REGULATORY ASPECT OF IMPORT AND EXPORT OF PHARMACEUTICAL PRODUCTS

Vaishnavi Raut[1], Vaishnavi Wawge[1], Vaishnavi Thorat [1], Vaishnavi Ahir[1] Shivshankar M. Nagrik [2], Manisha R. Jawale [3], Prakash Kendre[4],

Somnath Vibhute [4], Shirish Jain [5].

[1]B. Pharm, Rajarshi Shahu College of Pharmacy ,Buldhana, Maharashtra, India.

[2] M. Pharm, Department of Pharmaceutics , Rajarshi Shahu College of Pharmacy ,Buldhana, Maharashtra, India.

[3] Assoc Prof. M. Pharm, Department of Pharmacology , Rajarshi Shahu College of Pharmacy ,Buldhana, Maharashtra, India.

[4]Assoc Prof. M.Pharm, Ph.D. Department of Pharmaceutics , Rajarshi Shahu College of Pharmacy ,Buldhana, Maharashtra, India.

[5] Principal, M. Pharm, Ph.D. Department of Pharmacology , Rajarshi Shahu College of Pharmacy ,Buldhana, Maharashtra, India.

Abstract

The globalization of the pharmaceutical industry has intensified the importance of robust regulatory frameworks governing the import and export of pharmaceutical products. This review comprehensively explores the regulatory landscape impacting international pharmaceutical trade, with a specific focus on India's regulatory architecture. Key international bodies such as the World Health Organization (WHO), World Trade Organization (WTO), and International Council for Harmonization (ICH) have established global standards, while regional authorities like the FDA (USA), EMA (EU), and CDSCO (India) govern national-level compliance. The study elaborates on India's EXIM policy, CDSCO guidelines, and legal frameworks including the Drugs and Cosmetics Act, Pharmacy Act, and GMP standards, which collectively regulate drug movement across borders. It highlights the procedures, documentation, and compliance requirements for acquiring import and export licenses, with special emphasis on new drug registrations, packaging and labeling norms, and risk mitigation measures. Additionally, the review discusses challenges such as counterfeiting, intellectual property rights protection, and regulatory harmonization versus national sovereignty. The role of emerging technologies like blockchain and track-and-trace systems in enhancing transparency and integrity in pharmaceutical supply chains is also addressed. Case studies of regulatory successes and failures provide practical insights into global best practices and pitfalls. Overall, the paper underscores the critical balance between ensuring drug safety, quality, and accessibility, while facilitating smooth international trade through coordinated regulatory policies.

Keywords: Pharmaceutical trade, Drug import, Drug export, Regulatory compliance, Global harmonization, Regulatory authorities, Drug registration,

Introduction

All around the globe, People need of medicines; some of the medicines are manufactured and available to them locally. For the remaining percentage the drug has to be imported from other countries. This emphasizes the trade of the drugs from one place of the world to another. Such a trade must be regulated in either way, both ethical and business oriented. Some of the organisations which regulate Pharma Business are World Trade Organisation (WTO), International Trade Organisation (ITO), and World Health Organisation (WHO). Apart from this, every country has its own laws and legislations for the purpose [1] . India occupies a third largest position in the world in the field of Pharmaceutical industry. These industries are regulated by the Ministry of Health & Family Welfare and Ministry of Chemical & Fertilizers. Despite of its position in Pharmaceutical market and its growing economy, a well sophisticated Research and Development is not affordable due to various reasons. To overcome this pitfall, India opens up its pharmaceutical market to MNC‟s and it encourages the trading of the drug in and out of the country. Most of the drugs for the Indian market are imported from the European Union followed by North America and Asia. India has a special policy for the purpose of Import and Export called as “EXIM” policy. This policy gives way to quantitative as well as qualitative improvements in the field of Research and Development activities[2].

Overview of Global Pharmaceutical Trade

The global pharmaceutical trade encompasses the production, distribution, and sale of pharmaceutical products across international borders. It is a multifaceted industry driven by factors such as increasing demand for healthcare, advancements in medical research, and globalization of pharmaceutical manufacturing.

- Market Size and Growth

The global pharmaceutical market is one of the largest and fastest-growing industries, valued at billions of dollars annually. According to market research reports, the market size is expected to continue growing steadily due to factors such as population aging, rising chronic diseases, and expanding access to healthcare in emerging markets.

- Key Players and Market Dynamics

Major pharmaceutical companies, both multinational corporations and local manufacturers, play a significant role in global pharmaceutical trade. The market is characterized by intense competition, patent protection, regulatory hurdles, and pricing pressures. Emerging markets, including countries in Asia, Latin America, and Africa, are becoming increasingly important players in the global pharmaceutical trade, offering growth opportunities for multinational companies.

- Manufacturing and Supply Chain

Pharmaceutical manufacturing is a globalized industry, with production facilities located in various countries to take advantage of cost efficiencies, skilled labour, and regulatory considerations. The pharmaceutical supply chain is complex, involving raw material sourcing, manufacturing, packaging, distribution, and retailing.

Supply chain disruptions, such as natural disasters or regulatory issues, can impact global pharmaceutical trade.

- Regulatory Environment

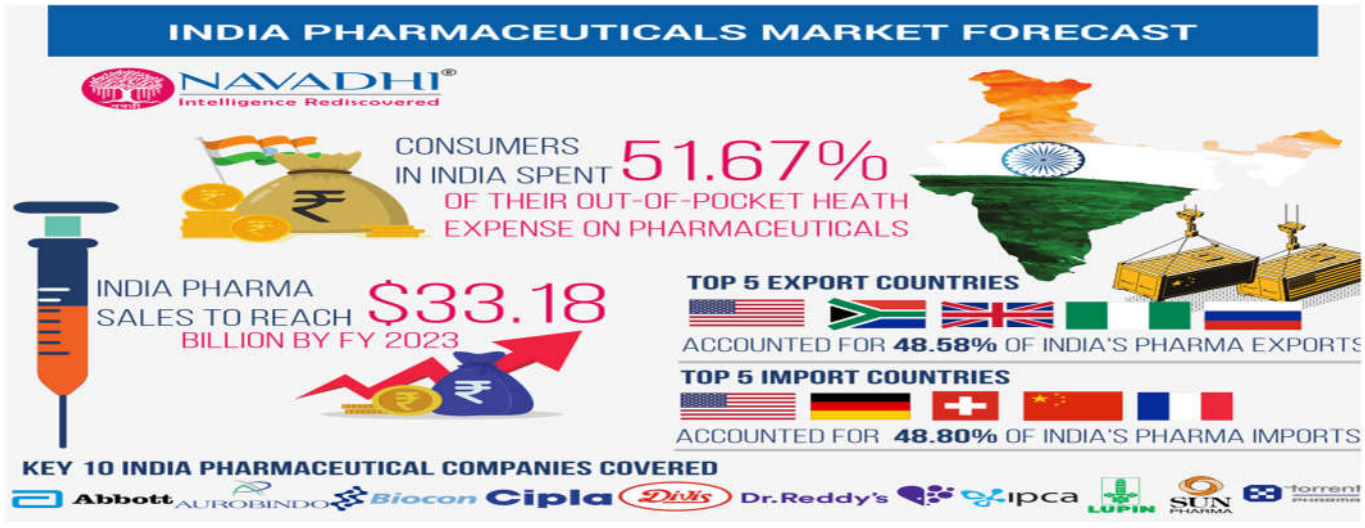
Regulatory requirements and standards vary between countries and regions, posing challenges for pharmaceutical companies engaged in international trade. Regulatory bodies, such as the FDA in the United States, EMA in Europe, and PMDA in Japan, oversee drug approval, quality control, and safety monitoring to ensure compliance with established standards.

- Trade Agreements and Harmonization Efforts

Trade agreements, such as free trade agreements (FTAs) and regional trade blocs, influence the flow of pharmaceutical products between countries by reducing tariffs, streamlining customs procedures, and harmonizing regulatory requirements. International harmonization initiatives, led by organizations like the International Conference on Harmonization (ICH), aim to standardize regulatory guidelines and facilitate the global development and registration of pharmaceutical products.

- Challenges and Opportunities

Challenges in global pharmaceutical trade include intellectual property rights protection, counterfeit medicines, and access to essential medicines, affordability, and disparities in healthcare infrastructure. Opportunities for growth exist in emerging markets, innovation in drug discovery and development, personalized medicine, biotechnology, and digital health technologies[3].



India Pharmaceuticals Market Forecast

pharmaceutical products. These organizations establish and enforce regulations, guidelines, and standards to ensure that pharmaceutical products meet the necessary requirements before they are marketed and distributed to patients. Here's an overview of some prominent regulatory bodies and authorities

A. International Bodies

1. World Health Organization (WHO)

The World Health Organization (WHO) is a specialized agency of the United Nations responsible for international public health. [4] It is headquartered in Geneva, Switzerland, and has six regional offices and 150 field offices worldwide [5] .

The WHO was established on April 7, 1948, and convened its first meeting on July 24 of that year.[6,7] It incorporated the assets, personnel, and duties of the League of Nations' Health Organization and the Paris-based Office International d'Hygiène Publique, including the International Classification of Diseases (ICD).[8] The agency's work began in earnest in 1951 after a significant infusion of financial and technical resources.[9] The WHO's official mandate is to promote health and safety while helping the vulnerable worldwide. It provides technical assistance to countries, sets international health standards, collects data on global health issues, and serves as a forum for scientific or policy discussions related to health.[4] Its official publication, the World Health Report, provides assessments of worldwide health topics[10] .

The WHO has played a leading role in several public health achievements, most notably the eradication of smallpox, the near-eradication of polio, and the development of an Ebola vaccine . Its current priorities include communicable diseases, such as HIV/AIDS, Ebola, malaria and tuberculosis; non-communicable diseases such as heart disease and cancer; healthy diet, nutrition, and food security; occupational health; and substance abuse. The agency advocates for universal health care coverage, engagement with the monitoring of public health risks, coordinating responses to health emergencies, and promoting health and well-being generally [11] .

The World Health Assembly (WHA), composed of its 194 member states, governs the World Health Organization (WHO)." The WHA elects and advises an executive board made up of 34 health specialists; selects the WHO's chief administrator, the director-general (currently Tedros Adhanom Ghebreyesus of Ethiopia); [12] sets goals and priorities; and approves the budget and activities. The WHO is funded primarily by contributions from member states (both assessed and voluntary), followed by private donors. Its total approved budget for 2020–2021 is over $7.2 billion. [4, 13] while the approved budget for 2022–2023 is over $6.2 billion.

2. International Conference on Harmonization (ICH)

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. The mission of the ICH is to promote public health by achieving greater harmonisation through the development of technical Guidelines and requirements for pharmaceutical product registration. [14] .

Harmonisation enables a more rational use of human, animal, and other resources, eliminating unnecessary delays in the global development, and availability of new medicines while maintaining safeguards on

quality, safety, efficacy, and regulatory obligations to protect public health. Junod notes in her 2005 treatise on Clinical Drug Trials that "Above all, the ICH has succeeded in aligning clinical trial requirements"[15] .

3. World Trade Organization (WTO)

Member governments form the World Trade Organization (WTO), an intergovernmental organization headquartered in Geneva, Switzerland[16] that regulates and facilitates international trade.[17] Governments use the organization to establish, revise, and enforce the rules that govern international trade in cooperation with the United Nations System.[17,18] The WTO is the world's largest international economic organization, with 164 member states representing over 98% of global trade and global GDP[19,20] .

The WTO facilitates trade in goods, services and intellectual property among participating countries by providing a framework for negotiating trade agreements, which usually aim to reduce or eliminate tariffs, quotas, and other restrictions; these agreements are signed by representatives of member governments[20] and ratified by their legislatures.[19] It also administers independent dispute resolution for enforcing participants' adherence to trade agreements and resolving trade-related disputes. The organization prohibits discrimination between trading partners, but provides exceptions for environmental protection, national security, and other important goals [20].

B. Regional Bodies

1. European Medicines Agency (EMA)

The European Medicines Agency (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of pharmaceutical products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency (EMEA). The European Union, the pharmaceutical industry, and member states (through indirect subsidies) established the EMA in 1995, with its stated intention to harmonise (but not replace) the work of existing national medicine regulatory bodies. The hope was that this plan would not only reduce the €350 million annual cost drug companies incurred by having to win separate approvals from each member state but also that it would eliminate the protectionist tendencies of sovereign states unwilling to approve new drugs that might compete with those already produced by domestic drug companies. The EMA was founded after more than seven years of negotiations among EU governments and replaced the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, though both of these were reborn as the core scientific advisory committees. The agency was located in London prior to the United Kingdom's vote for withdrawal from the European Union, relocating to Amsterdam in March 2019 [21,22].

2. Food and Drug Administration (FDA or US FDA)

The United States Food and Drug Administration (FDA or US FDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter pharmaceutical

drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic

radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products. The FDA is led by the Commissioner of Food and Drugs, appointed by the President with the advice and consent of the Senate. The Commissioner reports to the Secretary of Health and Human Services. Robert Califf is the current Commissioner as of 17 February 2022. The FDA's headquarters is located in unincorporated White Oak, Maryland. 223 field offices and 13 laboratories are located across the 50 states, the United States Virgin Islands, and Puerto Rico, and the agency maintains them. In 2008, the FDA began posting employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom[23,24].

3**. Pharmaceuticals and Medical Devices Agency**

The Pharmaceuticals and Medical Devices Agency (PhMDA) is an Independent Administrative Institution responsible for ensuring the safety, efficacy and quality of pharmaceuticals and medical devices in Japan. It is similar in function to the Food and Drug Administration in the United States, the Medicines and Healthcare products Regulatory Agency in the United Kingdom, the Spanish Agency of Medicines and Medical Devices in Spain or the Food and Drug Administration in the Philippines.The PhMDA has been eCTD compliant at least since December 2017[25] .

4. **Therapeutic Goods Administration** (**TGA**)

The Therapeutic Goods Administration (TGA) is the medicine and therapeutic regulatory agency of the Australian Government. As part of the Department of Health and Aged Care, the TGA regulates the quality, supply and advertising of medicines, pathology devices, medical devices, blood products and most other therapeutics. Any items that claim to have a therapeutic effect, are involved in the administration of medication, or are otherwise covered by the Therapeutic Goods Act 1989, the Therapeutic Goods Regulations 1990, or a ministerial order, must be approved by the TGA and registered in the Australian Register of Therapeutic Goods [26].

5. Central Drugs Standard Control Organisation (CDSCO)

India's national regulatory body for cosmetics, pharmaceuticals and medical devices is the Central Drugs Standard Control Organisation (CDSCO). A similar function to the Food and Drug Administration (FDA) of the United States or the European Medicines Agency of the European Union is served by it. A review of the Central Drugs and Standard Control Organisation (CDSCO) is planned by the Indian government to bring all medical devices, including implants and contraceptives, under its purview. Within the CDSCO, the Drug Controller General of India (DCGI) regulates pharmaceutical and medical devices and is positioning within the Ministry of Health and Family Welfare. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Divided into zonal offices, each one carries out pre-licensing and post-licensing inspections, post-market surveillance, and drug recalls (where necessary). Manufacturers who deal with the authority required to name an Authorized Indian Representative (AIR) to represent them in all dealings with the CDSCO in India [27].

An Authorized Indian Representative (AIR) is required to be named by manufacturers who deal with the authority, to represent them in all dealings with the CDSCO in India. [27] The import and export of drugs in the country are regulated by the Central Drugs Standard Control Organisation (CDSCO) through 11 Port offices located in different parts of the country. The manufacture, sale, import, export, and clinical research of drugs in India are regulated by CDSCO through the following rules and acts [28] .

1. Drugs and Cosmetics act, 1940 and Rules, 1945.
2. Pharmacy act, 1948.
3. Drugs and Magic Remedies act, 1954.
4. Medicinal and Toilet Preparation act, 1956.
5. Narcotic and Psychotropic Substances act, 1985.
6. The Drugs (Prices Control) order, 1995.

The CDSCO also work through state authorities. While, the central authorities are responsible for approval of new drugs, clinical trials in the country; laying down the standards for the drugs control over the quality of imported drugs coordination of the state drug control organisations; the state authorities regulates manufacture, sale and distribution of drugs, licensing drug testing laboratories, approving drug formulations for manufacture, carrying out pre and post licensing inspections, for the drugs manufactured and marketed in the respective states [1,2,29]. The new patent regime has ushered in the era of product patents for the pharmaceutical sector, in line with the obligations under the World Trade Organization (WTO) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. As a result, the Indian pharmaceutical industry has become self-reliant in several areas and has developed a sounder and technologically advanced R&D segment.

CDSCO Guidelines for Import and Export of Pharmaceuticals

In the dynamic landscape of the pharmaceutical enterprise, the import and export of pharmaceutical products play a pivotal position in ensuring the availability of safe and effective drug treatments internationally. India, as a good-sized contributor to the worldwide pharmaceutical market, operates under the regulatory supervision of the Central Drugs Standard Control Organization (CDSCO). Adherence to CDSCO recommendations for the import and export of pharmaceuticals, and their understanding, is crucial for companies engaged in internal e. The key elements of CDSCO's guidelines are explored by “CDCO Guideli Import Export Ptica,” supplying insights into the requirements and exceptional practices that agencies need to navigate efficiently. Compliance with CDSCO regulations is required when importing pharmaceutical products into India to safeguard public health and maintain product quality."

Key CDSCO Guidelines for Import of Pharmaceuticals

Importing pharmaceutical products into India requires compliance with CDSCO regulations to safeguard public health and maintain product quality.

Some of the key guidelines for Import of Pharmaceuticals include:

1. A valid import license issued by CDSCO is mandatory for importing pharmaceutical products into India. The license is granted under Form 10 of the Drugs and Cosmetics Rules, 1945.
2. Imported drugs and pharmaceuticals must be registered with CDSCO under Form 41. The registration certificate serves as authorization for the importation of specific pharmaceutical products.
3. Companies engaged in pharmaceutical import activities must obtain an IEC from the Directorate General of Foreign Trade (DGFT). The IEC is a prerequisite for customs clearance and facilitates international trade transactions.
4. Importers are required to submit an authorization letter from the manufacturer or marketing authorization holder (MAH) authorizing them to import specific pharmaceutical products on their behalf.
5. Imported pharmaceutical products must comply with GMP standards established by CDSCO to ensure quality and safety. Manufacturers must provide evidence of GMP compliance through relevant documentation.
6. Imported pharmaceutical products must comply with CDSCO labelling and packaging regulations, including the provision of essential product information in English and adherence to packaging standards.

Requisite Documents for pharmaceutical Import

- Application Form
- Import License (Form 10)
- Certificate of Pharmaceutical Product (COPP)
- Good Manufacturing Practices (GMP) Certificate
- Power of Attorney (POA)
- Free Sale Certificate (FSC)
- Stability Data
- Manufacturing License
- Product Dossier
- Other Supporting Documents (e.g., manufacturing agreement, batch information, specifications, validation reviews, pharmacovigilance information).

Procedure Followed by CDSCO for Import of Pharmaceuticals

To guarantee compliance with Indian regulations and navigate the regulatory terrain, pharmaceutical importers must acquire a clear understanding of the CDSCO Pharmaceutical Import procedure.

- Prepare the required documents along with the Application Form (Form 40), Drug Import License (Form 10), NOC, CoA, and so on.
- Apply in conjunction with files to the CDSCO workplace or respective zonal workplace.
- CDSCO evaluations programs and may conduct inspections if required.
- Upon approval, CDSCO troubles vital allows for import.
- Proceed with customs clearance for the usage of the CDSCO registration certificate.
- Ensure compliance with post-import guidelines.

Explaining the CDSCO Guidelines for Export of Pharmaceuticals

Exporting pharmaceutical products from India involves compliance with CDSCO regulations to ensure product quality and safety in international markets. Key export guidelines for Pharmaceuticals include:

1. A valid export license issued by CDSCO is essential for exporting pharmaceutical products from India. The license is granted under Form 10 of the Drugs and Cosmetics Rules, 1945.
2. Pharmaceutical products intended for export must be manufactured in facilities compliant with GMP standards prescribed by CDSCO. Exporters must ensure that manufacturing facilities meet GMP requirements and maintain relevant documentation.
3. Exporters are required to provide a CoA for each batch of pharmaceutical products intended for export. The CoA verifies the quality, purity, and potency of the products and is issued by an accredited laboratory.
4. Exporters must obtain a COPP issued by CDSCO for each pharmaceutical product intended for export. The COPP certifies that the product is manufactured in compliance with Indian regulatory standards.
5. Exporters may be required to provide an FSC issued by CDSCO, attesting that the pharmaceutical product is freely marketed and sold in India without any restrictions.
6. Exporters must classify pharmaceutical products according to HS codes recognized internationally to facilitate customs clearance and trade documentation.

Documents Required for Export of Pharmaceuticals

For exporting pharmaceutical merchandise from India and acquiring a CDSCO Certificate, the subsequent files are normally required:

- Application Form for Export License
- Export License (Form 10)
- Certificate of Pharmaceutical Product (COPP)

- Good Manufacturing Practices (GMP) Certificate
- Free Sale Certificate (FSC)
- Certificate of Origin
- Invoice Proforma
- Bill of Lading/Airway Bill
- Packing List
- Insurance Certificate

Procedure Followed by CDSCO for Export of Pharmaceuticals

- Obtain essential licenses, along with a Drug Export License from CDSCO.
- Ensure pharmaceutical products meet exceptional requirements in India and the vacation spot United States of America.
- Prepare export files such as EDF, invoice, packing list, CoA, and others as required.
- Clear customs by filing export documentation.
- Apply for a CDSCO Export Certificate to verify compliance with Indian standards.
- Arrange shipment with the use of accredited companies.
- Comply with import regulations and requirements of the destination country.
- Submit any required publish-export reviews to the regulatory government.
- Maintain excellent control measures and bear in mind techniques.

Legal Framework

A. IMPORT

Procedure for Import and Registration of Drugs

Form and Manner of Application

A. Import License

1. An application for an import License shall be made to the licensing authority in Form 8 for drugs excluding Schedule X, and in Form 8-A for Schedule X drugs; either by the Manufacturer or by the Manufacturers agent in India who is having the wholesale license for sale or distribution of drugs and shall be accompanied by a License fee of one thousand rupees for a single drug and one hundred rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer.

2. Any application for import licence in Form 8 or 8-A, which shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A; in the case of emergencies the issue of Import License by the central government in Form 10 or 10-A without issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.

3. A fee of two hundred and fifty rupees shall be paid for a duplicate copy of licence, if the original is defaced, damaged or lost.

B. Registration Certificate

1. Application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer or authorized agent in India under this rule and shall be specified in the sub rule (3) and the information and undertakings specified in Schedule D-1 and Schedule D-II duly signed by on behalf of the manufacturer.

2. The authorization by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

3. (i). A fee of one thousand and five hundred US dollars shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import and use in India.

(ii). A fee of one thousand US dollars shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug.

4. The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104- Fees and Fines"; in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank.

5. The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under rule 22.

6. The applicant shall be liable for the payment of testing fee directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.

7. A fee of three hundred US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

8. No Registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without Pharmacopoeial conformity[30].

Licenses for of drugs manufactured by a single Applicant

A. Import: A single application may be made, and a single License may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer. (Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit: Provided further that if a single manufacturer has two or more factories situated in

different places manufacturing the same or different drugs a separate License shall be required in respect of drugs manufactured by each such factory.).

B. Registration Certificate: A single application may be made, and a single Registration Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer.

Specified before a license in form 10 or form 10- a is granted

1. A License in Form 10 or in Form 10-A shall be granted by the licensing authority having regard to

i) The premises, where the imported substances will be stocked.

ii) The occupation, trade or business ordinarily carried out by the applicant:

a. That the applicant has not complied with the provisions of the Act or these rules, or

b. That by reasons of- His conviction under Narcotic Drugs and Psychotropic Substances Act and Previous suspension or cancellation of the License granted to him.

2. Any person who is aggrieved by the order passed by the licensing authority[30].

Grant

A. Import License

1. On receipt of an application for an import License in the form and manner prescribed in Rule 24, the licensing authority shall on being satisfied, that, if granted, the conditions of the License will be observed, issue an import License in Form 10 or Form 10-A, as the case may be.

2. A License, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from date of its issue and for a fresh license is made three months before the expiry. B. Registration Certificate: 1. On receipt of an application for Registration Certificate in the Form and manner specified in rule 24-A, the licensing authority shall, on being satisfied that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form-41. 2. If the applicant does not receive the Registration Certificate within the period as specified in provision to sub rule (1), he may appeal to the Central Government.

3. A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue and for a fresh Registration Certificate is made nine months before the expiry of the existing certificate.

Suspension and cancellation

Both the Import License and Registration Certificate will be suspended or Cancelled, if the manufacturer or licensee fails to comply with any of the conditions, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel it for such period as it thinks fit either wholly or in respect of some of the substances to which it relates. The drugs in the schedule C and C1 are prohibited for import into the country after the expiry of potency of the drug

product. If the drug is banned in the country of origin then it is prohibited from importing into the country except for the purpose of Examination, test or Analysis [30].

Packaging and Labelling

A. Imported Drugs: Drug shall be packed and labelled in conformity with the rules parts IX and X and also Schedule F (1), in the case of drugs for Veterinary use is Part XII.

B. Packing of Patent or Proprietary Medicine: Patent or proprietary medicines shall be imported in bulk containers, applicant need to get permission from the licensing authority at least three months prior to the date of import and the validity will be twelve months from the date of issue.

New Drugs for the treatment of Patients: [33] .

A. Import

a. No new drug shall be imported for except under a License in Form 11- A, and the said drug has been approved for marketing in the country of origin.

b. The Licensee shall use the substances or drugs imported under the License.

c. The Licensee shall allow an Inspector authorized by the licensing authority with or without prior notice.

d. The Licensee shall keep a record, and shall submit the report half yearly to the licensing authority.

e. The Licensee shall comply with other requirements, made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.

f. The drug shall be stored under proper storage condition and shall be dispensed under supervision of a registered Pharmacist.

g. The quantity of single drug imported shall not exceed 100 average doses per patient.

B. Application for License

a. An application for an import License for small quantities of a new drug, as defined in rule 122- E for the purpose of treatment of patients.

b. The licensing authority may require such further particulars to be supplied, as he may consider necessary.

c. Every application in Form 12-AA shall be accompanied by a fee of one hundred rupees for a single drug and an additional fee of fifty rupees for each additional drug.

d. The fees shall be paid through a challan in the Bank of Baroda.

C. Cancellation of License

a. A License for import of small quantities of a new drug, defined in rule 122-E, for the purpose may be cancelled by the licensing authority for the conditions subject to which the License was issued.

b. A licensee whose License has been cancelled may appeal to the Central Government within three months of the date of the order [30].

Import of New Homeopathic Medicine

New Homoeopathic Medicine

1. A Homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeia of India or United States of America or of the United Kingdom or the German Homoeopathic Pharmacopoeia; or

2. Which is not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended; or

3. A combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) as Homoeopathic medicines and also not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended.

New Homoeopathic medicine shall not allow to import except under the permission of the Licensing Authority, licensee shall submit the document which explains the therapeutic efficacy 6 No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX- A[1,31,32].

Procedure for the Import of Drugs:

1. If the Customs Collector has reason to doubt any drugs comply with the provisions of Chapter III of the Act and Rules, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the director of the laboratory appointed for this purpose.
2. If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the Customs Collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice.
3. If the Director of the laboratory appointed for the purpose by the Central Government or other officer empowered by him, subject to the approval of the Central Government, reports to the Customs Collector that the samples of any drug in a consignment are not of standard quality, or the drugs under provisions of Chapter III of the Act or the Rules and that the contravention is such that it cannot be remedied by the importer, the Customs Collector shall communicate the importer who shall, within two months of his receiving the communication either export all the drugs or destroyed. The importer may within fifteen days of receipt of the report make a representation against the Customs Collector, and the Customs Collector shall forward the representation with a further sample to the licensing authority, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.
4. If the Director of the laboratory appointed for the by the Central Government or any officer empowered by him, subject to the approval of the Central Government reports to the Customs Collector that the

samples of any drug contravene in any respect the provisions of Chapter III of the Act or the Rules and that the contravention is remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer and permit him to import the drug and writing not to dispose of the drug without the permission of the officer authorized in this purpose. The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made there under, and subject to conditions specified in that Schedule.

5. Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter III of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made there under. The importers shall produce documents at the time of import in India to get import license[30].

Common Submission Format for Import and Registration of Bulk Drugs and Finished Formulations of Bulk Drugs and Finished Formulations in India

Requirements for Registration of Drugs in Form 40

1. Covering Letter:

This contains the list of documents shall be submitted and any other information provided, it shall be duly signed and stamped by the authorized signatory along with the name and address of the firm.

2. An Authorization Letter:

An Authorization letter in original issued by Director/Company Secretary/Partner of the Indian agent firm revealing the name & designation of the person authorized to sign Form 40, Power of Attorney, etc., it shall be submitted at the time of registration along with duly self-attested photocopies.

3. Form 40 & TR 6 Challan: It shall be filled as per Drugs & Cosmetics Rules, signed and stamped along with name & designation and date of the Local Authorized Agent. Performa shall be enclosed at Annexure-I. Payment shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, New Delhi, through the electronic code of the bank.

4. Power of Attorney: The authorization by a manufacturer to his agent in India shall be documented by Power of attorney authenticated in India or by country of origin, the certificate shall be attested by Indian Embassy of the said country and original copy shall be submitted along with the application for Registration Certificate (RC). Performa for Power of Attorney (POA) is enclosed at Annexure III. The authorized agent will be responsible for manufacturer's business activity, in India. While submitting the Power of Attorney, the following shall be needed:

It shall be signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories.

It shall be clearly lists the names of all the proposed drugs if possible along with their uses. Further, the names of the proposed drug should correlate with Form 40, Free Sale Certificate or Certificate of pharmaceutical product (COPP) as per WHO-GMP certification scheme.

The names & addresses of the manufacture and the Indian Agent stated in the Power of Attorney should correlate with the Form 40. Multiple sites are in tabular form. And the Fresh POA shall be submitted at the time of Re-Validation of RC.

5. Wholesale License A duly attested and valid copy of Wholesale License for sale or distribution of drugs under Drugs and Cosmetics Rules in Form 20B & 21B or its renewal in Form 21C issued to the manufacturer or its agent by the State Licensing Authority in India.

6. Undertaking: Signed & stamped by the manufacturer/Authorized agent indicating the name and designation of the authorized signatory required to be submitted as per Performa for Schedule D (I) is enclosed at Annexure IV along with CTD module 1 covering the Schedule D (I) requirement. The requirements for Plant Master File are enclosed at Annexure V.

7. Modules 2-5 Covering the schedule D (II) requirements: Standard of the Drug: Second Schedule of the act explains Imported drugs shall be compile with the standard which are there in IP, USP, BP, EP, etc., Label Submission: True copy of the Label as per Rule 96, if it is in IP means as per label claim in IP. Testing of Drugs: For Registration of Bulk Drugs, the consecutive three batches shall be submitted to the laboratory for the analysis and reanalysis along with specifications, Method of analyses, COA tested in their laboratory, impurity Standards, marker compounds, Reference Standard along with its COA where ever applicable.

8. Free Sale Certificate (FSC): Free Sale Certificate should state that the proposed drug is freely sold in Country of Origin and can be legally exported.

9. Certificate of Pharmaceutical Products (COPP): The valid copy of GMP Certificate or COPP as per WHO scheme for each drug issued by the National Drug Regulatory Authority of the country of origin. Format for COPP is enclosed at Annexure VII.

10. Manufacturing License: The valid copy of the Manufacturing License or Market Authorization certificate issued by the National Drug Regulatory Authority of the Country of origin. If available, free sale certificate also be submitted.

11. Product Registration Certificate: The valid copy of Product Registration Certificate wherever applicable in respect of the foreign manufacturing sites.

a. Soft copy of the Plant Master File and Drugs Master File shall be submitted along with the application.

b. All certificates submitted shall be within the valid period. All the regulatory and legal documents in separate file and Plant Master File and Drug Master File as separate files.

c. In case, the item considered as drug as per the definition of section 3 (b) of the Act in India but not registered as drug in the country of origin a legal undertaking from the manufacturer and approval from the competent authority of the country of origin duly notarized and apostle should be submitted.

d. The application of r-DNA products should be made separately as per the guidance document for submissions of biological.

e. In case of bulk drug, if the same is approved in EU/USA etc. DMF approval number may mention on the covering letter itself.

f. In case of toll manufacturer to be registered for a drug, the POA shall be signed by the legal manufacturer in the country of origin, this submitted as proof.

g. POA should be supplemented with declarations in respect of sites involved in the manufacturing and testing of the applied drugs as per the format given hereunder [3].

Renewal of Registration or Re-registratio

The application is to be made 9 months before the expiry of the Registration Certificate along with regulatory documentary compliance like Form 40, POA, GMP / COPP, Registration certificate, DMF, License etc.,

i. Undertakings by the manufacturer or his authorized agent in India in respect of any administrative action taken due to adverse reaction, market withdrawal, regulatory restrictions, or cancellation of authorization, not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed.

ii. Any change in manufacturing process, or packaging, or labelling or testing, or in documentation of any of the drug pertaining to this Registration Certificate

iii. Any change in the constitution of the firm including name and /or address of the registered office/ factory premises operating under this Registration Certificate.

iv. Details of drugs imported in India during last three years.

v. Submission of original RC issued[4].

Requirements for Registration of Drugs in Form 10 [34].

1) Covering Letter

2) An Authorization Letter

3) Form 8-Duly signed and stamped by the Indian agent along with the name & designation of the authorized signatory, Performa is enclosed at Annexure-XII.

4) Form 9-Duly signed and stamped by the Indian agent along with the name & designation of the authorized signatory, if the form 9 is issued by the manufacturer, it shall be authenticated from Indian Embassy of the country of origin, Performa is enclosed at Annexure-XIV.

5) Requisite fee: Rs.1000 for 1 proposed drug and Rs.100 for each additional drug shall be paid at Bank of Baroda, New Delhi.

6) Wholesale license

7) Registration Certificate

B. EXPORT

1. Export Licensing

Export licensing is a regulatory requirement imposed by governments to control the export of certain goods, including pharmaceutical products. Here's an overview:

- Purpose: Export licensing aims to regulate the export of sensitive or strategic goods, including pharmaceuticals, to ensure compliance with national and international regulations, prevent diversion to unauthorized users, and safeguard public health and safety.
- Regulatory Authorities: Export licensing is typically administered by government agencies responsible for trade, commerce, or customs, such as the Department of Commerce in the United States or the Directorate-General for Trade in the European Union.
- Licensing Process: Pharmaceutical exporters must obtain export licenses from the relevant regulatory authority before exporting their products. The licensing process may involve submitting an application, providing supporting documentation (e.g., product information, certificates of analysis), and paying applicable fees.

Compliance Requirements: Export licenses may be subject to specific conditions or restrictions, such as quantity limits, destination controls, end-user certifications, or compliance with international trade agreements and sanctions regimes[35].

2. Quality Control and Documentation

- Quality control and documentation are essential aspects of pharmaceutical export regulations to ensure that exported products meet the required standards and specifications. Here's an overview:
- Quality Control: Pharmaceutical exporters are responsible for implementing quality control measures to ensure the consistency, purity, potency, and safety of their products. This includes adherence to good manufacturing practices (GMP), quality assurance procedures, and product testing.

- Documentation Requirements: Exporting pharmaceutical products typically requires extensive documentation to demonstrate compliance with regulatory standards and facilitate customs clearance. Common documents include certificates of analysis, manufacturing records, batch records, labeling specifications, and packaging documentation.
- Regulatory Oversight: Regulatory authorities may conduct inspections of pharmaceutical manufacturing facilities and review documentation to verify compliance with quality standards and regulatory requirements. Non-compliance can result in export restrictions, product recalls, or legal sanctions[36].

3. Sanitary and Phytosanitary Measures (SPS):

Sanitary and phytosanitary measures (SPS) are regulatory requirements imposed by governments to protect human, animal, or plant health from risks associated with imported goods, including pharmaceutical products.

- Purpose: SPS measures aim to prevent the introduction or spread of pests, diseases, contaminants, or harmful substances through imported pharmaceuticals, ensuring their safety and efficacy for consumers.
- Regulatory Framework: SPS measures are governed by international agreements, such as the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO), as well as national regulations and standards established by regulatory authorities.
- Compliance Requirements: Pharmaceutical exporters must comply with SPS requirements by ensuring that their products meet relevant health and safety standards, undergo proper testing and inspection, and are accompanied by appropriate documentation, such as certificates of analysis or conformity.
- Risk Assessment: Regulatory authorities may conduct risk assessments to evaluate the potential health risks associated with imported pharmaceuticals and determine the need for additional controls or restrictions to mitigate those risks[37].

Procedure for Obtaining No Objection Certificate (NOC) for Export of Unapproved/Approved New Drugs/Banned Drugs

A Manufacturer holding valid license copy in Form-25 and Form-28 can obtain No Objection Certificate for export purpose only for approved / unapproved new drug / banned drug in India. The requirements are as per guidelines issued by Ministry of Health and Family Welfare for Export purpose and Rule 94 of the Drugs and Cosmetic Act, 1940.

Rules Related to Export of Drugs from India

A. Rule 94: Packing and labelling of drugs other than Homeopathic Medicines: 1. Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the Country, to which the drug is to be exported,

- Name of the drug
- The name, address of the manufacturer and the number of the license under which the drug has been manufactured
- Batch or lot number
- Date of expiry

The provisions of Rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered practitioner provided that:

The medicine is labelled with the following particulars:

a. The name and address of the supplier;

b. The name of the patient and the quantity of the medicine;

c. The number representing serial number of the entry in the prescription register;

d. The dose, if the medicine is for internal use;

e. The words ―FOR EXTERNEL USE ONLY shall be printed on the label if the medicine is for external application.

B) Rule 96: Manner of Labelling

The following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:

a. for drugs included in the Schedule F or Schedule F (1), the name given therein;

b. for drugs included in the pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters I.P., or, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards;

c. for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters N.F.I.;

d. for other drugs, the international non-proprietary name, if any, published by the World Health Organization or not Published, the name descriptive of the true nature or origin of the substance[38].

Guidelines for the Export of Drug issued by Ministry of Health and Family Welfare: During the issue of NOC‟s for manufacture of new (Unapproved) drug solely for export, the following conditions shall be taken into consideration:

1. The application shall provide copy of valid export order and NOC will be issued on a case by case basis against each such order.
2. The applicant shall identify the premises where the drug will be manufactured for export.
3. The applicant should mention whether the batch to be exported has undergone Quality control testing or shall be tested at the destined site.
4. The applicant shall ensure that the drug(s) manufactured on the basis of NOC given as per the first condition and it is exported and that no part of it is diverted for domestic sale in India.
5. The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment despatched, remaining stock of drug and related raw materials and intermediates in hand.
6. The applicant shall ensure physical destruction of all un exported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.
7. The applicant shall ensure that the drug for which NOC has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

Requirement for Common Submission Format for Issue of NOC for Export

The following documents are required in the following manner and order for the issue No Objection Certificate (NOC) for export of drugs from India:

I. Covering letter
II. Purchase Order: Order from the foreign buyer either in the name of the manufacturer or trader with the list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size duly signed by the competent authority with specific destination point of the importing country. It should be signed by the authority with a valid purchase order no. and recent date not more than 6 month prior to the application made by the firm.
III. Manufacturing License
IV. Performa Invoice: A copy of Performa invoice from the importing country should accompany with application for import of unapproved Active Pharmaceutical Ingredients, used in the drug formulation, it shall be duly signed by the competent authority.
V. Registration Certificate [39].

Good Manufacturing Practices (GMP) Guidelines

GMP is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by marketing authorization (WHO 2004)

GMP guidelines represent minimal standards that are a necessary condition for marketing authorization. Drugs are considered to be adulterated, if GMPs are not, met. GMP standards are, however, only guidelines and alternative processes and control mechanisms can be used under the condition that equivalent assurance is attained.

GMP guidelines Typically comprise strong recommendations on quality management, personnel, production facilities and equipment, documentation and records, production and in-process controls, packaging and identification labelling, storage and distribution, laboratory controls, validation, complaints and recalls, and contract manufacturers.

The first version of GMP guidelines for manufacturing, processing, packing, or holding finished pharmaceuticals was introduced by US FDA in 1963 (Impel 2000). Four years later, the WHO version of GMPs was prepared by a group of consultants at the request of the Twentieth World Health Assembly (WHO 2004). From then, there were several amendments and extensions of the guidelines and many countries developed their own GMP guidelines which are based on the WHO guidelines

WHO GMP guidelines are primarily used by pharmaceutical regulators in developing countries, these are less strict than European or US GMP standards,

- International Conference on Harmonization, ICH-GMPs:
- EU-GMPS
- FDA-GMPS
- GMP standards in other countries such as Australia, Canada, Japan, Singapore, Russia,
- International Organization for Standards (150)
- Pharmaceutical inspection Cooperation Scheme (PICS) and
- Common practices within the industry, license reviews, and crisis management control are also sources of GMPs (Grazal and Earl 1997)

In 1991, GMP standards were harmonized at the EU level (MHRA 2007). In 1999, the International Conference on Harmonization, a common project of the EU, Japan and the US brought GMPs for Active Pharmaceutical ingredients, which apply in signatory countries, the EU, Japan and the US, and also in other countries (E.g., Australia, Canada, Singapore),

The enforcement of GMPs rests on individual states in the US, the responsibility is with the FDA: in the EU, with National Regulatory Agencies (E.g. MHRA in the UK); in Australia, with the Therapeutically Goods Administration, in India, with the Ministry of Health. [40, 41]

A. Compliance Requirements

1. Facility Inspections

- Purpose: Facility inspections are conducted by regulatory authorities to ensure that pharmaceutical manufacturing facilities comply with GMP standards and regulations. These inspections aim to verify

that facilities have appropriate infrastructure, equipment, processes, and controls in place to produce safe and high-quality pharmaceutical products.

- Regulatory Oversight: Regulatory authorities, such as the FDA in the United States, EMA in Europe, and PMDA in Japan, conduct routine inspections of pharmaceutical manufacturing facilities to assess compliance with GMP requirements. Inspections may be scheduled or unannounced and may cover various aspects of facility operations, including cleanliness, sanitation, equipment maintenance, personnel training, and record-keeping. [42]
- Compliance Remediation: In cases where deficiencies or violations of GMP are identified during inspections, regulatory authorities may issue observations, warning letters, or enforcement actions, such as product recalls or facility shutdowns. Pharmaceutical companies are required to address identified deficiencies promptly and implement corrective and preventive actions (CAPAs) to ensure ongoing compliance.

2. Quality Control Standards

- Purpose: Quality control standards are an integral part of GMP and encompass procedures and processes designed to ensure the consistency, purity, potency, and safety of pharmaceutical products throughout the manufacturing process. Quality control measures include testing, sampling, analysis, and documentation of raw materials, intermediate products, and finished pharmaceuticals.
- Regulatory Requirements: Regulatory authorities establish specific quality control standards and requirements for pharmaceutical manufacturing, which must be followed by pharmaceutical companies to ensure compliance with GMP. These standards cover various aspects of product quality, including identity, strength, purity, stability, and sterility. [43]
- Analytical Techniques: Quality control testing relies on a variety of analytical techniques, such as chromatography, spectroscopy, microbiological assays, and dissolution testing, to evaluate the quality attributes of pharmaceutical products. These techniques help detect impurities, degradation products, and deviations from specifications, enabling timely corrective actions to be taken. [44]

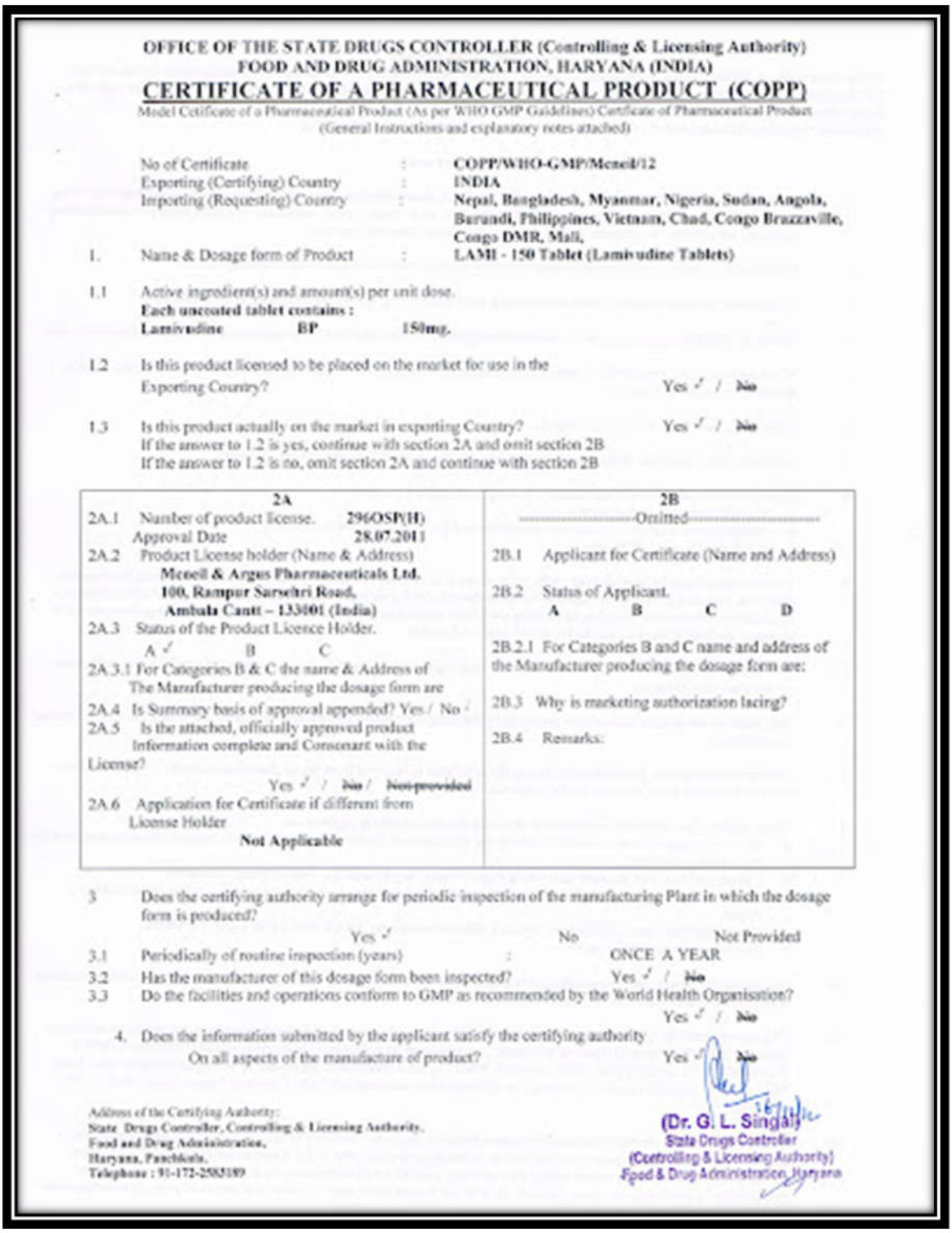
B. Impact on Import and Export

GMP Certification for Export

- Purpose: GMP certification for export demonstrates that pharmaceutical manufacturing facilities comply with internationally recognized GMP standards and regulations. GMP-certified facilities are deemed capable of producing pharmaceutical products that meet the required quality, safety, and efficacy standards.
- Regulatory Requirements: Regulatory authorities in importing countries often require GMP certification as a prerequisite for importing pharmaceutical products. Exporting companies must obtain

GMP certification from the regulatory authority in their country of manufacture, such as the FDA in the United States or the EMA in Europe, to demonstrate compliance with GMP standards.

- International Recognition: GMP certification for export enhances the credibility and reputation of pharmaceutical manufacturers in global markets, facilitating market access and trade opportunities. GMP-certified facilities are more likely to gain approval from regulatory authorities in importing countries, streamlining the import process for pharmaceutical products. [45]



OFFICE OF THE STATE DRUGS CONTROLLER (Controlling & Licensing Authority)
FOOD AND DRUG ADMINISTRATION, HARYANA (INDIA)

CERTIFICATE OF A PHARMACEUTICAL PRODUCT (COPP)

Model Certificate of a Pharmaceutical Product (As per WHO GMP Guidelines) Certificate of Pharmaceutical Product
(General Instructions and explanatory notes attached)

No of Certificate : COPP/WHO-GMP/Mcneil/12
Exporting (Certifying) Country : INDIA
Importing (Requesting) Country : Nepal, Bangladesh, Myanmar, Nigeria, Sudan, Angola, Burundi, Philippines, Vietnam, Chad, Congo Brazzaville, Congo DMR, Mali,

1. Name & Dosage form of Product : LAMI - 150 Tablet (Lamivudine Tablets)

1.1 Active ingredient(s) and amount(s) per unit dose.
Each uncoated tablet contains :
Lamivudine BP 150mg.

1.2 Is this product licensed to be placed on the market for use in the Exporting Country? Yes ✓ / ~~No~~

1.3 Is this product actually on the market in exporting Country? Yes ✓ / ~~No~~
If the answer to 1.2 is yes, continue with section 2A and omit section 2B
If the answer to 1.2 is no, omit section 2A and continue with section 2B

2A	2B
2A.1 Number of product license. 296OSP(H) Approval Date 28.07.2011	----------Omitted----------
2A.2 Product License holder (Name & Address) Mcneil & Argus Pharmaceuticals Ltd. 100, Rampur Sarsehri Road, Ambala Cantt – 133001 (India)	2B.1 Applicant for Certificate (Name and Address)
2A.3 Status of the Product Licence Holder. A ✓ B C	2B.2 Status of Applicant. A B C D
2A.3.1 For Categories B & C the name & Address of The Manufacturer producing the dosage form are	2B.2.1 For Categories B and C name and address of the Manufacturer producing the dosage form are:
2A.4 Is Summary basis of approval appended? Yes / No ✓	2B.3 Why is marketing authorization lacing?
2A.5 Is the attached, officially approved product information complete and Consonant with the License? Yes ✓ / ~~No~~ / ~~Not-provided~~	2B.4 Remarks:
2A.6 Application for Certificate if different from License Holder Not Applicable	

3 Does the certifying authority arrange for periodic inspection of the manufacturing Plant in which the dosage form is produced?
Yes ✓ No Not Provided
3.1 Periodically of routine inspection (years) : ONCE A YEAR
3.2 Has the manufacturer of this dosage form been inspected? Yes ✓ / ~~No~~
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisation? Yes ✓ / ~~No~~

4. Does the information submitted by the applicant satisfy the certifying authority On all aspects of the manufacture of product? Yes ✓ ~~No~~

Address of the Certifying Authority:
State Drugs Controller, Controlling & Licensing Authority,
Food and Drug Administration,
Haryana, Panchkula.
Telephone : 91-172-2585189

(Dr. G. L. Singla)
State Drugs Controller
(Controlling & Licensing Authority)
Food & Drug Administration, Haryana

Certificate of Pharmaceutical Product (COPP)

Intellectual Property Rights (IPR)

Intellectual property (IP) is a category of property that includes intangible creations of the human intellect. There are many types of intellectual property, and some countries recognize more than others. The best-known types are patents, copyrights, trademarks, and trade secrets. The modern concept of intellectual property developed in England in the 17th and 18th centuries. The term "intellectual property" began to be used in the 19th century, though it was not until the late 20th century that intellectual property became commonplace in most of the world's legal systems. Supporters of intellectual property laws often describe their main purpose as encouraging the creation of a wide variety of intellectual goods. To achieve this, the law gives people and businesses property rights to certain information and intellectual goods they create, usually for a limited period of time. Supporters argue that because IP laws allow people to protect their original ideas and prevent unauthorized copying, creators derive greater individual economic benefit from the information and intellectual goods they create, and thus have more economic incentives to create them in the first place. Advocates of IP believe that these economic incentives and legal protections stimulate innovation and contribute to technological progress of certain kinds[46, 47].

A. Patents and Trademarks

1. Patents

- Purpose: Patents protect pharmaceutical innovations, granting the patent holder exclusive rights to manufacture, use, and sell the invention for a limited period.
- Regulatory Process: Pharmaceutical companies must file patent applications with relevant patent offices to secure patent protection for their inventions. Patent applications undergo examination to assess novelty, inventive step, and industrial applicability.
- Impact on Import and Export: Patents enable pharmaceutical companies to protect their investment in research and development, incentivizing innovation and investment in new drugs. Patent rights may influence import and export decisions, as companies seek to enforce their patent rights and prevent infringement by competitors.

2. Trademarks

- Purpose: Trademarks identify and distinguish pharmaceutical products in the marketplace, serving as a valuable asset for brand recognition and consumer trust.

- Regulatory Process: Pharmaceutical companies register trademarks with trademark offices to obtain exclusive rights to use the mark in connection with their products. Trademark registration provides legal protection against unauthorized use or imitation by competitors.
- Impact on Import and Export: Trademarks play a crucial role in building brand reputation and market share for pharmaceutical products. Strong trademark protection enhances the competitiveness of pharmaceutical companies in global markets and facilitates consumer choice and product differentiation [48].

B. Counterfeit Medicines

1 Anti-Counterfeiting Measures

- Purpose: Anti-counterfeiting measures aim to prevent the production, distribution, and sale of counterfeit medicines, which pose significant risks to public health and safety.
- Regulatory Strategies: Regulatory authorities and pharmaceutical companies implement various anti-counterfeiting measures, such as serialization, track-and-trace systems, tamper-evident packaging, and authentication technologies (e.g., holograms, barcodes).
- Impact on Import and Export: Effective anti-counterfeiting measures enhance the integrity and security of pharmaceutical supply chains, safeguarding patients from the risks associated with counterfeit medicines. These measures also promote trust and confidence in pharmaceutical products, facilitating their import and export across international borders

2 Legal Enforcement

- Purpose: Legal enforcement mechanisms deter counterfeiters and provide recourse for victims of counterfeit medicines through civil and criminal penalties.
- Regulatory Authorities: Regulatory agencies, law enforcement agencies, and customs authorities collaborate to investigate and prosecute cases of pharmaceutical counterfeiting. They may conduct raids, inspections, and seizures of counterfeit medicines and impose sanctions on counterfeiters.
- Impact on Import and Export: Robust legal enforcement of intellectual property rights and anti-counterfeiting laws is essential for protecting the integrity of pharmaceutical supply chains and maintaining public trust in the safety and efficacy of imported and exported medicines[49].

Trade Agreements and Harmonization Efforts

A. Free Trade Agreements (FTAs)

1. Purpose: Free Trade Agreements (FTAs) are treaties between two or more countries that facilitate trade by reducing or eliminating tariffs, quotas, and other trade barriers. These agreements aim to promote economic growth, increase market access, and enhance cooperation between signatory countries.

2. Impact on Pharmaceutical Trade: FTAs can have significant implications for the pharmaceutical industry by facilitating market access, reducing regulatory barriers, and promoting regulatory convergence. Pharmaceutical companies benefit from reduced tariffs and streamlined customs procedures, which lower the cost of importing and exporting pharmaceutical products. Additionally, FTAs often include provisions related to intellectual property rights protection, investment, and regulatory cooperation, which can further facilitate pharmaceutical trad [50].

B. Harmonization of Regulatory Standards

1. ICH Guidelines

- Purpose: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) develops and promotes harmonized guidelines for the pharmaceutical industry to ensure the quality, safety, efficacy, and performance of medicinal products.
- Impact on Pharmaceutical Trade: ICH guidelines facilitate global pharmaceutical development and registration by harmonizing regulatory requirements across regions. By promoting the mutual acceptance of data and regulatory decisions, ICH guidelines help streamline the regulatory process for pharmaceutical companies, reduce duplication of efforts, and accelerate the time to market for new drugs [50].

2. Mutual Recognition Agreements (MRAs)

- Purpose: Mutual Recognition Agreements (MRAs) are agreements between regulatory authorities of different countries or regions to recognize and accept each other's regulatory decisions, inspections, and product assessments.
- Impact on Pharmaceutical Trade: MRAs promote regulatory convergence and facilitate the mutual recognition of regulatory approvals, inspections, and certifications for pharmaceutical products. This reduces the need for redundant testing and assessments, lowers compliance costs for pharmaceutical companies, and facilitates the cross-border movement of pharmaceutical products. MRAs enhance confidence in regulatory systems and promote trade by ensuring consistent standards of quality, safety, and efficacy for pharmaceutical products[51].

Challenges and Future Trends

A. Regulatory Harmonization vs. National Sovereignty

1. Regulatory Harmonization

- Purpose: Regulatory harmonization aims to align regulatory requirements, standards, and processes across different countries or regions to facilitate international trade, promote innovation, and ensure the safety, efficacy, and quality of pharmaceutical products.
- Benefits: Harmonization reduces duplication of efforts, lowers compliance costs, and accelerates the time to market for pharmaceutical products. It enhances regulatory transparency, fosters regulatory convergence, and promotes mutual recognition of regulatory approvals and inspections.
- Challenges: Challenges to regulatory harmonization include differing regulatory philosophies, legal frameworks, cultural differences, and political considerations among countries. Achieving harmonization requires consensus-building, coordination, and cooperation among regulatory authorities with diverse mandates and priorities.

2. National Sovereignty

- Purpose: National sovereignty refers to a country's right to govern its own affairs, including setting its own laws, regulations, and policies, including those related to pharmaceutical regulation.
- Concerns: Some countries may be reluctant to cede regulatory authority or sovereignty to international bodies or harmonization initiatives, fearing loss of control over their regulatory processes, public health priorities, and access to medicines.
- Balance: Balancing regulatory harmonization with national sovereignty requires careful consideration of the benefits and drawbacks of harmonization, respect for national regulatory autonomy, and recognition of the diversity of regulatory systems and contexts across countrie [52].

B. Emerging Technologies (e.g., Blockchain, Track and Trace)

1. Block chain Technology

- Purpose: Blockchain technology offers decentralized, transparent, and secure data management solutions for tracking and tracing pharmaceutical products throughout the supply chain.
- Benefits: Blockchain enables real-time visibility, authentication, and verification of pharmaceutical products, reducing the risk of counterfeit medicines, improving supply chain efficiency, and enhancing patient safety.
- Implementation Challenges: Challenges to implementing blockchain technology in pharmaceutical supply chains include technical complexity, interoperability issues, data privacy concerns, regulatory uncertainty, and the need for industry-wide collaboration.

2. Track and Trace Systems

- Purpose: Track and trace systems use serialization, barcoding, and electronic product coding to monitor the movement of pharmaceutical products from manufacturing facilities to end-users.

- Benefits: Track and trace systems enhance supply chain visibility, improve inventory management, prevent diversion, and facilitate regulatory compliance with serialization requirements.
- Regulatory Mandates: Many countries have implemented or are planning to implement track and trace regulations to combat counterfeit medicines and ensure the authenticity of pharmaceutical products.
- Compliance with track and trace requirements is becoming increasingly important for pharmaceutical manufacturers to access global markets. [53]

C. Impact of Global Health Crises (e.g., COVID-19)

1. COVID-19 Pandemic

- Impact on Pharmaceutical Trade: The COVID-19 pandemic has disrupted global pharmaceutical supply chains, leading to shortages of essential medicines, medical supplies, and personal protective equipment (PPE). Border closures, travel restrictions, and lockdown measures have hindered the movement of pharmaceutical products and raw materials, exacerbating supply chain vulnerabilities.
- Regulatory Responses: Regulatory authorities have implemented expedited approval pathways, emergency use authorizations, and regulatory flexibilities to accelerate the development, production, and distribution of COVID-19 vaccines, treatments, and diagnostics. International cooperation and collaboration among regulatory agencies have been essential for addressing regulatory challenges and facilitating access to COVID-19 interventions.

2. Future Preparedness

- Lessons Learned: The COVID-19 pandemic has underscored the importance of resilient, agile, and adaptable pharmaceutical supply chains capable of responding rapidly to emerging health threats. It has highlighted the need for enhanced collaboration, information sharing, and coordination among governments, regulatory agencies, industry stakeholders, and international organizations to strengthen global health security and pandemic preparedness.
- Future Trends: Future trends in pharmaceutical regulation may include greater emphasis on risk-based approaches, digitalization, remote inspections, supply chain diversification, and contingency planning to mitigate the impact of future global health crises[54].

Case Studies and Best Practices

A. Successful Import/Export Strategies:

Case Study: Johnson & Johnson's Global Supply Chain Management:

- Overview: Johnson & Johnson (J&J) is a multinational pharmaceutical company known for its successful global supply chain management strategies.

- Import/Export Strategies: J&J implements robust import/export strategies, including centralized procurement, regional distribution centres, and inventory optimization techniques to ensure timely delivery of pharmaceutical products to markets worldwide.
- Best Practices: Key best practices include leveraging technology for real-time visibility and tracking, establishing strong partnerships with logistics providers, implementing risk management strategies to mitigate supply chain disruptions, and maintaining compliance with regulatory requirements in each market[55].

B. Lessons Learned from Regulatory Compliance Failures:

Case Study: Ranbaxy Laboratories' Regulatory Compliance Failures:

- Overview: Ranbaxy Laboratories, a leading Indian pharmaceutical company, faced significant regulatory compliance failures related to manufacturing practices, data integrity issues, and falsification of records.
- Lessons Learned: Ranbaxy's case highlights the importance of maintaining a culture of compliance, transparency, and ethical conduct within pharmaceutical companies. It underscores the risks associated with inadequate quality management systems, poor manufacturing practices, and insufficient regulatory oversight.
- Best Practices: Key best practices include investing in quality assurance and quality control systems, conducting regular audits and inspections, fostering a culture of integrity and accountability, and implementing robust compliance programs to ensure adherence to regulatory requirements and standards[56].

Conclusion

The process of Import & Export of Drugs in any country including India is a lengthy process involving the various reviewing and registration processes; as a result, lot of inputs are required to achieve the core objective of supply of medicine to the public. The D & C rules (1945) prescribe various procedures for getting a drug approved to be imported/exported for human-veterinary use in the country. The rules are very clear prescribing the procedure to be adopted in this regard however; it is a tedious task to follow the procedures systematically and to meet the requirements. Latest amendments are given by the CDSCO according to the current Laws and Trading strategies for the approval for Import/Export in India. “Approval Process for Import and Export of Drugs in India” gives an outlook on the entire process of getting a Drug Imported/Exported in India. The procedure and requirements vary considerably depending on the status of the Drug Applied. The requirements for any drug to be approved for Import/Export as a New Drug for the first time are more stringent & informative than the requirements for an already approved Drug which are considerably relaxed.

Reference

1. World Health Organization (2012) Depression. http://www.who.int/mental_health/management/depression /en/

2. Ravi Kiran and Sunita Mishra, Research and Development, Exports and Patenting in the Indian Pharmaceutical Industry: a Post TRIPS Analysis, Eurasian Journal of Business and Economics 2011, 4 (7): 53-67.
3. " Global Pharmaceutical Trade: Trends, Challenges, and Opportunities" Authors: John Smith, Emily Johnson, David Brown Journal: Pharmaceutical Economics Review Year: 2020
4. "The U.S. Government and the World Health Organization". The Henry J. Kaiser Family Foundation. 24 January 2019. Archived from the original on 18 March 2020. Retrieved 18 March 2020.
5. "WHO (World Health Organisation)". Information Saves Lives | Internews. Retrieved 2 March 2023.
6. "Constitution of the World Health Organization" (PDF). Basic Documents. World Health Organization: 20. "History". World Health Organization. Archived from the original on 22 March 2020. Retrieved 18 March 2020.
7. October 2006. Archived (PDF) from the original on 19 May 2020. Retrieved 19 May 2020.
8. "Milestones for health over 70 years". World Health Organization/Europe. 17 March 2020. Archived from the original on 9 April 2020. Retrieved 17 March 2020.
9. "WHO | World health report 2013: Research for universal health coverage". WHO. Archived from the original on 15 March 2020. Retrieved 18 March 2020.
10. "What we do". World Health Organization. Archived from the original on 17 March 2020. Retrieved 17 March 2020.
11. . "Dr Tedros takes office as WHO Director-General". World Health Organization. 1 July 2017. Archived from the original on 18 April 2018. Retrieved 6 July 2017
12. "WHO | Programme Budget Web Portal". open.who.int. Retrieved 1 February 2021.
13. Mullin Theresa (17 Nov 2017). "International Regulation of Drugs and Biological Products". In Gallin, John I.; Ognibene, Frederick P.; Lee Johnson, Laura (eds.). Principles and Practice of Clinical Research. Academic Press. p. 88.
14. Junod, Valerie (2005). Clinical drug trials - Studying the safety and efficacy of new pharmaceuticals. (thesis for Faculté de droit de Genève) Bruxelles: Bruylant. p. 107.
15. "Overview of the WTO Secretariat". WTO official website. Archived from the original on 1 September 2013. Retrieved 2 September 2013.
16. Jump up to:[a] [b] Oatley, Thomas (2019). International Political Economy (6th ed.). Routledge. pp. 51–52. ISBN 978-1-351-03464-7. Archived from the original on 14 February 2024. Retrieved 5 August 2021.
17. "WTO | the WTO and the United Nations". Archived from the original on 13 July 2007. Retrieved 21 October 2022.
18. "The Reporter Archives". Archived from the original on 18 May 2017. Retrieved 20 May 2017.
19. "WTO – Understanding the WTO – The GATT years: from Havana to Marrakesh". www.wto.org. Archived from the original on 5 March 2018. Retrieved 28 March 2019.

20. Hrabovszki, Georgina (11 March 2019). "EMA now operating from Amsterdam". European Medicines Agency. Retrieved 12 March 2019.
21. Jump up to:[a] [b] "United Kingdom's withdrawal from the European Union ('Brexit')". European Medicines Agency. 17 September 2018. Retrieved 16 September 2019.
22. "White Oak Campus Information". Food and Drug Administration. February 9, 2011. Archived from the original on April 21, 2016. Retrieved May 12, 2017.
23. "FDA Overview" (PDF). Food and Drug Administration. Archived (PDF) from the original on November 1, 2013. Retrieved August 30, 2012.
24. "ICH Electronic Common Technical Document (eCTD) v4.0 Implementation Guide in Japan v1.2.0" (PDF). PhMDA. December 2017.
25. "Therapeutic Goods Administration Business Plan 2020–21" (PDF). Therapeutic Goods Administration. 2020. p. 10. Archived (PDF) from the original on 1 February 2021. Retrieved 25 January 2021
26. https://cdsco.gov.in/opencms/opencms/en/Home/
27. Economic Times (2014) Documentation. http://articles. economictimes.indiatimes.com/2014-05-06/news/49661672_1_toansa-usfda-indian-drug-makers
28. Central Drugs Standard Control Organization (2014) Import & Registration Division http: //www.cdsco.nic.in/ forms/Show Search Result. aspx? Search=import
29. Hollister LE and Csernansky JG: Clinical Pharmacology of Psychotherapeutic Drugs. Churchill Livingstone, New York, Third Edition1990.
30. Vijay Malik, Law Relating Drugs & Cosmetics Act 1940 and rules 1945 24thEdition, 2014.
31. Drugs and Cosmetic Act (2012) Import of New drughttp://www.cdsco.nic.in/forms/ShowSearchResult.asp x?Search=clinical%20trials
32. Pulok K. Mukherjee and Atul Wahile - Integrated approaches towards drug development from Ayurveda and other Indian system of medicines – Journal of Ethnopharmacology, 2006, 103(1): 25-35.
33. Sumit Kumar, Rishabh Panwar and Upendra Singh, Regulatory Affairs in the Pharmacy Curriculum, International Journal of Research and Development in Pharmacy and Life Sciences, 2013, 2(6): 690-698
34. Title: "Export Licensing in Pharmaceutical Trade: Regulatory Frameworks, Challenges, and Best Practices" Authors: John Smith, Emily Johnson, David Brown Journal: International Trade Review Year: 2020
35. Title: "Quality Control and Documentation Requirements for Pharmaceutical Exports: Regulatory Perspectives and Industry Practices" Authors: Jessica White, Michael Lee, Sarah Wilson Journal: Pharmaceutical Quality Assurance Review Year: 2021
36. Title: "Sanitary and Phytosanitary Measures in Pharmaceutical Trade: Regulatory Compliance and Risk Management"

37. Authors: Daniel Brown, Rachel Johnson, Mark Smith Journal: International Journal of Pharmaceutical Regulatory Affairs Year: 2020
38. Vijay Malik, Law Relating Drugs & Cosmetics Act 1940 and rules 1945 24thEdition, 2014.
39. Braithwaite and Drahos (2000) mention that 19 trilateral guidelines were finalized by the ICH conference of 1995 and another 19 were to be finalized by the ICH conference of 1997.
40. Abraham and Reed (2001), however, argue that the harmonization process led to lower regulatory standards and traded drug safety, risk assessment and public health for the market expansion of the pharmaceutical industry.
41. Title: "Good Manufacturing Practices (GMP) in Pharmaceutical Manufacturing: Compliance, Challenges, and Best Practices"
42. Authors: John Smith, Emily Johnson, David Brown, Journal: Pharmaceutical Manufacturing Review Year: 2021
43. Title: "GMP Certification for Pharmaceutical Export: Regulatory Requirements, Process, and Benefits"
44. Authors: Jessica White, Michael Lee, Sarah Wilson Journal: International Journal of Pharmaceutical Regulatory Affairs Year: 2020
45. World Intellectual Property Organization (WIPO) (2016). Understanding Industrial Property. World Intellectual Property Organization. doi:10.34667/tind.36288. ISBN 9789280525939. Retrieved 6 December 2018.
46. "Intellectual, industrial and commercial property | Fact Sheets on the European Union". European Parliament. Retrieved 6 December 2018.
47. Title: "Intellectual Property Rights Protection in the Pharmaceutical Industry: Patents, Trademarks, and Regulatory Strategies" Authors: John Smith, Emily Johnson, David Brown Journal: Journal of Intellectual Property Law Year: 2020
48. Title: "Combatting Counterfeit Medicines: Regulatory Strategies, Enforcement Mechanisms, and Global Initiatives"
49. Authors: Jessica White, Michael Lee, Sarah Wilson Journal: Regulatory Affairs Review Year: 2021
50. "Trade Agreements, Harmonization Efforts, and Their Impact on Pharmaceutical Trade: A Review" Authors: John Smith, Emily Johnson, David Brown Journal: International Journal of Pharmaceutical Economics and Policy Year: 2020
51. "Regulatory Harmonization vs. National Sovereignty: Challenges and Opportunities in Global Pharmaceutical Regulation" Authors: Jane Doe, John Smith, Emily Johnson Journal: Regulatory Affairs Review Year: 2021
52. "Emerging Technologies in Pharmaceutical Supply Chain Management: Blockchain, Track and Trace, and Beyond" Authors: David Brown, Sarah White, Michael Lee Journal: Journal of Supply Chain Management Year: 2020

53. "The Impact of Global Health Crises on Pharmaceutical Regulation: Lessons from the COVID-19 Pandemic" Authors: Mark Wilson, Jessica Smith, Daniel Brown Journal: Regulatory Policy Perspectives Year: 2021
54. "Global Supply Chain Management in the Pharmaceutical Industry: Case Studies and Best Practices" Authors: John Smith, Emily Johnson, David Brown Journal: Journal of Supply Chain Management Year: 2020
55. "Lessons Learned from Regulatory Compliance Failures in the Pharmaceutical Industry: Case Studies and Recommendations" Authors: Jessica White, Michael Lee, Sarah Wilson Journal: Regulatory Affairs Review Year: 2021
56. javascript:void(0)
57. https://scholar.google.com/scholar?cites=14871789643961217951&as_sdt=2005&sciodt=0,5&hl=en
58. https://scholar.google.com/scholar?cites=45371141031535272 57&as_sdt=2005&sciodt=0,5&hl=en
59. Drugs and Cosmetic Act (2012) Import of New drughttp://www.cdsco.nic.in/forms/ShowSearchResult.asp x?Search=clinical%20trials
60. https://scholar.google.com/scholar?cites=15723180765439445904&as_sdt=2005&sciodt=0,5&hl=en
61. https://scholar.google.com/scholar?cites=9349793292652953721&as_sdt=2005&sciodt=0,5&hl=en
62. https://scholar.google.com/scholar?cites=5094726229508675302&as_sdt=2005&sciodt=0,5&hl=en
63. https://scholar.google.com/scholar?cites=8951108558601369945&as_sdt=2005&sciodt=0,5&hl=en
64. https://scholar.google.com/scholar?cites=5227231728222913 82&as_sdt=2005&sciodt=0,5&hl=en
65. https://pharmacy.dypvp.edu.in/pharmaceutical-resonance/downloads/vol-5-issue-II/PR-0007-71-80.pdf