

Status of Recognition and Acceptance of Indian Pharmacopoeia in Foreign Countries

As per the Second Schedule of the Drugs and Cosmetics Act 1940, Indian Pharmacopoeia (IP) is designated as the official book of standards for drugs imported and/or manufactured for sale, stock or exhibition for sale or distribution in India. In order to ensure the quality of medicinal products, the legal and scientific standards of IP are published at regular intervals by the Indian Pharmacopoeia Commission (IPC). Standards prescribed in the IP are authoritative in nature and are enforced by the regulatory authorities for quality control of medicines in India. IPC has been making sincere efforts towards recognition and acceptance of IP in foreign countries and proposals in this regard have been submitted to various countries through Ministry of Health & Family Welfare, Ministry of External Affairs, Department of Commerce, and Department of Pharmaceuticals.

It is a matter of delight to share that in pursuant to sincere efforts and guidance provided by the Hon'ble Union Minister of Health & Family Welfare to get IP recognized in foreign countries, IP has been accepted as a book of standards in following countries with details as appended below:

o **Afghanistan**

IP has been recognised formally by the National Department of Regulation of Medicines and Health Products of the Ministry of Public Health of Islamic Republic of Afghanistan and also will be used based on the requirement as reputable pharmacopoeia in the laboratory of medicines and health products quality. With this, a new beginning has been made as Afghanistan has become the first country to recognize the IP. ([Click here to view letter issued by Ministry of Foreign Affairs of Afghanistan](#))

o **Ghana**

IP is considered as an approved reference when its monograph compares with the monographs in recognized pharmacopoeias in the Fourth Schedule of the Public Health Act. ([Click here to view letter issued by Food & Drugs Authority of Ghana](#))

o **Nepal**

IP is recognised as the book of standards in Drugs Category Rules 1986 of Nepal. As per the list of pharmacopoeia or encyclopedia related to the category of drugs under Schedule 1 (related to Rule 5) of the Drugs Category Rules 1986, "Pharmacopoeia of India" published by the Ministry of Health of Government of India has been included at Sr. No. 3. ([Click here to view Drugs Category Rules 1986 of Nepal](#))

o **Mauritius**

In order to include IP in the standards of pharmaceuticals authorized in Mauritius, Section 2 of the Pharmacy Act 1983 has been amended through Section 50 of the legal supplement published in August 2020 and in the definition of "specified standards" of the Section 2 of the Pharmacy Act, the word "or European" has been deleted and replaced with the words "European or Indian". Accordingly, the amended section reads as: "specified standards" means such standards as are specified in the British, French, United States, European or India Pharmacopoeia; ([Click here to view Pharmacy Act 1983 of Mauritius and its amendment](#))

- **Suriname**

A memorandum of understanding (MoU) has been signed between the IPC and Health Ministry of Republic of Suriname to recognize the importance of close cooperation and exchange of information in the field of regulation of medicine. IP is accepted as a book of standards for medicines in the Republic of Suriname so as to ensure quality of medicines being manufactured and/or imported in Suriname ([Click here to view signed MoU](#))

- **Nicaragua**

The governments of India and Nicaragua have signed an MoU on pharmacopoeia cooperation to accept IP as a book of standards for medicines in Nicaragua so as to ensure quality of medicines being manufactured and/or imported in Nicaragua ([Click here to view signed MoU](#))

- **Bhutan**

An MoU has been exchanged between India and Bhutan on cooperation concerning sharing reference standards, pharmacopoeia, vigilance and testing of medicinal products. The MoU allows for acceptance of the IP by Bhutan as a book of standards for medicines and supply of generic medicines at affordable price ([Click here to view signed MoU](#))

- **Mozambique**

India and Mozambique signed an MoU on pharmacopoeia to cooperate in the field of the regulation of medicines. The MoU allows for acceptance of the IP by Mozambique as a book of standards for medicines manufactured and/or imported in Mozambique ([Click here to view signed MoU](#))

- **Solomon Islands**

India and Solomon Islands signed an MoU on pharmacopoeia cooperation to accept IP as a book of standards for medicines in Solomon Islands ([Click here to view signed MoU](#))

- **Sri Lanka**

IP standards are being accepted by the National Regulatory Authority (NMRA) of Sri Lanka while issuing marketing authorization. Sri Lanka has included the IP along with other pharmacopoeias in the guidelines issued by the NMRA for registering of medicinal products. Further strengthening this collaboration, a Memorandum of Understanding (MoU) on pharmacopoeial cooperation has now been signed between India and Sri Lanka. ([Click here to view signed MoU](#))

- **Nauru**

A Memorandum of Understanding (MoU) has been signed between the IPC and the Government of the Republic of Nauru, through its Department of Health and Medical Services. This MoU facilitates the acceptance of the IP as the official book of standards for medicines in Nauru, ensuring the quality of both domestically manufactured and imported medicines ([Click here to view signed MoU](#))

- **Malawi**

A Memorandum of Understanding (MoU) has been signed between the IPC and the Government of Malawi, through its Pharmacy and Medicines Regulatory Authority . This MoU fosters cooperation in pharmacopoeial standards. It aims to facilitate the recognition of the Indian

Pharmacopoeia (IP) within Malawi's regulatory frameworks and enhance the exchange of analytical methods published in the IP, ensuring the quality of medicines consumed in Malawi. ([Click Here to view signed MOU](#))

- **Guyana**

A Memorandum of Understanding (MoU) has been signed between the IPC and the Ministry of Health, Guyana. This MoU establishes the Indian Pharmacopoeia as the recognized compendium of standards for medicines in Guyana, ensuring the quality of both locally produced and imported pharmaceuticals. ([Click here to view signed MOU](#))

- **Fiji**

A Memorandum of Understanding (MoU) has been signed between the IPC and the Ministry of Health & Medical Services, Government of Fiji. This MoU recognizes the Indian Pharmacopoeia (IP) as one of the standards for medicinal products manufactured in India for use in Fiji. It will also aid Fiji in its ongoing initiatives to protect the health and safety of its citizens by ensuring that medicinal products available for use in Fiji are safe, effective, and of assured quality. ([Click here to view signed MOU](#))

- **Cuba**

A Memorandum of Understanding (MoU) on pharmacopoeial cooperation was signed between the IPC and Center for State Control of Medicines and Medical Devices (CECMED), Ministry of Public Health of the Republic of Cuba. Under the MoU, Cuba will recognize the Indian Pharmacopoeia (IP) for the quality control of medicines manufacture and/or imported into the country and accept Certificates of Analysis from Indian manufacturers as per IP, removing the need for duplicate testing. It also allows access to IP reference substances and impurity standards at affordable rates and supports collaboration to improve access to quality-assured, affordable medicines in Cuba. ([Click here to view signed MoU](#))

- **Trinidad & Tobago**

A Memorandum of Understanding (MoU) on pharmacopoeial cooperation was signed, under which the Republic of Trinidad and Tobago will recognize the Indian Pharmacopoeia (IP) for the quality standards of medicines. This recognition will pave the way for closer collaboration in the pharmaceutical sector and enhance access to quality-assured, affordable generic medicines from India for the people of Trinidad and Tobago. ([Click here to view signed MoU](#))

- **Maldives**

A Memorandum of Understanding (MoU) on pharmacopoeial cooperation has been signed, pursuant to which the Maldives now recognizes the Indian Pharmacopoeia (IP) as a reference standard for the quality of medicines. This recognition is expected to foster deeper collaboration in the pharmaceutical domain and facilitate improved access to quality-assured, affordable generic medicines from India for the citizens of the Maldives. ([Click here to view signed MoU](#))

Discussions with other countries are ongoing to expand this list. Stakeholders are encouraged to benefit from the recognition of the IP in these countries.