ISSUE No. 59

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. - Aug. - Sep. 2023

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MOVING GLOBALLY

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R & D and Manufacturing of Formulations

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Surgical

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 59 Jul. - Aug. - Sep. 2023

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 59th issue of Pharma Web Newsletter for Jul – Sep 2023.

This 59th issue contains the program highlights as well as the following articles published by eminent person in Pharma industry.

- **Effective Implementation of Quality Management System - Regulatory Compliance** **Mr. Sajay Kumar Dasmohapatra**, President –Technical & Operations, Medopharm Pvt. Ltd., Chennai
- **Role of IPC in Setting Pharmacopoeia Standards for Ensuring Quality of Medicines** **Dr. Gaurav Pratap Singh Jadaun**, Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad

We have also published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules, important circulars issued by DCGI pertaining to Drugs & Pharmaceuticals.

Important news items connected to our Pharmacy profession appeared in various national newspapers & Parliament Question & Answers relevant to our Pharmacy profession are published

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

Effective Implementation of Quality Management System - Regulatory Compliance

by
Mr. Sajay Kumar Dasmohapatra
President –Technical & Operations, Medopharm Pvt. Ltd., Chennai

Lecture Delivered during Pharmexcil Seminar held on 17th November 2023 in Chennai

What is GMP

Good Manufacturing Practice is a system for ensuring that products are **consistently** produced and **controlled** according to Quality Standards.

It is designed to **minimize the risks** involved in any pharmaceutical production that cannot be eliminated through testing the final product.

GMP covers all aspects of production from the starting materials, premises, equipment, training, and personal hygiene of staff.

All Regulatory Authorities have published detailed guidelines to ensure compliance with the GMP.

Importance of GMP

- Aim is to produce medicine meeting the standard for **effective treatment of patients.**
- Poor quality medicine will lead to health hazards as it may contain toxic substances, enhancement of impurities beyond stated limits, failure to meet critical product quality parameters, etc.
- Medicines that contain little or none of the claimed ingredients will not have the intended therapeutic effect.

Why GMP is necessary although there is a QC Laboratory

- **Good Quality must be built** in during the manufacturing process, it cannot be tested into the product afterward.
- **GMP prevents errors** that cannot be eliminated through quality control of the finished product. It is one way, you cannot turn back to correct your errors.
- Without GMP it is impossible to be sure that every unit of medicine produced at the site is of the same quality.

Discussion points:

- To discuss the tricks and techniques to ensure GMP compliance in the facility all the time.
- How to inculcate the culture of compliance at the site.
- Ownership building at each level and its effective monitoring.
- How to achieve consistency in the middle of all variables.
- Importance of Risk Assessment and its effective implementation.

Discussion points:

- How to forecast failures in advance and proactive steps to avoid them.
- How to handle failures and what it indicates.
- Techniques for successful get-through of any GMP inspection at the site.
- Investigation techniques of Market Complaints.
- Important factors to consider while writing a compliance report.

All time GMP compliance at site

- Focusing on the 3M: Man, Machine, and Method
- Why is the **'Culture of Compliance'** so important and how to develop?
- How to design a perfect JD and why it helps towards GMP compliance.
- What is ownership and how it is built?
- Effective training through visuals and mentoring. Challenging mechanism to understand and record competency.

Consistency in the middle of all variables

- What are the variables
- How to identify variables
- Risk assessment for impact assessment of all such variables.

Importance of Risk Assessment and its effective implementation

- Why is risk assessment important?
- Concept of risk assessment.
- Mitigation of risks.
- Elimination of risks.

How to forecast failures and avoid

- Focusing on the indications
- Uncontrolled variables
- Ineffective execution of change controls.
- Multiple minor deviations of the same nature.
- Random allotment of responsibilities to handle manpower crisis.
- Managing certain activities with less or incompetent manpower.
- Introduction or change of any formulation/pack with supportive study.
- Failure to adopt a timely change of regulatory requirements.

How to handle failures and what it indicates

- A failure indicates a partial crash of the laid-down QMS although it may not be a direct GMP failure.
- Investigation of failure on the 'Why / How' concept and not the 'Who' concept.
- The core focus of the investigation must be product quality relating to patient safety as the nucleus.

Successful get-through of GMP Inspections

- Preparation
- Presentation
- Participation
- Understanding the intention of the inspector when question asked.
- What to talk about and what not to talk.

Investigation of Market Complaints

- Acceptance
- Check for spurious.
- Thorough investigation with an open mind.
- Ask for more input from the complainant.
- Trend checks.
- Review of History sheets.
- Interviewing all personnel involved till the bottom line.
- Carry out all hypotheses.
- Submit meaningful conclusions after concluding the root cause with CAPA.

Writing a Compliance Report is an Art

- How to read and understand a deficiency report.
- In what context this observation was recorded and what opinion did the inspector share.
- Root cause: Wrong interpretation of the regulation, gap in execution or integrity issue.
- Expanding the arena to understand and address in a complete manner to mitigate hidden risks in and around the deficiency.
- Cost of compliance: Every commitment towards compliance is a cost to the company. Identify the best option to comply with minimal cost.

Role of IPC in Setting Pharmacopoeia Standards for Ensuring Quality of Medicines

by

Dr. Gaurav Pratap Singh Jadaun

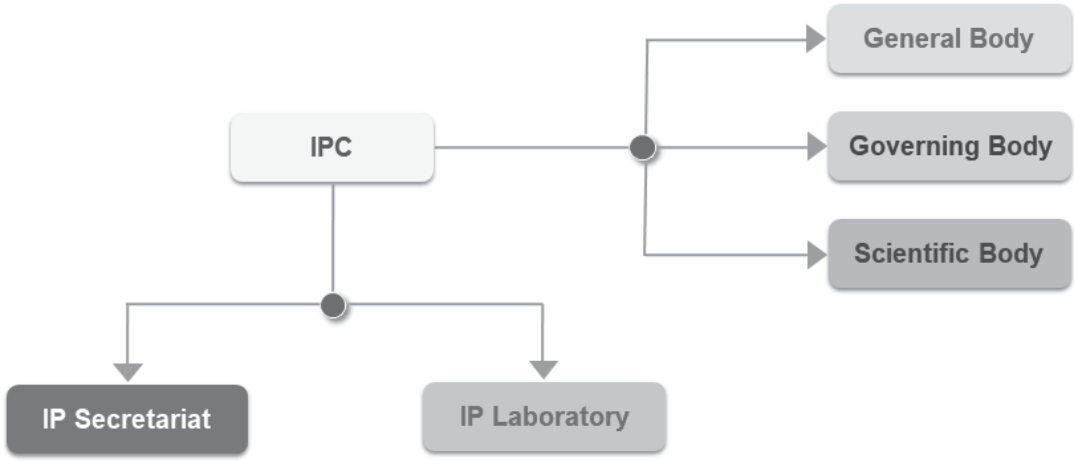
Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad

Lecture Delivered during Pharmexcil Seminar held on 17th November 2023 in Chennai

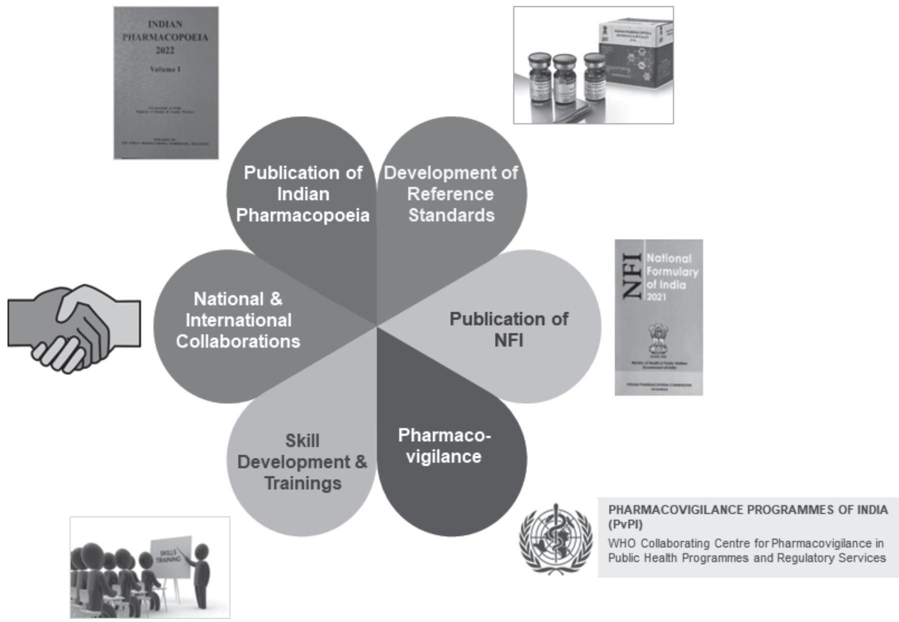
Indian Pharmacopoeia Commission (IPC)

- An autonomous Institute under Ministry of Health & Family Welfare, Govt. of India
- Established on 1st January, 2009 to set official standards of drugs in India
- Three tier structure comprising of the General Body, Governing Body, and Scientific Body
- Expert Working Groups (EWGs) with subject experts to guide on standards setting

Indian Pharmacopoeia Commission (IPC)



IPC Mandates & Functions



Indian Pharmacopoeia (IP)

1. Book of drug standards as per Drugs & Cosmetics Act 1940. Published by the Indian Pharmacopoeia Commission (IPC)

2. Monograph development by public comments and expert consultations

3. IP standards are authoritative and legally enforceable

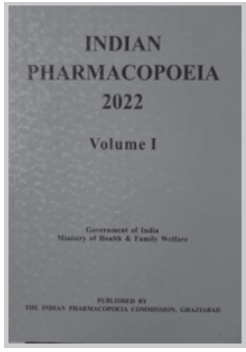
4. Helps ensuring quality of marketed medicinal products in India

5. Contains monographs on APIs, formulations, excipients, veterinary medicines etc.

Monograph Inclusion & Exclusion Criteria

Inclusion Criteria

- Drugs approved by the CDSCO
- Drugs included in the National List of Essential Medicines
- Drugs used in National Health Programs of India
- Drugs considered appropriate by the IPC

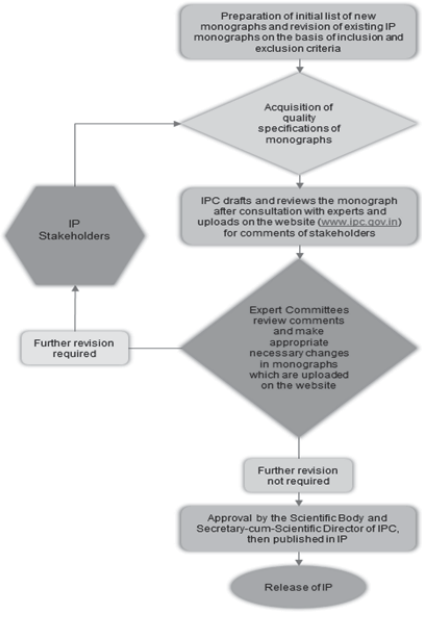


Exclusion Criteria

- Drugs banned in India
- Obsolete drugs
- Drugs considered inappropriate by the IPC

Monograph Development Process

- Selection of monographs based on specific inclusion criteria
- Quality specifications sourced from manufacturers
- Monograph development in consultation with experts of EWGs and stakeholders
- Pharmacopoeia text published on IPC website for inviting public comments
- Approval of the Scientific Body before publication in the IP



EWGs of IP

Active Pharmaceutical Ingredients	Anti-Cancer	Biological & r-DNA Products	General Chapters	Impurity Standard Review
Anti-Retroviral	Excipients	Blood & Blood related Products	General Chapter on Dosage Form	IPRS Review
Fixed Dose Combinations	Ophthalmic	Allergen	Microbiology-General	
Vitamins, Minerals, Amino Acids Fatty Acids etc.		Vaccines & Immunosera for Human use	Parenteral Preparations General	
		Anti-Sera		

Toxicology	Phytopharmaceuticals	Radiopharmaceuticals	Veterinary Products
Medical Devices	Plastic Containers	IP Digitalization	Website

Proposing Monograph Development & Revision

Monograph Development

- Need for new monograph
- Proposal submitted to the IPC on lab.ipc@gov.in
- CDSCO approval, validation data, test samples/Ref. Std. required
- Approval by the EWG as per inclusion criteria
- Monograph development through standard process of public comments

Monograph Revision

- Need for revision due to harmonization, modernization or amendment
- Proposal submitted to the IPC on lab.ipc@gov.in
- Test samples/Ref. Std. required for verification
- Inviting public comments on revised text
- Approval by the EWG

Structure of IP Standards

General Notices

- Provide rules to understand pharmacopoeia text for its interpretation and application
- Applicable to all pharmacopoeia texts

General Chapters

- Not mandatory 'per se'
- Mandatory when referred to in a specific monograph
- Some General Chapters are not referred in monographs and are published as useful guidance
- Can be used for substances not covered by monographs
- May contain validity or equipment-verification equirements

General Monographs

- Containing centralized methods and specifications common to all dosage forms (e.g. tablets, capsules, injections)
- Include aspects that cannot be treated in each specific monograph
- Mandatory for all the products within the scope of definition section
- Usually referred for substances where there is no monograph

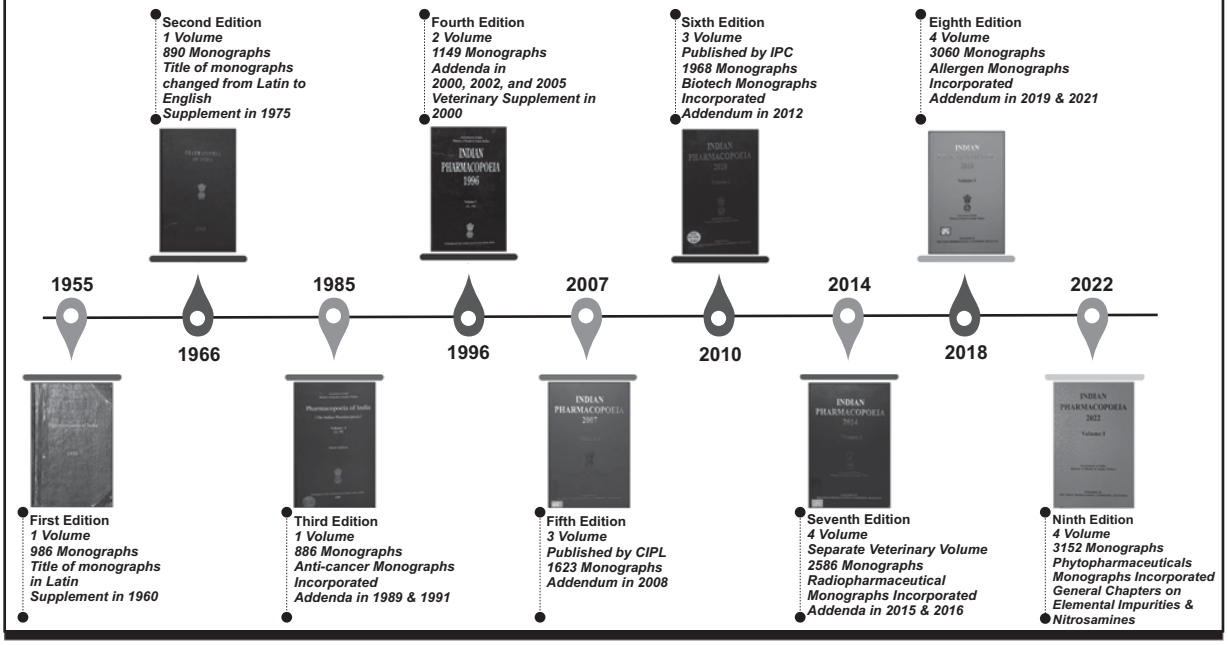
Specific Monographs

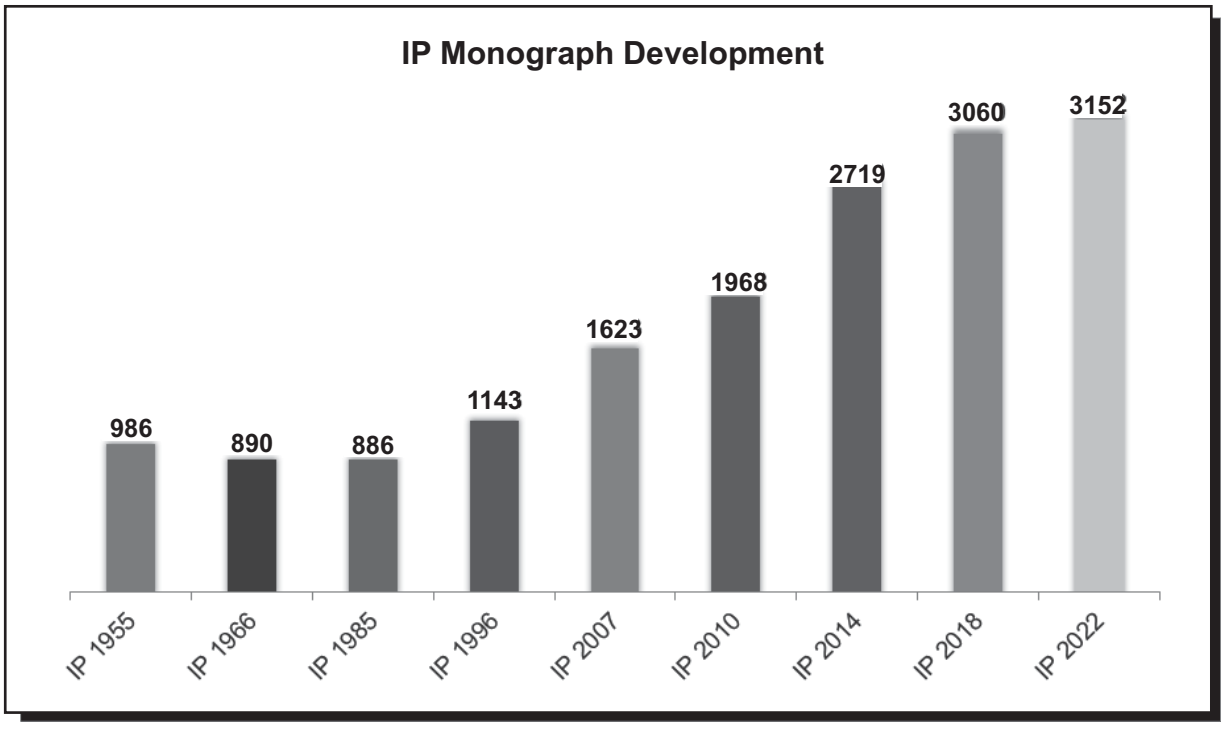
- Developed based on approved specifications for drug substances or finished products
- Analytical procedures and acceptance criteria to demonstrate that the substance meets required quality standards
- Specifications for pharmaceutical products in commerce (from release through product shelf life)

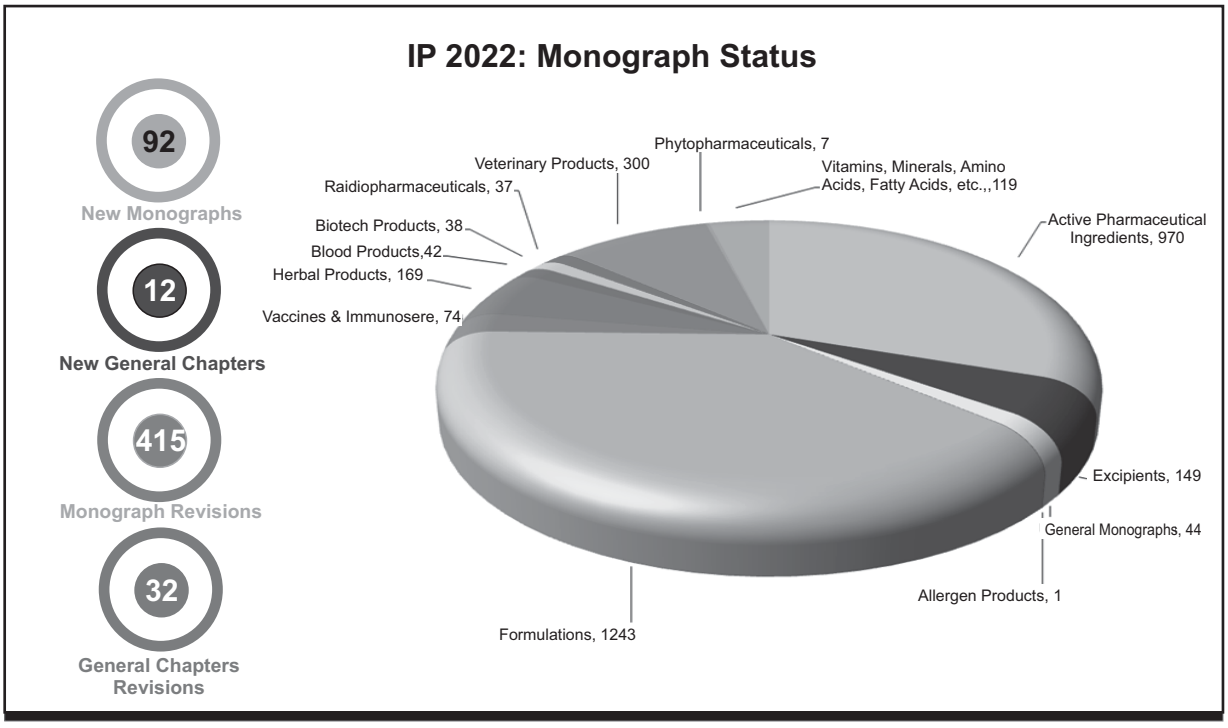
Reference Standards

- Physical materials to be used in conjunction with the test methods in the monograph
- Assesses specific quality attributes of the drug product or ingredient, including assay and impurities

History of IP Editions




IP Monograph Development
986
890
886
1143
1623
1968
2719
3060
3152
IP 1955
IP 1966
IP 1985
IP 1996
IP 2007
IP 2010
IP 2014
IP 2018
IP 2022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Response to COVID-19

Pharmacopoeia Monographs

- Developed monographs on COVID-19 drugs (Remdesivir, Favipiravir,Ivermectin)
- IP became first Phamacopoeia to have monographs on Remdesivir and Favipiravir

Guidance to Industry

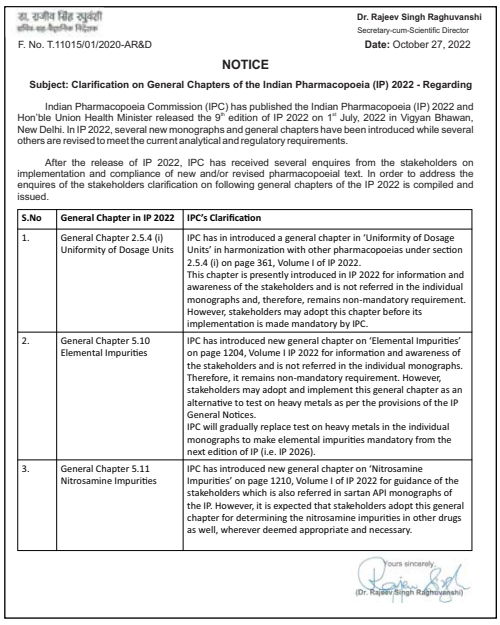
- Developed guidance on 'Rapid Microbiological Methods' for early batch release of COVID-19 related drugs during pandemic

Reference Standards

- Developed IPRS on COVID-19 related drug and made available to stakeholders (Remdesivir, Favipiravir, Ivermectin, Azithromycin, Hydroxychloroquine sulphate, Doxycycline hydrochloride, Dexamethasone)

Clarification on General Chapters

- Elemental Impurities
  - Non-mandatory requirement
  - Stakeholders may adopt and implement as an alternative to heavy metals
  - Test on heavy metals to be replaced with Elemental impurities in next IP edition (i.e. IP 2026)
- Nitrosamine Impurities
  - For guidance of stakeholders and referred in sartan API monographs
  - Expected that stakeholders adopt for determining nitrosamine impurities in other drugs as well



डा. राजीव सिंह रघुवंशी
सचिव एवं वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D

Date: October 27, 2022

NOTICE

Subject: Clarification on General Chapters of the Indian Pharmacopoeia (IP) 2022 - Regarding

Indian Pharmacopoeia Commission (IPC) has published the Indian Pharmacopoeia (IP) 2022 and Hon'ble Union Health Minister released the 9th edition of IP 2022 on 1st July, 2022 in Vigyan Bhawan, New Delhi. In IP 2022, several new monographs and general chapters have been introduced while several others are revised to meet the current analytical and regulatory requirements.

After the release of IP 2022, IPC has received several enquires from the stakeholders on implementation and compliance of new and/or revised pharmacopoeial text. In order to address the enquires of the stakeholders clarification on following general chapters of the IP 2022 is compiled and issued.

S.No	General Chapter in IP 2022	IPC's Clarification
1.	General Chapter 2.5.4 (i) Uniformity of Dosage Units	IPC has in introduced a general chapter in 'Uniformity of Dosage Units' in harmonization with other pharmacopoeias under section 2.5.4 (i) on page 361, Volume I of IP 2022. This chapter is presently introduced in IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs and, therefore, remains non-mandatory requirement. However, stakeholders may adopt this chapter before its implementation is made mandatory by IPC.
2.	General Chapter 5.10 Elemental Impurities	IPC has introduced new general chapter on 'Elemental Impurities' on page 1204, Volume I IP 2022 for information and awareness of the stakeholders and is not referred in the individual monographs. Therefore, it remains non-mandatory requirement. However, stakeholders may adopt and implement this general chapter as an alternative to test on heavy metals as per the provisions of the IP General Notices. IPC will gradually replace test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of IP (i.e. IP 2026).
3.	General Chapter 5.11 Nitrosamine Impurities	IPC has introduced new general chapter on 'Nitrosamine Impurities' on page 1210, Volume I of IP 2022 for guidance of the stakeholders which is also referred in sartan API monographs of the IP. However, it is expected that stakeholders adopt this general chapter for determining the nitrosamine impurities in other drugs as well, wherever deemed appropriate and necessary.

Yours sincerely

(Dr. Rajeev Singh Raghuvanshi)

Clarification on Elemental Impurities

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2023-AR&D

Date: August 1, 2023

NOTICE

Subject: Ensuring compliance with the Indian Pharmacopoeia General Chapter (5.10) on Elemental Impurities - reg.

This is in continuation of IPC's Notice No. T.11015/01/2020-AR&D dated October 27, 2022 wherein clarification was issued on the subject mentioned above. This is once again brought to the notice of all concerned that:

1. IPC has introduced a new General Chapter on 'Elemental Impurities' in the IP 2022 for information of the stakeholders which is not yet referred in the individual monographs and; therefore, it remains a non-mandatory requirement. However, stakeholders are encouraged to adopt and implement this general chapter as an alternative to the test on heavy metals as per the provisions of the IP General Notices.

2. Meanwhile, IPC has started working on gradually replacing test on heavy metals in the individual monographs to make elemental impurities mandatory from the next edition of the IP (i.e. IP 2026). IPC will discuss such charges with the Expert Working Group(s) along with publishing the same on IPC website prior to their adoption in the IP 2026.

3. Accordingly, the general chapter on elemental impurities (5.10) shall be referred in the General Requirements of Active Pharmaceutical Ingredients and in individual monographs of drug products in the IP 2026 so as to make it a mandatory requirement.

In view of the above, all concerned are requested to start working on required necessary changes in their quality systems for the readiness and ensuring compliance with the revised elemental impurities standards of the IP 2026. For further information, please keep on visiting IPC website (www.ipc.gov.in)

(Dr. Rajeev Singh Raghuvanshi)

Using Alternative Methods

Alternative Methods. The tests and assays described are the ofificial methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the of ficial methods were used. Automated procedures utilising the same basic chemistry as the rest procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorised manufacturer of substance or product.

In the event of doubt or dispute, the methods of analysis of the Pharmacopoeia are alone authoritative and only the result obtained by the procedure given in this Pharmacopoeia is conclusive.

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar, Ghaziabad 201 002

F. No. T.11013/02/2018-AR&D

Date: 26th February 2021

NOTICE

Subject: Clarification on Alternative Methods in the Indian Pharmacopoeia - regarding

Indian Pharmacopoeia Commission (IPC) has been receiving many enquires on the subject of use of *alternative methods instead of Of ficial methods included in the Indian Pharmacopoeia (IP)*. General Notices of IP (Volume I, Page 12) have the provision to use alternative methods and the same is reproduced below:

Alternative Methods. The tests and assays described are the of ficial methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purpose, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the of ficial methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacturer of substance or product.

2. For removal of doubts, it is clarified that the authority competent to authorise manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval.

3. All concerned are requested to bring the above clarification to the notice of all authorities under their control.

(Dr Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director

Other FAQs

Is 'Solubility' mandatory

Solubility. Statements on solubility are given in chapter 2.4.26 and are intended as information on the approximate solubility at a temperature between 15° to 30°, unless otherwise stated, and are not to be considered as official requirements. However, a test for solubility stated in a monograph constitutes part of the standards for the substance that is the subject of that monograph.

Is 'Description' part mandatory

Description. The Statements under the heading Description are not to be interpreted in a strict sense and not to be regarded as official requirements.

What is 'Usual Strength'?

Usual strength. The Statements on the usual strength(s) of a preparation given in the individual monograph indicates the strength(s) usually marketed for information of the pharmacist and the medical practitioner. It does not imply that a strength other than the one(s) mentioned in the individual monograph meeting all the prescribed requirements cannot be manufactured and marketed with the approval of the appropriate authority

Monograph Development for Next IP Edition

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निर्देशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D

Date: August 13, 2023

Subject: Sharing the list of marketed drug products along with their test specifications for development of monographs for the Indian Pharmacopoeia - reg.

Dear all,

As you are aware that, in order to fulfill requirements of the Drug and Cosmetics Act, 1940 and Rules 1945 there under, the Indian Pharmacopoeia Commission (IPC) functions as an autonomous Institute under the Ministry of Health & Family Welfare to publish the Indian Pharmacopoeia (IP) at regular intervals.

2. Accordingly, IPC has come up with the publication of the 9th edition of the IP 2022 which was released on 1st July, 2022 by the Hon'ble Union Minister of Health and Family Welfare and became ef fective from 1st December, 2022. This edition contains a total of 3152 monographs.

3. Meanwhile, IPC has started working on developing monographs for the next edition of the IP I 2026 with the aim to include monographs to cover drugs included in the National List of Essential Medicine (NLEM), National Health Programmes (NHPs), and other drugs which are widely prescribed and marketed in India.

4. In India, the Central and State Drugs Testing Laboratories are involved in the regulatory quality analysis of marketed drug products and have a repository of the test specifications of many drug products which are widely prescribed but their monographs are not available in the IP. There is a need to utilize this repository as a source for the development of monographs for their inclusion in the IP.

5. In view of the above, it is requested that Central and State Drugs Testing Laboratories shall share the list of non-IP drug products with the IPC (email: lab.ipc@gov.in) along with their test specifications for initiating monograph development for the IP 2026.

I am sure each laboratory will join hands with the IPC for this national cause towards strengthening the drug standards in the IP.

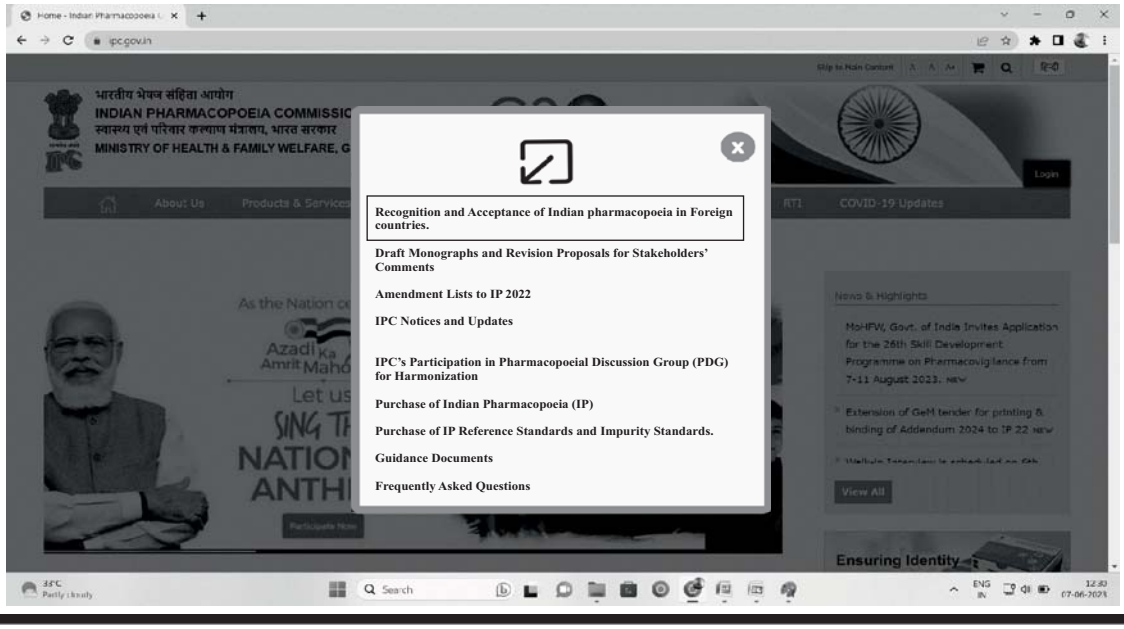
Thanking you

(Dr. Rajeev Singh Raghuvanshi)

Future Updates

- Publication of IP Addendum 2024 (by end of 2023)
- Developing IP on-line Platform (by Feb 2024)
- Participation in PDG for Pharmacopoeial Harmonization (ongoing)
- Introduction of Elemental Impurities and Dissolution Specifications (ongoing)
- Monograph Revisions (ongoing)

Accessing IPC Website



Update on Recognition of IP

IPC Updates

June 13, 2023

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 of ficial 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 ef forts 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, Department of Commerce, Department of Pharmaceuticals, and Ministry of External Af fairs.

It is a matter fo delight to share that in pursuant to sincere ef forts and guidance provided by the Hon'ble Union Minister of Health & Family to get IP recognized in foreign countries. IP has been accepted as a book of standards in a total of five countries with details as apended below:

- **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 Af fairs of Afghanistan)
- **Ghana**
  IP is considered as an approved reference when its monograph compares with the monographs in recognized pharmacopoeias in the Forth Schedule of the Public Health Act, (Click here to view letter issued by Food & Drugs Authority of Ghana)
- **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)
- **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)

Indian Pharmacopoeia Commission

E-mail: lab.ipc@gov.in
Website: www.ipc.gov.in

Recognition of IP in Suriname

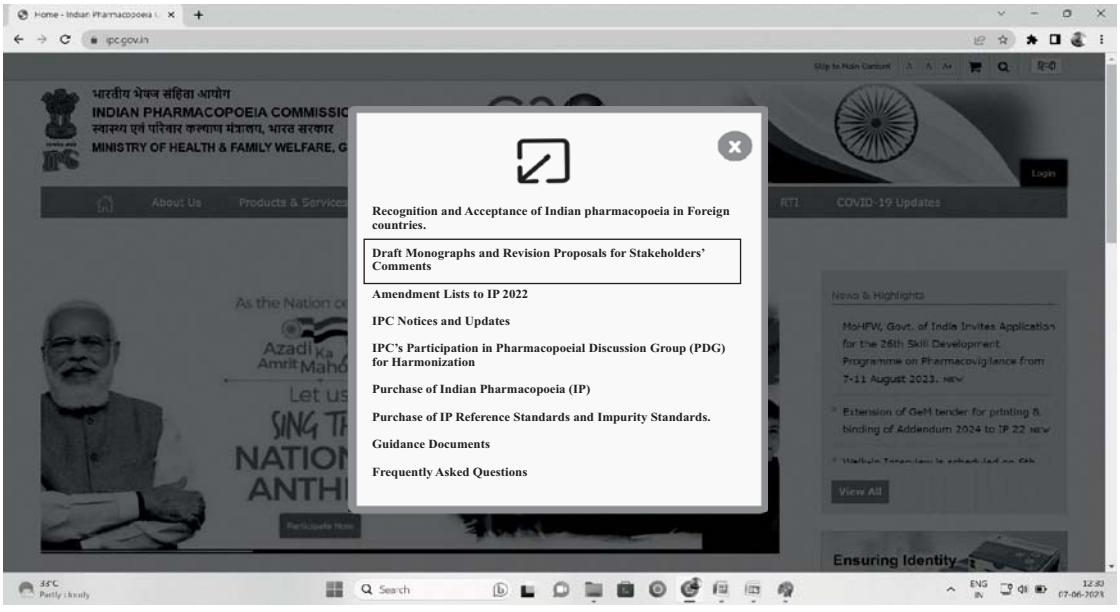
Jun 05, 2023, 9.05PM

President Murmu holds talks with Suriname President; 3 MoUs signed in Agriculture and Health sectors

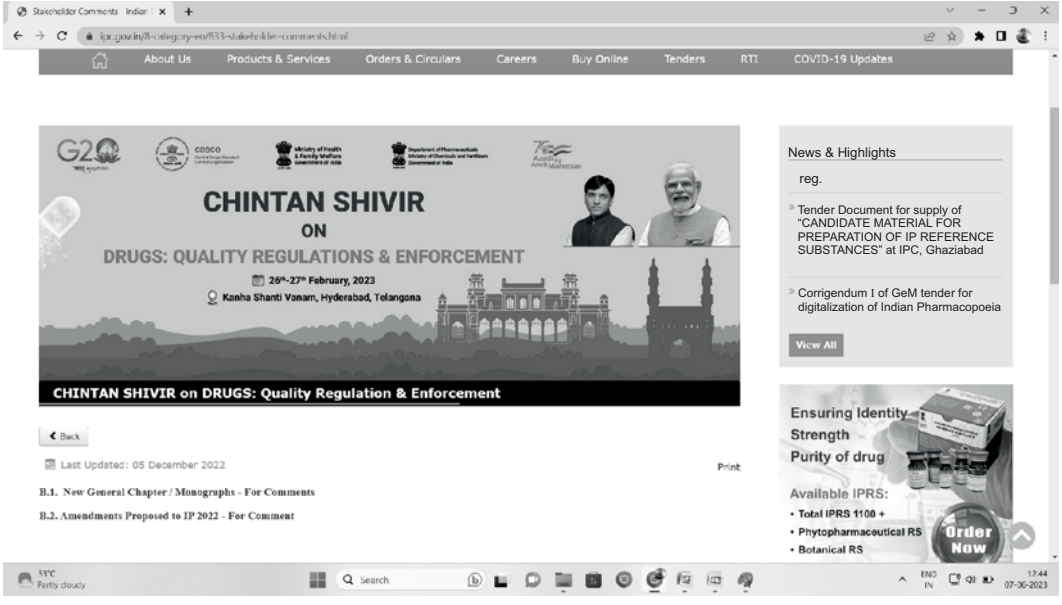
President Droupadi Murmu held restricted talks and delegation level talks with Surinam President Chandrikapersad Santokhi on Monday. Three MoUs in Health and Agriculture sectors were signed between India and the Republic of Suriname in Paramaribo. These MoUs include a Joint Work Plan for Cooperation in the Field of Agriculture and Allied Sectors for the period of 2034-2027; an MoU between the Indian Pharmacopoeia Commission and the Health Ministry of Suriname for recognition of the Indian Pharmacopoeial standards and an MoU between Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health of Suriname on cooperation in the field of Medical products regulations

On a three-day visit to Suriname, as President Droupadi Murmu arrived at the Presidential Palace, she was received by the President of the Republic of Suriname, Chandrikapersad Santokhi. The National Anthems of both India and Suriname were played upon her arrival. The first lady of Suriname, Mellisa Santokh-Seenacherry, was also present at the occasion.

Accessing IPC Website



Pharmacopoeia Text for Comments



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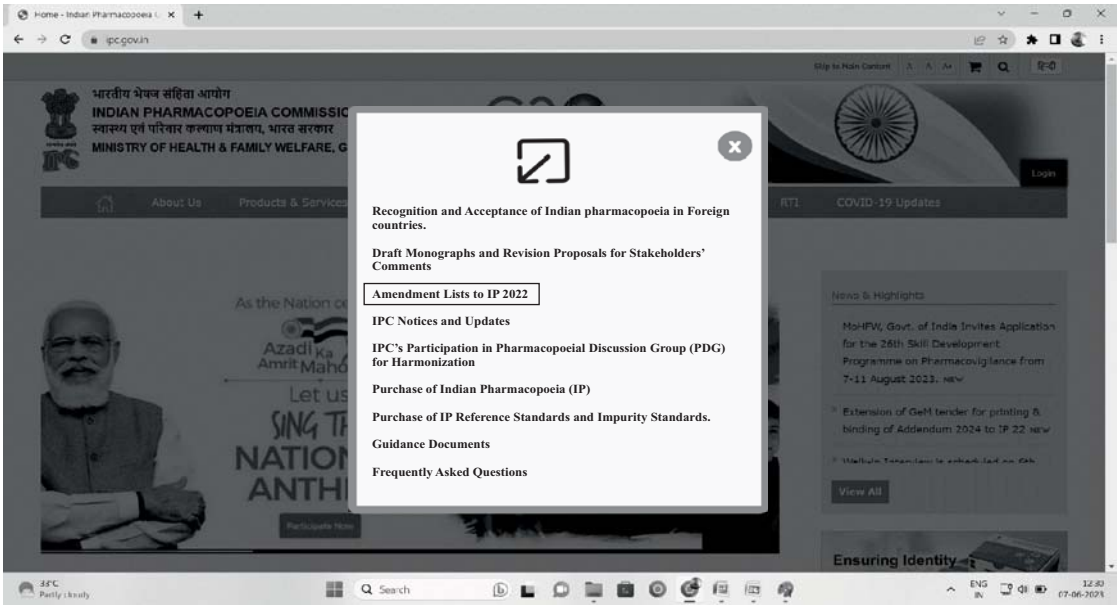
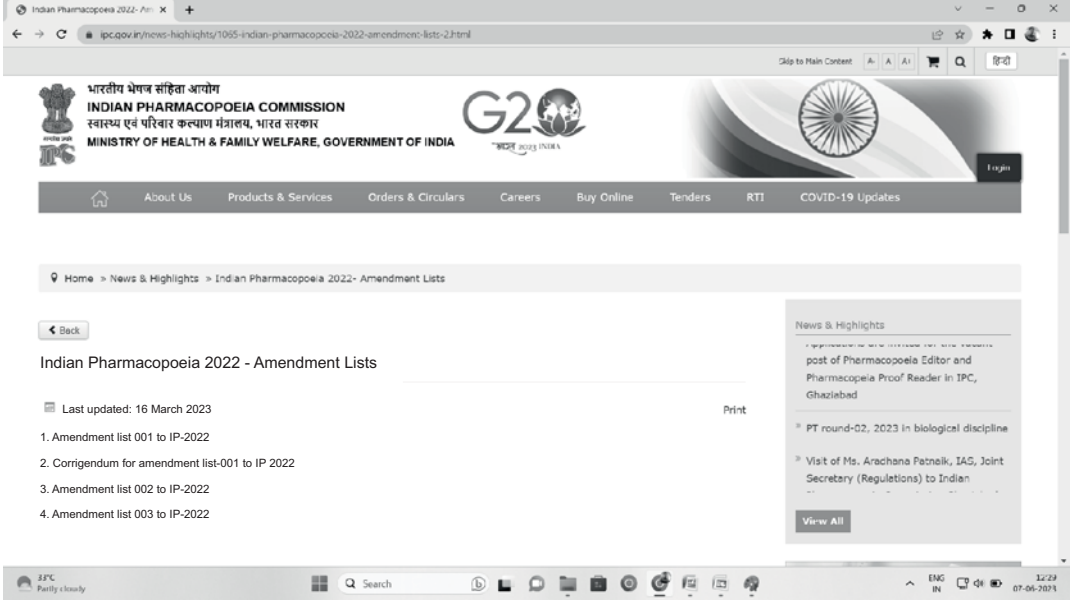


Amendment Lists to IP 2022



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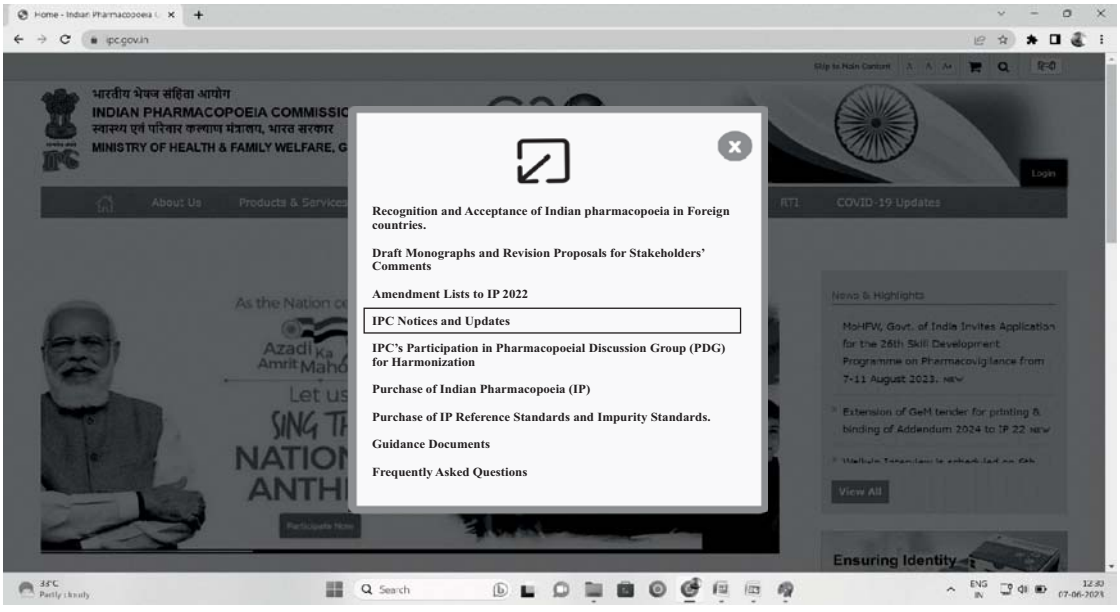
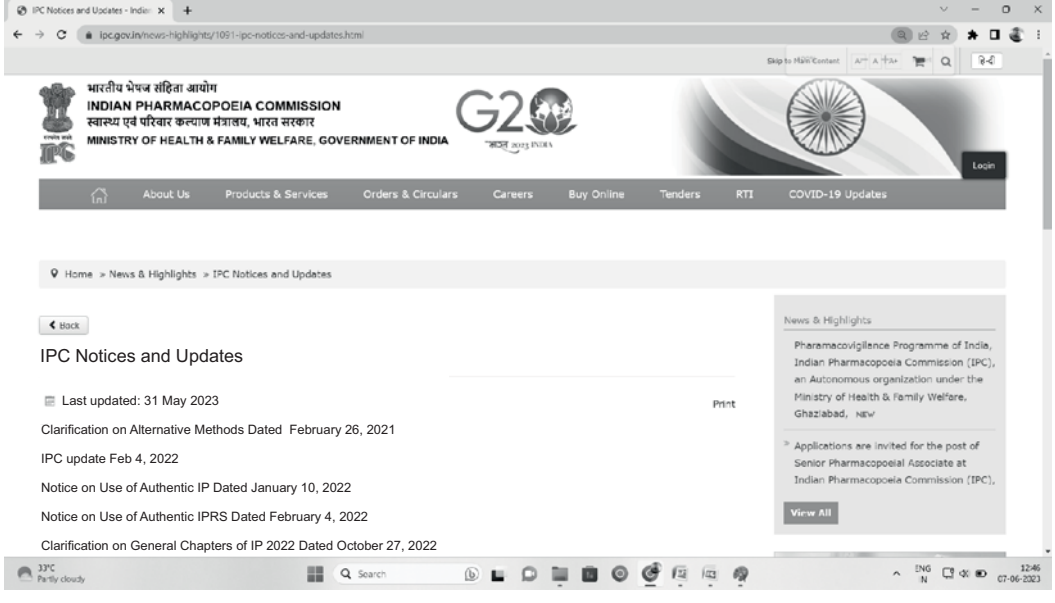


IPC Notices & Updates



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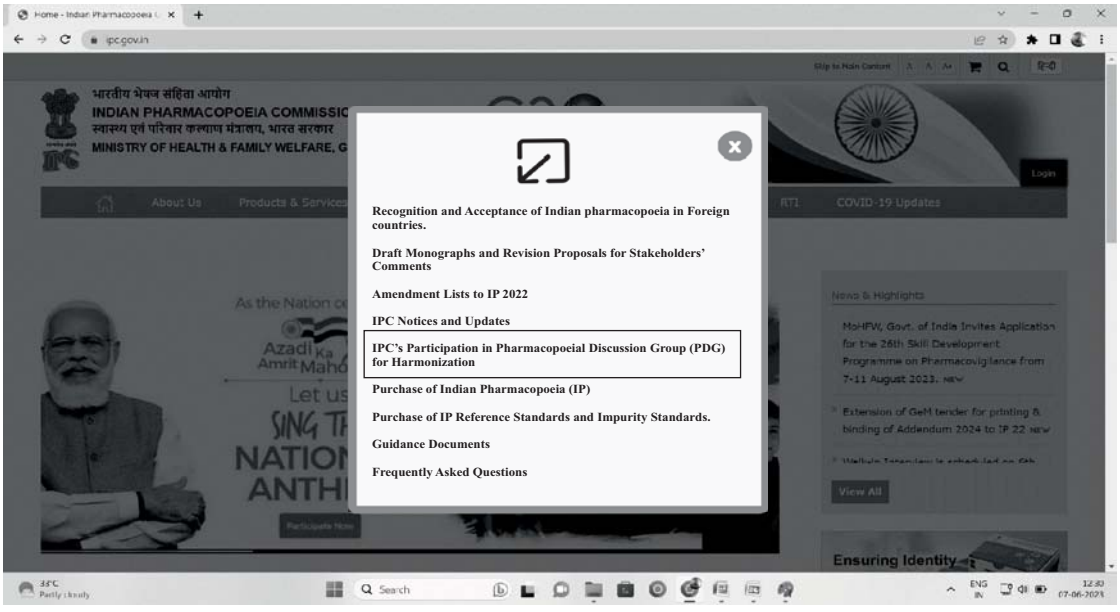
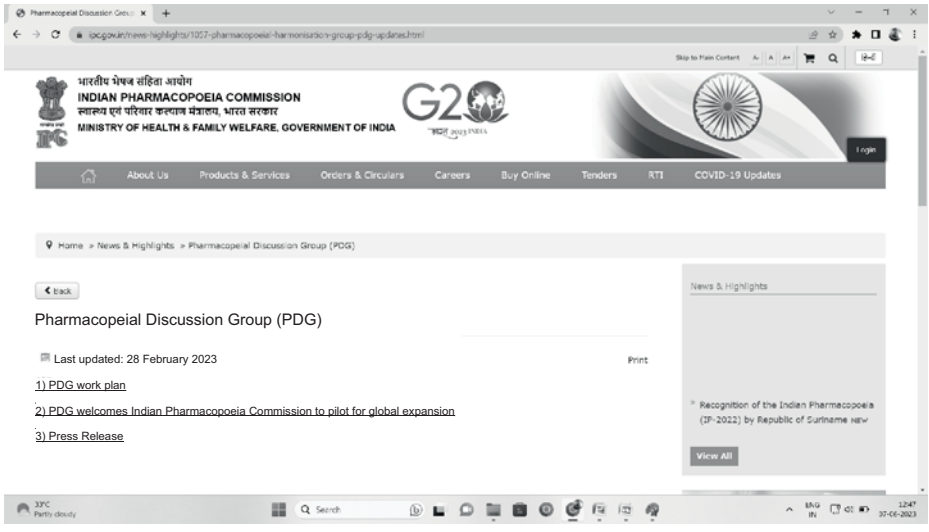
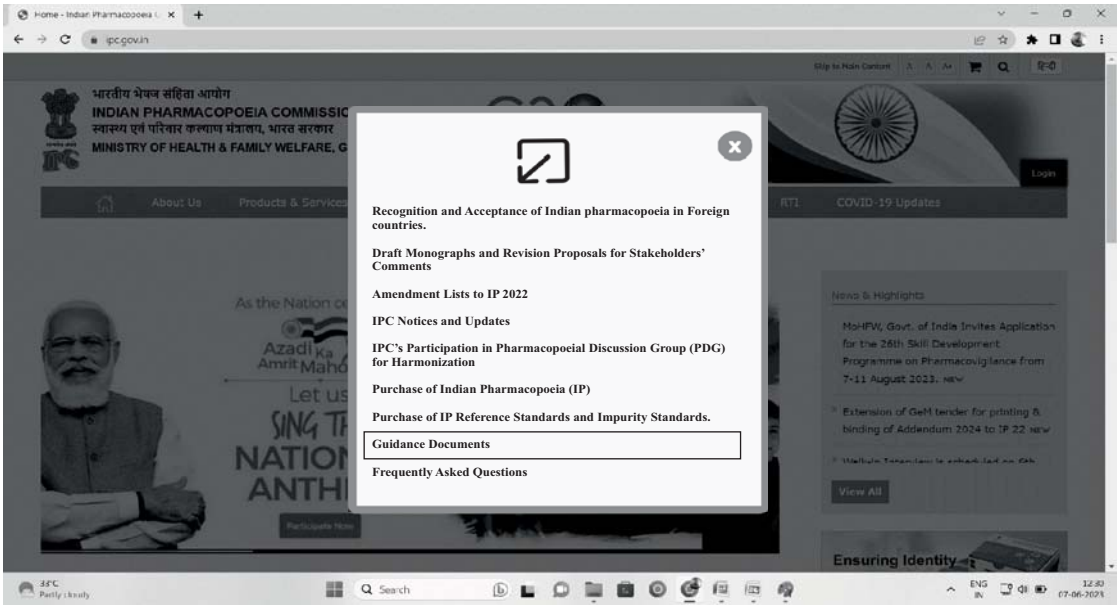


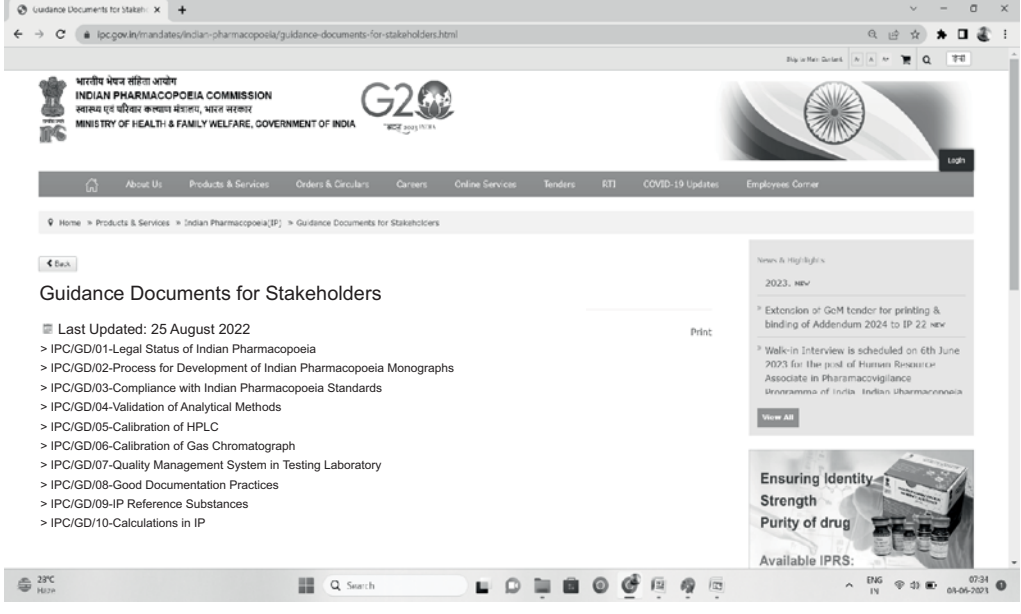
IPC's Participation in PDG



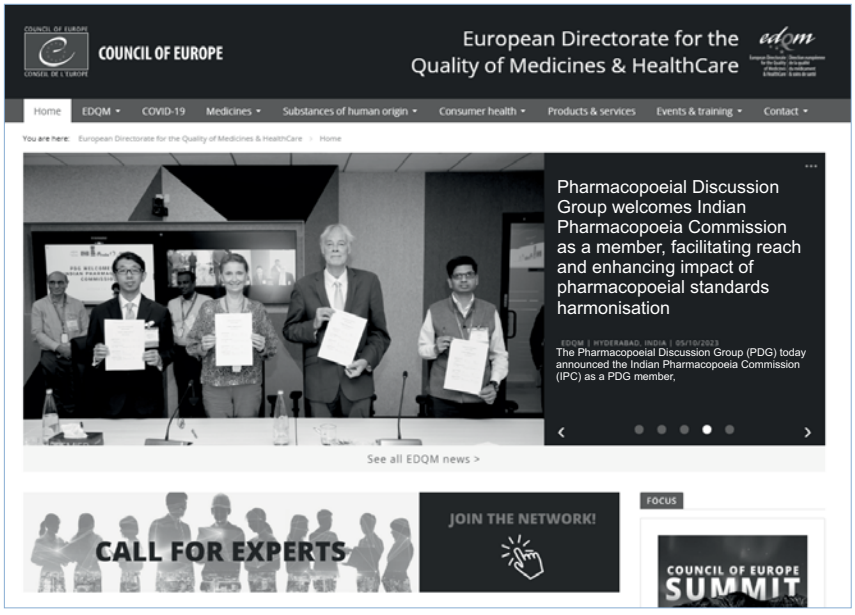
Accessing IPC Website



Guidance to Stakeholders



PDG Welcomes IPC as a Member



PDG Welcomes IPC as a Member

Pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Press Release

Pharmacopoeial Discussion Group Welcomes Indian Pharmacopoeia Commission as a Member, Facilitating Reach and Impact of Pharmacopoeial Standards Harmonisation

Hyderabad, India, October 5, 2023 – The Pharmacopoeial Discussion Group (PDG) today announced the Indian Pharmacopoeia Commission (IPC) as a PDG member. IPC officially joined as a member in the PDG which was established by the European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the U.S. Pharmacopeia (USP), at the PDG's Annual Meeting on Oct. 3-4 in Hyderabad. The World Health Organization (WHO) also continues to serve as observer of the group.

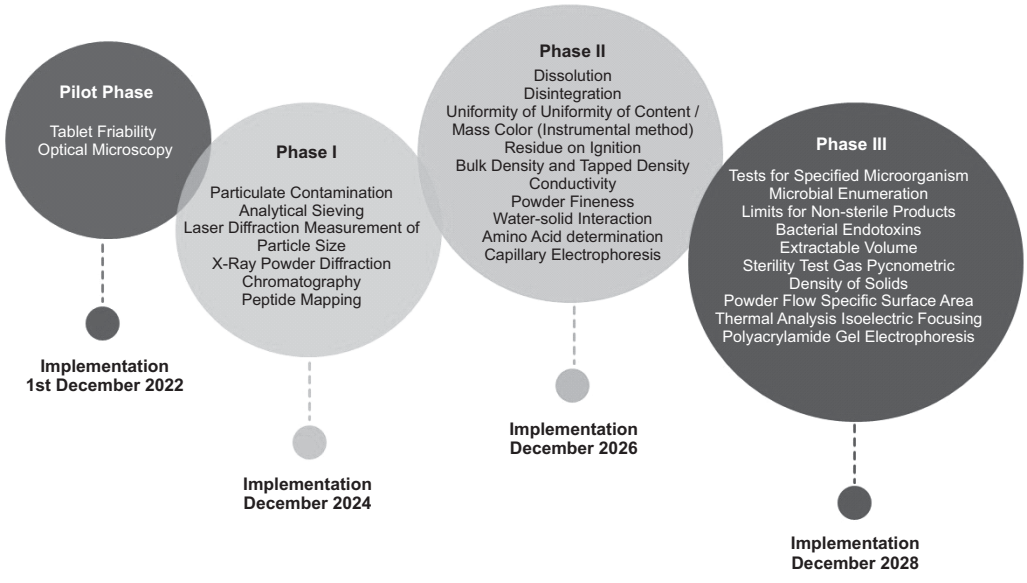
"IPC is honored to be considered for membership in the PDG," said Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC. "Since becoming PDG's pilot for expansion to its membership in October 2022, IPC has participated in PDG meetings and technical discussions, and submitted implementation timelines for various PDG standards. As a PDG member, we look forward to continuing to work to advance standards convergence around the world."

"We warmly welcome IPC to PDG," said Cathie Vielle, Secretary to the European Pharmacopoeia Commission. "This is a milestone in PDG's commitment to expanding recognition of harmonised pharmacopoeial standards. Working together will further advance convergence around robust science - based quality standards across pharmacopoeias for the benefit of public health."

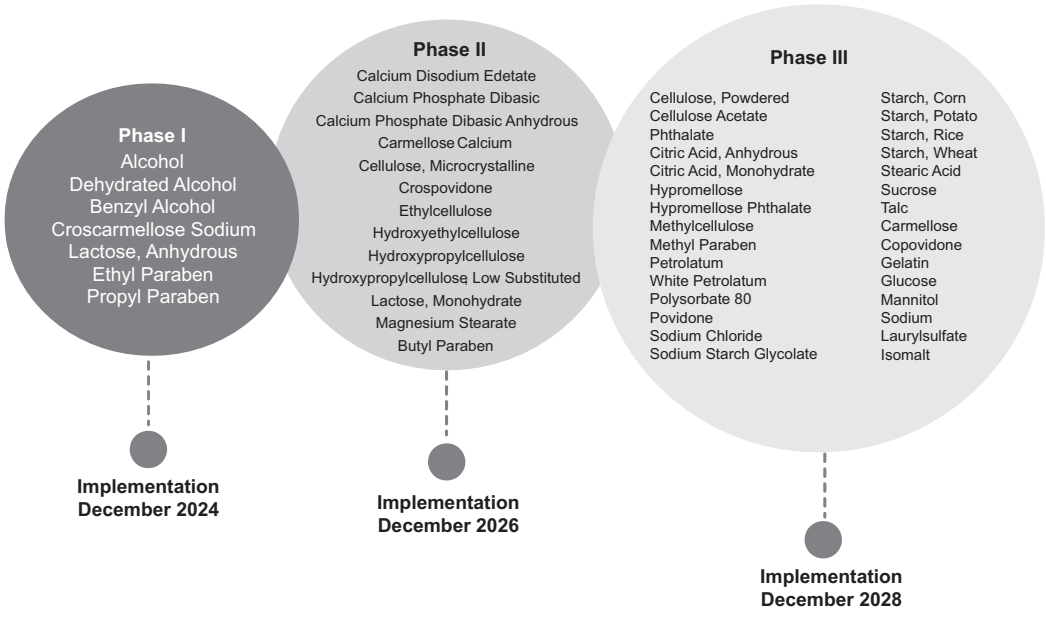
"For over three decades, the original PDG members – including JP, Ph. Eur., and USP – have worked to increase the reach and impact of global standards harmonisation efforts," said Yoshiro Saito, Ph.D., Deputy Director General of National Institute of Health Sciences and Chair of the JP Expert Committee. "Adding IPC marks the culmination of several years of discussions on new member participation to help increase global access to quality medicines and ensure PDG's continued success."

PDG Welcomes IPC as a Member

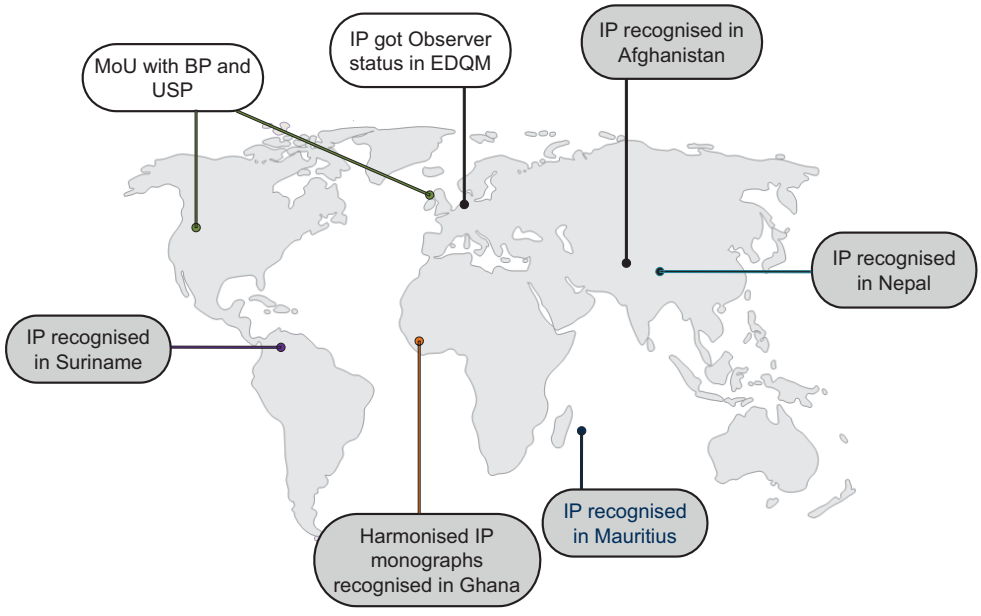
PDG Harmonization Plan: General Chapters



PDG Harmonization Plan: Excipients



Global Recognition of IP



IP Reference Standards (IPRS)

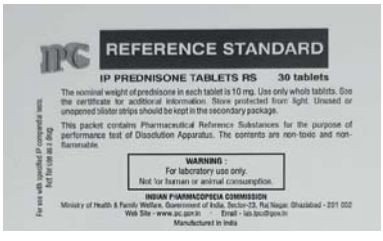
- IPRS is a primary standard that has the appropriate quality within a specified context and is accepted without requiring comparison to another standard
- IPRS are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the IP

Types of Reference Standards

IP Reference Substances

Impurity Reference Substances

Phytochemical Reference Substances



Legal Status of IPRS

- IP is published by the IPC to fulfill the requirements of the Second Schedule of the Drugs and Cosmetics Act 1940 and Rules there under.
- IPRS are authoritative standards for determining the quality of medicines in India.

Drugs and Cosmetics Act, 1940

Class of Drug	Standard to be complied with
1	2
'[5. Other drugs (a) Drugs included in the Indian Pharmacopoeia	**Standards of Identity, purity and strength specified In the edition of the Indian Pharmacopoeia for the time being in force and such other standards as may be prescribed.** In Case the standards of Identity, purity and strength for drugs are not specified in te edition of the Indian Pharmacopoeia for the time being in force bit are specified in the edition of the Indian pharmacopoeia immediately preceding the standards of identity, purity and strength shall be those occurring in such immediately preceding edition of the Indian Pharmacopoeia and such other standards as may be prescribed

Second Schedule of the Drugs and Cosmetics act 1940

IP Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substances abbreviated, as IPRS in the individual monographs, are issued by the Indian Pharmacopoeia Commission (IPC) or be laboratories authorized by the IPC **assume the of ficial status in India**. Where an IPRS is referred to in an of ficial IP monograph, it becomes a part of the of ficial standard **that is alone authoritative in case of doubt or dispute to determine compliance with the IP**

Legal Notices

In India, under the Drugs and cosmetics Act 1940, the current edition of Indian Pharmacopoeia is a book of standards for drugs included therein and the standards as included in the Indian Pharmacopoeia would be of ficial. Also, in several other laws of India, the Indian Pharmacopoeia is recognised as the standard bool. It is expedient that enquiry be made in each

Use of IPRS in Monographs

is not more than 5 times the area of the peak in the chromatogram obtained with the reference solution (a) (0.5 per cent). Disregard any peak which is 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.01 per cent).

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method A (20 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Water (2.3.43). 4.0 to 6.0 per cent, determined on 0.4 g.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 25 mg of the substance under examination in 25.0 ml of the mobile phase. Dilute 5.0 ml of the solution to 100.0 ml with the same solvent.

Reference solution. A 0.005 per cent w/v solution of *secnidazole IPRS* in mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 35 volumes of *methanol* and 65 volumes of 0.14 per cent w/v solution of *potassium dihydrogen phosphate*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 318 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_7H_{11}N_3O_3$.

Storage. Store protected from light and moisture.

Secnidazole Tablets

Secnidazole Tablets contain not less than 95.0 per cent and not more than 110.0 per cent of the stated amount of secnidazole, $C_7H_{11}N_3O_3$.

Usual strengths. 1 g; 2 g.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Medium. 900 ml of *0.1 M hydrochloric acid*.

Speed and time. 100 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter promptly through a membrane filter disc having an average pore diameter not greater than 1.0 µm, rejecting the first 1 ml of the filtrate. Dilute the filtrate, if necessary, with the same solvent. Measure the absorbance of the resulting solution at the maximum at about 277 nm (2.4.7). Calculate the content of $C_7H_{11}N_3O_3$ in the medium from the absorbance obtained from a solution of known concentration of *secnidazole IPRS* in the same medium.

Q. Not less than 80 per cent of the stated amount of $C_7H_{11}N_3O_3$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Weigh a quantity of powdered tablets containing 50 mg of Secnidazole, disperse in 100 ml of mobile phase and filter.

Reference solution (a). A 0.05 per cent w/v solution of *secnidazole IPRS* in the mobile phase.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with mobile phase.

Chromatographic system as described under Assay.

Inject reference solution (a). The test is not valid unless the tailing factor is not more than 2.0 and the column efficiency in not less than 2000 theoretical plates.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the peak in the chromatogram obtained with reference solution (b) (1.0 per cent) and the sum of areas of all the secondary peaks is not more than 2.0 times the area of the peak in the chromatogram obtained with the reference solution (b) (2.0 per cent).

Water (2.3.43). Not more than 6.5 per cent, determined on 0.5 g.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

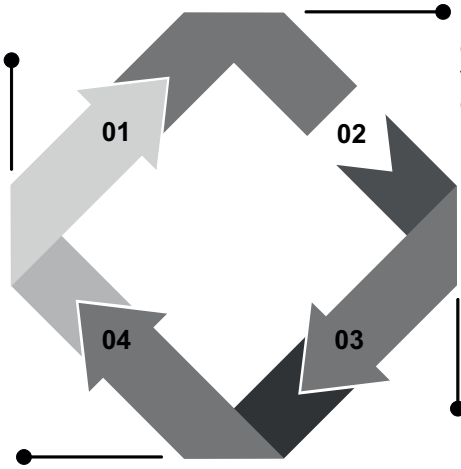
Test solution. Weigh and powder 20 tablets. Disperse a quantity of powdered tablet containing 50 mg of Secnidazole, disperse in 100.0 ml of mobile phase and filter. Dilute 5.0 ml of the filtrate to 50.0 ml with mobile phase.

Reference solution. A 0.005 per cent w/v solution of *secnidazole IPRS* in mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm packed with octadecylsilane chemically bonded to porous silica

IP Reference Standards & Impurity Standards

- IPRS developed through collaborative approach
- Reference material producer per ISO 17034
- PT provider per ISO 17043

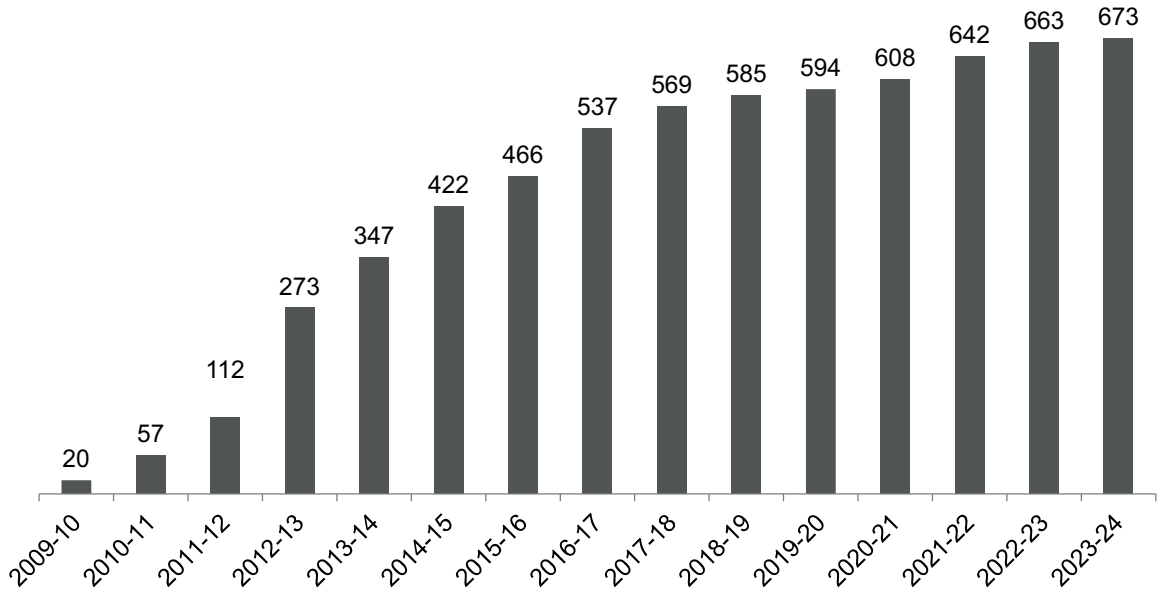


IPRS are authoritative in case of doubt or dispute to determine compliance with the IP

- 673 IPRS & 545 Impurity standards available from IPC (www.ipc.gov.in)
- 3rd highest number among global pharmacopoeias

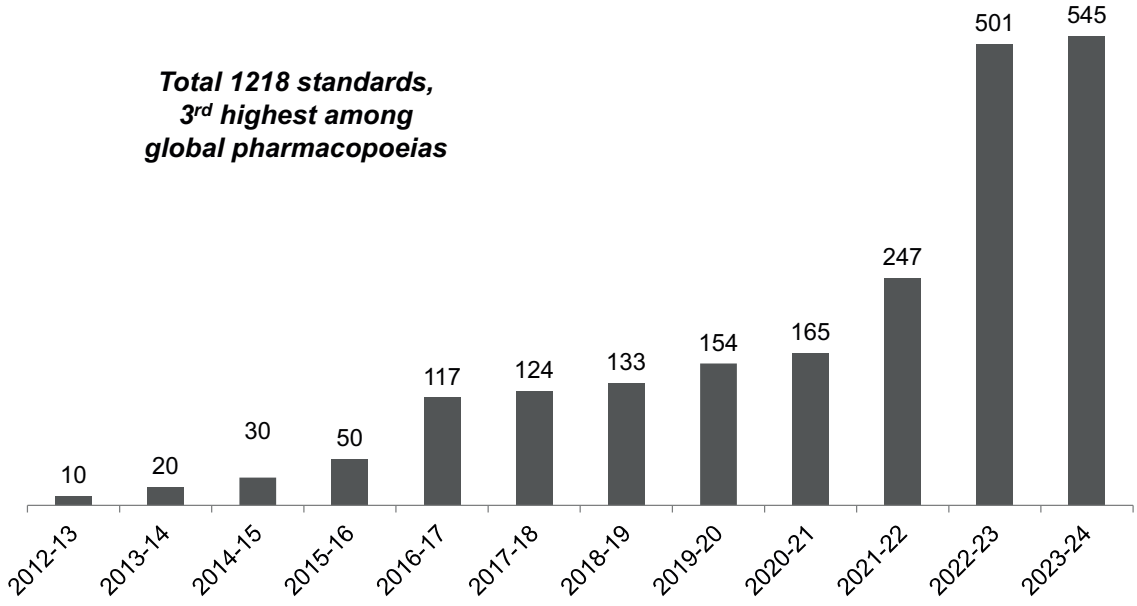
- Vaccine NRS available from CDL, Kasauli
- Reference Microbial Cultures available from IMTech, Chandigarh

Development of IPRS



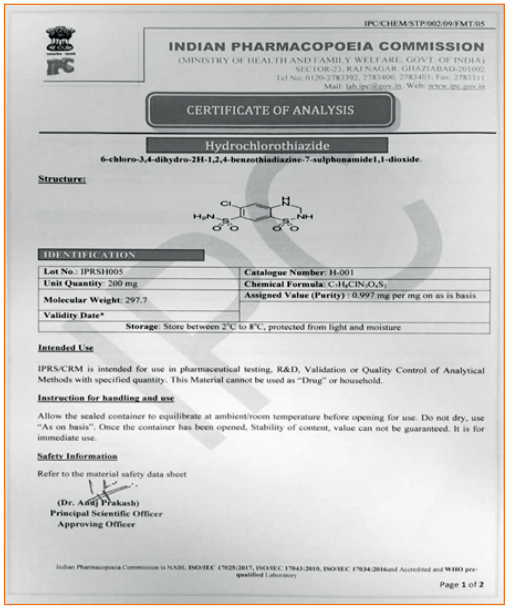
Development of Impurity Standards

Total 1218 standards, 3rd highest among global pharmacopoeias



Development of Impurity Standards

COAs of IPRS and Impurity RS are now available online at official website of IPC (www. ipc.gov.in) and can be downloaded by using CAT no. written on the purchased vial as password.



IPC/CHEM/STP/002/09/FMT/05

INDIAN PHARMACOPOEIA COMMISSION
(MINISTRY OF HEALTH AND FAMILY WELFARE, GOVT. OF INDIA)
SECTOR-23, RAJ NAGAR, GHAZIABAD-201002
Tel No: 0120-2783392, 2783400, 2783401; Fax: 2783311
Mail: lab.ipc@gov.in, Web: www.ipc.gov.in

CERTIFICATE OF ANALYSIS

Hydrochlorothiazide

6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulphonamide1,1-dioxide.

Structure:

IDENTIFICATION

Lot No.: IPRSH005	**Catalogue Number**: H-001
Unit Quantity: 200 mg	**Chemical Formula**: $C_7H_8ClN_3O_4S_2$
Molecular Weight: 297.7	**Assigned Value (Purity)** : 0.997 mg per mg on as is basis
Validity Date*	
Storage: Store between 2°C to 8°C, protected from light and moisture	

Intended Use

IPRS/CRM is intended for use in pharmaceutical testing, R&D, Validation or Quality Control of Analytical Methods with specified quantity. This Material cannot be used as "Drug" or household.

Instruction for handling and use

Allow the sealed container to equilibrate at ambient/room temperature before opening for use. Do not dry, use "As on basis". Once the container has been opened, Stability of content, value can not be guaranteed. It is for immediate use.

Safety Information

Refer to the material safety data sheet

(Dr. Adal Prakash)
Principal Scientific Officer
Approving Officer

Indian Pharmacopoeia Commission is NABL ISO/IEC 17025:2017, ISO/IEC 17043:2010, ISO/IEC 17034:2016and Accredited and WHO pre-qualified Laboratory

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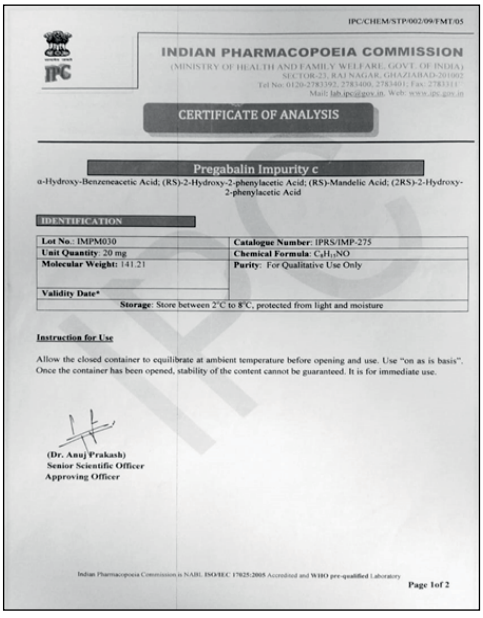
Certificate of Impurity Standards



IPC/CHEM/STP/002/09/FMT/05

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Mail: lab.ipc@gov.in, Web: www.ipc.gov.in

CERTIFICATE OF ANALYSIS

Pregabalin Impurity c

α-Hydroxy-Benzeneacetic Acid; (RS)-2-Hydroxy-2-phenylacetic Acid; (RS)-Mandelic Acid; (2RS)-2-Hydroxy-2-phenylacetic Acid

IDENTIFICATION

Lot No.: IMPM030	**Catalogue Number**: IPRS/IMP-275
Unit Quantity: 20 mg	**Chemical Formula**: C_8H_8NO
Molecular Weight: 141.21	**Purity**: For Qualitative Use Only
Validity Date*:	
Storage: Store between 2°C to 8°C, protected from light and moisture	

Instruction for Use

Allow the closed container to equilibrate at ambient temperature before opening and use. Use "on as is basis". Once the container has been opened, stability of the content cannot be guaranteed. It is for immediate use.

(Dr. Anuj Prakash)
Senior Scientific Officer
Approving Officer

Indian Pharmacopoeia Commission is NABL ISO/IEC 17025:2005 Accredited and WHO pre-qualified Laboratory

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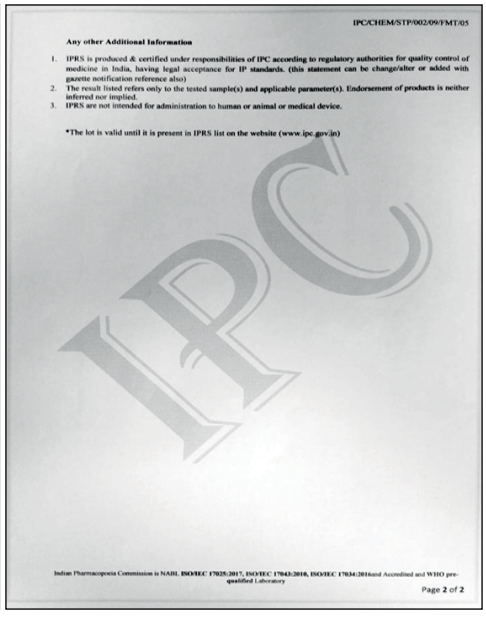


IPC/CHEM/STP/002/09/FMT/05

Any other Additional Information

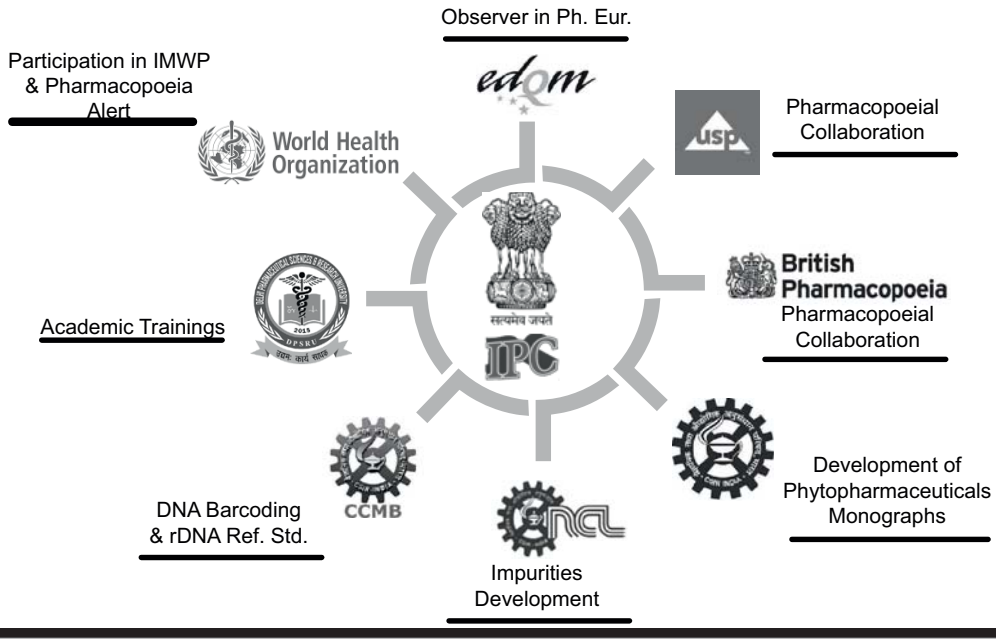
1. IPRS is produced & certified under responsibilities of IPC according to regulatory authorities for quality control of medicine in India, having legal acceptance for IP standards. (this statement can be change/alter or added with gazette notification reference also)
2. The result listed refers only to the tested sample(s) and applicable parameter(s). Endorsement of products is neither inferred nor implied.
3. IPRS are not intended for administration to human or animal or medical device.

*The lot is valid until it is present in IPRS list on the website (www.ipc.gov.in)

Indian Pharmacopoeia Commission is NABL ISO/IEC 17025:2017, ISO/IEC 17043:2010, ISO/IEC 17034:2016and Accredited and WHO pre-qualified Laboratory

Page 2 of 2

IPC Collaborations



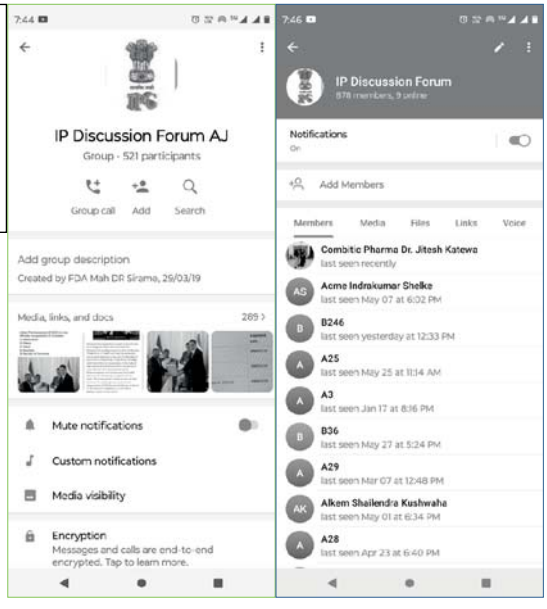
Collaboration Opportunities

Get Connected with IPC

For general queries: Email: lab.ipc@gov.in

For purchase of IP and IPC publications: E-mail: publication-ipc@gov.in

For purchase of IPRS and impurity standards: E-mail: sales-ipc@gov.in



PHARMACIST IN PATIENTS WELFARE

by

Ms. Keerthana, S
Saveetha College of Pharmacy, Thandalam, Chennai

Note: This article was awarded 3rd prize in the Essay Competition conducted by our Trust

The word "health" is well-known, but it also contains a lot of difficulties and issues. The WHO define health has a comprehensive condition of difficult, mental and social well-being rather than only the absence of disease. A healthcare team is essential to the health care system. A health care team is essential to the health care community who work together toward a common aim of improving the health of the community. Despite being a critical concern, health is often overlooked in India, the country with largest ethnic diversity. Due to concerns with inappropriate drug usage, the disease has gotten worse. The challenge of providing better healthcare and better results is in hands of the pharmacist, especially the community pharmacist Although a community pharmacist is crucial to giving patients better healthcare, in India, unlike other developed nations, there is little acknowledgement for pharmacists in the healthcare system.

Knowing the typical progression of pregnancy and infancy gives the pharmacist a great edge because they may help the mother with basic hygiene and management issues. The neighbourhood pharmacist can support breastfeeding and play a significant role in helping the mother protect the child by adhering to the recommended immunisation schedule. There are undoubtedly efforts being made in this area. The newest idea in medicine today is to personalise pharmacological treatment. Individualizing drug therapy becomes necessary when prudent patient care is required, and a pharmacist can play a key part in this. A doctor may not have time to devote to patient counselling addressing pharmaco-economics, pharmacological information, alternative therapies, spiritual support, etc. if they are focused on diagnosing and treating their patients. The patient can receive counselling from the pharmacist in a separate consultation room.

Health care providers are motivated by education. Students gain a wide range of knowledge via their basic education course work and pre- registration training comprehension of the scientific theories and methods used in pharmaceutical sciences, as well as the capacity to stay up with medicine and pharmacy throughout their careers. All facets of the manufacture,

distribution, action, and application of pharmaceuticals and medicines are covered by their knowledge and skills, which also enables individuals who choose to post graduate training and research. Programs for educational training assist professionals in maintaining their current expertise. Through their practical training, pharmacists gain specialised effects, which is generally referred to as the academic pharmacist's first step in the pharmacy profession.

Standard pharmacists with special interests are involved with developing their skill and expertise in specialist areas such as cancer or diabetes. Almost half of all pharmacists (42%) offered additional clinical and educational services to community residents including blood pressure checks, screening and diabetes counselling, tabacco cessation programs, immunizations. As per government of India now pharmacist is considered as " arogyadoot" who can formulate, compound and dispense medicine in his pharmacy.

Druggists who has special interests play a role in someone's skill development and knowledge in specialised fields like cancer or diabetes. Nearly 42% of all pharmacist provided further educational and clinical services for, members of the community, including blood pressure checks, cholesterol, osteoporosis, and glucose testing, cigarette and screening, cessation diabetes education, programmes and vaccinations. As per the Indian government. Currently, a pharmacist is regarded as a ":arogyadoot: who create, assemble, and distribute medication in his pharmacy.

Pharmacist work at the frontline of healthcare in cities, towns and villages across nation. They work from their own pharmacies or out of local healthcare centre and doctors surgeries. As community pharmacist job would be all about helping the public, assessing their condition and making decision about which medicines they should take. They will be involved in dispensing medicine and offering patient advice and practical help on keeping health. It is very responsible job and community pharmacist tend to be highly respect members of their communities. Communities.

Community pharmacist also taking on more of then clinical roles that have traditionally been undertaken by doctors, such as the management of asthma and diabetes as well as blood pressure testing. they also help people give up smoking, alter their diets to make them healthier and advise on sexual health matters. Some community pharmacist owns their own business and

enjoy the challenges of financial management and responsibilities for staff, stock and premises that this brings. Other work for large high street pharmacy chain and have the opportunity to move around within an established company structure.

Hospital pharmacists are a vital part of the healthcare team. Working in either the PHC or private hospitals, being a hospital pharmacist means you're part of a team where the focus is firmly on patients. In a hospital pharmacy department there are many areas we can get involved in. like doctors, pharmacist regularly attends wards rounds and more involved in selecting treatments for patients than ever before. Aside from working on the wards, there is the manufacturing of sterile medicines, managing the care of patients with all types of condition, working in the dispensary, providing information on medicines for the whole hospital. You can also get involved in general management of hospital itself. Some pharmacists specialize as consultant(or as pharmacists with specialist interests) in many areas as haematology (blood), nephrology (kidneys), respiratory medicines, cardiology (heart), urology (urinary), diabetes, gastroenterology (stomach and intestine), infection diseases, and care of the elderly.

Pharmacy professionals play a variety of responsibilities in the health care system, including academic pharmacists, industrial pharmacists, and community pharmacists. Pharmacy professionals, including clinical and hospital pharmacists, veterinary pharmacists, and other. The nation's health is impacted by all pharmacists who work in various professions in some way.

Finally, it is the duty of pharmacists to ensure that" the appropriate drug is given to the right channel in the right method". So that pharmacies are a crucial component of the healthcare system.

INFORMATION

M.PHARM & PHARM D SCHOLARSHIPS 2022-23 AWARDED BY TNPSW TRUST

Profile of 3rd Rank

PHARMACEUTICS

Name: Mr. A. M. Aswin Kumar

Project Title: Formulation Optimization, Characterization and Evaluation of Terbinafine Nanosponge Gel for the treatment of Onychomycosis.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. S. Daisy Chellakumari

PHARMACEUTICAL CHEMISTRY

Name: Mr. B. Jeeva

Project Title: Design, Synthesis, Characterization and Biological Evaluation of Novel Hydrazine and SCHIF'S Base Derivative as Ant-tubercular agents targeting L.D Transpeptidase.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. D. Priyadharsini

PHARMACEUTICAL ANALYSIS

Name: Mr. M. Velmurugan

Project Title: Method Development and Validation for simultaneous estimation of Azelnidipine and Chlorthalidone in bulk and tablet dosage form by RP-HPLC and HPTLC method.

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Dr. N. Tamilselvi

PHARMACOLOGY

Name: Mr. R. Vinoth Kumar

Project Title: Pharmacological Evaluation of Memantine Nano-Suspension on Alzheimer's disease induced by D- Galactose and Aluminium Chloride model in Rats.

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Mr. G. Sivakumar

PHARMACOGNOSY

Name: Ms. K. Hamsaveni

Project Title: Pharmacognostical, Phytochemical Studies and Evaluation of Anti-gout activity in leaves of Musa paradisiaca linn. Musaceae

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. R. Radha

PHARMACY PRACTICE

Name: Mr. U. Polireddy

Project Title: A Study on the Effect of SGLT2 Inhibitors in Myocardial Infarction Patients with Acute Left Ventricular Dysfunction

College: SRM College of Pharmacy, Chennai

Guide's Name: Dr. S. Sarumathy.

PHARM D

Name: Mr. S. Mukesh, Mr. B.T. Udhaya Moorthy, Mr. S. Vignesh, Mr. V. Siva Shankar

Project Title: Prospective study of non-steroidal anti – inflammatory drug induced adverse reaction in a tertiary care hospital.

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Dr. D. Geetha

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi the 31st July, 2023

S.O. 3448(E).—Whereas the Central Government is satisfied that the use of drug formulations containing Ketoprofen and Aceclofenac are likely to involve risk to animals;

And whereas, safer alternatives to the said drugs are available;

And whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the manufacture, sale and distribution of—

(i) Ketoprofen and its formulations; and

(ii) Aceclofenac and its formulations,

for animal use;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), and after consultation with the Drugs Technical Advisory Board, the Central Government, hereby prohibits the manufacture, sale and distribution of the following drugs, with immediate effect, namely:-

"(i) Ketoprofen and its formulations for animal use

(ii) Aceclofenac and its formulations for animal use

[F. No.X.11035/65/2023-DRS]

ARADHANA PATNAIK, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th October, 2023

S.O. 4351(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment further to amend the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) vide number S.O. 2808(E), dated the 30th November, 2012, published in Gazette of India, Extraordinary Part II, Section 3, Sub-section (ii) , namely:—

In the said notification, after item number (xix) and the entries relating thereto, the following shall be inserted, namely:—

"(xx) Shri Pankaj P Thakur, Junior Scientific Assistant"

[F. No. X.11014/5/2021-DR]

ARADHANA PATNAIK, Jt. Secy.

Editorial Policy and Disclaimer

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F. No. 29/Misc/03/2023-DC (344)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated

12 OCT 2023

Subject: Clarification on the Regulation of all Class C & D Medical Devices under Licensing regime, w.e.f 01.10.2023, as per G.S.R. 102(E) dt 11.02.2020- Regarding.

In continuation to this office Circular vide No.29/Misc/03/2023-DC(344) dated 12.10.2023 on the Regulation of all Class C & D Medical Devices under Licensing regime, w.e.f 01.10.2023, as per G.S.R. 102(E) dt 11.02.2020.

In this connection, it is to clarify that the said circular is applicable only to the manufacturers/importers who have already filed the application to Central Licensing Authority on or before 30th September 2023.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To
All Stakeholders/Associations.

Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.
3. CDSCO- IT Cell for publication on website

F. No. 29/Misc/03/2023-DC (344)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated 12 OCT 2023

CIRCULAR

Subject: Regulation of all Class C & D Medical Devices under Licensing regime, w.e.f 01.10.2023, as per G.S.R. 102(E) dt 11.02.2020 - Regarding.

The Ministry of Health & Family Welfare (MoHFW) has published notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, which is effective from 01.04 2020.

In order to regulate all the medical devices, MoHFW has published G.S.R. 102 (E) dated 11.02.2020 for regulation of such devices in phase wise manner. As per the said notification the Class C & D medical devices will be under licensing regime from 01.10.2023.

In the meantime, representations from various Associations and Stakeholders have been received by this office, requesting that the business continuity should not be disrupted due to the implementation of licensing regime w.e.f. 01.10.2023 for Class C & D medical devices.

In view of the above, it has been decided that, in case, if an existing importer/ manufacturer who is already importing/ manufacturing any of the above said Class C or Class D Medical Devices, has submitted application to Central Licensing Authority, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of Medical Devices Rules, 2017, the said application shall be deemed valid and the importer/manufacturer can continue to import/manufacture the said device(s) up to six months from the date of issue of this order or till the time, the Central Licensing Authority, takes a decision on the said application, whichever is earlier.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To
All Stakeholders/Associations.
Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.
3. CDSCO- IT Cell for publication on website

"(3) (1) The State Government may, by notification, establish State Medical Devices Testing Laboratory for the purpose of, –

(a) testing and evaluation of medical devices; or

(b) to carry out any other function as may be specifically assigned to it.

(4) Without prejudice to provisions of sub-rule (3), the State Government may also designate any laboratory having facility for carrying out test and evaluation of medical devices as State Medical Devices Testing Laboratory for the purposes specified in sub-rule (3):

Provided that no medical devices testing laboratory shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories.".

[F. No. X.11014/7/2022-DR]
ARADHANA PATNAIK, Jt. Secy.

Note : The Medical Device Rules, 2017 were published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 777(E), dated the 14th October, 2022.

PARLIAMENT QUESTION AND ANSWERS

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
STARRED QUESTION NO. 203
TO BE ANSWERED ON THE 8TH AUGUST, 2023

QUALITY OF COUGH-SYRUPS

203 SHRI VIVEK K. TANKHA:

Will the Minister of Health and Family Welfare be pleased to state:

(a) the steps being taken in the aftermath of hundreds of deaths of infants reported worldwide linked to cough-syrups manufactured in the country;

(b) whether any form of testing/reporting by the Central Drugs Standard Control Organisation (CDSCO) is mandatory for pharmaceuticals manufactured in the country, before they are permitted for use or to be exported; and

(c) if so, the details of the drugs which have been tested and if not, the reasons therefor?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. MANSUKH MANDAVIYA)

(a) to (c) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 203 * FOR 8TH AUGUST, 2023

(a) to (c) The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country. The cases concerning quality or safety of drugs when reported, the matter is taken up with the concerned State Licensing Authority (SLA) in order to take necessary action under the provisions of Drugs and Cosmetics Act 1940 and its Rules. The SLAs are legally empowered to take action of violation of any conditions of such licenses including prosecution in appropriate Court of law.

Central Drugs Standard Control Organization (CDSCO) along with SLAs have conducted risk-based inspections of 162 pharmaceutical firms and based on findings, show cause notices have been issued in 143 cases. So far, stop production order has been issued in 40 cases, cancellation & suspension of product/section Licenses in 66 cases, issuance of warning letter in 21 cases and in 1 case, FIR has been lodged and three persons have been arrested as per the provisions of the Drugs Rules, 1945.

Further, the Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry has issued a notification (No. 06/2023) dated 22.05.2023 for amendment in export policy of cough syrups, making it compulsory for cough syrup manufactures to get certificate of analysis from a government-approved laboratory before exporting their products with effect from 01.06.2023.

Accordingly, more than 900 such cough syrup samples have been analysed and Certificate of Analysis (CoA) released as on date.

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO. 1410
TO BE ANSWERED ON 01ST AUGUST, 2023

REGULATORY CHALLENGES OF INDIAN DRUGS

1410: SHRI MOHAMMED NADIMUL HAQUE:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has taken cognizance of the fact that Drugs and Cosmetics Act, 1940 does not cover many aspects such as clinical trials, bioequivalence studies, good manufacturing practices and is outdated and inadequate to deal with the complexities and challenges of the modern pharma market;

(b) if so, the plan of Government to cover aspects such as clinical trials, bioequivalence studies and good manufacturing practices;

(c) if not, the reasons therefor; and

(d) the steps taken by Government to ensure transparency and accountability in Central Drugs

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): The clinical trials, bioequivalence studies, good manufacturing practices arecovered under the New Drugs and Clinical Trial Rules, 2019 and various Schedules of the Drugs and Cosmetics Act, 1940 which regulates import, manufacture, distribution and sale of Drugs and Cosmetics. Also, amendment of Drugs & Cosmetics Rules carried out for incorporating new provisions in accordance with the changing requirements to deal with the complexities and challenges of the modern pharma market.

(d): Various measures have been taken to ensure transparency and accountability in Central Drugs Standard Control Organisation (CDSCO) like online submission, processing and tracking of various applications, prescribing timelines for applications, evaluation of applications of clinical trials; New Drugs and Investigational New Drug (IND) including r-DNA derived products and vaccines; new medical devices in consultation with Subject Experts Committees/IND committee.

Further, CDSCO regularly uploads various guidance documents / FAQs and details of drugs declared as spurious/substandard/adulterated/misbranded by Central Drug Testing Laboratories on its website (www.cdsco.nic.in). A Public Relation Office is also in place in CDSCO for resolving the issues of stakeholders.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 2109
TO BE ANSWERED ON 8th August, 2023

Prices of medicines

2109 Shri Rajeev Shukla:

Will the Minister of Chemicals and Fertilizers be pleased to state:

(a) whether the Ministry is aware of the hardships faced by people due to increase in prices of medicines as a consequence of rise in Wholesale Price Index (WPI);

(b) if so, whether the Ministry has taken steps to provide relief to people in this regard;

(c) total number of medicines in respect of which price capping has been implemented by Government; and

(d) the details of medicines in respect of which price capping is proposed to be implemented by Government?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (b): Prices of drugs in India are regulated as per the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). National Pharmaceutical Pricing Authority (NPPA) under the aegis of Department of Pharmaceuticals (DoP) fixes the ceiling price of scheduled medicines specified in the Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). All manufacturers of scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. The maximum permissible annual increase allowed in the case of Scheduled formulations is up to the level of annual revision in Wholesale Price Index (WPI), which may or may not be availed by the manufacturers based on market dynamics.

In case of non-scheduled formulation, no manufacturers can increase MRP by more than 10% of MRP during preceding 12 months.

The annual WPI of all commodities increased by 12.1218% with effect from 01.04.2023. Meanwhile, the National List of Essential Medicines (NLEM), 2022 was notified by Ministry of Health and Family Welfare (MoHFW) on 13.09.2022, the Revised Schedule-I of DPCO, 2013, was notified by DoP on 11.11.2022. Accordingly, based on the revised Schedule-I, NPPA has fixed the ceiling prices of 691 formulations under NLEM, 2022 of which 91 are newly added formulations. The revision of ceiling price resulted in average reduction of 16.71% in the ceiling prices of 600 formulations when compared to their ceiling prices fixed earlier under NLEM, 2015. Therefore, even after allowing increase of upto 12.1218% according to WPI w.e.f. 01.04.2023, the revision of the ceiling prices of these 600 formulation under NLEM 2022 resulted in an estimated net reduction of 6.73%.

(c) to (d): The details of drugs brought under price control/regulation by NPPA are given below:

(i) Ceiling price of 915 scheduled formulations have been notified as on 17.07.2023. Out of these, ceiling prices of 691 formulations have been fixed under NLEM, 2022 and for 224 formulations have been fixed under NLEM, 2015.

(ii) Retail price of around 2450 new drugs have been fixed under DPCO, 2013 till 17.07.2023.

(iii) In 2014, NPPA capped the MRP of 106 non-scheduled drug formulations under Para 19 of DPCO, 2013 which includes 22 diabetic and 84 cardiovascular drugs.

(iv) Ceiling price of cardiac stents and Orthopaedic Knee Implants fixed under Para 19 of DPCO, 2013 since 16th August, 2017 in public interest.

(v) Trade Margin of non-scheduled formulations of 42 select Anti-cancer medicines capped under "Trade Margin Rationalization" approach as a pilot for proof of concept, wherein price of about 500 brands of 42 medicines were reduced up to 90%.

(vi) NPPA invoked Para 19 of the DPCO, 2013 to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under "Trade Margin Rationalisation" approach in June / July 2021.

The details of prices fixed by NPPA till date are available on the website of NPPA i.e., nppaindia.nic.in.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
STARRED QUESTION NO. 331
TO BE ANSWERED ON THE 11th August, 2023

Upgradation of NIPER

†*331. SHRIMATI BHAVANA PUNDALIKRAO GAWALI:
SHRI KRUPAL BALAJI TUMANE:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government proposes to improve/ upgrade the National Institute of Pharmaceutical Education and Research (NIPER) located in various cities across the country and if so, the details thereof;

(b) the details of NIPER located in various cities across the country particularly in Maharashtra;

(c) whether the Government proposes to upgrade the equipments and machinery in NIPER across the country and if so, the details thereof and if not, the reasons therefor;

(d) the details of various upgradation works undertaken/proposed to be undertaken by the Government for the development of NIPER as a model Pharmaceutical Research Organisation during the last three years including the amount of funds allocated for the said purpose, year-wise; and

(e) the manner in which people have been trained by the said institutes in National Pharmaceutical Education along with details including the number of people who have been educated so far from such institutes?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(Dr. MANSUKH MANDAVIYA)

(a) to (e): A Statement is laid on the Table of the House.

Statement referred to in reply to the LOK SABHA STARRED Q. No. 331 (10th POSITION) for answer on 11.08.2023 raised by Smt. Bhavana Pundalikrao Gawali and Shri Krupal Balaji Tumane regarding Upgradation of NIPER

(a) to (e): The first National Institute of Pharmaceutical Education and Research (NIPER) as an institute of national importance was set up at SAS Nagar (Mohali, Punjab) through NIPER Act, 1998 to nurture and promote quality and excellence in pharmaceutical education and research and run master's, doctoral and post-doctoral courses.

Subsequent thereto, with amendment of the Act in the year 2007, six more NIPERs were set up at Ahmedabad (Gujarat), Guwahati (Assam), Hajipur (Bihar), Hyderabad (Telangana), Kolkata (West Bengal) and Raebareli (Uttar Pradesh). On amendment of the Act in December, 2021, the mandate of NIPERs has been enhanced, amongst others, to include undergraduate, integrated and other short-term courses, etc.

Government has provided adequate budgetary support for setting up permanent campuses, well equipped laboratories and filling up of regular faculty and administrative posts in NIPERs. Expenditure Finance Committee (EFC) in March, 2018 had approved an outlay of Rs. 959.53 cr. for a period of 3 years for continuation and strengthening of the scheme. Subsequently, EFC in September, 2021 has approved an outlay of Rs. 1,500 cr. for a period of five years (2021-22 to 2025-26) for the seven existing NIPERs.

These institutes presently offer courses in 16 different specializations in various streams of pharmaceuticals and medical devices. NIPERs have published about 7,000 research papers in various reputed journals, filed more than 370 patents and signed about 263 MOUs with Industries and other academic institutions. As per National Institutional Ranking Framework (NIRF), 2023 released by the Ministry of Education, under the 'Pharmacy' category, 5 of the 7 NIPERs have been ranked in the top 20 with NIPER Hyderabad as the top most institute in the country.

Since their inception, in total about 7,814 students (7,347 Masters + MBA; 467 PhD) have passed out from the seven existing NIPERs, who are working with the industry and/ or R&D and academic institutions.

The details of funds released to NIPERs during the last three years, i.e. from 2020-21 to 2022-23, for their capital and other recurring expenditure are as under:

NIPERs	2020-21	2021-22	2022-23
SAS Nagar (Mohali)	60.55	51.00	84.05
Ahmedabad	60.50	54.00	76.10
Guwahati	79.45	59.45	106.49
Hyderabad	44.50	72.91	69.54
Hajipur	26.00	41.00	37.00
Kolkata	34.82	47.64	45.45
Raebareli	28.00	46.00	32.50
Total	**333.82**	**372.00**	**451.13**

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 335
TO BE ANSWERED ON THE 21ST July, 2023

Research and Development in Pharmaceutical Sector

†335. SHRI SUNIL KUMAR SINGH:
SHRIMATI RANJEETA KOLI:
SHRI SUMEDHANAND SARASWATI:
DR. MANOJ RAJORIA:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the steps taken by the Government for promotion of research and development in pharmaceutical sector of the country during the last five years, year-wise;

(b) the positive outcomes achieved therefrom;

(c) whether steps have been taken/proposed to be taken by the Government to promote the involvement of the private sector in research and development in pharmaceutical sector; and

(d) if so, the details thereof along with the outcome of public and private participation in the said sector?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (d): Research and Development (R&D) in pharma sector is undertaken by number of institutions and organizations under various ministries/ departments. As part of its mandate, the Department of Pharmaceuticals (DoP) has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance to nurture and promote quality and excellence in pharmaceutical education and research in India. The Government announced in Budget 2023–24 about a new programme to promote research and innovation in pharmaceuticals to be taken up through centres of excellence and to encourage industry to invest in research and development in specific priority areas. A scheme has been prepared by the department in line with this announcement and is under appraisal.

Council of Scientific and Industrial Research (CSIR) through its constituent laboratories has been pursuing R&D activities for drug discovery and development. CSIR-CDRI has built a unique model for drug research in India – having everything under one roof, from synthesis, screening, development studies, proces up-scaling to clinical studies for the development of drugs. CSIR has successfully developed numerous medicines and transferred them to various pharmaceutical companies.

Department of Biotechnology (DBT), along with its Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC) has facilitated the implementation of R&D projects for drug discovery in the areas of Tuberculosis (TB), Anti-Microbial Resistance (AMR), Diabetes, Cancer, Rare Diseases, etc., through its regular schemes, including the Biotechnology Ignition Grant, Small Business Innovation Research Initiative, Biotechnology Industry Partnership Programme, and the Social Innovation Programme for Products: Affordable & Relevant to Societal Health. It also supports bio-incubation centers in the pharmaceutical sector through the Bioincubators Nurturing Entrepreneurship for Scaling Technologies (BioNEST) and Empowering Youth for Undertaking Value Added Innovative Translational Research (EYUVA) schemes. Over the past five years, 17 pharmaceutical products or technologies have been developed, transferred, or commercialized under these schemes.

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.402
TO BE ANSWERED ON 21ST JULY, 2023

COUGH SYRUPS MANUFACTURED BY INDIAN COMPANIES

402: SHRI T.R.V.S. RAMESH:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government has taken cognizance of the reports of the toxins found in cough syrups manufactured and exported by Indian companies to Uzbekistan and Gambia and if so, the details thereof;

(b) whether the Government intends to launch an investigation into the manufacturing standards of the Indian companies involved therein and if so, the the details thereof;

(c) whether the Government has found the said cough syrups to be in circulation in Indian markets; and

(d) whether the Government intends to issue a global alert on the cough syrups manufactured and exported by the involved Indian companies?said sector?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (d): Subsequent to reports of deaths of children in Gambia, CDSCO in coordination with State Drug Controller, Haryana carried out investigation at the manufacturing unit of M/s Maiden Pharmaceuticals Limited, to ascertain the facts. Control samples of the aforementioned drugs from the manufacturing unit were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) of CDSCO by the investigating team. The said samples were found to be negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

Based on investigations conducted which revealed violation of Good Manufacturing Practices (GMP), State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma under Rule 85(2) of the Drugs Rules, 1945 and order has been issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat with immediate effect.

In case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd., Gautam Budh Nagar, Noida-201301 (U.P.), India to ascertain the facts that allegedly led to the death of children in Uzbekistan. Drug samples were drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test & analysis.

Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. RDTL, Chandigarh has forwarded the test reports of 30 drug samples so far, wherein 24 samples of drugs/raw material were declared as "Not of Standard Quality". Out of these 24 samples declared as "Not of Standard Quality", 22 samples fall under the category of adulterated/spurious under Section 17A and 17B of the Drugs and Cosmetics Act, 1940. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

Following the suspension of manufacturing license, all the manufacturing and export activities of the said companies are halted.

The joint investigation conducted by CDSCO and State Drugs Controller revealed that the State Drugs Controller had given license to the said companies for manufacture of the drugs, for export purpose only. These drugs were not licensed for manufacture and sale in India.

Further, the Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry has issued a notification (No. 06/2023) dated 22.05.2023 for amendment in export policy of cough syrups, making it compulsory for cough syrup manufacturers to get certificate of analysis from a government approved laboratory before exporting their products with effect from 01.06.2023.

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GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO.444
TO BE ANSWERED ON 21ST JULY, 2023

REGULATION OF SALE OF MEDICINES WITHOUT PRESCRIPTION

444: SHRI NALIN KUMAR KATEEL:
SHRIMATI SUMALATHA AMBAREESH:
SHRI D.K. SURESH:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government is aware of the number of medicines including antibiotics being sold without proper prescription by chemists across the country;

(b) if so, the details thereof;

(c) whether the Government has any proposal to take stringent steps to regulate over-thecounter sale of medicines without prescription; and

(d) if so, the details thereof alongwith the response of the Government in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a): Sale of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder by the State Licensing Authorities (SLAs) appointed by State Government through a system of licensing and inspection. SLAs are legally empowered to take action against violation of provisions of the said Act and Rules.

(b) to (d): CDSCO and Ministry of Health and Family Welfare have taken various measures in this regard.

The Drug & Cosmetics Rules, 1945 was amended vide GSR 588 (E) dated 30.08.2013 incorporating a new, namely, Schedule H1 under the Drugs & Cosmetics Rules containing antibiotics, anti TB drugs and certain habit forming drugs. The drugs falling under Schedule H1 are sold in the country with the following conditions:

(i) The supply of a drug specified in Schedule H1 is recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records are maintained for three years.

(ii) The drug specified in Schedule H1, is labelled with the symbol Rx which is in red and conspicuously displayed on the left top corner of the label, and is labelled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG-CAUTION

- It is dangerous to take this preparation except in accordance with the medical advice.

- Not to be sold by retail without the prescription of a Registered Medical Practitioner

The State Drugs Controllers/other stakeholders have been sensitized in this regard. Various notices/Advisories/Letters have been issued to all State Drugs Controllers, other stakeholders for strict compliance of the requirements of Drugs and Cosmetics Act and Rules made there under and raising awareness in the public regarding adverse effects of misuse of drugs including antibiotics.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 1462
TO BE ANSWERED ON 28th July, 2023

Selling Price and MRP of Non-Essential Drugs

1462. SHRIMATI MALA ROY:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government is aware that there is a significant markup between the sale price and maximum retail price of non-essential drugs;

(b) if so, the details thereof;

(c) whether the Government is aware that drug prices constitute a very significant percentage of Out of pocket expenditure in health sector;

(d) if so, the details thereof; and

(e) the steps taken/proposed to be taken by the Government in this regard?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) & (b): The prices of drugs are regulated as per the provision of Drugs (Prices Control) Order, 2013 (DPCO, 2013). National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals regulates and monitors the prices of drugs as per the provisions of DPCO, 2013. The DPCO, 2013 provides for monitoring the increase in prices of non-scheduled formulations [i.e., drugs not included in the National List of Essential Medicines (NLEM) that is notified by Ministry of Health and Family Welfare (MoHF&W)] and such medicines are not allowed to increase the maximum retail price (MRP) by more than 10% of the MRP during preceding twelve months.

(c) to (d): As per the National Health Accounts Estimates 2019-20, brought out by MoHF&W in the year 2023, Household's Out of Pocket Expenditure on health is 41.1% of the Total Health Expenditure (THE). Further for the same period, the total Pharmaceutical Expenditure (includes prescribed medicines, over-the-counter drugs, and those provided during an inpatient, outpatient, or any other event involving contact with health system) is 35.1% of the Current Health Expenditure.

(e): The government has undertaken several initiatives to bring down Out-of-Pocket Expenditure on drugs in the country. Some of these initiatives include regulation of prices of drugs by NPPA; provision of quality generic medicines at significantly cheaper rates through the Pradhan Mantri Bhartiya Janaushadhi Kendreas under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP); Pradhan Mantri Jan Arogya Yojana (PM-JAY) under Ayushman Bharat - a government-funded insurance scheme; Free Drugs Service Initiative of National Health Mission (NHM) under which support is provided for provision of essential drugs free of cost in public health facilities; Free Treatment for TB under RNTCP; Janani Shishu Suraksha Karyakram for all pregnant women and children upto the age of one year; and Pradhan Mantri Ayushman Bharat Health Infrastructure Mission to strengthen grass root public health institutions to universal comprehensive primary healthcare services including diagnostics and treatment to critical care services.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1586
TO BE ANSWERED ON 28th July, 2023

Revenue Earned from Export of Drugs

1586. SHRIMATI APARAJITA SARANGI:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of revenue earned by the Government exporting drugs from India in last three years, year-wise;

(b) whether the Government has taken any measures for promoting export of generic drugs from India and reducing the time cost involved in obtaining necessary approvals;

(c) if so, the details thereof; and

(d) the step taken/proposed to be taken by the Government to address the issue of counterfeit drugs in international markets and ensure authenticity of Indian pharmaceutical products throughout the export process?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): The data of India's Pharmaceutical Export for the last three years is as under: -

India's Pharmaceutical Exports (Rs. in crore)				
S. No	DESCRIPTION	2020-21	2021-22	2022-23
1	Bulk Drugs and Drug Intermediates	32,856.71	33,320.93	37,852.77
2	Drug Formulations and Biologicals	1,41,207.04	1,41,634.12	1,56,401.43
	Total	1,81,260.76	1,83,339.97	1,94,254.20
Year on Year Growth			1.1%	6.0%

[Source: DGCIS, Ministry of Commerce and Industry]

(b) to (c): Under the MAI (Market Access Initiative) Scheme of Department of Commerce, financial assistance is provided to develop new markets, to promote new products and new exporters as well as to consolidate the existing Indian exports markets. The activities supported under the MAI scheme include organising/participating in Fairs, Exhibitions and Buyer Seller Meets abroad. Pharmaceuticals Export Promotion Council of India (Pharmexcil) under Department of Commerce organizes export promotion activities including business delegations to different foreign regions such as ASEAN, Africa, CIS, LAC and Oceania countries and also participates in the prominent pharma events worldwide. The participation in the prominent events enables exporters to showcase their products and services to the potential buyers and helps in promotion of export of generic drugs. The business delegations to foreign regions provide an opportunity to interact with the Food and Drug authorities in these countries thus enabling networking and facilitating discussion on fast tracking of registration of Indian products. There is already existing arrangement with some of the countries for fast tracking of approvals for Indian pharma products under FTAs such as with Singapore, UAE and Australia. Indian is also negotiating fast track approval for Indian pharma products with EU, UK and Canada under FTA discussions.

(d): As per Department of Commerce, the Government has introduced a policy of track and trace system to ensure the authenticity of the exported finished pharmaceutical products. Under the present system, the barcoding is mandatory on secondary and tertiary packages of export consignments.

As per Ministry of Health and Family Welfare, they have taken various regulatory measures to ensure the quality of medicines in the country: -

(i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

(ii) The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(iii) The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

(iv) CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 2595
TO BE ANSWERED ON THE 04th August, 2023

Funds for Research & Development of New Drugs

2595. SHRI RAMESH CHAND BIND:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of the funds allocated for Research and Development of new drugs/vaccines in the country for the last three years, year-wise;

(b) whether the Government has prepared any roadmap for pharma industry to reduce dependency for raw materials on foreign nations; and

(c) if so, the details thereof?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): Research & Development and innovation in the pharma sector is done by number of institutions and organisations under various Ministries/ Departments, which have their own budgetary provisions.

The Department of Pharmaceuticals (DoP) has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance, to nurture and promote quality and excellence in pharmaceutical education and research in India. The allocation for NIPERs over last three years including grants for building and Infrastructure as well as research and academic activities is given in table below.

Council of Scientific and Industrial Research (CSIR) under the Department of Scientific and Industrial Research (DSIR), through its constituent laboratories, has also been pursuing R&D activities for drug discovery and development. Further, Department of Biotechnology (DBT), along with its Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC) has facilitated implementation of R&D projects for drug discovery in for research and development of new drugs/vaccines.

Allocation during the last three years for these schemes/ programmes are as under:

Financial year	NIPERs under DoP*	CSIR under DSIR	BIRAC under DBT
2020-21	Rs. 333.82 cr.	Rs. 24.64 cr.	Rs. 64.52 cr.
2021-22	Rs. 372.00 cr.	Rs. 101.37 cr	Rs. 62.57 cr.
2022-23	Rs. 451.13 cr.	Rs. 74.79 cr	Rs. 46.34 cr.

Department of Scientific & Technology (DST) has taken steps for development of therapeutic strategies for preventing rare/orphan disorders, for which Rs. 8.56 Cr. has been sanctioned during the current financial year. '

(b) & (c): Government has launched Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores for a tenure from FY 2020-2021 to FY 2029-30. In addition, financial assistance for setting up Common Infrastructure Facilities (CIF) in three Bulk Drugs parks to the tune of Rs. 3,000 cr. for a tenure from FY 2020-21 to 2024-25, with Rs. 1,000 cr for each park, is being provided.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 3700
TO BE ANSWERED ON 11th August, 2023

Import of Refurbished Medical Devices

3700. SHRI M.K. RAGHAVAN:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has observed large scale import of refurbished medical devices into India and if so, the details thereof;

(b) whether import of such refurbished medical devices have caused threat to lives of our citizens in the country and if so, the details thereof along with the steps taken/proposed to be taken by the Government to prevent such imports;

(c) the steps measures taken/proposed to be taken by the Government to promote aatmanirbharata in medical devices sector in the country;

(d) whether the Government has observed that certain tender norms for procuring assisted robotic technologies for medical surgery favours import over indigenization; and

(e) if so, the details thereof and the steps taken/ proposed to be taken by the Government to prevent the same?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): As a Regulator, CDSCO issues import licences to the importers. The Export/Import data as maintained by DGCIS includes the import of Finished products, refurbished items and parts of medical devices.

(b): Ministry of Environment, Forest and Climate Change has notified Hazardous and other Wastes (Management and Transboundary Movement) Second Amendment Rules, 2022 on 23rd December 2022 wherein High End and High Value Used Medical Equipment other than Used Critical Care Medical Equipment is included in Part "B" of Schedule III of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016. Directorate General of Health Services (DGHS) forwarded the list of High End and High Value used Medical Equipment other than Critical care Medical Equipment and MoEFCC on 19.06.2023 allowed 50 High End and High Value used Medical Equipment other than Critical care Medical Equipment to be imported by actual user or by original Equipment Manufacturers (OEM) or Indian Subsidiary of OEM or Trader on behalf of actual user for re-use.

However, for licensed products, IPC runs Materiovigilance Programme of India (MvPI) with the aim to generate indigenous adverse event data (with the use of medical devices) from Indian population and recommend/communicate regulatory measures to be taken by CDSCO to ensure the safety of medical devices.

(c): The Government of India has taken several measures to encourage domestic manufacturing of Medical Devices. The steps taken to support Medical Devices Industries are as under:-

i. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD) with total financial outlay of Rs. 3,420 crore and tenure from FY 2020-2021 to FY 2027-28. The financial incentive is to be given to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. 26 participants have been approved under the scheme

ii. Production Linked Incentive Scheme for Pharmaceuticals has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020-2021 to FY 2028-29. The scheme covers the In-Vitro Diagnostic (IVD) devices under product Category 3. Total 55 participants have been approved under the scheme, out of which 5 participants are selected for In-Vitro Diagnostic (IVD).

iii. The scheme Promotion of Medical Devices Parks, with a total financial outlay of Rs. 400 crore and the tenure from FY 2020-2021 to FY 2024-2025, provides for the maximum financial assistance of Rs. 100 crore each to 4 selected States/Union Territories for creation of Common Infrastructure Facilities in the upcoming Medical Devices Parks. Under the scheme, final approval for financial assistance of Rs. 100 crore each, has been given to the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu, and Uttar Pradesh.

iv. The scheme Assistance to Medical Device Clusters for Common Facilities (AMD-CF) provides for financial incentive to Medical devices clusters to develop common infrastructure facilities like Medical devices testing labs, E-waste treatment facility, logistic centers. The scheme also provides for financial assistance to National or State level Government or Private institutions interested to establish or strengthen testing facilities for medical devices.

v. To attract investments in Medical Devices sector, the Government has allowed 100% FDI under automatic route

vi. In addition, the Department has recently notified National Medical Devices Policy, 2023 and has set up Export Promotion Council for Medical Devices.

(d) & (e): Based on revised Public Procurement (Preference to Make in India) Order issued by DPIIT dated 16.09.2020, DoP also revised its PPO guidelines on 16.02.2021 giving preference to Class-I Local supplier & Class-II Local supplier, having local content equal to or more than 50% & having local content more than 25% but less than 50% respectively, in Public Procurement.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3773
TO BE ANSWERED ON THE 11th August, 2023

Bureau of Pharma PSUs of India

†3773. SHRI SANJAY JADHAV:
SHRI ARVIND GANPAT SAWANT:
DR. SANGHMITRA MAURYA:
SHRIMATI KESHARI DEVI PATEL:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has conducted any study/analysis and review of the current status of the implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and if so, the details and the current status thereof, State/UT, district/ block-wise;

(b) the current status of Bureau of Pharma PSUs of India along with the number of experts of pharmaceutical field working therein at present;

(c) whether the Government proposes to nominate renowned medical administrators or Industry expert representatives therein and if so, the details thereof along with the number of representatives who are likely to be nominated; and

(d) whether the Government proposes to provide grant to BPPI to meet the administrative expenses, salary etc. on account of it not having financial autonomy and if so, the details thereof and if not, the reasons therefor?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a): An evaluation study for 'Improving effectiveness of Janaushadhi Stores' was got conducted by the Department of Pharmaceuticals during January, 2019. Considering the various suggestions made in the study report, the Scheme was approved for further continuation. An analysis of implementation of the scheme based on availability of PMBJKs vis a vis density of the population has subsequently been conducted wherein 651 districts of the country were found having deficient number of Kendras. Based thereon, online applications have been invited from these districts. Till 31.07.2023, about 9,668 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) have been opened all across the country.

(b) & (c): Pharmaceuticals & Medical Devices Bureau of India (PMBI) [previously Bureau of Pharma PSUs of India (BPPI)], the implementing agency of the scheme is a society registered under the Societies Registration Act, 1860. The Bureau is headed by Chief Executive Officer (CEO). Governing Council, under the chairmanship of the Secretary, Department of Pharmaceuticals has CMD/ MDs of the Pharma PSUs as members, as industry representatives. Further, a committee has been constituted to review the product basket, having academic, medical and regulatory experts from National Institute of Pharmaceutical Education & Research (NIPER), Directorate General of Health Services (DGHS), Central Drugs Standard Control Organization (CDSCO) and National Pharmaceutical Pricing Authority (NPPA) respectively.

(d): Government releases grants to PMBI for providing incentives to Kendra owners, procurement of products to be sold at discounted rates, media & publicity and establishment expenses of Pharma Bureau set up under PMBI.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3813
TO BE ANSWERED ON THE 11th August, 2023

Strengthening of Pharmaceutical Industry Scheme

3813. SHRI G.M. SIDDESHWAR:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has recently issued any guidelines regarding "Strengthening of Pharmaceutical Industry" (SPI) scheme in Karnataka;

(b) if so, the details thereof along with the details of funds allocated for the said scheme;

(c) whether the Government also proposes to improve the existing infrastructural facilities of the pharma sector in Karnataka;

(d) if so, the details thereof along with the targets fixed by the Government under the said scheme; and

(e) the steps taken/proposed to be taken by the Government to establish India as a global leader in the pharma sector?

ANSWER
MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) to (d): Department of Pharmaceuticals, Government of India has released the guidelines for the scheme "Strengthening of Pharmaceutical Industry" (SPI) on 11.03.2022. The financial outlay of the Scheme is Rs. 500 Crores for the period from F.Y. 2021-22 to F.Y. 2025-26. The Scheme aims to address the rising demand for support to the existing Pharma clusters and MSMEs across the country to improve their productivity, quality, sustainability and to strengthen the existing infrastructure facilities in order to make India a global leader in Pharma sector. The scheme is applicable throughout the country and no state specific target is fixed.

The SPI Scheme has following three sub-schemes:

i. **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)** is provided to strengthen the existing pharmaceuticals clusters' capacity for creating common facilities. This will not only improve the quality but also promote competitiveness and sustainable growth of the units in the cluster.

ii. **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)** aims to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M). Under the Scheme, interest subvention or capital subsidy on loan of such enterprises are provided, which further facilitates the growth in volumes as well as in quantity of these units, and

iii. **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)** to facilitate growth and development of Pharmaceuticals and Medical Devices Sector through study/survey reports, awareness programs, creation of database, and promotion of industry.

(e): In addition to the SPI Scheme, Government of India has taken various measures to establish India as a global leader in the pharma sector. The Programmatic interventions in this regard are as follows:

i. The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs), with a financial outlay of ₹ 6,940 crores over the tenure from FY 2020-2021 to FY 2029-30, for financial incentive provided for 41 identified products.

ii. The Production Linked Incentive (PLI) Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of eligible products falling under three product categories.

iii. The Scheme for support of setting up of Bulk Drug Parks provides for support of upto Rs 1000 crore each for creating common infrastructure facilities in setting up of three Bulk Drug Parks.

NEWS

Packages of Top Drug Brands to have QR Codes from Today

India's top 300 brands of drugs including widely-used analgesics, pain relievers, anti-platelet, vitamin supplements, blood-sugar lowering medicines and contraceptive tablets will have to put QR codes on their packages from August 1. The move will ensure authenticity of drugs and enable tracing.

The National Pharmaceuticals Pricing Authority (NPPA) had last year identified brands including Dolo, Saridon Fabiflu, Ecosprin, Limcee, Sumo, Calpol, Corex syrup, Unwanted 72 and Thyronorm. They were shortlisted on the basis of their moving annual turnover value as per data from market research firm Pharmatrac.

Prior to this, the health ministry had asked the department of pharmaceuticals (DoP) to shortlist top 300 drugs so that necessary amendments can be made in the drug rules for its implementation.

"All stocks manufactured after this date will have to bear QR codes," said a senior government official.

The stored data or information would include the unique product identification code, the name of the API, brand name (if any), name and address of the manufacturer, batch number, batch size, date of manufacture, date of expiry or retesting, serial shipping container code, manufacturing licence number or import licence number and the special storage conditions required.

According to the official, this will further assert health minister Mansukh Mandaviya's statement that India follows a zero-tolerance policy on spurious medicines.

In June this year about 71 companies were issued show-cause notices following global concerns of contaminated drugs, and strict action was taken against 18 of them.

Source: *ET Healthworld,* 1st August 2023

Health Ministry Sets Deadline for Pharma Industry to Implement Revised Schedule M

To bring in better quality management that will help Indian pharmaceutical manufacturers grow their business nationally and internationally, the Health Ministry has given six months for small manufacturers and 12 months to large units, to get their World Health Organisation-Good Manufacturing Practices (WHO-GMP) certification.

GMP comprises mandatory standards that build and bring quality to products by way of control on materials, methods, machines, processes, personnel, and facility or environment, etc. The GMP system was first incorporated in 1988 in Schedule M of the Drugs and Cosmetics Rules, 1945, and the last amendment was done in June 2005. WHO-GMP standards are now part of the revised Schedule M.

Schedule M prescribes requirements of facilities and their aintenance, personnel, manufacture, control and safety testing, storage and transport of material, written procedures and records, traceability, etc.

"Observation from ongoing risk-based inspections indicated the need to take a re-look at the current GMP regulations and Quality Management Systems being followed by pharmaceutical manufacturers. We have inspected 162 units and 14 public testing labs till now. Major issues found during inspections included - poor documentation, lack of process and analytical validations, absence of self-assessment, absence of quality failure investigation, absence of internal product quality review, absence of testing of incoming raw material, infrastructural deficiency to avoid cross-contamination, absence of professionally qualified employees, faulty design of manufacturing and testing areas etc," said a senior Health Ministry official.

He added that based on these findings and to keep pace amid the fast-changing manufacturing and quality domain, there was a necessity to revisit and revise the principles and concept of GMP mentioned in Schedule M.

"A draft notification was issued in 2018 to upgrade and synchronise Schedule M comparable to international standards. Now, considering the importance of upgraded and revised GMP in ensuring quality of drugs, the Government has decided to finalise the draft rules. The time that is provided to the industry, then, is for their smooth transition from the present Schedule M to revised Schedule M," he added.

While WHO-GMP certification is valid for three years, violation will invite cancellation of licence and monetary penalty, the Ministry added.

Some of the major changes which will happen with introduction of the revised Schedule M are introduction of pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, change control management, self-inspection, quality audit team, suppliers audit and approval, stability studies as per recommended climate condition, validation of GMP-related computerised system, specific requirements for manufacturing of hazardous products, etc.

There are around 10,500 manufacturing units in the country out of which around 8,500 fall under Micro, Small and Medium Enterprises (MSME) category. India is a major exporter of medicines to low- and middle-income (LMIC) countries which require WHOGMP certification. The country has about 2,000 units in MSME category in the country having WHO-GMP certification.

Source: *The Hindu,* 2nd August 2023

India Medical Devices to become $50billion Industry soon by Govt Holistic Approach: Dr Mansukh Mandaviya

India is set to emerge as the global manufacturing hub for medical devices through the holistic development of healthcare, pharmaceuticals, and medical devices sectors. The market size of the Indian medical devices sector is likely to reach $50 billion in coming years from the current $11 billion, said Mansukh Mandaviya, Union Minister for Health and Family Welfare.

Speaking at the curtain raiser of 'India MedTech Expo 2023', scheduled to be held in Gandhinagar, Gujarat from August 17-19, 2023, Dr Mandaviya emphasised that to make healthcare affordable, the government is targeting to increase the share of generic medicines to 50-60 per cent from current level of 14 per cent alongside localisation of medical devices.

Informing that the medical device sector is considered one of the sunrise sectors in the country, he stated that the development of healthcare, pharmaceuticals, and medical devices sectors has put India on the path of being the global hub for manufacturing medical devices and producing innovative medical technologies.

Briefing about the India MedTech Expo, themed as 'India: The Next MedTech Global Hub' Future of Devices, Diagnostics, and Digital', which is being organised alongside G20 Health Ministers' Conference, S Aparna, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Government of India said, “The government is working to support the medical devices sector by initiating various reforms and policies including PLI scheme for domestic manufacturing and financial support for R&D and we are open to ideas and suggestions to help localised production.”

According to the Department of Pharmaceuticals, the MedTech Expo will see 231 delegates from 50 countries from ASEAN, Africa, CIS, the Middle East. Over 400 exhibitors including MSMEs, domestic and international manufacturers, start-ups, regulatory bodies, state governments, and central ministries and departments will participate. It will have various pavilions, including Future Pavilion, R&D Pavilion, Start-up Pavilion, State Pavilion, Regulators Pavilion, and Make in India Showcase. As many as seven states - Madhya Pradesh, Tamil Nadu, Uttar Pradesh, Himachal Pradesh, Rajasthan, Andhra Pradesh, and Gujarat are setting up pavilions during the expo.

Source: *ET Healthworld,* 10th August 2023

For Strong Pharma Supply Chains, India, US Have to Work Together: US Health Secy

Xavier Becerra is the United States Secretary of Health and Human Services, making him the senior most cabinet-ranking executive official in charge of America's vast and complex healthcare system. Before departing for India, where he is attending a G20 health ministerial and engaging in bilateral conversations with his Indian counterpart, health minister Mansukh Mandaviya, Becerra spoke to HT about the India-US health partnership, pharma supply chains, and the role of pharma companies.

Q: Since the pandemic, we have seen an increased focus on the health collaboration between India and the US? What's the rationale and potential in this domain?

A: In order to make sure we are safe in the US and safe in India – as we have learnt that no one is safe till everyone is safe – we have to have those who are global leaders like India and the US to work in partnership to ensure that one of us will be safe so that all of us will be safe. The fact that India and the US and a few other global leaders have decided to step up to try to ensure a pandemic like Covid can never happen again and devastate so many communities around the world is indispensable, it is essential. The G20 session will give a chance to many of the leaders of the world will give a chance to affirm that we wish to work together in partnership to ensure that all of us are safe.

Q: Public memory is short. Do you see a diminished appetite in putting in resources to deal with pandemic preparedness, despite what happened during the Covid-19 pandemic?

A: There is always the need for more commitment to resources and action. We can't let our guard down. One of the first things we have to do is prepare and prevent. For all of us, and it makes no difference where you are in the world, the most important thing is to do things that keep us safe, that are easy, accessible and straightforward. It doesn't cost money to wear a mask in a public place where there are people who are coughing. It doesn't, today, cost much to have a vaccine against Covid. It needs coordination. So centres of gravity, India, the US, and others, are working together so we can cover the gaps that we saw so prevalent during the pandemic.

Q: During PM Narendra Modi's state visit to the US, he and President Joe Biden decided to step up cooperation on cancer treatment and research. This is an issue close to Biden's heart. What's driving it?

A: I think the President was enthusiastic to see PM's interest and commitment to this issue. We know that with all these diseases, we cannot be safe if there continues to the scourge of cancer that's spreading around the world. And so to have a country like India with its research capabilities and its known commitment to go beyond its borders to help other people, that will make sure this effort to battle cancer will be taken by the greatest leaders in the world.

Q: And what form will it take – joint investment in research on prevention and treatment?

A: All of the above, from research to treatment. One of the greatest weapons against cancer is screening, simple screening to detect cancer before it consumes your body. We want to make sure we are taking advantage of every opportunity to ensure that people get screened for cancer, not just in US and India but beyond. That's where we can use the prowess of US and India in their scientific capabilities and application of therapies and medicines to help people not just live long lives but be cancer free.

Q: Given the focus of de-risking from China and concentration of APIs (active pharmaceutical ingredient) in China, what do you hope to do with India in terms of building more resilient supply chains?

A: If we want to have resilience throughout the world, and certainly here in the US, and want to provide discovered vaccines and therapies that work, we have to have resilience in supply chains. India is a critical player in the supply chain, not just because it has so much material and APIs but because India is a leader in production, in research, innovation, production of these treatments and therapies. If we want a resilient supply chain, India and the US will have to work together in partnership with other countries to make sure that's the case.

Q: One of the factors that has inhibited the development of deeper health ties is what India considers Big Pharma lobby in the US, and US considers generic drugs production in India that your companies don't think conform to IP obligations. How do you see the role of US big pharma in inhibiting this partnership and how do you reconcile this tension?

A: That's a great question. We are making progress in how we ensure that the innovation and the life-saving capabilities of our new technologies and medicines reach all people. I think you are going to find we have a good dancing partner in India. In so many ways, we can complement each other in our capabilities. The question will be will all stakeholders wish to dance with us and so our job is to make sure that we marry all the great capabilities into a fruitful initiative that lets not just American and Indians benefits from these life-saving medicines but we can get them to other parts of the world quicker and cheaper.

Q: Do you think there is greater political will to address this tension today?

A: Yes, I do. You are familiar with the debate we are having here in the US on pharmaceuticals. We have always known that we need to have incentives for research and innovation. We need to make sure that there is someone out there thinking about what will be the cure for cancer, what would be the way to address Alzheimer's, how do we end hunger. We want those innovative minds to be incentivised. At the same time, we want to make sure that once there is a discovery, it reaches all corners of the globe as quickly as possible. That is to our benefit, as to India's. I believe we are going to see a growing dynamic that favours more innovation but quicker application of those innovations around the world. At the end of the day, pharma companies will benefit generously in their profits from their innovative work but we will also be able make sure more people have access to those innovative medicines.

Source: *Hindustan Times,* 17th August 2023

PCI Seeks Fee Details After Health Ministry's Communication on National Fee Regulation Committee

The Pharmacy Council of India (PCI) is collecting fee details for pharmacy courses from pharmacy institutions and state governments in order to provide the data to the Union health ministry in connection with framing of the National Fee Regulation Committee.

The current practice is that the fee structure is fixed by the State governments, mainly through a fee regulation committee, based on the minimum fee structure recommended by the All India Council for Technical Education (AICTE) through the National Fee Committee, said sources.

The Council said that it has received communication from the health ministry regarding framing of a National Fee Regulation Committee to prescribe minimum and maximum fee for students for different Pharmacy Courses, in early July.

The matter was discussed in the executive committee meeting of PCI held at the end of July, 2023 and decided to come out and collect the details from all pharmacy colleges, state governments and union territories (ut) in 10 days.

"The Union health ministry has asked the Council to give the minimum and maximum fee structure in pharmacy and following the directions we are going to prepare it by collecting information from various states and submit it to the Ministry. PCI is not going to be involved directly in the fee fixation," clarified a PCI source.

The Council has decided to seek the fee details from all pharmacy colleges and state governments and Union Territories (UTs) to share the information through a google form.

Publishing the form link in a circular, the Council said that all pharmacy institutions and universities have to provide the fee structures for pharmacy courses by September 4, 2023. After the date of completion, the link will be deactivated, it added.

The form seeks details of fees for D.Pharm, B.Pharm, B.Pharm (practice), Pharm.D, PharmD (Post Baccalaureate), and M Pharm.

The fee details for each M.Pharm specialisation including pharmaceutics, industrial pharmacy, pharmaceutical technology, pharmaceutical chemistry, pharmaceutical analysis, pharmaceutical quality assurance, regulatory affairs, pharmaceutical biotechnology, pharmacy practice, pharmacology, pharmacognosy, and phytopharmacy and phytomedicine are to be submitted in the details.

Source: *ET Healthworld,* 10th August 2023

CDSCO Issues Advisory on Fake Cancer Drug; Urges Doctors to be Cautious

The Drug Controller General of India (DCGI) has issued an alert on falsified versions of Adcetris injection that is prescribed to treat cancer. In a letter dated September 5, the drug regulator highlighted that the World Health Organization (WHO) has informed about a safety alert identified with multiple falsified versions of Adcetris injection 50 mg (Brentuximab Vedotin).

The drug, manufactured by Takeda Pharmaceuticals, is a CD30-directed antibody-drug conjugate indicated for the treatment of patients with Hodgkin Lymphoma after failure of autologous stem cell transplant and systemic anaplastic large cell lymphoma.

The letter, as seen by Financial Express.com, revealed that falsified versions of the drug has been identified in four different countries including India.

"These products are most often available at patient level and distributed in the unregulated supply chains (mainly online). The products have been identified in both regulated and illicit supply chain, sometimes at patient levels as well," the letter revealed.

According to the drug regulator, WHO has reported that there are at least 8 different batch numbers of falsified versions in circulation.

In a statement shared over email, a spokesperson of Takeda Pharmaceuticals told Financial Express.com: "We would like to clarify that the Central Drugs Standard Control Organization has issued a general advisory cautioning against falsified versions of Adcetris Injection (Brentuximab vedotin) identified in India."

The spokesperson also revealed that Takeda has been authorised by the Drug Controller General of India to import, sell and distribute Adcetris in India, and they make it available to the patients here through well-established supply chain networks.

"We strongly recommend that Adcetris should be procured from Takeda authorized distribution sources only. Falsified medical products present a significant threat to public health. Takeda India is committed to safeguarding the integrity of its products and supporting the fight against falsified medicines in order to protect patient safety, which is our highest priority," the spokesperson told Financial Express.com.

It has advised doctors and patients to carefully prescribe and educate their patients to report any adverse drug reactions (ADRs). Additionally, it warned consumers to be careful and only procure the medical products from authorised sources with the proper purchase invoice.

Source: *Financial Express,* 6th September 2023

USFDA Declines to Approve ARS' Emergency Nasal Spray for Allergic Reactions

The US Food and Drug Administration (FDA) has declined to approve ARS Pharmaceuticals' nasal spray for allergic reactions and requested completion of a repeat-dose study to support a potential approval, the company said.

ARS Pharma was seeking approval for the nasal spray treatment, Neffy, as an emergency treatment of allergic reactions including anaphylaxis, in adults and children who weigh more than 30 kg.

"We are very surprised by this action and the late requirement at this time to change the repeat-dose study from a post-marketing requirement, which we had previously aligned on with FDA, to a preapproval requirement, particularly given the positive Advisory Committee vote," CEO Richard Lowenthal said.

ARS Pharma said it anticipates a resubmission in the first half of 2024 an FDA action date in the second half, adding that it plans to appeal the issuance of the FDA's Complete Response Letter.

Patients have to be dependant on EpiPen and other autoinjectors like Sanofi Auvi-Q filled with epinephrine, a life-saving drug used by people at risk of experiencing anaphylaxis. Anaphylaxis is a life-threatening allergic reaction that can occur within seconds of being exposed to an allergen and can be fatal if untreated.

The company's application was based on trials in healthy patients and in those having a rhinitis attack. The nasal spray showed a comparable response to injectable products in delivering epinephrine.

Studies did not test the treatment in people with anaphylaxis due to ethical concerns, but rival Viatris in June petitioned the FDA to require that ARS conduct more trials that closely mimic real-world conditions.

The biggest concern with the drug is that it has not been studied in a real-world setting with people who have suffered anaphylaxis due to ethical purposes, said James Tarbox, an allergist at Texas Tech University Health Sciences Center.

Source: *ET Healthworld,* 20th September 2023

No Shortage of TB drugs in India: Union Health Ministry

There is no shortage of anti-tuberculosis medicines in India, the Union Health Ministry said on Sunday, slamming media reports claiming that such a shortage exists as “false, motivated and misleading”.

In a sharp statement, the Ministry asserted that there is a sufficient stock of all anti-TB drugs in the country. The Centre proactively undertakes regular assessments to evaluate the stock positions at various

levels, from central warehouses to peripheral health institutes, it said.

Citing information mentioned in the media reports, the Ministry said they were "not only inaccurate and misleading, but also do not reflect the correct picture of the available stock of anti-TB drugs in the country".

'Sufficient stocks'

Treatment for drug-sensitive TB consists of two months of taking four drugs, available as 4FDC (Isoniazid, Rifampicin, Ethambutol and Pyrazinamide), followed by two months of three drugs available as 3 FDC (Isoniazid, Rifampicin and Ethambutol), the Ministry explained.

All these drugs are available with sufficient stocks for a period of at least six months, the statement said, adding that the procurement process for drugs for the next financial year 2024-25 has already started.

The treatment regimen of multi drug resistant TB usually consists of four months of taking seven drugs, followed by five months of four drugs. Patients on multidrug resistant TB medicines form 2.5% of the total TB-affected population, and even for this group there is no shortage of drugs, the Ministry said.

Procurement process

The procurement, storage, maintenance of stock, and timely distribution of anti-TB drugs and other materials are done at the Central level under the National TB Elimination Programme (NTEP). "In rare situations, States are required to procure a few drugs locally for a limited period using the budget under National Health Mission so that individual patient care is not affected," the statement said.

At present, more than 15 months' stock of Moxifloxacin 4 00mg and Pyridoxine are available under NTEP. The government had also procured Delamanid 50 mg and Clofazimine 100 mg in August, and supplied them to all States and Union Territories.

The government had also issued purchase orders for the supply of medicines such as FDC (P), Linezolid 600 mg and Cap Cycloserine 250 mg in August. Pre-dispatch inspection for 3FDC(P), Linezolid 600 mg, and Cap Cycloserine 250 mg, and quality test reports for 3FDC(P) and Cycloserine, have been received, and the drugs are being dispatched to the States, the Ministry said, adding that the release orders began to be issued from September 25.

Source: *The Hindu,* 2nd October 2023

MDC Recommends Exemption for Panacea Biotec's Easyfourpoi Vaccine from Drug Price Control

The Multi-Disciplinary Committee (MDC) of Experts under the National Pharmaceutical Pricing Authority (NPPA) has recommended to grant exemption to Panacea Biotec's EasyFourPoI vaccine, an adsorbed diphtheria, tetanus, pertussis, inactivated poliomyelitis,and haemophilus influenzae type B conjugate vaccine, from drug price control.

The decision was taken after the Committee considered the inputs of the Patent Office regarding the patent owned by the company for the vaccine. The expert panel observed that the company fulfills the conditions of Para 32(i) of Drugs (Prices Control) Order (DPCO), 2013 with respect to the formulation.

The Para 32(i) of the DPCO, 2013 states that the provisions in the Order shall not apply to a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous research and development, for a period of five years from the date of commencement of its commercial production in the country.

Panacea Biotec applied for exemption for the formulation under Para 32 through a communication on March 6, 2023 and later on June 29, 2023. It also submitted that it has received a patent for 'Novel Combination Vaccines with Whole Cell Pertussis and method of manufacturing the same'.

The Committee observed that the ministry of health and family welfare confirmed in a letter on November 11, 2022 that the vaccine is not covered under Universal Immunisation Programme (UIP) and it received permission from the Drugs Controller General (India) (DCGI) in May, 2022 and from the State Licensing Authority in November, 2022, which is valid upto September 28, 2027.

It may be noted that the company has earlier applied for retail price fixation of the vaccine and later informed the Authority that the application was filed inadvertently since the vaccine is covered under a patent dated March 30, 2016. Hence, it requested to ignore the application and consider the same under the exemption of pre approval of prices as per the Para 32 of the DPCO, 2013.

The MDC then directed that Panacea Biotec may apply afresh under Para 32 if the exemption is to be sought in respect of Easy Four Pol

"The exemption under Para 32 is not self-invocable. After receding the application for exemption under Para 32, NPPA shall examine the same for further deliberations by MDC," said the Committee.

In a related matter, the MDC earlier this year also suggested the NPPA to take necessary action against the company for launching Easy Six, a purified diphtheria toxoid, purified tetanus toxoid, whole cell pertussis, recombinant hepatitis B, haemophilus influenzae type B conjugate inactivated poliomyelitis trivalent vaccine, without price approval of the Authority.

Source: *Pharmabiz,* 4th October 2023

Pharma Dealmaking Recovers with PE Push

Multinationals' drug portfolios are thinning. Consolidation is underway in the formulations business. Some Indian promoters are seeking an exit. These factors are heating up dealmaking activity in the domestic pharma sector.

Mergers and acquisitions in the pharma sector are expected to pick up as promoters of high leverage companies cash out amid rising compliance costs and pricing pressures in the domestic and the US market.

CHANGING HANDS... Top Pharma M&A Deals Since 2010

Target Co	Acquirer	Amount ($ mn)	Deal Date
Ranbaxy	Sun Pharma	4,000	April 2014
Piramal Health*	Abbott Lab	3,800	May 2010
Viatris*	Biocon Biologics	3,300	Feb 2022
Strides Shasun*	Mylan Labs	1,434	Feb 2013
Gland Pharma	Fosun Pharma	1,085	July 2016
Gavis Pharma	Lupin	880	July 2015
Famy Care*	Mylan Labs	800	Feb 2015
Actavis UK*	Intas Pharma	767	Oct 2016
Suven Pharma	Advent	762	Dec 2022

*Indicates asset/ business sale; data as of Sept 21, 2023 Source: Venture Intelligence

Indian strategic buyers are increasingly acquiring domestic assets, while private equity (PE) biggies like KKR, Caryle, and Advent are getting aggressive and building platforms in both highgrowth domestic formulations and API businesses - as in the case of recent deals such as JB Chemicals and Suven Pharma. The PE activity that started just before the pandemic will accelerate over the next few years, industry experts say.

Over the years, promoters have been cashing out in the wake of increasing price control, higher regulatory scrutiny in the US, and the disappearing lucrative Para IV opportunities, leading to a tough business environment, said PwC India's global health industries advisory leader Sujay Shetty.

Incidentally, some of these factors also triggered the sell-out of pharma biggie Ranbaxy by the Singh family in 2008. Ranbaxy's promoters, led by Malvinder Singh, decided to sell their entire family stake of nearly 35% to Japan's Daiichi Sankyo for Rs 10,000 crore - one of the largest deals in Indian pharma.

Now, the promoters of Cipla - India's thirdlargest drug firm – are planning to divest the family's stake, with the second generation not keen to continue running the business. Recently, Mumbai-based Glenmark Pharma announced a divestment of 75% in its subsidiary, Glenmark Life Sciences, to Ahmedabad-based detergents-to-cement conglomerate Nirma for Rs 5,652 crore, and in another deal, US-based Viatris (erstwhile Mylan), is selling its active pharmaceutical ingredients and women's healthcare businesses in India for a combined value of $1.2 billion (nearly Rs 10,000 crore), as part of a $3.6-billion global divestment.

Further, large domestic players are doubling down on India as an attractive diversification from a US generics market beaten up heavily by price erosion. As a result, several deals were inked where Indian companies snapped up high-growth brands

from local sellers at attractive valuations. For instance, last year, Mankind Pharma swooped on Panacea's domestic formulations' business while three years ago, Dr Reddy's acquired some Wockardt brands, and Torrent Pharmaceuticals bought Unichem's branded formulations assets in 2017 (see graphic).

As against this, a decade back, mainly foreign firms like Abbott, Daiichi Sankyo, Sanofi made headlines with sizeable buy-outs of domestic firms like Piramal Healthcare,Ranbaxy and Shantha Biotec, respectively.

Source: *The Times of India,* 9th October 2023

IPC invites recommendations from stakeholders on draft revision monograph in IP 2026

The Ghaziabad-based Indian Pharmacopoeia Commission (IPC) has invited recommendations from manufacturers, regulators and health authorities on draft revision monograph in Indian Pharmacopoeia (IP) 2026 for Morphine Sulphate Injection, Ceftriaxone Injection and Ceftriaxone Sodium.

The draft revision monograph, which will be included in the IP 2026, is with reference to Bacterial Endotoxins Test (BET). "Comments on the draft document may be sent to lab.ipc@gov.in by November 24, 2023," according to IPC.

The BET is an important quality control step that is used to confirm that the pharmaceutical products are not contaminated before they are administered for use in humans. Pharmaceutical products can be contaminated during purification, production or packaging stages.

A pharmacopeial monograph provides a reliable basis for making an independent and objective judgement as to the quality of a pharmaceutical substance. It states the quality or test parameters, the acceptance criteria, and details of the tests that are to be performed to determine compliance with the criteria.

Bacterial endotoxin, if present in a higher amount, can cause septic shock, fever, a severe form of allergy, organ failure, and, in worst cases, even seem fatal to the patient. The BET is an in-vitro test that is usually carried out to detect and quantify endotoxins, toxins that are famously known for causing fever in humans. Endotoxins are mainly produced by gram-negative bacteria.

The BET is useful to determine the harmful pyrogen in pharmaceutical products and water for injection using a gel clot method. The test is performed as part of the lot release testing for medical devices with direct or indirect contact to the cardiovascular system, lymphatic system, or cerebrospinal fluid.

Morphine is an opioid analgesic (pain reliever) which works by blocking transmission of pain signals to the brain to lower pain perception. Ceftriaxone is an antibiotic medicine used to treat bacterial infections in your body. It is effective in infections of the brain, lungs, ear, urinary tract, skin and soft tissues, bones and joints, blood and heart. It is also used to prevent infections during surgery.

Source: *Pharmabiz,* 13th October 2023

A Platform of Contract Manufacturers Will Benefit Pharma Industry, but Who Will Own It?

The contract manufacturing business is witnessing impressive growth in the pharmaceutical industry.According to MarketsandMarkets , a competitive intelligence and market research platform, the global pharmaceutical contract manufacturing market size is estimated at $176B in 2023 and expected to be growing at 7.9% CAGR till 2028. Several factors are contributing to this growth. Many pharmaceutical companies want to focus on R&D to support the pipeline of generic, biologics, biosimilars, and personalized medicines, and do not think of manufacturing as a core competency. Outsourcing also helps in decreasing time-to-market and may lead to lower cost than in-house manufacturing. Greater demand for their services has prompted contract manufacturers to expand existing facilities, set up new facilities, and form joint ventures.

Despite the demand for contract manufacturing services and the presence of the associated ecosystem, matchmaking remains a challenge. The process of selecting and onboarding CMOs can be very tedious and can take 6-12 months based on the complexity of the manufacturing process.One reason is that the information on the number of equipment, availability of FDA (and other local) approvals, availability of staff at CMOs is not readily available to client companies. The long and tedious contract negotiation process, fragmented nature of contract manufacturing market with 5,000+ CMOs, and geographic diversity of the CMOs also do not help. This inability to timely onboard a CMO has a real business cost since it hampers the time-to-market, which is a critical parameter for generics drugs. It is typically seen that a company that launches the first generic drug significantly captures the market.

The problem of finding a partner is not one-sided. The CMOs also face their share of frustrations as a substantial portion of the drugs do not make it to the market after the clinical trial manufacturing phase. Additionally, the must-have comprehensive quality checks by the pharmaceutical and biopharmaceutical companies take time.

One solution to this problem is a CMO platform/aggregator, which can facilitate information sharing by exhibiting the relevant data of the CMOs and keeping it up to date. For example, the platform can present a CMO scorecard based on past commercials; operational; quality; environment, health, and safety (EHS); and technical parameters. This will significantly reduce the transaction time and the time-to-onboard a CMO. We estimate the reduction in the total transaction and onboarding time to be 50% - 75%. The platform can also provide additional services such as performing quality checks of the CMOs while they are onboarded, and contract management services.

A CMO platform will be a major boost to the Indian pharma industry. Indian Brand Equity Foundation (IBEF) highlights that contract research and manufacturing services is the fastest growing segment in the pharmaceutical and biotechnology industry in India. As per Mordor Intelligence, a market research consulting firm, the Indian contract manufacturing market size is estimated to be at $19.63B in 2023 and expected to grow at 14.67% CAGR till 2028, approximately double the global CAGR.Clearly, with the presence/ of 60000+ different generic brands over 60+ therapeutic categories, a CMO platform is the need of the hour.

But then, who should own the CMO platform? One possibility is an independent start-up.Unfortunately, the platform is unlikely to be sustainable as a business unit. Our analysis indicates that the revenue is unlikely to cover the cost of operating the platform, which includes the technology cost and the cost of timely updating the CMO details. Additionally, incentivizing CMOs to share their details can be a challenge for a single-firm platform.

This is where we take inspiration from the Open Network for Digital Commerce (ONDC) and suggest that this task of incubating a CMO platform can be either taken-up by a consortium of pharmaceutical and biopharmaceutical giants, or bodies like International Pharmaceutical Federation (IFP), Confederation of Indian Pharmaceutical Industry (CiPi), Organization of Pharmaceutical Producers of India for the greater good of the entire pharmaceutical industry.

Source: *ET Healthworld,* 26th October 2023

Research and Innovation in the Pharmaceutical Sector

The National Policy on Research and Development and Innovation in the Pharma-MedTech Sector ("Policy") aims to strengthen the domestic production of new drugs and cutting-edge medical devices to boost the pharmaceutical sector in India. The Policy also aims to reduce dependence on the import of Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs). One of the main objectives of the Policy is to promote self-reliance through the integration of research and ease investments in the industry. The Scheme for Promotion of Research and Innovation in the Pharma MedTech Sector ("PRIP") was launched with the Policy to provide an impetus to the research infrastructure in the country by linking academia with industry in identified priority areas.

The Policy uses a three-pronged approach to achieve its objectives:

Streamlining the regulatory framework

While the Central Drug Standard Control Organisation (CDSCO) is the licensing authority in India, there are several

compliances that must be adhered to with respect to different agencies and other governmental bodies. The Policy proposes a mechanism to avoid overlapping compliances and have stricter timelines in order to align with Ease of Doing Business. This step will be important for matters relating to data protection and should reduce the time for processing approvals by half in the coming years. A single end to end online portal is proposed to be created to this effect. This portal would act as a singular interface between companies and various regulatory agencies, thereby making the process easier and reducing the compliance burden on various entities. This move should also ensure more transparency in the entire process. Furthermore, existing institutions will be developed with focus on in-house expertise on biologics, imaging technologies, AI based tools in the sector, etc.

Incentivizing investment in research and development

The Policy is intended to incentivize investment specifically in production of biopharmaceuticals, patented drugs, new technology in medical devices for cancer care, imaging, etc. It may be noted that due to longer periods of research and development as well as cumbersome regulatory requirements, investment in the said areas has been challenging. Therefore, the Policy aims to provide fiscal as well as non-fiscal incentives through introducing direct or indirect funding. Such funding would include financial support provided for late-stage research. Funding would be further facilitated through blended finance products and a proposed innovation fund in the pharmaceutical sector, thereby alleviating reluctance in investments relating to long-term research.

PRIP is also an attempt to promote investments and allow companies to benefit from the research and institutional infrastructure present in the country. It is divided into two components, where component A would focus on establishment of better institutional infrastructure, and component B would focus on providing financial assistance to entities involved in research and innovation. PRIP is designed to be highly beneficial as it aims to provide financial assistance to companies across various levels of technological readiness under set criteria. This will benefit entities with large turnovers as well as startups in terms of research opportunity in specific priority areas.

Creating an ecosystem to enable innovation

While creating investment opportunities and optimization of regulatory procedures are immediate steps that have been taken to boost the pharma industry, long term solutions include creating stronger institutional and academic infrastructure in the MedTech area. The Policy aims to do so by linking industry with academia. It is proposed that institutes of national importance will be set up for skill development. Further, since the MedTech sector is multidisciplinary in nature, various technical institutes will have to collaborate to train manpower, thereby increasing employment opportunities.

Esteemed international institutes will also be invited to establish their presence in the country. Such steps are proposed to be taken by the Indian Council of Pharmaceuticals and MedTech Research and Development (which is proposed to be created under this Policy).

Apart from promotion of research institutions, investments made by entrepreneurs and start-ups are intended to be incentivized through Atal Incubation Centres (AICs) and Established Incubation Centres (EICs), Further, such innovations hubs will also be integrated with reputed institutions.

It must be noted that through PRIP, the government intends to set up Centres of Excellence at National Institute of Pharmaceutical Education & Research (NIPERs) in cities like Mohali, Guwahati, Raebareli, Hajipur, etc. This measure should help in ensuring that employment and training opportunities are available in tier two cities and rural areas. Further, bulk drug parks and medical device parks are proposed to be established, amongst others, in Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu. This will pave the way for even development of the pharmaceutical sector across the country, along with more cost-effective medical solutions for the citizens.

The aftermath of COVID-19 also has bearing on the Policy as its implementation is an effort to ensure that the country is not only self-reliant but also prepared for national health crises like the pandemic. The new Policy will be a milestone in the development of the pharma sector as it shifts focus from the low value generic drugs produced in the country to research and innovation. This will aid in shifting from a "cost-based to a value-based and innovation-based industry."

Source: *Financial Express,* 31st October 2023

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