna N. is an Assistant Professor of Community Medicine at Dr. Vithalrao Vikhe Patil Foundation's Medical College, Ahilyanagar. The institution is a premier medical foundation dedicated to advancing healthcare education, community health services, and clinical research. Her work focuses on tuberculosis policy, health systems strengthening, implementation research, and context-appropriate, data-driven health solutions.

DR. TANWI SHAMS, ASSISTANT PROFESSOR OF LAW & DIRECTOR CDLA, NLUO



Dr. Tanwi Shams is an Assistant Professor of Law and Director of the Centre for Disability Law and Advocacy at National Law University Odisha. NLUO is a premier national law school dedicated to clinical legal education, rigorous research, and social empowerment. Her work focuses on the intersection of Intellectual Property Rights, Artificial Intelligence, and Human Rights Law.

ABOUT RESOURCE PERSONS:

DR. TRISHA WALIA, CLINICAL PSYCHOLOGIST, YESMINDY



Dr. Trisha Walia is a Clinical Psychologist based in Bangalore, India, with ten years of experience. She operates a specialized psychological practice providing tech-enabled teleconsultations and objective clinical assessments. Her work focuses on utilizing integrative subjective-objective therapeutic tools to cultivate client independence, emotional resilience, and sustainable mental health self-sufficiency.

ANANYA RAI, ASSISTANT PROFESSOR OF LAW, NLUO



Ms. Ananya Rai is an Assistant Professor of Law at National Law University Odisha. NLUO is a premier national law school dedicated to clinical legal education, rigorous research, and social empowerment. Her work focuses on corporate and commercial laws, transnational legal frameworks, celebrity rights protection, mergers and acquisitions, and trial and appellate advocacy.

FEE STRUCTURE AND REGISTRATION:

FEE STRUCTURE:
STUDENTS: RS 1500/-
PROFESSIONALS: RS 2000/-

EARLY REGISTRATION
(BY 31ST JULY 2026):
RS 1200/-
(FOR ALL CATEGORIES)

REGISTRATION DEADLINE:
10TH AUGUST 2026

REGISTRATION LINK: [CLICK HERE](#)

COURSE CO-ORDINATOR :

DR. TANWI SHAMS

**ASSISTANT PROFESSOR OF LAW & DIRECTOR, CDLA
NATIONAL LAW UNIVERSITY, ODISHA**

ANANYA RAI,

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