

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai

Approved by Pharmacy Council of India, New Delhi.

Coimbatore -641035

COURSE NAME: PHARMACY LAW AND ETHICS

D.PHARM/ II YEAR

TOPIC : PHARMACY PRACTICE REGULATION IN INDIA

Design Thinking Approach in Pharmacy Law & Ethics





Overview of Pharmaceutical Regulations in India



Pharmacy Practice Regulation 2015

Sets standards for pharmacy practice



Drugs and Cosmetics Act 1940

Governs drug and cosmetic manufacturing and sale



Rules 1945

Provides detailed rules for drug and cosmetic quality control



Legal Framework

Establishes the legal basis for pharmaceutical activities

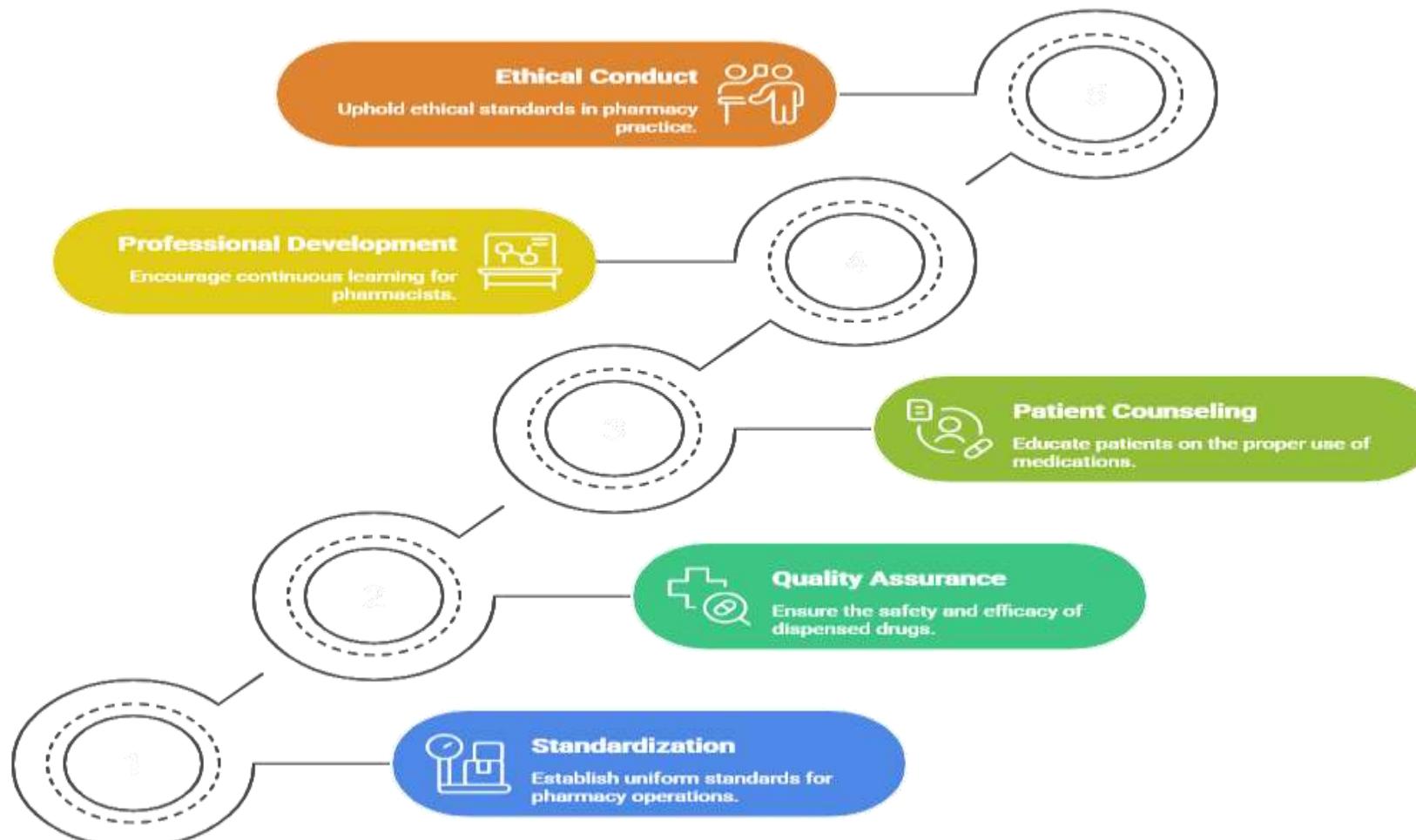


Quality Control

Ensures the safety and efficacy of pharmaceutical products

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Achieving Quality Pharmaceutical Care



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Core Principles of Pharmacy Practice

Standardization



Patient
Counseling



Ethical Conduct



Quality
Assurance



Professional
Development

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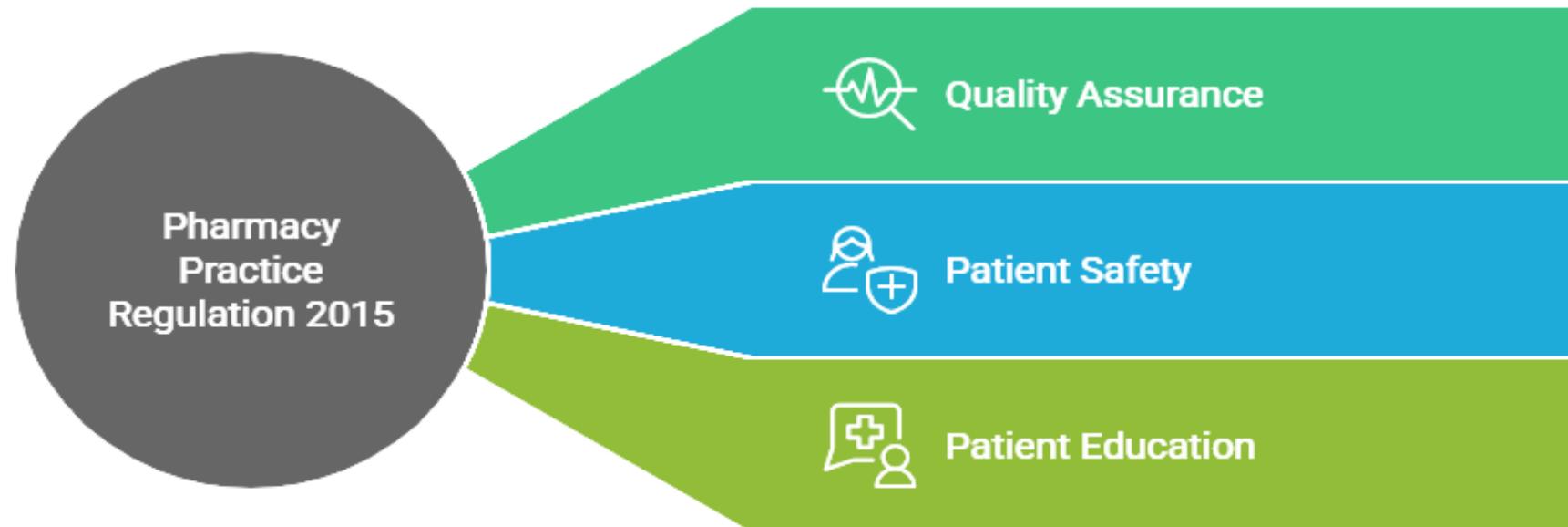
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Ensuring Quality Pharmacy Practice



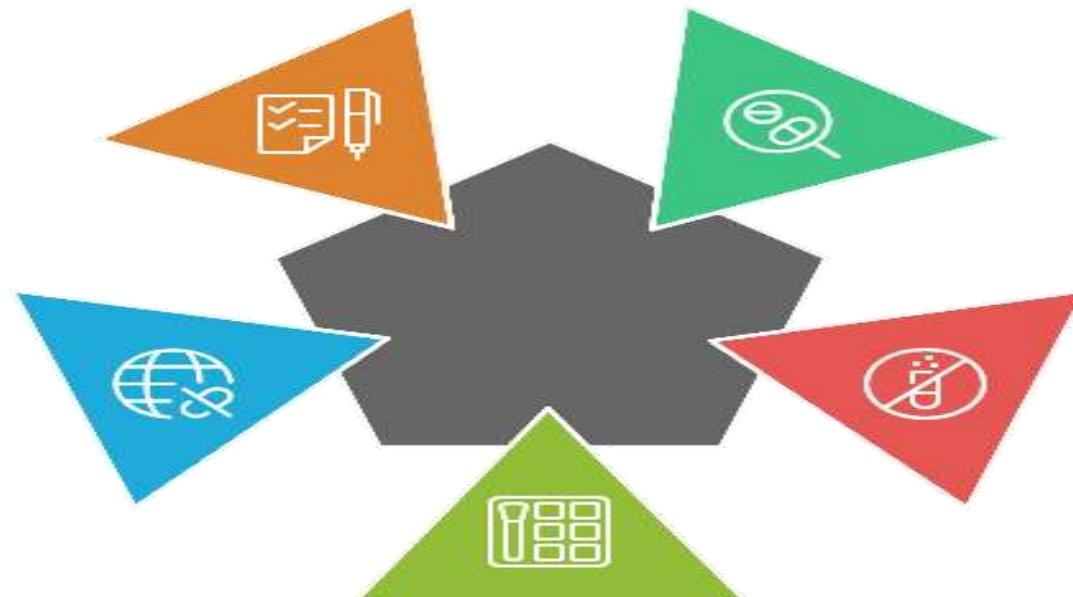
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Unveiling the Impact of Pharmacy Practice Regulation 2015



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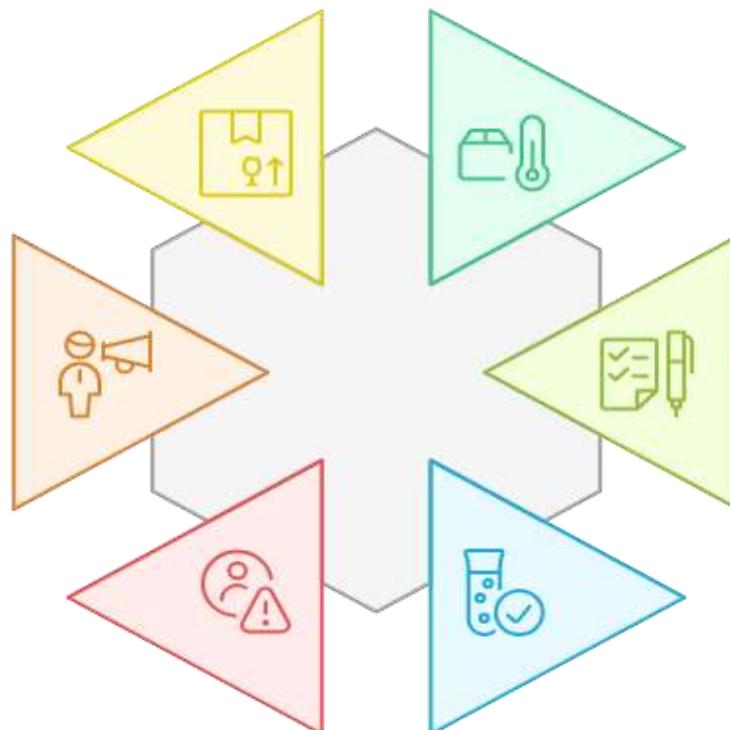
Ensuring Drug and Cosmetic Safety and Quality



- ▶ **Drug Quality Regulation**
Ensuring drugs meet specified standards
- ▶ **Prevention of Spurious Drugs**
Preventing the sale of fake or adulterated drugs
- ▶ **Cosmetic Regulation**
Regulating cosmetics for consumer safety
- ▶ **Control of Drug Imports**
Ensuring imported drugs meet Indian standards
- ▶ **Licensing and Inspection**
Licensing and inspecting businesses for compliance

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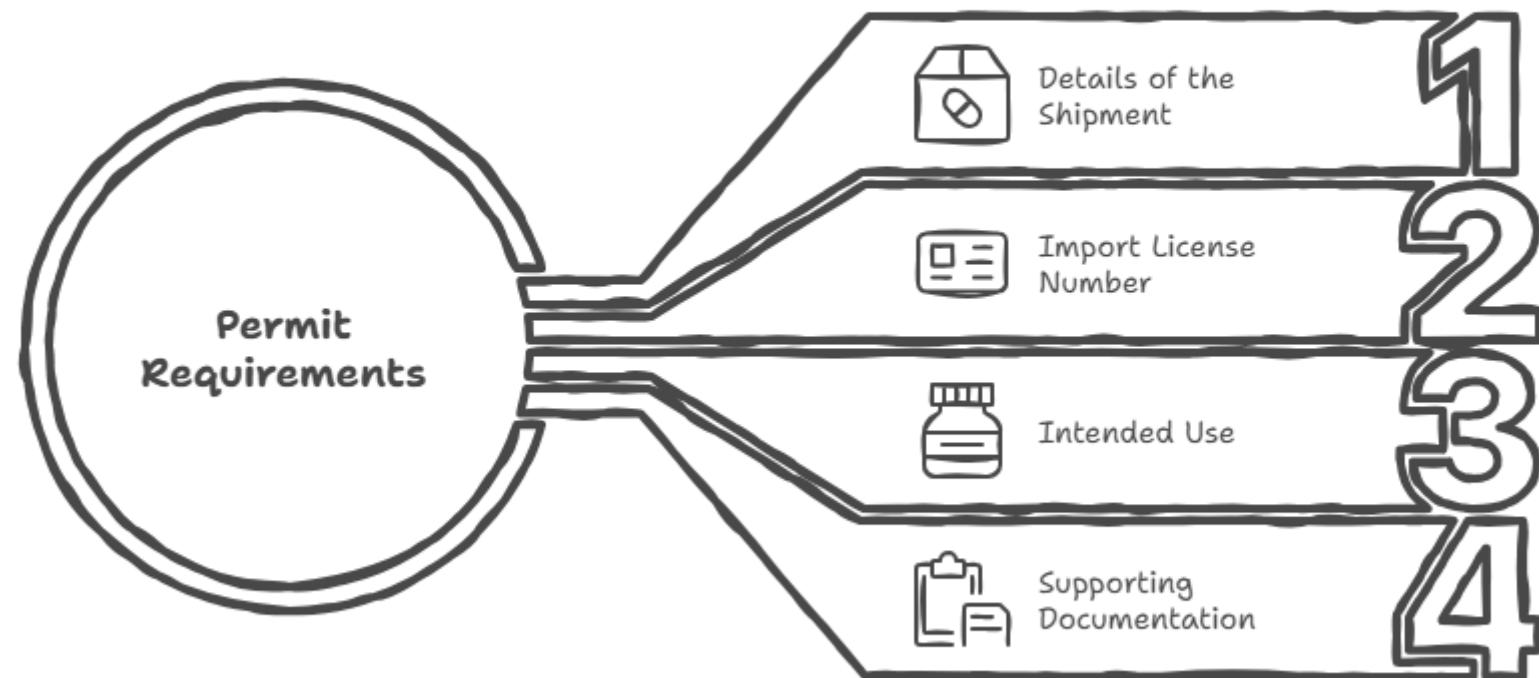
Ensuring Drug Safety and Quality



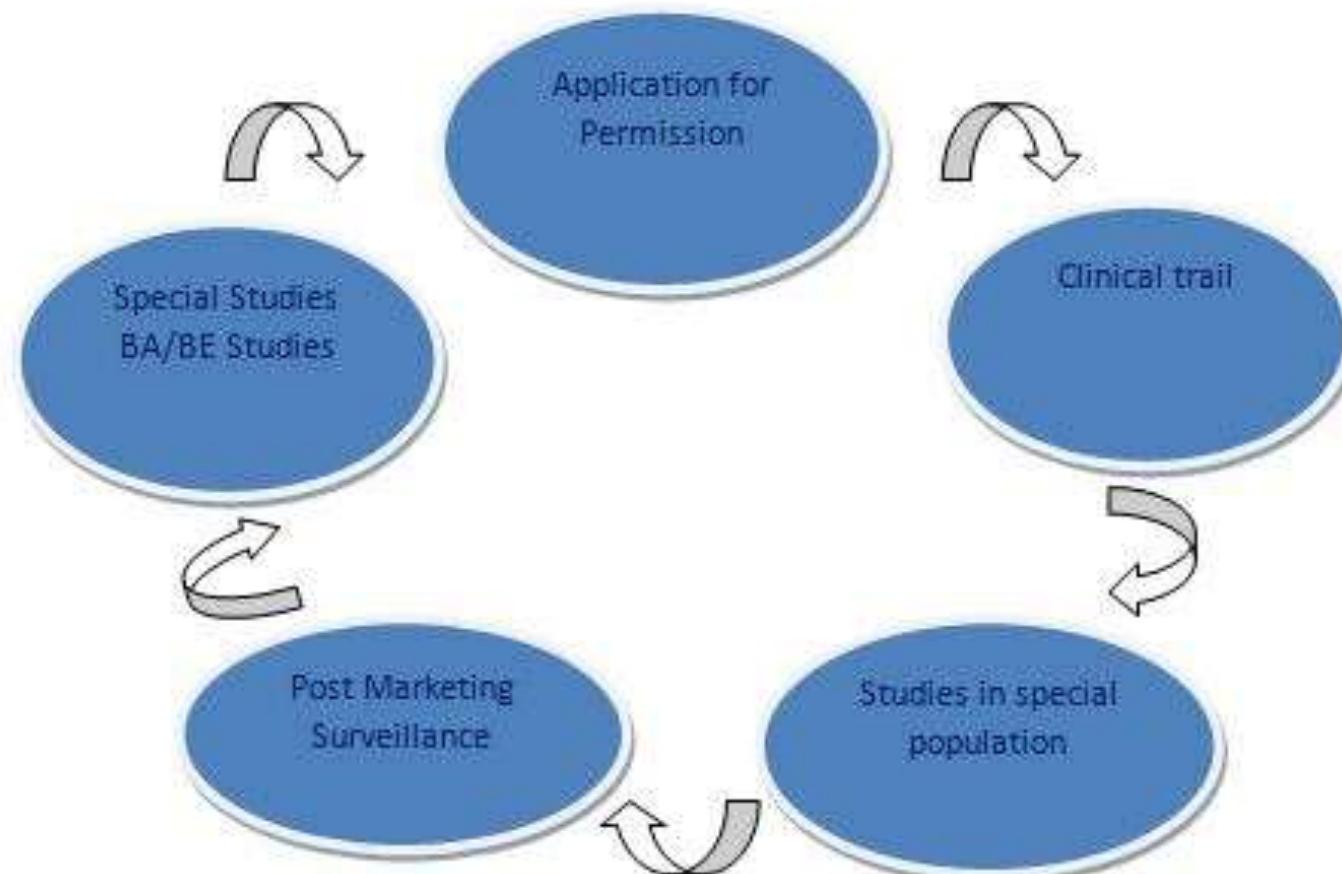
- ▶ **Storage and Handling**
Maintaining proper conditions to prevent degradation
- ▶ **Record Keeping**
Accurate documentation for traceability
- ▶ **Quality Control**
Testing to meet specifications
- ▶ **Adverse Event Reporting**
Reporting any negative effects
- ▶ **Recall Procedures**
Steps for removing unsafe drugs
- ▶ **Labeling and Packaging**
Proper identification and protection

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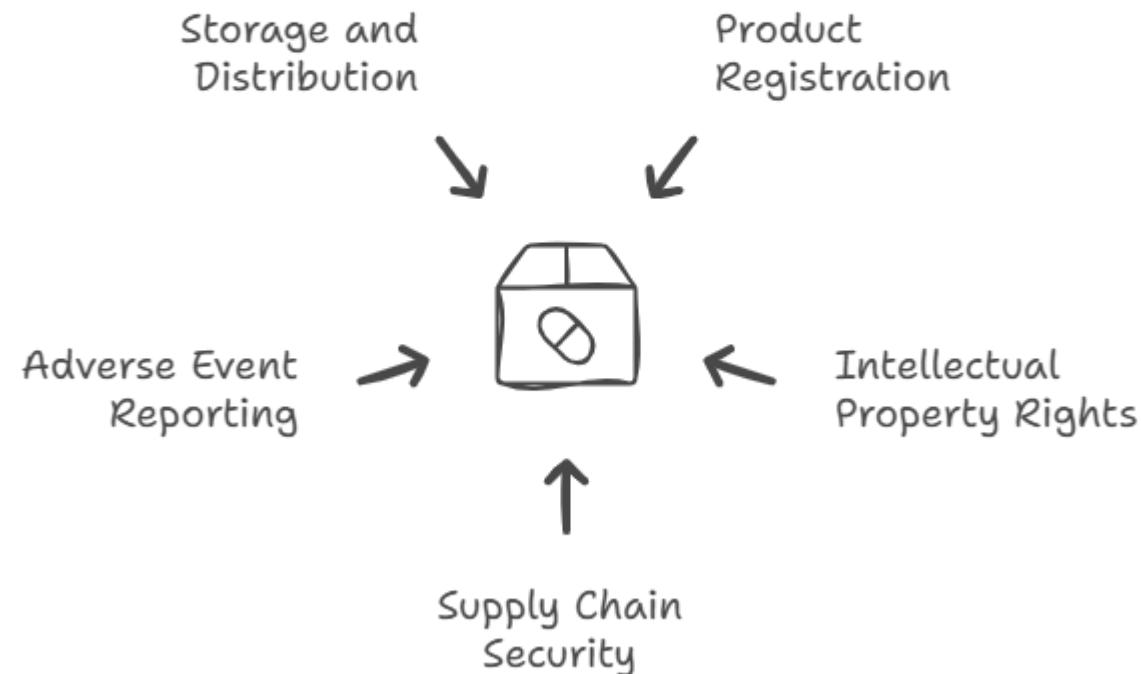
Unveiling Drug Import Permit Requirements



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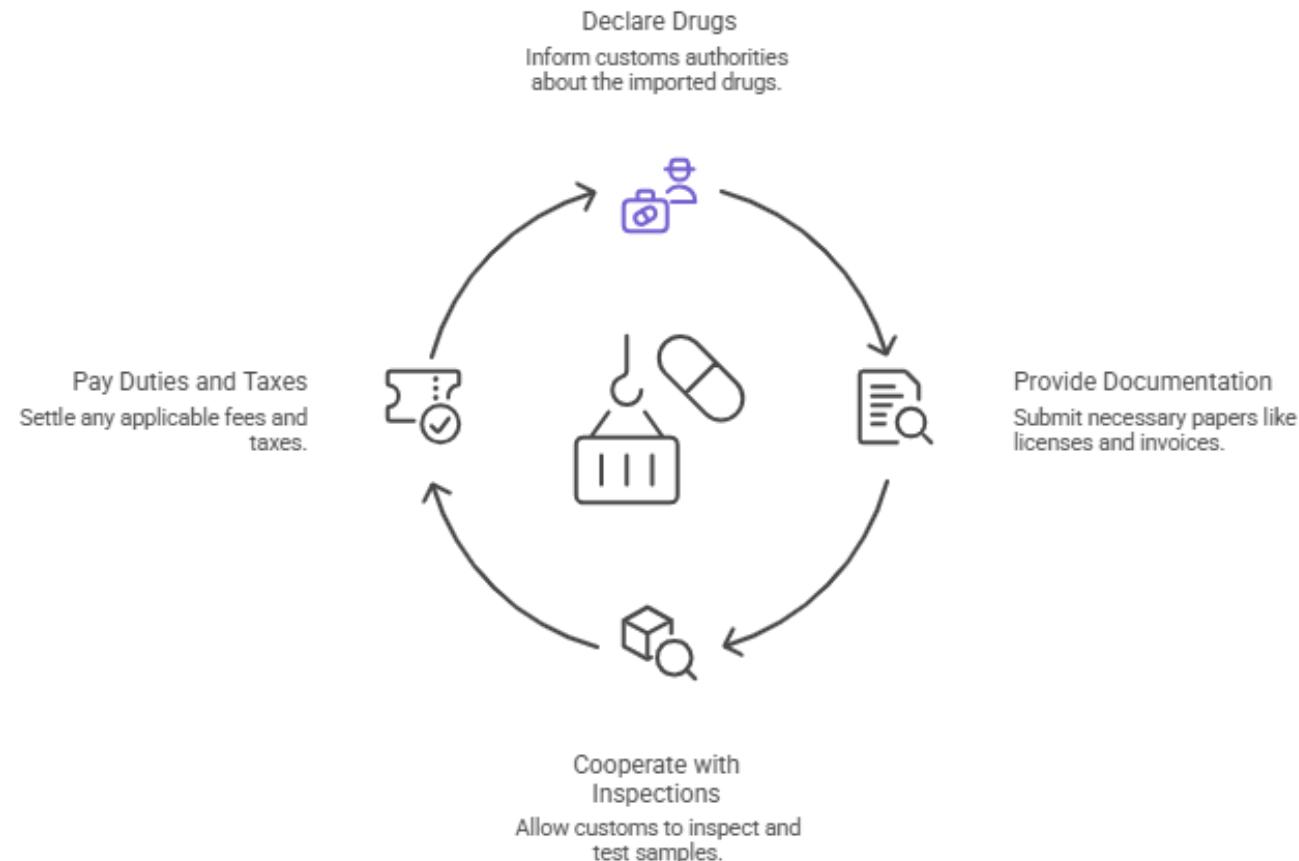


Factors Ensuring Safe and Legal Drug Importation



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Customs and Border Control Procedures Cycle

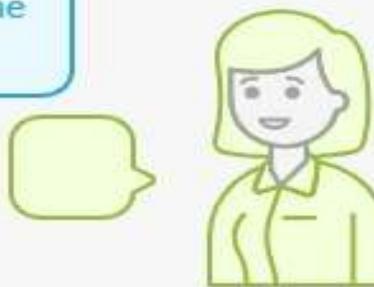


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ASSESSMENT

Pharmaceutical Import License Requirements

Explain the key regulatory requirements and documentation needed to obtain and maintain a license for importing pharmaceutical products into a specific country (choose either the United States or the European Union).



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How to obtain a drug import license?



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Importing a Novel Anti-Cancer Drug into the EU for Clinical Trials



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REFERENCE

1. Law and Ethics – B. K. Mathew Easy book for beginners on legal and ethical principles.
2. Ethics and Law – Dr. P. D. Sharma Simple explanation of ethics used in law and society.
3. Professional Ethics – K. C. Joshi Explains moral duties and professional conduct.
4. Legal Ethics – V. D. Mahajan Basic book on ethics followed by legal professionals.
5. Legal Information Institute (LII) – www.law.cornell.edu
6. Britannica – Law and ethics – www.britannica.com

