



Bridging Borders with Botanicals: A Review of Herbal Drug Import–Export Documentation Worldwide

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ABSTRACT

The safety, therapeutic advantages, and cost of herbal medications are becoming more widely acknowledged. However, the lack of consistent regulatory requirements complicates international trading in herbal goods. The paperwork requirements for the import and export of herbal medicines in the major regulatory regions—China, India, the US, and the EU—are compared in this review. Data was gathered from World Health Organization (WHO) publications and official government websites. The Importer Exporter Code (IEC), Form 40, Certificate of Pharmaceutical Product (CPP), Free Sale Certificate (FSC), and WHO GMP certificate are the essential documents needed for compliance. The results show that every nation has its own set of protocols and standards for documentation, which frequently leads to trade obstacles and delays. Simplifying procedures, improving quality control, and promoting international trade would all be aided by a single global framework for the regulation of herbal drugs.

Keywords: AYUSH, CDSCO, FDA, EMA, NMPA, WHO, harmonization, import-export and herbal medications

INTRODUCTION

Traditional medical systems like Ayurveda, Unani, and Traditional Chinese Medicine (TCM) have historically relied heavily on herbal medicines, which are derived from plant sources. Due to growing acceptance of traditional therapies and increased awareness of natural cures, the market for herbal medications has increased significantly over the past few decades. Despite these advancements, the commerce and commercialization of herbal medicines are severely hampered by the absence of uniform international rules.

Different regulations and documentation procedures are used in each nation. The Drugs and Cosmetics Act of 1940 governs herbal medications in India through the Ministry of AYUSH and CDSCO. Under the Dietary Supplement Health and Education Act (DSHEA), the U.S. FDA regulates botanical medications and dietary supplements. The Traditional Herbal Medicinal Product Directive (2004/24/EC) is enforced by the European Medicines Agency (EMA), while TCM license and paperwork are governed by China's NMPA. Finding regulatory gaps and advancing global harmonization are made easier by comprehending and contrasting these frameworks.

1) India's Ministry of CDSCO and AYUSH

India has two primary bodies that oversee herbal and traditional medicines:

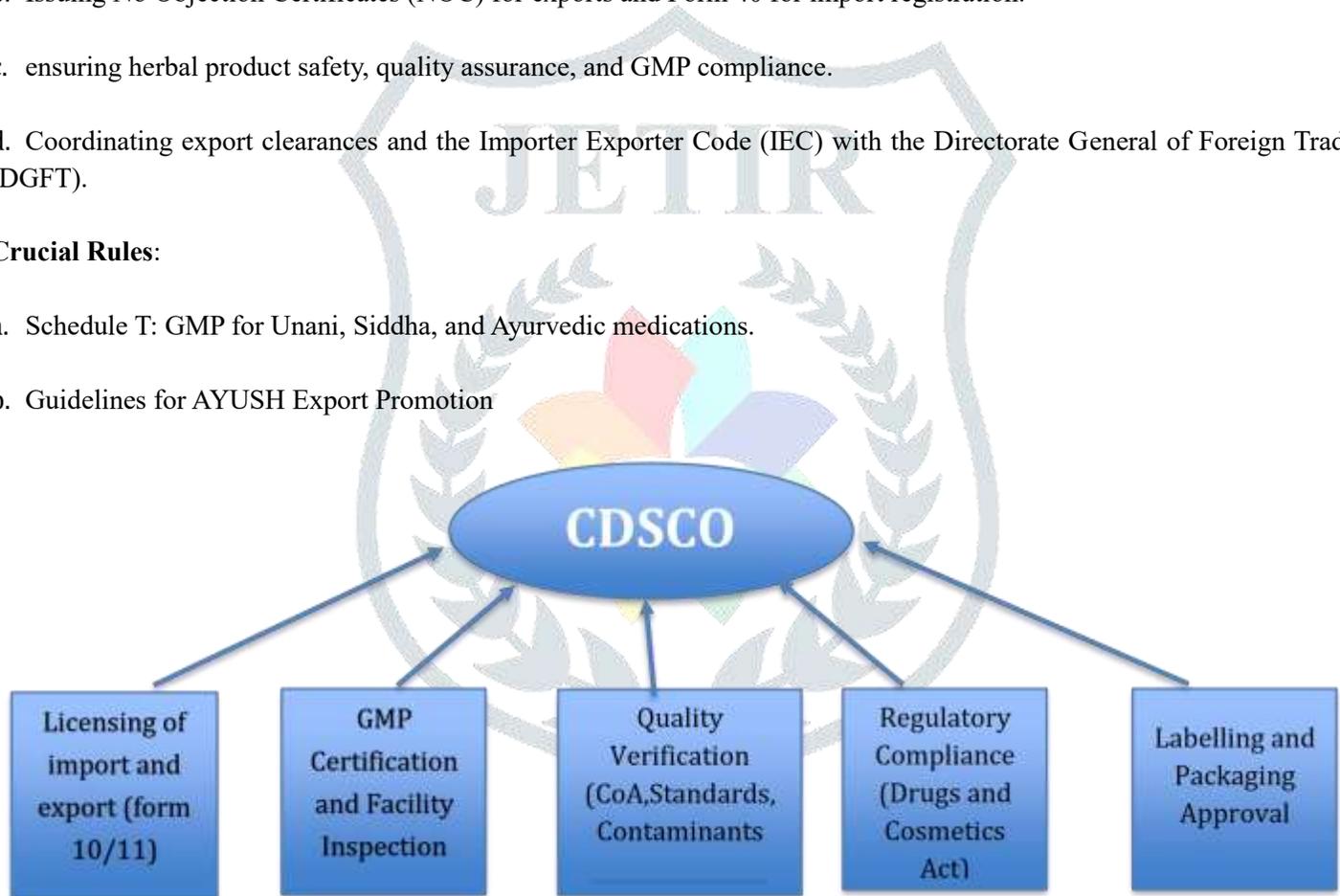
- a. In order to promote and oversee traditional Indian medical systems, the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy) was founded in 2014.
- b. The Ministry of Health & Family Welfare's national regulatory body is the Central Drugs Standard Control Organization (CDSCO).

Principal Duties:

- a. Herbal compositions are licensed and approved under the 1940 Drugs and Cosmetics Act.
- b. Issuing No Objection Certificates (NOC) for exports and Form 40 for import registration.
- c. ensuring herbal product safety, quality assurance, and GMP compliance.
- d. Coordinating export clearances and the Importer Exporter Code (IEC) with the Directorate General of Foreign Trade (DGFT).

Crucial Rules:

- a. Schedule T: GMP for Unani, Siddha, and Ayurvedic medications.
- b. Guidelines for AYUSH Export Promotion



The Food and Drug Administration (FDA) in the United States

Two categories are used by the U.S. Food and Drug Administration (FDA) to regulate herbal and botanical products:

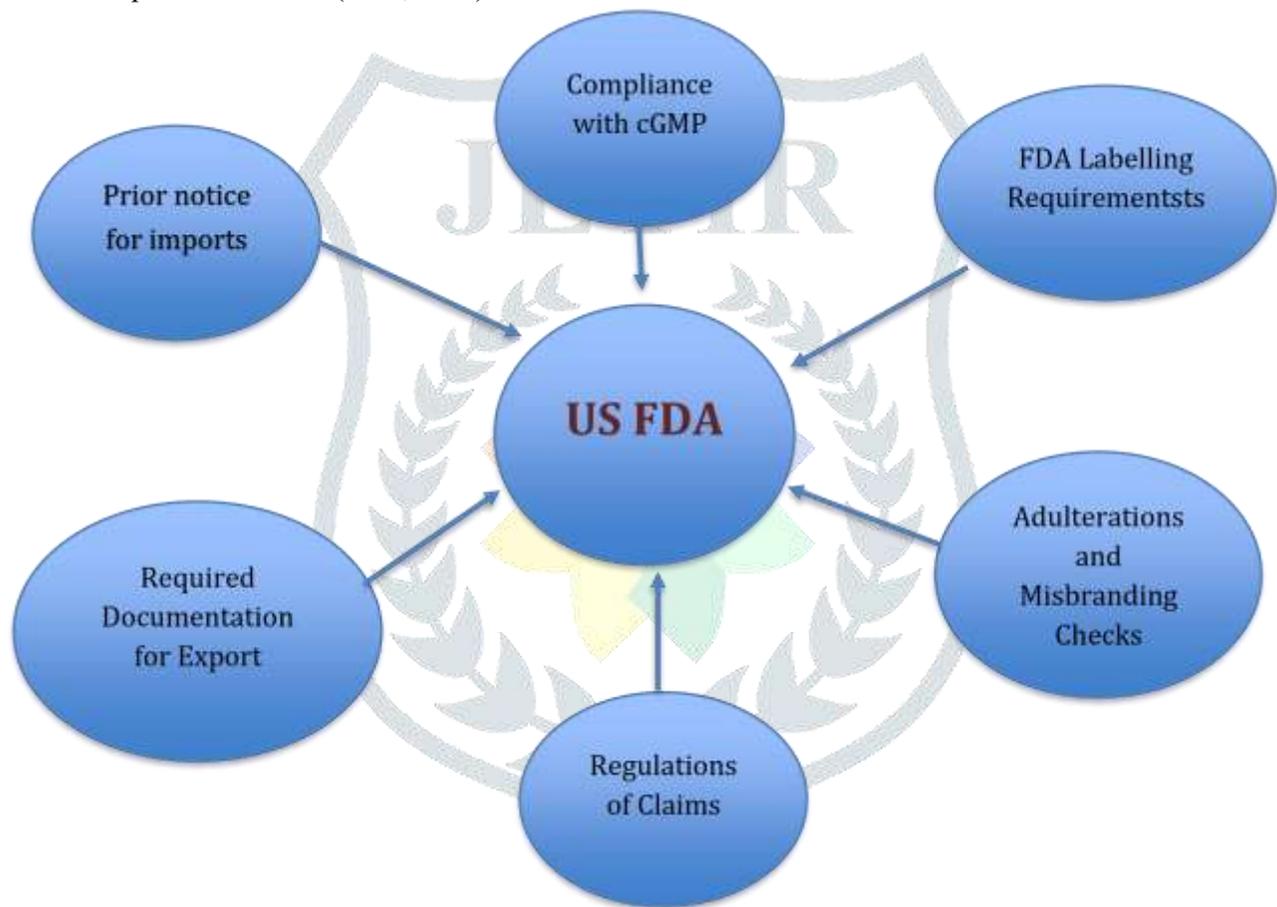
- a. The Dietary Supplement Health and Education Act (DSHEA, 1994) governs dietary supplements.
- b. The Federal Food, Drug, and Cosmetic Act (FD&C Act) governs botanical drugs as prescription medications.

Principal Duties:

- a. Approving applications for botanical pharmaceuticals under the New Drug Application (NDA) and Investigational New Drug (IND) categories.
- b. Supervising product safety, labeling, and import/export certification.
- c. Granting export-related Certificates of Pharmaceutical Product (CPP) and Certificates of Free Sale (CFS).

Crucial Rules:

- a. Industry Guidelines for Botanical Drug Development (FDA, 2016).
- b. Prior Food Import Notification (FDA, 2003).



European Medicines Agency (EMA) of the European Union

Under Directive 2004/24/EC, generally referred to as the Traditional Herbal Medicinal Products Directive (THMPD), the European Medicines Agency (EMA) regulates herbal medicines.

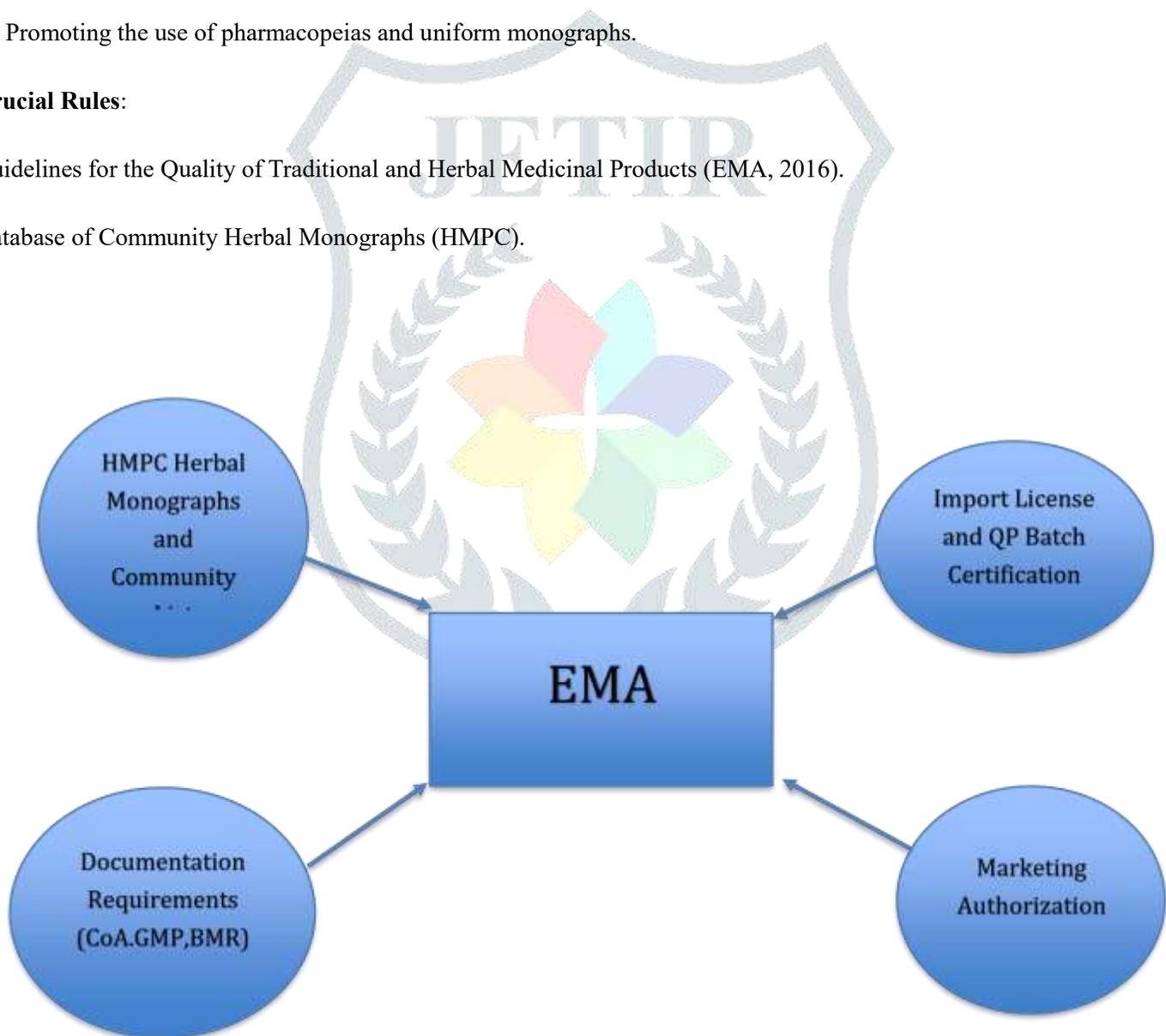
Principal Duties:

- a. Evaluating the effectiveness, safety, and quality of herbal products.
- b. Granting import licenses and marketing authorization (MA).
- c. Examining submissions through the Herbal Medicinal Products Committee (HMPC).
- d. Promoting the use of pharmacopeias and uniform monographs.

Crucial Rules:

Guidelines for the Quality of Traditional and Herbal Medicinal Products (EMA, 2016).

Database of Community Herbal Monographs (HMPC).



The National Medical Products Administration (NMPA) of China

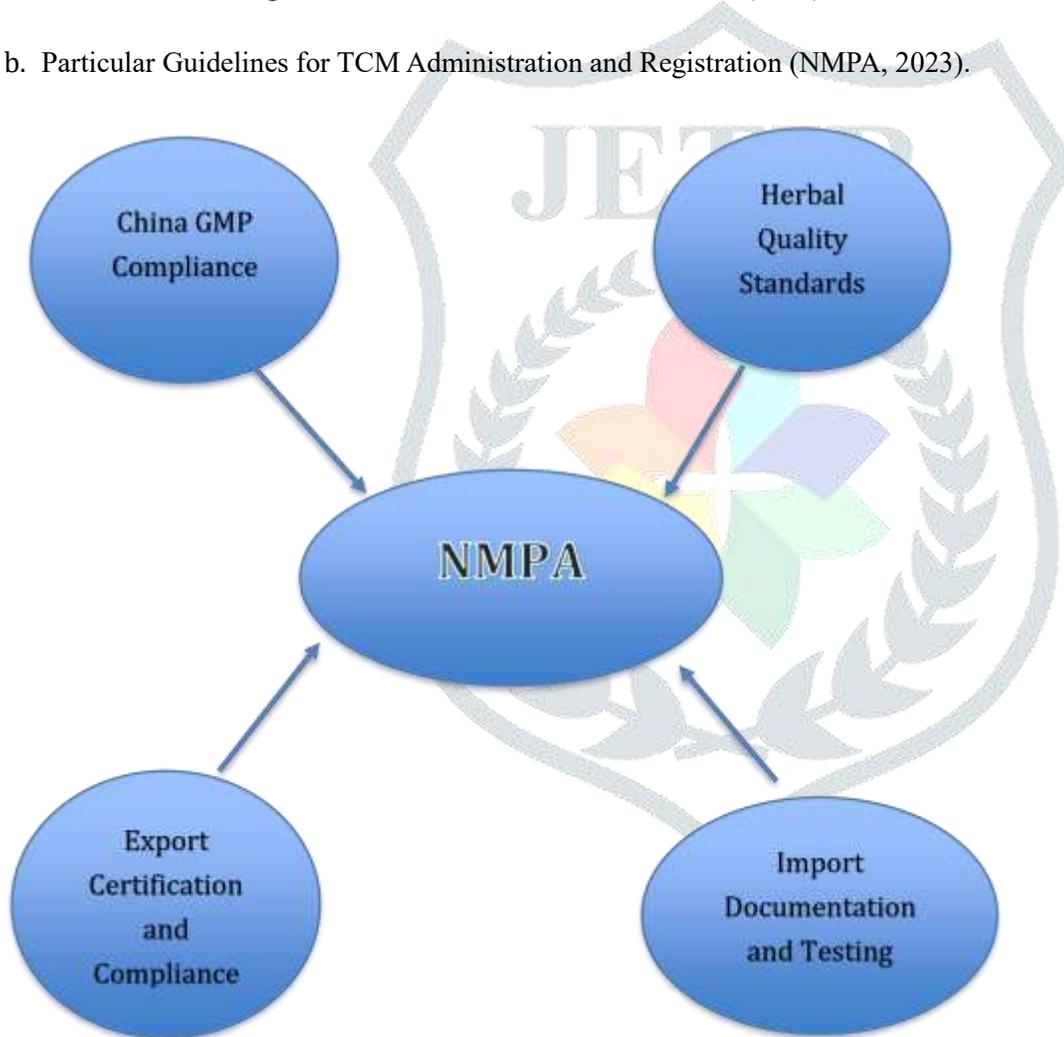
Traditional Chinese Medicines (TCMs), which account for a significant share of China's pharmaceutical market, are governed by the NMPA (previously CFDA).

Principal Duties:

- a. Herbal and TCM formulas are registered and approved.
- b. Granting licenses for imported drugs for herbal goods made elsewhere.
- c. Issuing GMP and Certificates of Pharmaceutical Product (CPP) for export.
- d. Enforcing regulations for herbal products' labeling, packaging, and clinical data.

Crucial Rules:

- a. Rules for the Management of Traditional Chinese Medicine (2023).
- b. Particular Guidelines for TCM Administration and Registration (NMPA, 2023).

**5. The World Health Organization (WHO)**

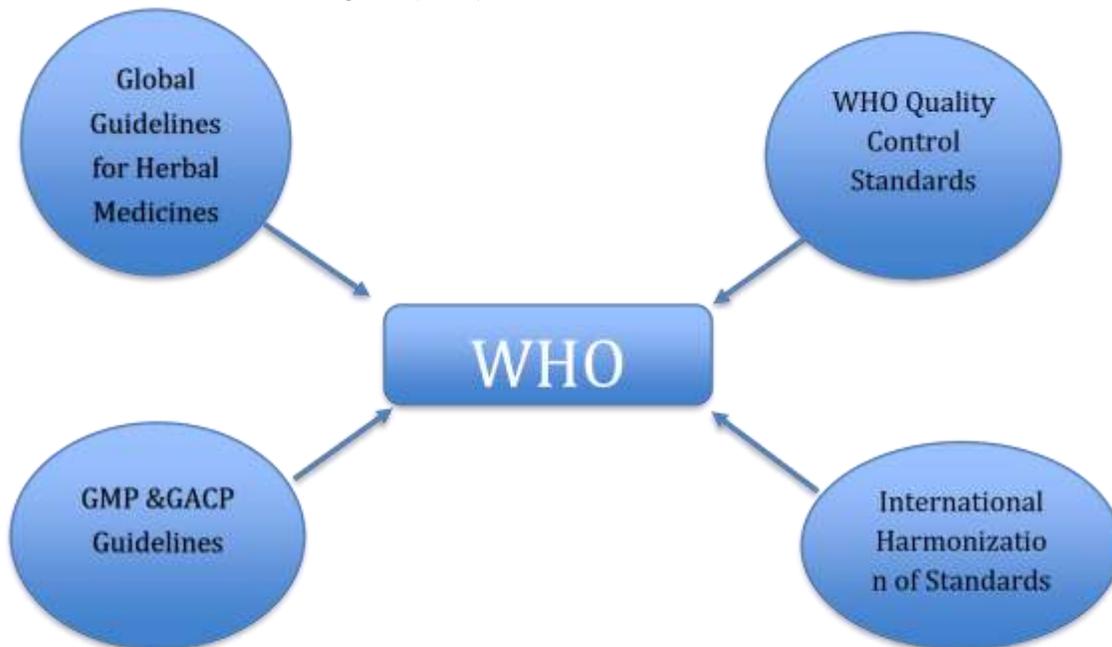
The WHO offers international guidelines and technical advice to unify the regulation of herbal medicines, but it is not a regulatory authority.

Principal Duties:

- a. Creating global standards like Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP).
- b. Encouraging herbal medicines' effectiveness, safety, and quality assurance.
- c. Helping national agencies create regulatory frameworks.

Significant Publications:

- a. GACP for Medicinal Plants: WHO Guidelines (2003).
- d. WHO GMP Certification Program (2014).



Methodology

The method used was a comparative review. The CDSCO, Ministry of AYUSH, DGFT (India), FDA (USA), EMA (EU), NMPA (China), and WHO official websites were used to gather regulatory data. A review was conducted of pertinent regulations, legal frameworks, and published documents from 2015 to 2024. For every nation, the gathered data was divided into two categories: import documentation and export documentation. To verify authenticity, official gazettes and government notifications were used for cross-verification.

Analysis of Documentation Requirements for Import and Export of Herbal Drugs Across Major Regulatory Authorities

Country	Regulatory Authority	Import Documents	Export Documents
India	CDSCO AYUSH	Form 40 (CDSCO) – Import Registration Certificate IEC (DGFT) Manufacturing License (State Licensing Authority) Certificate of Analysis (CoA) Labeling Compliance (CDSCO)	IEC (DGFT) No Objection Certificate (NOC) (CDSCO) Free Sale Certificate (FSC) (CDSCO) Certificate of Origin (CoO) (Chamber of Commerce) Phytosanitary Certificate (Plant Quarantine Authorities) WHO-GMP Certificate (CDSCO) AYUSH Export Compliance (Ministry of AYUSH)
USA	FDA	FDA Registration & Listing Labeling Compliance (FDA)	FDA Certificate of Free Sale Export Certificates Certificate of Pharmaceutical Product (CPP)
European Union (EU)	EMA	Import Authorization / Marketing Authorization Labeling Compliance (EU rules) Certificate of Analysis (CoA)	Export Certificate GMP / Equivalence Certificate Certificate of Pharmaceutical Product (CPP)
China	NMA	NMPA Registration Labeling Compliance (NMPA)	Export Registration Certificate Certificate of Pharmaceutical Product (CPP) GMP / Equivalence Certificate Notarial Deed

Obstacles & Difficulties

1. Lack of International Harmonization: Trade documentation is inconsistent because different countries have varied definitions and classifications of herbal medications.

2. Non-Uniform Quality Standards: Variable product quality results from the lack of standardized testing and analytical standards for herbal formulations.
3. Complicated Licensing Processes: Exporters have to file several regulatory forms and certificates for various markets, which might lead to delays.
4. Inadequate Research Data: Many herbal remedies do not have the thorough preclinical and clinical validation that regulatory bodies demand.
5. Trade Barriers: Easy export is hampered by strict phytosanitary and labeling regulations, particularly for raw plant materials.
6. Duplication of Documentation: To meet various national regulations, the same data frequently needs to be reformatted or recertified.

Future Prospects and Harmonization Efforts

The global herbal industry can benefit greatly from harmonized regulatory standards.

Organizations such as the **World Health Organization (WHO)** advocate the adoption of **Good Agricultural and Collection Practices (GACP)** and **Good Manufacturing Practices (GMP)** to ensure product consistency and safety.

Collaborative initiatives among major agencies — including **AYUSH (India)**, **FDA (USA)**, **EMA (EU)**, and **NMPA (China)** — could help establish a **Mutual Recognition Agreement (MRA)** framework, enabling acceptance of documents like CPP and GMP certificates across borders.

Digitalization of documentation and the use of blockchain-based traceability systems can reduce fraud and improve transparency. Developing **standardized pharmacopeias** and **shared herbal monographs** will further enhance product credibility and facilitate international acceptance.

Conclusion

Worldwide, herbal remedies constitute an essential component of healthcare systems. However, differences in regulatory processes and documentation requirements still make it difficult for them to conduct business internationally. India is in a good position to spearhead international harmonization initiatives because of its extensive history of herbal systems and robust manufacturing capabilities. The world can advance toward a single framework for the documentation of herbal drugs by coordinating national policies with WHO principles and promoting collaboration among regulatory agencies. In addition to guaranteeing product efficacy, safety, and quality, this integration would make traditional herbal medicine available to everyone.

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