



DEPARTMENT FOR PROMOTION OF
INDUSTRY AND INTERNAL TRADE
MINISTRY OF COMMERCE & INDUSTRY,
GOVERNMENT OF INDIA

MAHARASHTRA NATIONAL LAW UNIVERSITY MUMBAI

DEPARTMENT FOR THE PROMOTION OF
INDUSTRY AND INTERNAL TRADE
(DPIIT)-IPR CHAIR

WORKSHOP ON THE ORPHAN DRUGS REGIME IN INDIA

PART I OF MNLU MUMBAI'S RESEARCH PROJECT

5th November 2022

Brochure

SUPPORTED BY



limited seats only

ABOUT MNLU MUMBAI

MNLU Mumbai is one of the premier National Law universities located in the economic capital of India. It offers graduate, post-graduate, and research degrees in law and allied disciplines. The object of the university is to advance and disseminate learning and knowledge of the law and legal processes and their role in national development, to serve society in the field of law by developing skills in regard to advocacy, legal services, legislation, law reforms, and the like; to organize lectures, seminars, symposia and conferences to promote efficient instruments of social development. MNLU Mumbai has set up a Centre for Research in IP among fifteen centers for legal research. Department for the Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Govt. of India has also established IPR Chair in the University to advance these objects.

ABOUT DPIIT-IPR CHAIR

Department for Promotion of Industries and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India, launched a Scheme for Pedagogy & Research in IPRs for Holistic Education & Academia (SPRIHA) in the year 2016 under which IPR Chairs have been set up in the Maharashtra National Law University (MNLU) Mumbai. The main objective is to lead high-quality research and promote well-informed interdisciplinary work in the area of intellectual property law, policy and practice; conducting awareness programmes, seminars, workshops and conferences on IPRs. Through its activities, the chair aims to promote the understanding and critical appraisal of the important fields of IP law.

ABOUT CRIP

The Centre for Research in Intellectual Property (CRIP) is the focus of Intellectual Property activities and research at the Maharashtra National Law University Mumbai. The main objective of the Centre is to lead high-quality research and promote well-informed interdisciplinary work in the area of intellectual property law, policy and practice; conducting awareness programmes, seminars, workshops and conferences on IPRs. Through its activities, the Centre aims to promote the understanding and critical appraisal of the important fields of IP law.

WHAT ARE RARE DISEASES AND ORPHAN DRUGS??

WHO defines a rare disease as often debilitating lifelong disease or disorder with a prevalence of 1 or less, per 1000 population. However, different countries have their own definitions to suit their specific requirements and in the context of their own population, the health care system, and resources. In the US, rare diseases are defined as a disease or condition that affects fewer than 200,000 patients in the country (6.4 in 10,000 people). EU defines rare diseases as life-threatening or chronically debilitating conditions affecting no more than 5 in 10,000 people. Japan identifies rare diseases as diseases with fewer than 50,000 prevalent cases (0.04%) in the country. According to a study, that reviewed and analyzed definitions across jurisdictions, most definitions appear to consider disease prevalence, but other criteria may also apply sometimes.

Currently, in India, Orphan disease is used synonymously with a rare disease, and drugs to treat them are called Orphan Drugs. As per the New Drugs & Clinical Trial Rules 2019, an Orphan Drug is defined as a drug intended to treat a condition that affects not more than five lakh persons in India. Orphan drugs are the drugs and natural products used in the treatment, diagnosis, or prevention of rare diseases. Orphan drugs may be defined as drugs that are not developed by the pharmaceutical industry for economic reasons but which respond to public health needs.

NEED FOR RESEARCH

Public health and hospitals is primarily state subject. Stakeholder consultation with the State Governments requires an elaborate discussion. A fundamental challenge in research and development for the majority of rare diseases is that there is relatively little known about the pathophysiology or the natural history of these diseases. The challenge becomes even greater as rare diseases are chronic in nature, where long-term follow-up is particularly essential. As a result, rare diseases lack published data on long-term treatment outcomes and is often incompletely characterized.

As India is still developing, there is a setback in regard to regulation and development in orphan disease research. Recently, mobility is seen in terms of rare disease research in India. Different initiatives are in process which includes initiative from the regulatory side, initiatives from academic institutes, non-governmental organizations, and other related sectors. In the present scenario, there is a strong need for the assessment of the spectrum and burden of orphan diseases and awareness programs in mass regarding orphan diseases. Strong policies and initiatives are needed from the government and academic and private institutions for orphan drug development.

The revised National Policy for Rare Diseases (2021) makes mentions the need for the promotion of local development of drugs by pharmaceutical companies. The need legislative framework is evident which would strengthen the health infrastructure and provide relief to the numerous rare disease sufferers throughout the country.

India does not have a law on orphan drugs as yet but the draft rules released by the health ministry on a regulatory framework for clinical trials in India define orphan drugs as those intended to treat a condition that affects fewer than 200,000 people.

Equally important is the fact that it is unclear whether orphan drugs can be subject to compulsory licenses. Compulsory licenses are permitted under Article 31(5) of TRIPS and allow governments to circumvent patent rights on public health grounds by allowing generic manufacturers to produce and distribute the drug at a lower price, while fairly compensating the original rights-holder. The public health safety net, which is specifically designed to put the public's health above commercial profits in times of dire need, is also maybe not applicable when the public needs it most.

UNIVERSITY TEAM

Patron



Hon. Prof. (Dr.) Dilip Ukey
Vice Chancellor, MNLU Mumbai

Co-Patron



Prof. (Dr.) Anil G. Variath
Registrar (I/c), MNLU Mumbai

Director, CRIP



Dr. W. M. Dhumane
Ex-DPIIT IPR Chair Professor, MNLU Mumbai
Ex-Sr. Jt. Controller of Patents & Designs

Co-ordinator, CRIP



Mr. Sajid Sheikh
Assistant Professor (Law),
Coordinator, CRIP, MNLU Mumbai

DPIIT-IPR Chair Members



Adv. Gunjan Deshpande
Research Assistant, DPIIT-IPR
Chair, MNLU Mumbai



Adv. Teesta Hans
Coordinator, DPIIT-IPR Chair
MNLU Mumbai



Adv. Poorva Sharma
Research Assistant, DPIIT-IPR
Chair, MNLU Mumbai

WORKSHOP SCHEDULE

Inaugural Session: 11:00 to 11:30 am

THEME 1:

ORPHAN DRUGS: PUBLIC HEALTH ISSUES

Expert Session I: 11:30 to 01:30 pm

Lunch Break: 01:30 to 02:30 pm

THEME 2:

ORPHAN DRUGS: CURRENT LEGAL & POLICY FRAMEWORK

Expert Session II: 02:30 to 04:30 pm

High Tea: 04:30 to 05:00 pm

Valedictory: 05:00 to 05:30 pm

limited seats only 05

WORKSHOP REGISTRATION

Who Should Join?

- Professionals from Healthcare, Medical Science, Pharmacy, IP, Lawyers, and Academicians.
- Professionals from Research & Development, scientific & medico-legal, bio-medical and enforcement domains
- Medical, pharma, para-medical & law students.

The workshop will highlight the grey areas and issues in Law & Policy related to the Orphan Drugs Regime in India.

The workshop is bound to benefit all the participants by enriching their knowledge, skill, and expertise.

Workshop Fee

For professionals, lawyers, researchers, academicians Rs. 750/-
For medical, pharma, para-medical & law students* Rs. 500/-
(*Valid Student ID is required)

The fee once paid is non-refundable under any circumstances. Part payment of the fee is not acceptable.

*Registration will be on first come first serve basis.
Limited seats are available.

REGISTRATION LINK :

<https://forms.gle/mm4gNgVQF5miSX248>

Last Date of Registration: 01/11/2022

FOR QUERIES

Email IDs: iprchair@mnlumumbai.edu.in
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Mobile: +91 7350015966 (10:00 AM to 5:00 PM)

VENUE OF THE WORKSHOP:

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