ISSUE No. 63

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. 2024 - Dec. 2024

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

It is with great pleasure that we present the 63rd edition of the Pharma Web Newsletter, covering the period from July to December 2024. This issue is packed with valuable content, including program highlights and insightful presentations by distinguished experts from the pharmaceutical industry:

- **Digital Evolution in Pharma: A New Era of Efficiency and Innovation Shri. Duraisamy Rajan Palani,** Founder & CEO, Archimedis Digital, Chennai
- **Current Technological Development of Ayush Drugs Dr. R. Ilavarasan**, Former Assistant Director and Institute In-Charge, Captain Srinivasa Murthy Central Ayurveda Research Institute, Ministry of AYUSH, Government of India, Arumbakkam, Chennai.

Additionally, this edition features a collection of **Gazette Notifications** related to amendments in the Drugs & Cosmetics Act and Rules, as well as key circulars from the DCGI concerning drugs and pharmaceuticals. We've also curated significant news articles from national publications, providing a well-rounded perspective on recent developments in the pharmacy sector. Furthermore, pertinent Parliamentary Questions and Answers relevant to our profession are included to keep you informed of legislative updates.

We extend our sincere gratitude to **M/s. Delvin Formulations, M/s. Medopharm,** and **M/s. Tablets (India) Ltd.** for their unwavering support through advertisements, which play a vital role in sustaining this publication.

A special acknowledgment goes to **M/s. Fourrts (India) Laboratories Pvt. Ltd.** for their invaluable contributions to Pharma Web advertising and their dedication to nurturing talent in the field through the meritorious awards granted to B.Pharm students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai. Their commitment to fostering excellence in our profession is truly commendable.

We trust this newsletter will serve as a useful resource for our pharmaceutical professionals. Your feedback and suggestions for improvement are always welcomed and greatly appreciated.

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

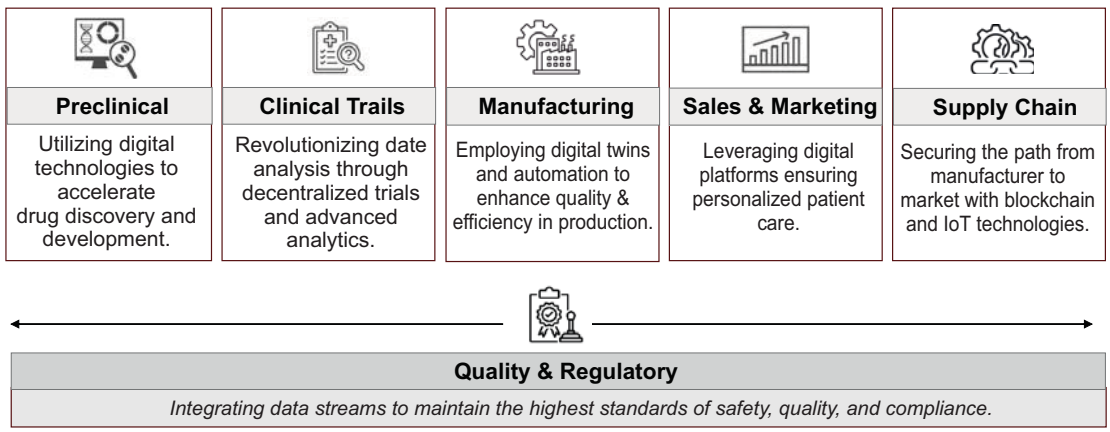
Digital Evolution in Pharma: A New Era of Efficiency and Innovation

by
Shri. Duraisamy Rajan Palani,
Founder & CEO, Archimedis Digital, Chennai

Lecture delivered during the conference held on 23rd December 2024 at
TN Dr. MGR Medical University, Guindy, Chennai.

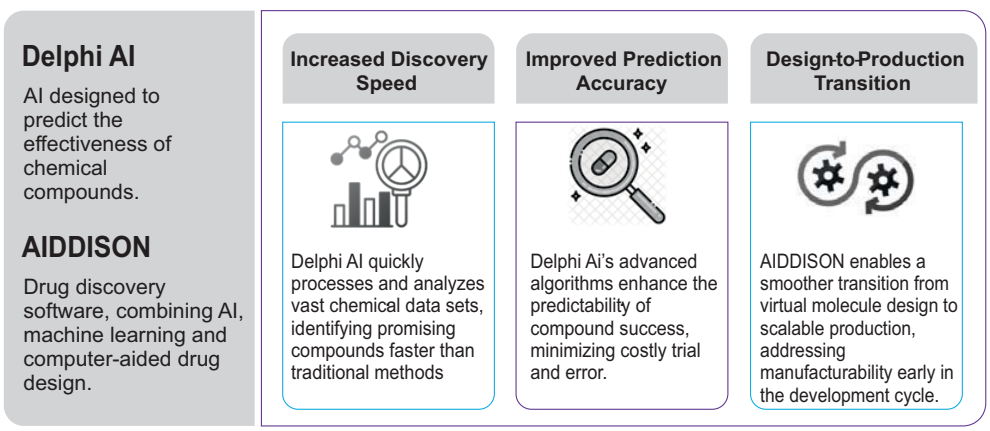
Introduction

Digital Transformation Across the Pharma Value Chain



AI-Driven Drug Discovery Revolution

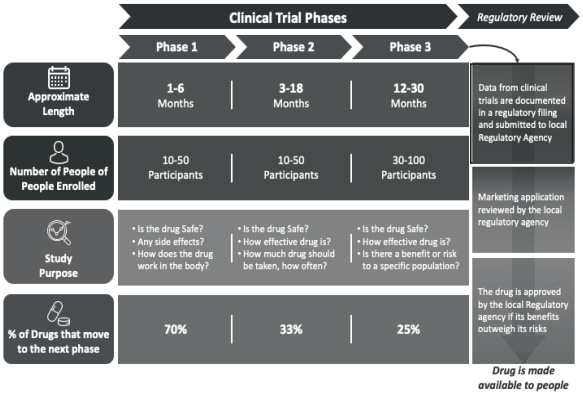
Drug discovery involves identifying molecules that can lead to effective treatments.



Merck Launches First Ever AI Solution to Integrate Drug Discovery and Synthesis (sigmaaldrich.com)

Digital Transformation in Clinical Trials

The Nordic Case Study



Decentralized Clinical Trials (DCTs):

- Employ digital tools to shift activities closer to patient's home.
- Use electronic consent and remote patient monitoring
- Implement telehealth visits instead of in-person visits

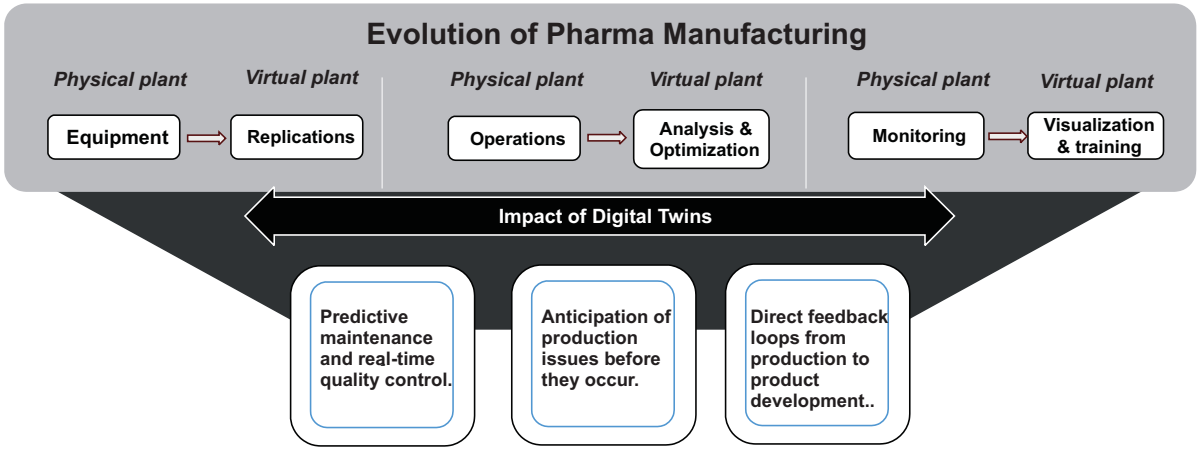
Clinical Data Analytics:

- Utilize electronic data capture (EDC) systems for real-time data
- Analyze large datasets quickly and accurately
- Employ algorithms for predictive analysis and monitoring

A Nordic pilot study for neuropathic pain treatment by AlzeCure Pharma, LINK Medical, and Viedoc Technologies demonstrated:

- *Effective use of web-based questionnaires for patient screening.*
- *Video conferencing and eConsent processes to facilitate participation.*
- *Real-time data integration into study databases, improving data quality.*

Digital Twin Innovation in Manufacturing



Patient Outcomes with Personalized Care

McKinsey's Insight on Personalization

McKinsey's consumer research highlights the pivotal role of personalized care in patient discharge planning

Reducing Readmissions

Studies and surveys indicate that up to 30% of hospital readmissions are preventable through effective patient engagement and personalized care guidance.

Engagement as a Solution

Encouraging patients to adhere to recommended care guidelines through personalized interaction significantly lowers the likelihood of readmissions, underscoring the need for tailored care strategies in post-discharge planning.

Impact → Personalization in the care journey presents a viable solution to the challenge of avoidable readmissions, promoting better health outcomes.

Role of personalization in the care journey | McKinsey

Enhancing Pharma Supply Chain Integrity

Blockchain technology introduces a secure, immutable ledger system for tracking transactions, significantly impacting the pharmaceutical supply chain by enhancing transparency, traceability, and security.

Traditional Supply-chain Challenges

- Manual tracking and traceability issues.
- Risk of counterfeit drugs entering the supply chain.

Blockchain Initiative by Merck and Walmart

- Collaboration under the FDA's Drug Supply Chain Security Act Pilot Program.
- Aimed at creating an electronic, interoperable system for drug traceability.

Outcome

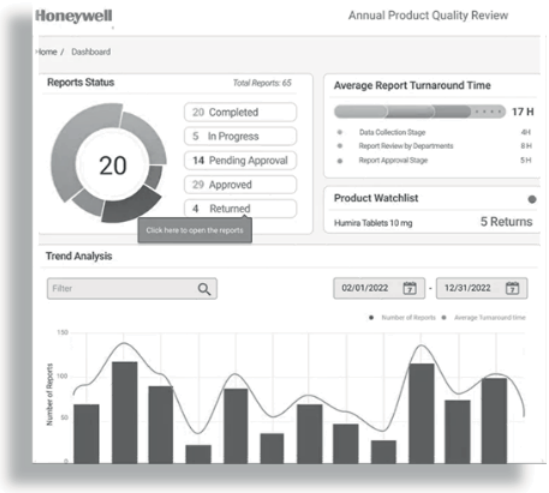
- Successful pilot demonstrating blockchain's potential in meeting FDA's traceability requirements.
- Increased patient safety with enhanced visibility and traceability of prescription medicines.

Block chain technology helps ensure the integrity of drug distribution from manufacturer to patient, reducing the risk of counterfeit medicines

Merck Walmart IBM KPMG's FDA Blockchain Pilot Here's What We Learned (pharmaceuticalonline.com)

Digitizing Quality & Regulatory

Current Challenges in APRQ : Data aggregation and siloed analysis leading to inefficiencies and potential errors



- Honeywell's HPQR App automates APQR report generation.
- Features automated data collection and analysis, enhancing efficiency and data integrity.
- Facilitates virtual PQRs for ongoing process assessment and improvement.
- Promotes real-time collaboration for rapid issue identification and resolution.

HPQR- Honeywell (spartasystems.com)

Essential Skills for Digital Readiness in Life Sciences

01 **Digital Literacy:**
The ability to operate devices, use software, and navigate digital interfaces

02 **Data Analysis:**
The ability to analyze and interpret complex datasets

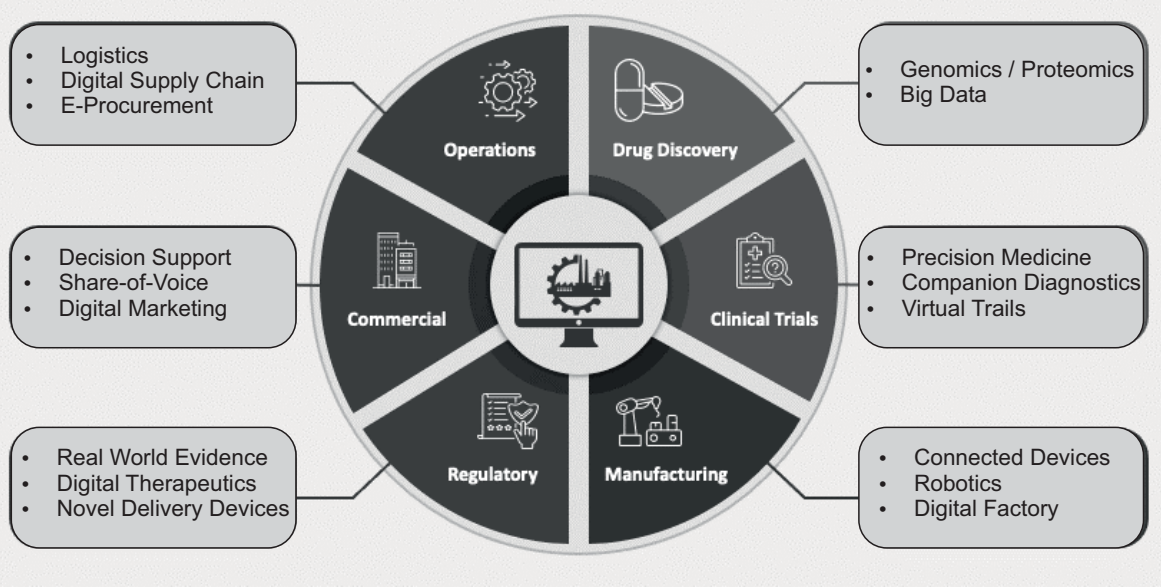
03 **AI & ML:**
Understanding the principles of AI and ML

04 **Blockchain Technology:**
Understanding its applications in drug traceability and supply chain management.

05 **Internet of Things (IoT):**
Familiarity with IoT devices and their applications in healthcare

06 **Cybersecurity:**
Understanding cybersecurity principles to protect sensitive health data.

Pharma Evolution & Digital Leap



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Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purposes.

This issue of Pharma Web is also available online at the Trust website : www.pictrust.com

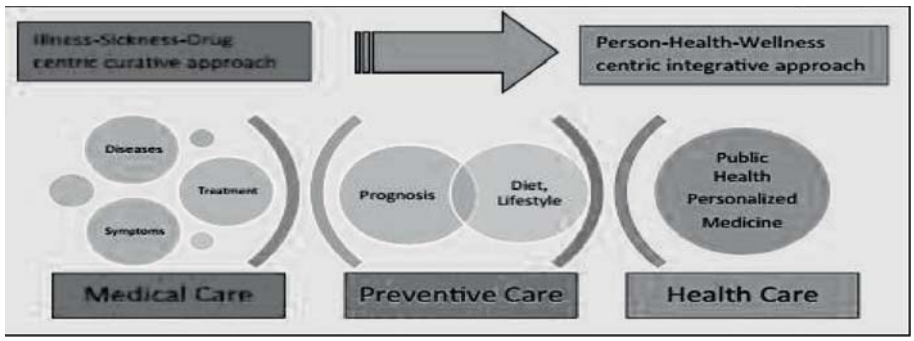
Current Technological Development of Ayush Drugs

by
Dr. R. Ilavarasan,
Ex. Assistant Director and Institute In-charge, Captain Srinivasa Murthy Central Ayurveda Research Institute, Ministry of AYUSH, Government of India, Arumbakkam, Chennai-600106.

Lecture delivered during the conference held on 23rd December 2024 at
TN Dr. MGR Medical University, Guindy, Chennai.

Global Scenario
Biomedical sciences have progressed significantly

- Double helix, human genome project
- Diagnostics, technologies like MRI and PET scan
- Bypass, transplants, and prosthetics changed life expectancies
- Chemotherapy and revolutionized longevity & quality of life
- Genomics and epigenomics towards personalized medicine
- Developing countries - disproportionate population growth, double burden of diseases and increasingly unaffordable health.
- Leaders, policy makers, and scholars, world over are grappling with possible solutions to these complex problems
- There is no magic bullet or no single solution
- Traditional Medicine can - needs Scientific research and evidence



Mind-set needs to be changed from sick-care and medical care to preventive care and health care. Illness-sickness-drug-centric curative therapies to person-health-wellness-centric integrative approaches.

Global Crisis – Opportunity Ayurveda
Going beyond past glory and self-pride

- Affordable???
- Available??
- Accessible?
- Acceptable

- Needs Space
- Needs Respect
- Needs Documentation
- Needs Methodology
- Needs Research
- Needs Evidence

Ministry of AYUSH

AAYUSH in India

- Indian health system is characterised by 'Medical pluralism'
- Several modern and traditional medical systems coexist:
    - Allopathy
    - Ayurveda
    - Yoga & Naturopathy
    - Unani
    - Siddha & Sowa Rigpa
    - Homeopathy
- The traditional systems together known as AYUSH are recognised by the Indian government with formal education and regulations

AYUSH Systems in India

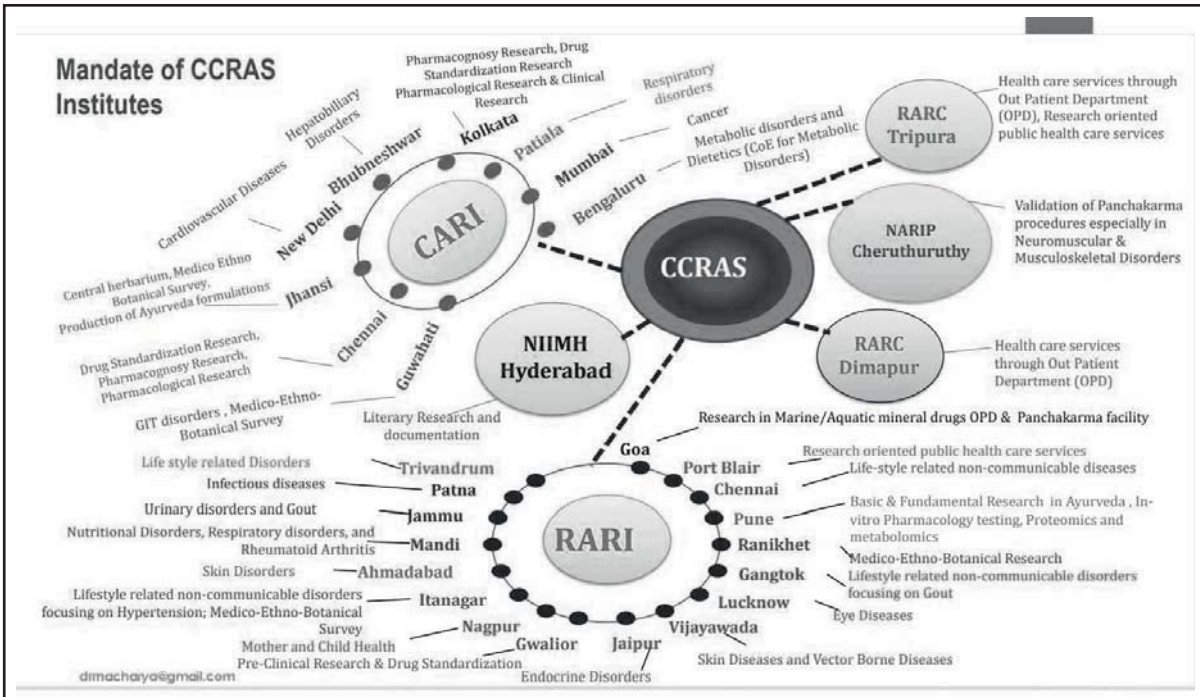
- Spending on AYUSH systems remains meagre- about 2% of national health budget compared to 98% on allopathic system
- Issues with quality of education, training, research and regulation of AYUSH systems
- Also rising interest through medical tourism, leads for drug discovery, potential for innovations in areas where biomedicine has challenges
- Integrative approach has great potential
- Requires trans-disciplinary learning and cogeneration of knowledge
- Breaking existing hierarchies in medical systems, mutual trust and respect between scientists

AYUSH systems- National Policy

- Attempts to integrate traditional systems in national public health sector
- National policy on Indian medicine systems was first formed in 2002
- Draft policy on AYUSH -2016
- National Health Policy 2017
- NITI Action Agenda 2017
- Government strategy to integrate AYUSH in national health care programmes and delivery systems
- Mainly co-location of AYUSH doctors and facilities in allopathic centres rather than integration

Central Council for Research in Ayurvedic Sciences

CCRAS is an apex body in India for the formulation, coordination, development and promotion of research on scientific lines in Ayurveda and Sowa-Rigpa system of medicine.



Core Research Areas

Clinical Research

Validation of Classical formulations

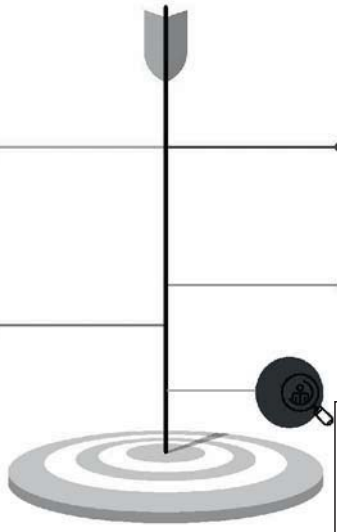
Clinical safety, efficacy, adherence, tolerability of New formulations

Drug Research

Medicinal plant research

Quality assurance and Drug Standardization

Pharmacological research



Literary Research

Revival, retrieval & preservation of Indian medicinal heritage, Medico Historical studies

Collation, Transcriptions, Translations and Publications

Fundamental Research

Basic principles of drug mechanism physiology ad metabolism

Other research avenues:

Documentation of Ethno medicine and validation of Local Health Tradition

Research oriented public health activities

Misuse & Abuse of the Term 'Research'

Mere compilations than original thoughts

Blindly following published literature

Following research methods and designs without understanding them

Invalid outcomes measures

Self-derived scales and measurements

Outdated analysis and data presentation

Word Cloud of perceptions of Ayurveda Postgraduates about Research

Need for Scientific Research & Evidence
Science is dynamic and so Ayurveda should be

- The objective of any medical research should be to assess health effects, minimize bias, chance effects and confounders.
- Ayurveda needs contemporary scientific evidence
- The nature of evidence for Ayurveda may be different than that of western biomedicine.
- Need for appropriate models to demonstrate scientific evidence.
- Blend of modern science, rigorous trial methods and observational studies.

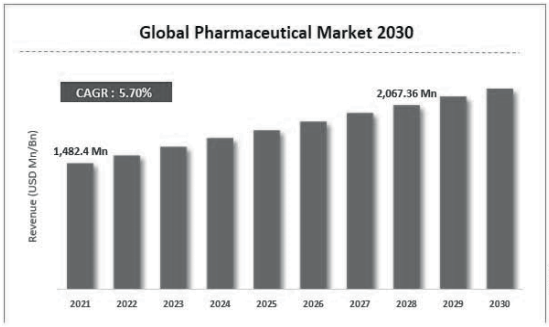
Drug Research: Focusing on Gaps and Barriers in Global Accessibility and Acceptability

Importance of Drug Research:

- Role in improving global health outcomes.
- Contribution to the advancement of medical science.

Current Landscape:

- Overview of the global pharmaceutical industry.
- Key players and market dynamics.



s://www.fnfresearch.com/
rmaceutical-market

Global Accessibility Challenges

High Costs:

- Research and development expenses.
- Pricing strategies and affordability.

Regulatory Barriers:

- Diverse regulatory requirements.
- Approval process complexity and duration.

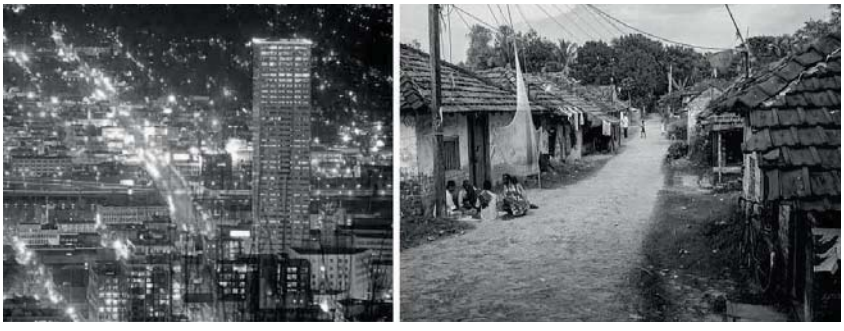
Geographic Disparities

Availability of Drugs:

- Developed vs. Developing countries.
- Urban vs. Rural areas.

Supply Chain Issues:

- Distribution challenges.
- Infrastructure limitations.



Acceptability Issues

Cultural and Social Factors:

- Perceptions and stigma.
- Traditional vs. Modern medicine.

Education and Awareness

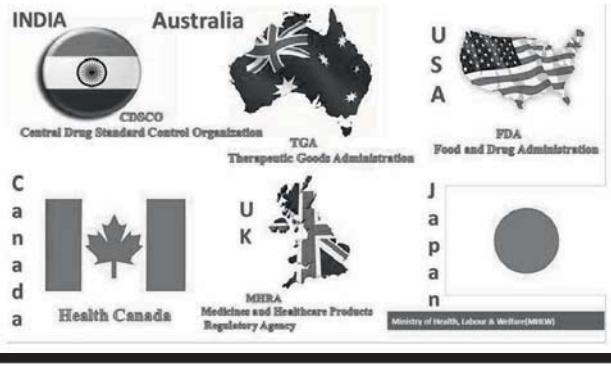
- Patient knowledge and understanding.
- Healthcare provider training.

Challenges in traditional medicines

Regulatory Variability:

There is significant variability in regulatory standards for traditional medicines across countries, impacting safety and quality control.

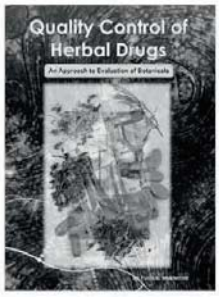
According to the World Health Organization (WHO), only about 25-60% of countries have regulations for traditional medicines that are comparable to those for modern medicines.

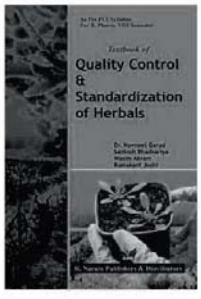


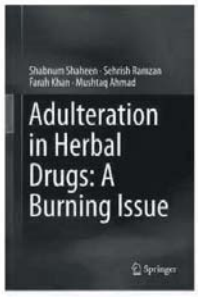
Quality Control Challenges:

Ensuring consistent quality in traditional medicines remainsa challenge due to factors such as variability in raw materials and lack of standardized manufacturing practices.

A study by the WHO found that in some cases, traditional medicines may contain undeclared pharmaceutical ingredients or contaminants due to inadequate quality control measures



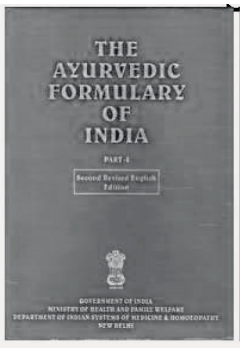


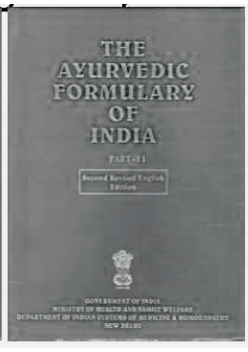


Standardization of Formulations:

Traditional medicines often lack standardized formulations, making it difficult to ensure consistent therapeutic effects.

According to a report by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), less than 20% of traditional medicines have standardized formulations globally.





Safety Concerns:

Safety issues are prevalent in traditional medicines, with reports of adverse reactions and contamination incidents.

For example, a systematic review published in the Journal of Ethnopharmacology found that contamination with eavy metals and microbial pathogens is a common problem in herbal medicines.

Why Standardization?

Because Quality is Very Important - Few Examples

Test Sample 1: Coded Herbal Drug Pellets

Sample Type	:	PELLET	
Received	:		
Sample Qty. Recd.	:	APPROX. 5G	
Test Start	:		
Test End Date	:		
Group	:	Residues in Food Products	: Trace metal elements

NABL Accredited Tests

Test/Parameter	Method	Result	Unit
DISCIPLINE: CHEMICAL			
Lead (as Pb)	SO-IN-MUL-TE-063 A by ICPMS	>10000.00	mg/kg
Arsenic (as As)	SO-IN-MUL-TE-063 A by ICPMS	9051.00	mg/kg
Cadmium (as Cd)	SO-IN-MUL-TE-063 A by ICPMS	BLQ (LOQ : 0.01)	mg/kg
Mercury (as Hg)	SO-IN-MUL-TE-063 A by ICPMS	1908.66	mg/kg

Acceptable Limits: Lead - 10 ppm, Arsenic - 03 ppm, Cadmium - 0.3 ppm , Mercury - 01 ppm

Few Examples

Test Sample 2: Coded Herbal Drug Tablets

Assay of Elements

S.No.	Element	Wavelength (nm)	Correlation coefficient	Results (mg/Kg)
1.	Arsenic (As)	193.696	0.999	37.80
2.	Cadmium (Cd)	226.502	0.999	6.39
3.	Mercury (Hg)	184.887	0.999	79,431
4.	Lead (Pb)	220.353	0.999	99,298

Test Sample 3: Coded Herbal Drug Tablets

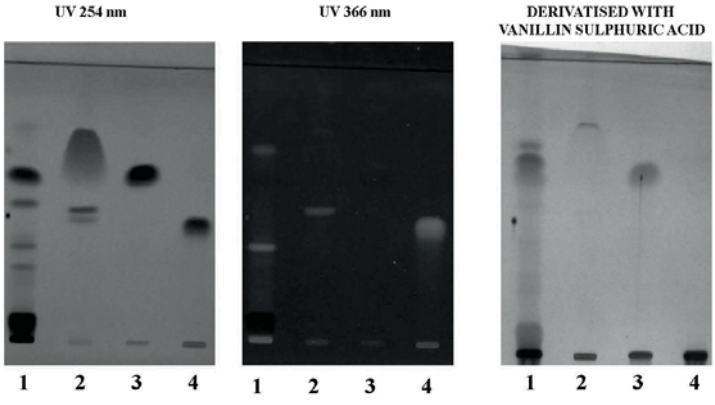
Assay of Elements

S.No.	Element	Wavelength (nm)	Correlation coefficient	Results (mg/Kg)
1.	Arsenic (As)	193.696	0.999	108.75
2.	Cadmium(Cd)	226.502	0.999	5.16
3.	Mercury(Hg)	184.887	0.999	964
4.	Lead(Pb)	220.353	0.999	1040

Acceptable Limits: Arsenic - 03 ppm, Cadmium - 0.3 ppm, Mercury - 01 ppm, Lead - 10 ppm

Few Examples

Test Sample 4: Unknown Herbal Drug (TLC photo documentation)



SOLVENT SYSTEM : TOLUENE : ETHYL ACETATE : FORMIC ACID (5 : 1.5 : 0.1)

TRACK 1 : SAMPLE 10 µl
TRACK 2 : BRUFEN 10 µl **(Ibuprofen)**
TRACK 3 : REACTIN 10 µl **(Diclofenac)**
RACK 4 : SUGANRIL 10 µl **(Piroxicam)**

Evidence-Based Research:

There is a lack of rigorous scientific research supporting the safety and efficacy of many traditional medicines.

According to a study published in PLOS ONE, only a small percentage of traditional medicines have undergone clinical trials to evaluate their efficacy and safety profiles.

Education and Training:

There is a need for standardized education and training for traditional medicine practitioners to ensure safe and effective use.

The WHO reports that less than 20% of countries have established systems for training traditional medicine practitioners according to standardized curricula.

Intellectual Property and Traditional Knowledge Protection:

Protecting traditional knowledge and ensuring fair benefit-sharing for indigenous communities remains a challenge.

According to the United Nations Conference on Trade and Development (UNCTAD), indigenous communities often face difficulties in protecting their traditional knowledge from misappropriation and exploitation.

https://doi.org/10.1016/j.jep.2011.06.003

Integration with Conventional Medicine:

Integration of traditional medicines into national health systems is uneven globally.

A survey conducted by the WHO found that while some countries have policies supporting integration, many still lack clear guidelines and mechanisms for collaboration between traditional and modern medicine systems.

Accreditations and Global recognition

Getting accreditation from any recognized international quality body is a big challenge for the herbal testing and manufacturing organizations

Majority of the labs remain unaccredited by any of the international bodies such as NABL, GLP, GMP etc.

NABL (Testing, Calibration, Medical, PTP, RMP)

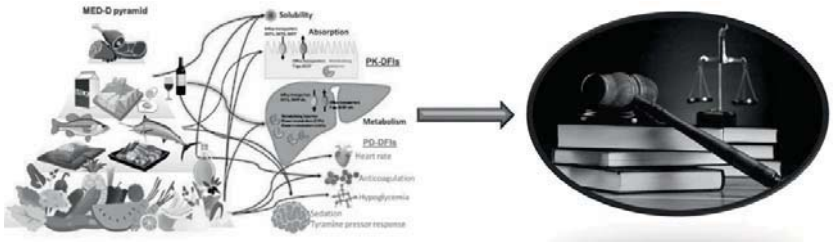
Testing
Biological
AYUSH Products – 73
Ayurvedic Drugs – 51
Herbal Formulations – 33
Homeopathic Drugs – 7
Others – 20
Siddha Drugs – 9
Unani Drugs – 11
Chemical
AYUSH Products – 89
Ayurvedic Drugs – 58
Herbal Formulations – 32
Homeopathic Drugs – 8
Others – 38
Siddha Drugs – 3
Unani Drugs – 8

Acceptance of Herbal Preparation as Drug

Overall, the reluctance of regulatory bodies to classify herbal preparations as drugs reflects a combination of
Scientific + regulatory + cultural + practical considerations

Efforts to address these challenges include

- enhancing research on herbal medicines
- improving quality control standards
- promoting evidence-based practices
- fostering international collaboration in regulatory harmonization.



Future Directions

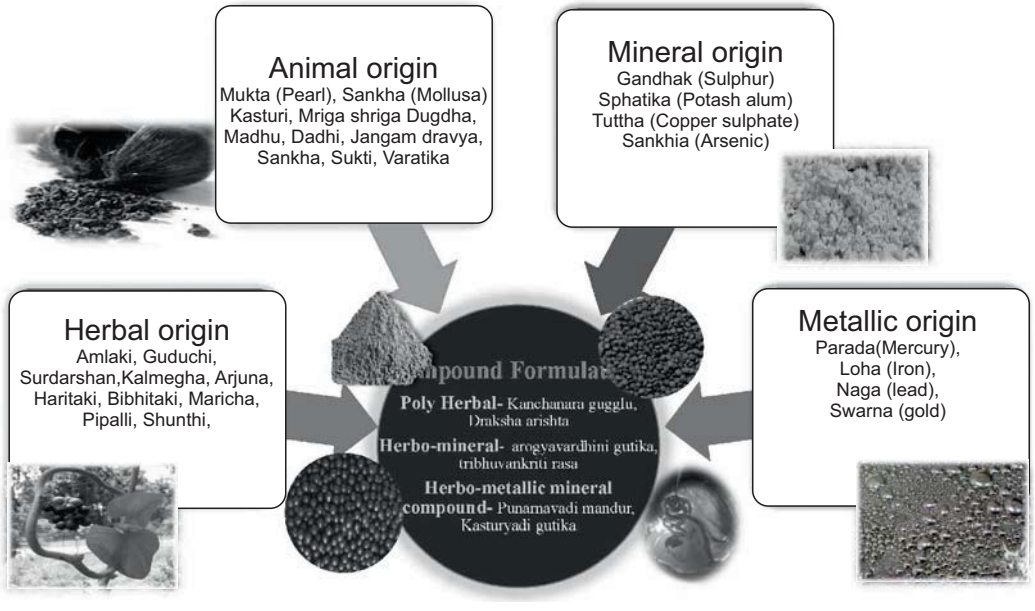
Research Focus:

- Targeting neglected diseases.
- Personalized medicine.

Global Initiatives:

- Public-private partnerships.
- Investment in healthcare infrastructure.

Source of drugs



Dosage forms in Modern pharmaceutics
Classification is based upon :

Physical state
1. Solid
2. semisolid
3. liquid, gas

Route of administration
1. Oral
2. Parenteral
3. Rectal
4. Sublingual
5. Vaginal
6. Ocular
7. Intranasal etc.

Site of application
Skin- Ointments, creams, lotions, liniments 2. Eye- Solutions, ointments, creams 3. Tooth- Tooth powder, tooth paste 4. Hand- Hand creams, lotions, hand washings 5. Foot- Creams, ointments, dusting powders 6. Hair- Hair cream, hair lotions, shampoos, hair fixing 7. Nasal- Solutions, sprays, inhalations

Intended therapeutic use
1. Internal – all preparations except external
2. External – Ointments, lotions, creams, powders, solutions,liniments, paste, hair dyes, hair colorants

Challenges faced by modern medicine

A

New Chemical Entity deficit

New Synthetic drug molecule are deficient

B

Resistance

Almost all antibiotics are facing antimicrobial resistance

C

Huge Expenditure

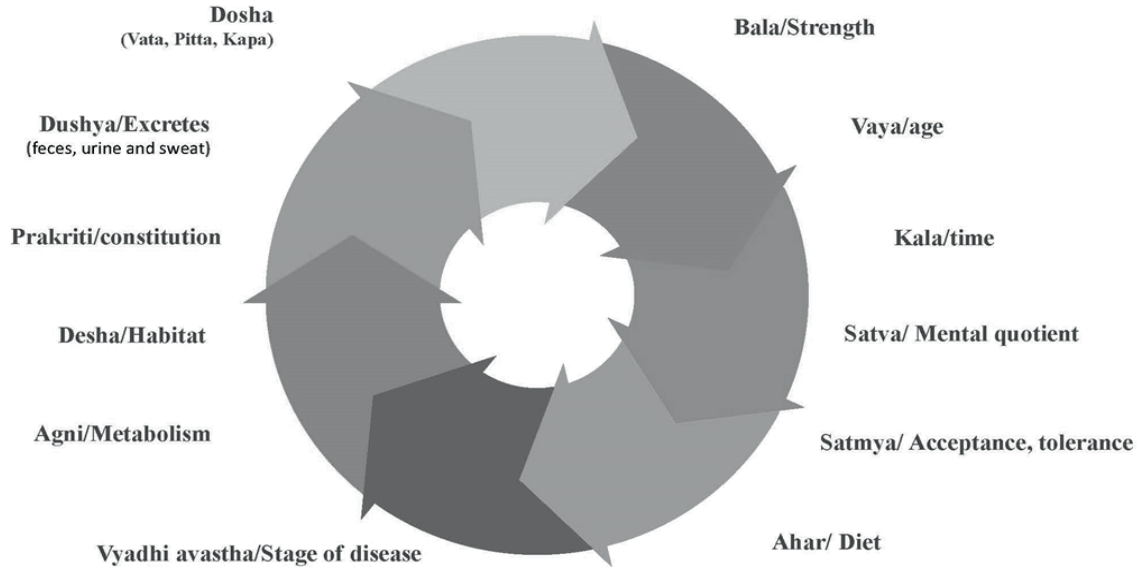
Costs for synthesizing new molecules is exponentially risen

D

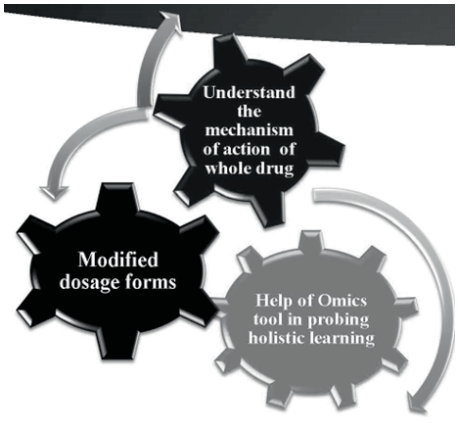
Limitation in Drug productivity

Inspite of high throughput screening, and combinatorial techniques, expected productivity is not achieved.

Unique factors that strengthen personalized approach in Ayurvedic pharmaceutics



How traditional medicine can address the lacunae???



- It is being stated that drug discovery and development need not always be confined to new molecular entities.
- Rationally designed keeping homogeneity and holistic approach in mind, carefully standardized, synergistic traditional herbal formulations with robust scientific evidence can aid in new avenue in drug development.
- Recapitulation and imbibing of the traditional science to modern drug discovery process can bring novel interest to the pharmaceutical world.
- High throughput screening with help of omics tool can serve well in integrating with modern technologies and safeguarding ayurvedic doctrines.
- Also, conducting studies with modified dosage forms without altering the underlying fundamentals

Carving out niche areas…

Literary research:

- A comprehensive database of medicinal plants with their uses and properties enriched with current inputs from high throughput screening and computational chemistry can be established.
- Digitization of the rare manuscripts.
- Digitization and accessibility of herbariums.

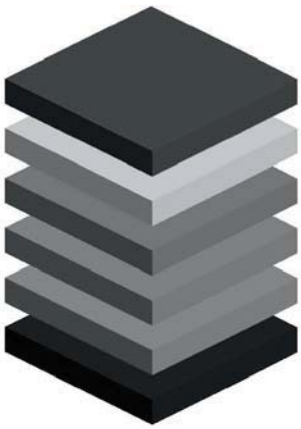
The National Institute of Indian Medical Heritage (NIIMH), Hyderabad, is a dedicated institute under the CCRAS for Literary Research. The institute works with a particular focus on the revival and retrieval of ancient medical manuscripts and rare books, medico-historical studies, preparation of biographies of eminent scholars, and preparation of e-books on classics of AYUSH Sdyrrsntaecmhasry oa@f gMmaeidl.ciocmine

Revival, Retrieval and Documentation of Ayurveda and Indian Medical Heritage- CCRAS

Revival and Retrieval of ancient manuscripts/rare books
- Conservation of Manuscripts
- Digitization of metadata
- Preparation of Catalogue

Medico-historical studies
- Biographies of eminent scholars.
- Drug studies in ancient texts.

Transcription
From different scripts to Devnagri and Roman.

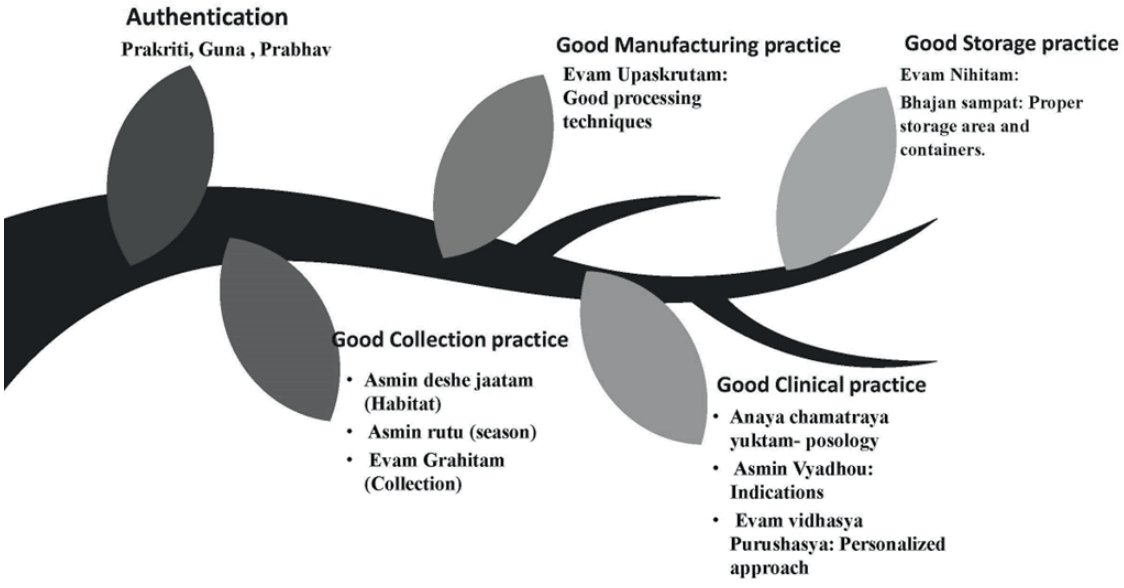


Translation
- From Sanskrit to Hindi and English
- From various regional languages to Hindi and English

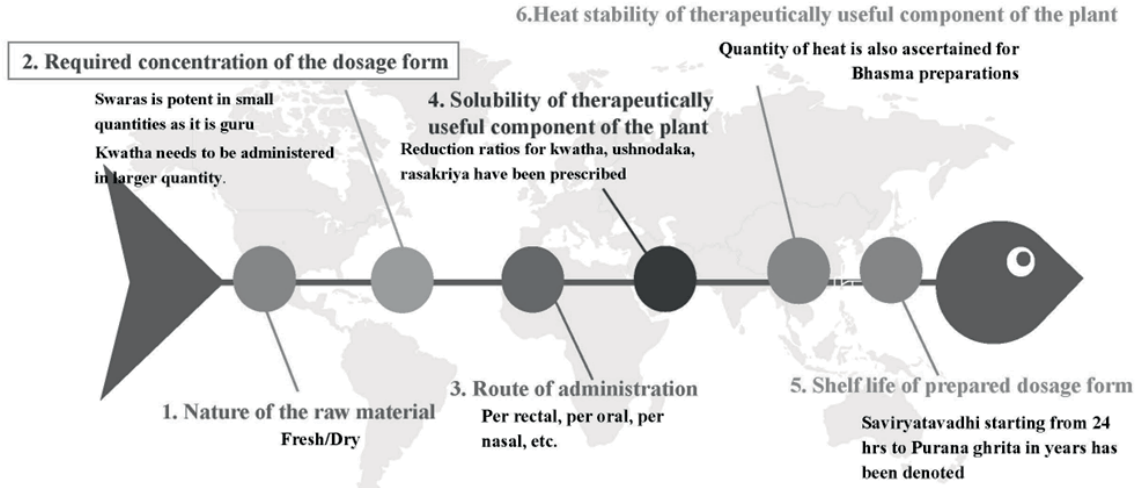
Publication
- Classical treatises
- Important/ rare works, unpublished texts, and their commentaries
- Books mentioned in Drug & Cosmetic Act Schedule 1

Preparation of E-books of Ayurved classical text

Factors affecting crude drug quality !! 43
Unique SOPs given by s e e r s CHA.VI . 8/87

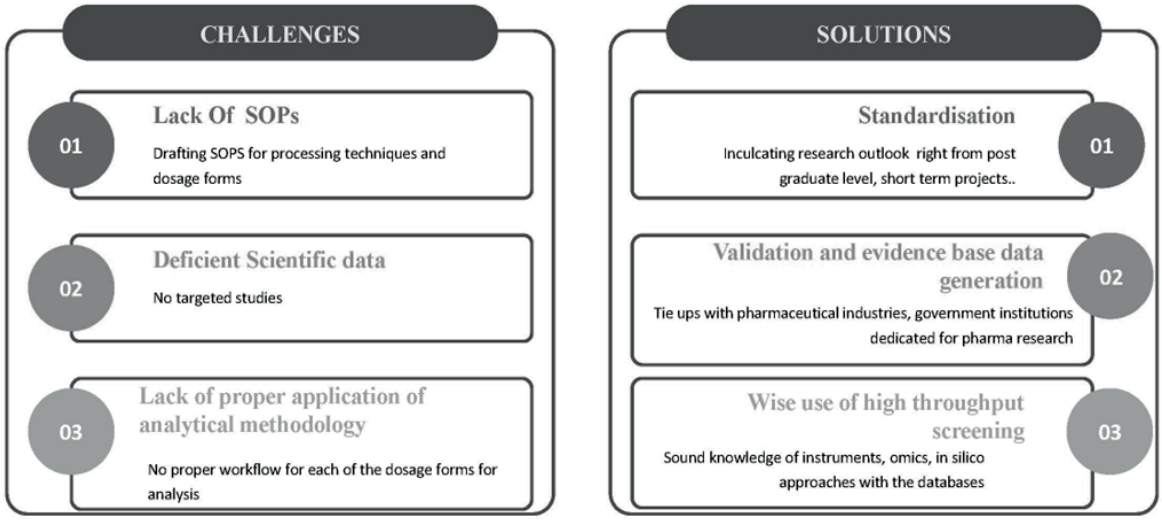


Factors influencing the pharmaceutical processing

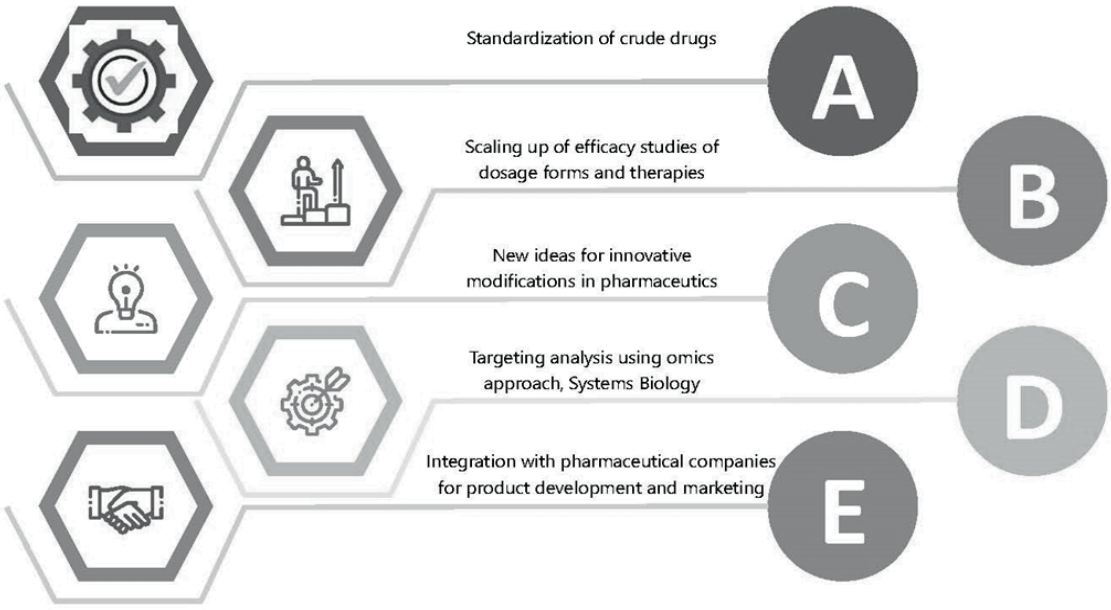


CHALLENGES versus possible SOLUTIONS

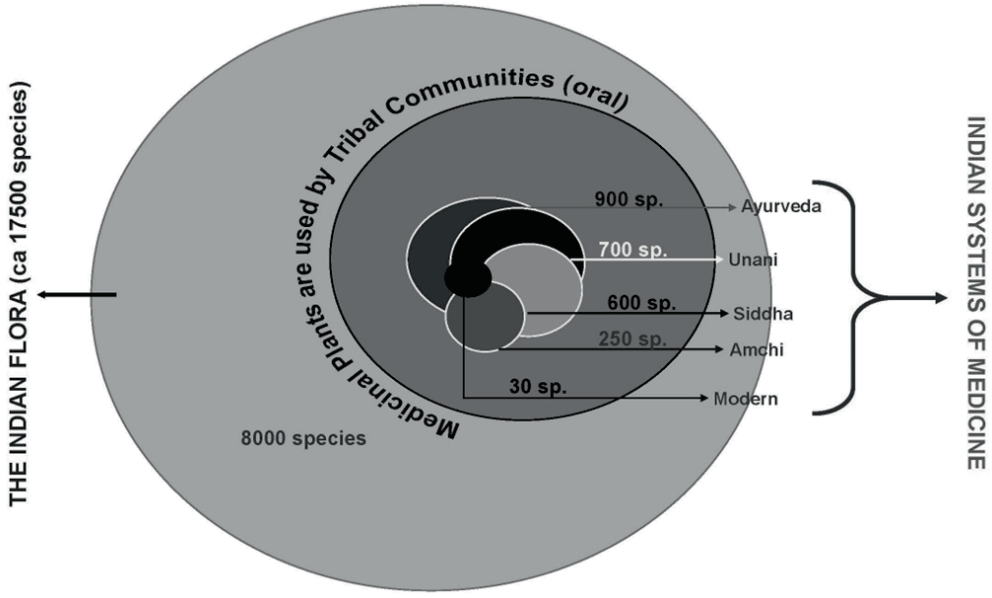
Taking a step forward for pharmaceutical integration!!!!!!



STEPS Forward…..to conclude for pharmaceutics



India's strength in Herbal Technology



THE GLOBAL HERBAL MEDICINE MARKET SIZE

US$ 550 billion(2030)

HERBAL DRUGS
Growing popularity

US$ 83 billion (2019)

February 16, 2021 07:49 ET Source: insightSLICE
(https://www.globenewswire.com)

Domestic Market of Indian System of Medicine (Rs. 4205 crores)

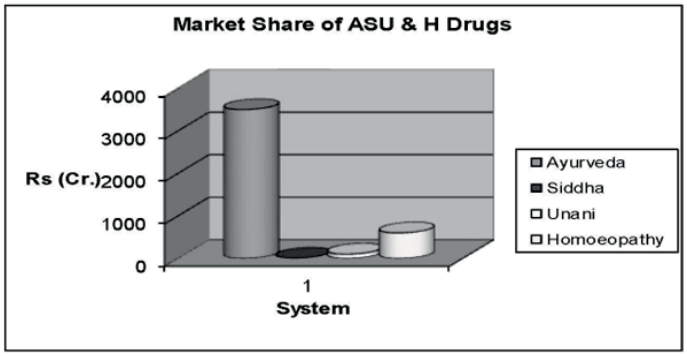
Ayurveda 3500 Cr.

Homeopathy 600 Cr.

Siddha 5 Cr.

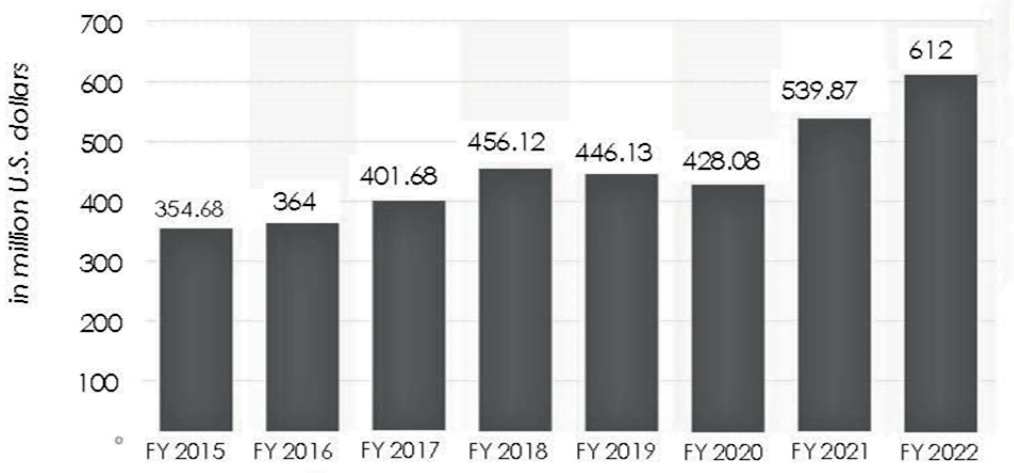
Unani 100 Cr.

Total 4205 Cr.



Annual Growth rate more than 11%.
Bigger Pharmaceutical companies are also attracted to this market.

- **Export value of Ayurvedic and herbal products from India from financial year 2015 to 2022 (in million U.S. dollars)**



Source: Directorate General of Commercial Intelligence and Statistics (DGCIS), Ministry of Commerce and Industry, GOI

- Total varieties of Medicinal Plants in India- 5662
- Species Traded – 460
- Species Exported – 178

Leading Medicinal Plants with respect to Trade

- Phyllanthus officinalis (Amla) - 10,000 Tonnes
- Glycyrrhiza glabra (Mulethi) - 5,000 Tonnes
- Saraca asoka (Ashok) - 1,200 Tonnes
- Strychnos vomica (Nux vomica) - 1,200 Tonnes
- Tinospora cordifolia (Guduchi) - 1000 Tonnes

178 species have annual consumption levels in excess of 100 metric tons

Source:

1. https://cdn.ayush.gov.in/wp-content/uploads/2021/03/National-AYUSH-Mission-.pdf
2. https://www.thehealthsite.com/news/india-ranks-second-in-the-world-after-china-in-exportof-medicinal-plants-18010/

Registered Companies Manufacturing Ayurvedic, Siddha, Unani and Homoeopathy Medicines

As per Ministry of AYUSH's Annual StatisticalPublication "AYUSH IN INDIA-2020", the total numbers of Ayurvedic, Unani and Homoeopathic Licensed Pharmacies (manufacturing units) is as follows

S. No	Name of the Ayush System of medicine	Total numbers of Licensed Pharmacies (manufacturing units) as on 01.04.2020
1	Ayurveda	6998
2	Unani	576
3	Homoeopathy	340
	Total	**7914**

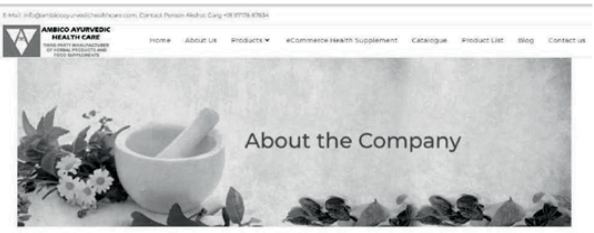
Source:
https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1845009
Posted On: 26 JUL 2022 5:04PM by PIB Delhi

Office of State Licensing Authority, Tamil Nadu

S No	Name of the Ayush System of medicine	Total numbers of GMP manufacturing units as on 01.12.2022
1	Siddha	222
2	Ayurveda	142
3	Unani	011
4	Combined	081
	Total	**456**

Source:
Office of State Licensing Authority,
Arumbakkam, Chennai-600106

Ashwagandha – An Example



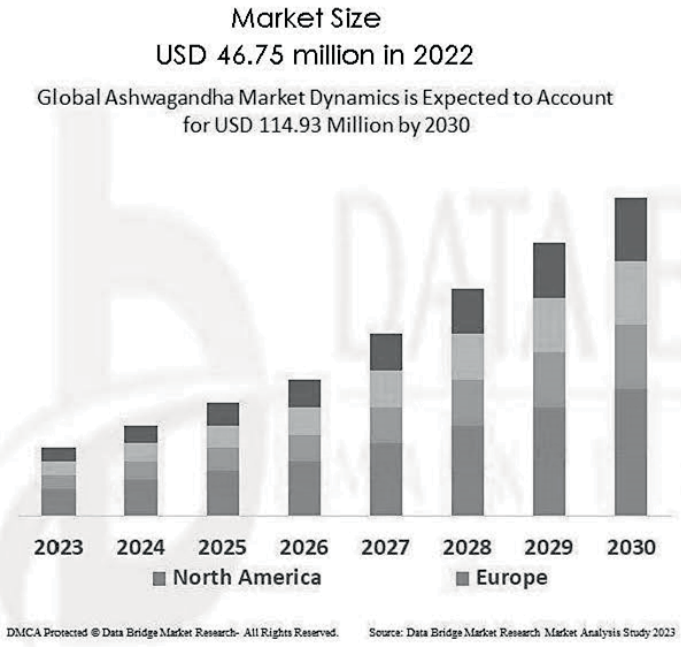
The annual requirement of Withania sominifera in India is about **9127 MT** where as the estimated production in India is only **5905 MT**.

Standardized extracts
Withanolides Content

1% Withanolides	Type
2% Withanolides	KSM-66
2.5% Withanolides	Sensoril
5% Withanolides	Hydro-alcoholic Ashwagandha.
10% Withanolides	Crude Ashwagandha

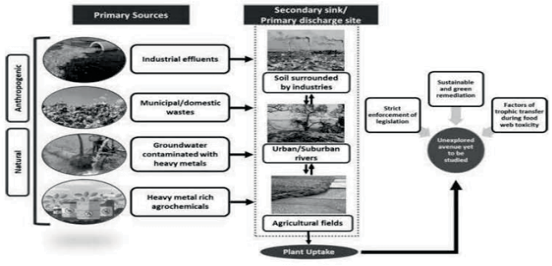
- Fully automatic plant
- In house labs for testing product quality with complete COA REPORT.
- Daily production of 300000 bottles of syrup, 5 lac capsule, 10000 bottles of juice, 20000 bottles of oil
- WHO GMP Certified
- ISO 9001:2015 Certified
- Ayush Certified
- FSSAI Certified
- Delivery All over the World
- Over 45 Years of Experience
- Extensive choice of MLM Products
- 24/7 Customer Service

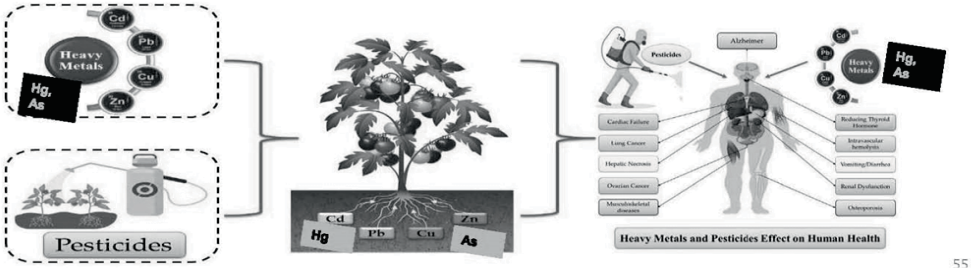
Medicinal Uses:
Improved Stamina
Improved Immunity
Overall Wellbeing
Reduced Anxiety and Stress
Brain Health
Muscle Strength



Need of Standardization

- Heavy Metal complaints
- Pesticide Residues
- Adulterants





55

Cost variation

Drug	Dosage	Formulation	Min. cost (INR)	Max. cost (INR)	% Cost variation
Shunthi Churna	3gm BD	100 gm	52	180	246
Simhanaad guggulu	500mg BD	60 tabs	56	149	166
Vaisvanar Churna	3gm BD	60 gm	72	96	33
Maharasnadi Kadha	30ml BD	450 ml	170	350	105
Aamvaatari Ras	250mg BD	60 tabs	54	135	150
Yograaj gug-gulu	500 mg BD	60 tabs	65	180	176
Chitrakadi Vati	250 mg BD	60 tabs	50	160	220

Adulterants & Diseases

S.N.	Name of Product	Common Adulterant	Disease Caused
1	Black pepper	Dried papaya seeds	Stomach irritation, liver damage, cancer
2	Arahar	Yellow dye, Kesari dal	Leprosy, paralysis
3	Coffee powder	Chicory	Deprived from nutrition Value
4	Gram dal	Kesari dal, clay, stone	Lathyrism
5	Butter and pure desi ghee	Starch, Vanaspati ghee	Food poisoning
6	Milk Water	starch, fatless milk	Stomach disorder
7	Jeera	Stone, alike seeds from wild Plants	Stomach disorder, liver damage
8	Chilly powder	Brick powder, artificial colours	Liver damage, stomach irritation
9	Sugar	Fine white sand, chalk powder, rawa	Stomach disorder
10	Cereals	Stone pieces, mud, ergot seeds	Stomach disorder

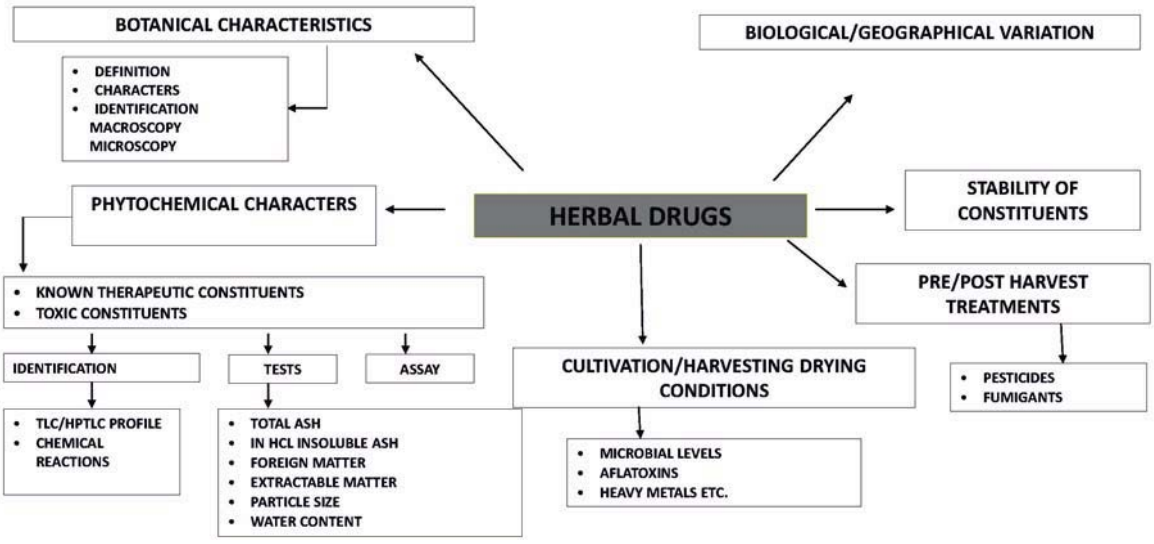
Adulterants & Diseases

To ensure quality, safety and efficacy of Ayurvedic, Siddha, Unani and Homoeopathic medicine Some standards were set by different countries

Herbal medicine regulation in EU, US and India.

Country	Regulatory authority	Description	Regulation/Act
EU	European Medicines Agency (EMEA): The Committee on Herbal Medicinal Products (HMPC)	Establishment of HMPC and regulation of herbal medicine	Directive 2004/24/EC (Traditional Herbal Medicinal Products Directive) and Regulation (EC) No 726/2004.
		Registration Procedure for traditional herbal medicinal products	Articles 16a to 16i of Directive 2001/83/EC
US	USFDA: Center for Drug Evaluation and Research (CDER)	Botanical drug definition	201(g)(1)(B), Federal Food, Drug, and Cosmetic Act
		Regulation of herbal product	Dietary Supplement Health and Education Act of 1994 (DSHEA)
		Procedure for marketing of Botanical drug as OTC drug	21 CFR 10.20, 10.30, 312, 314, 321, 324, 330, 331–358
	Center for Biologics Evaluation and Research (CBER)	Regulation of Allergenic extracts and vaccines that contain botanical ingredients	Section 351 of the Public Health Service Act (42 U.S.C. 262).
India	Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)	Production and marketing of ASU drugs	Drugs & Cosmetics Act, 1940 Drugs & Cosmetics Rules, 1945
		GMP for ASU drugs	Schedule T, Drugs & Cosmetics Act, 1940

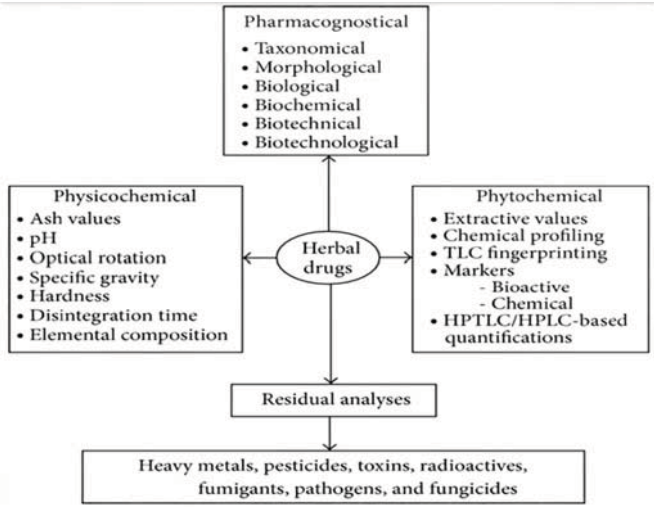
SPECIFICATIONS OF HERBAL DRUGS



Standardization

Chemical standardization, which decides the pharmacological action of drug

Triple 'P' Standardization



IDENTIFICATION

(Mandatory tests to identify the drug)

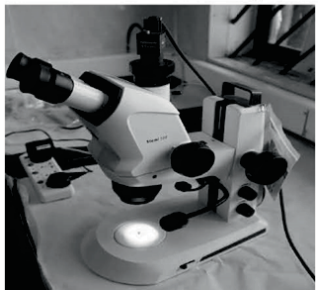
Macroscopic botanical characters:

Size, shape, colour, odour, taste, texture & fracture, etc.

Microscopical botanical characters:

- Microscopic examination of transverse section
- Powder microscopy

Stereo zoom Microscope



Compound Microscope

Fluorescence Microscope

Herbarium Scanner

Scanned Herbarium

A Set of Studies

S. No	Test parameter
1	Description Form, Colour, Odour, Taste, Texture, Size, Fracture, Etc.
2	Determination of pH
3	Determination of Total solids
4	Determination of Loss on Drying at 105°C
5	Determination of Total ash
6	Determination of Acid-insoluble ash
7	Determination ofWater-soluble extractive
8	Determination of Alcohol- soluble extractive
9	Determination of Volatile oil content
10	Determination of Fat content
11	Determination of Reducing sugar
12	Determination of Total sugar
13	Determination of Refractive index at 25°C
14	Test for heavy metals Lead, Cadmium, Mercury, Arsenic Using A.A.S and ICP-OES
15	Determination of Iodine value & Saponification value
16	Determination of Acid value
17	Determination of Peroxide value
18	Identifications using TLC/HPTLC/HPLC
19	Disintegration test
20	Determination of Uniformity of content
21	Hardness
22	Determination of Particle size
23	Test for Methanol
24	Determination of Assay (Ca, Fe, Na, K, etc.) Na and K using Flame Photometry
25	Determination of Resin Content

The First Line Analytical Techniques

High Performance Thin layer chromatography (TLC) and Liquid Chromatography (LC):

- Described under Tests
- Always under identification even GLC or HPLC are subsequently used
- Aimed at identifying the chromatogram of the drug with respect to Chemical Reference Substances (CRS).

Other than these various instruments are used in Herbal Drug Standardisation as shown below

HPLC

Flash Chromatography

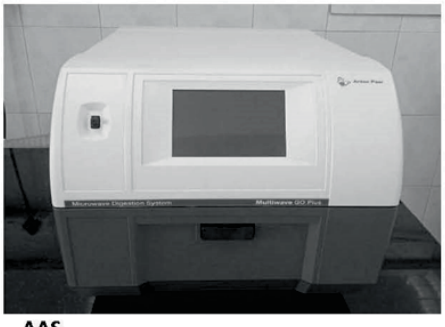
HPTLC

LC-MS

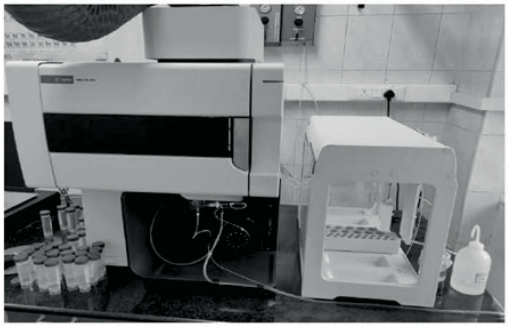
66

Flame photometry

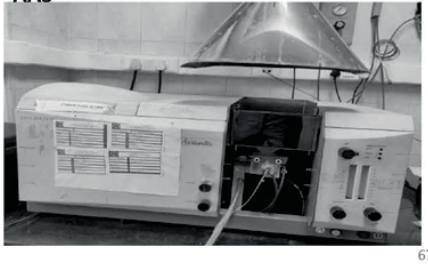
Microwave digester



ICP-OES



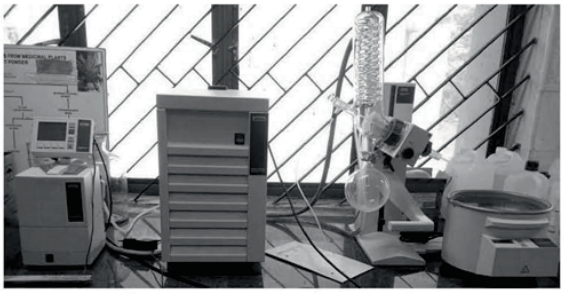
AAS



67

Uv-Vis Spectroscopy

Rotary evaporator

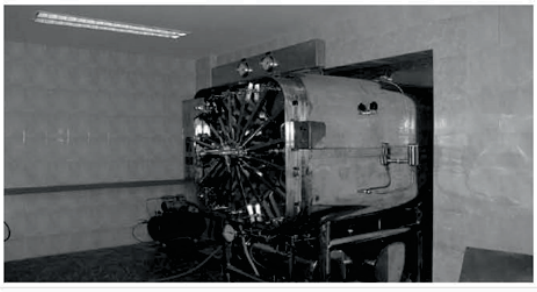


Other minor equipments

68

Animal house Facility

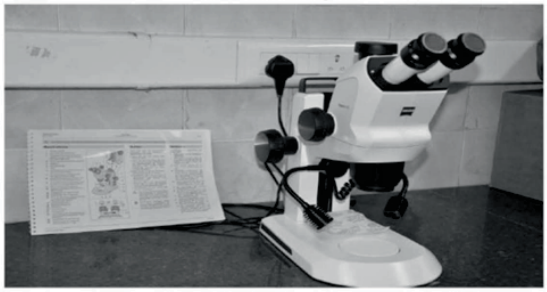
Industrial size autoclave



Rat Mice Cages with trolley and other accessories

Manual Rotary Microscope

Stereo Microscope 1

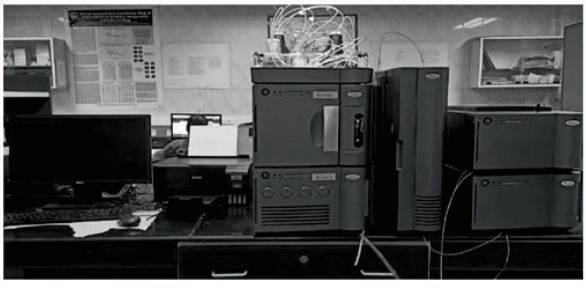


Plethysmometer

Hematology Analyzer

ELISA Reader and Washer

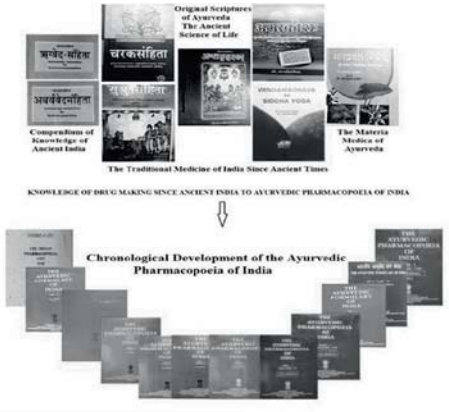
UHPLC



Power Lab

Clinical Chemistry Auto Analyser

The Pharmacopoeial standards are basic need to ensure quality, safety and efficacy of Ayurvedic, Siddha, Unani and Homoeopathic medicines.

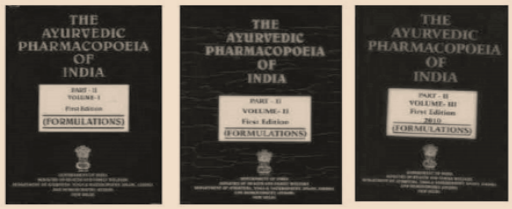


The first part of the Ayurvedic Formulary of India was published in 1978 and thereafter, the Ayurvedic Pharmacopoeia of India (mono-monograph) Part-I, Vol. I was published in the year 1989 and subsequently, the other volumes were published with their legalized status under Drugs and Cosmetics Act, 1940.

PHARMACOPOEIAL STANDARDS

AYURVEDIC PHARMACOPOEIA OF INDIA Part I

AYURVEDIC PHARMACOPOEIA OF INDIA Part II



AYURVEDIC FORMULARY OF INDIA

Macroscopic & Microscopic Atlas of Pharmacopoeial Drugs

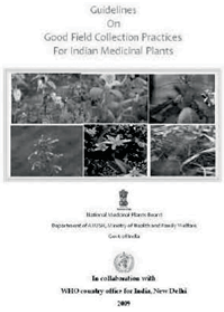
OTHER STANDARDS

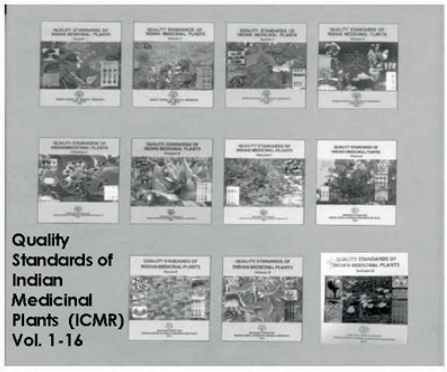
AYUSH STANDARD MARKS

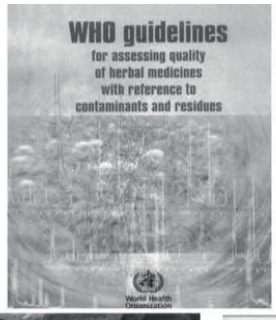
AYUSH Premium Mark:
Broadly based on international requirements

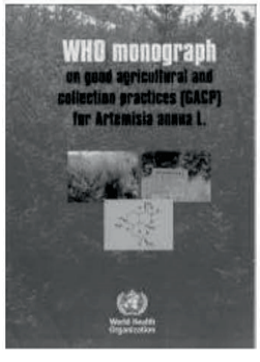
AYUSH Standard Mark:
Based on compliance to the domestic regulatory requirements

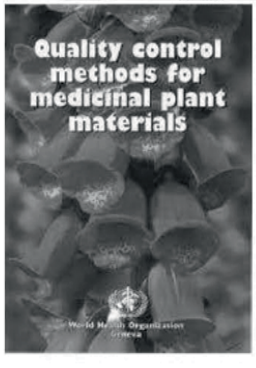
2024

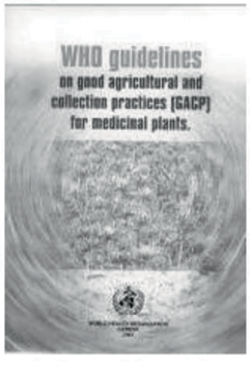




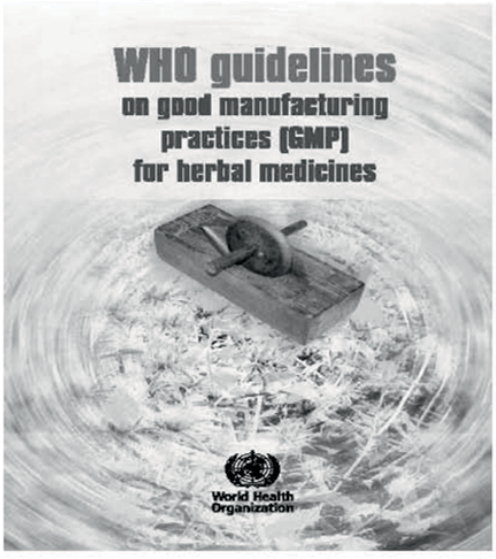


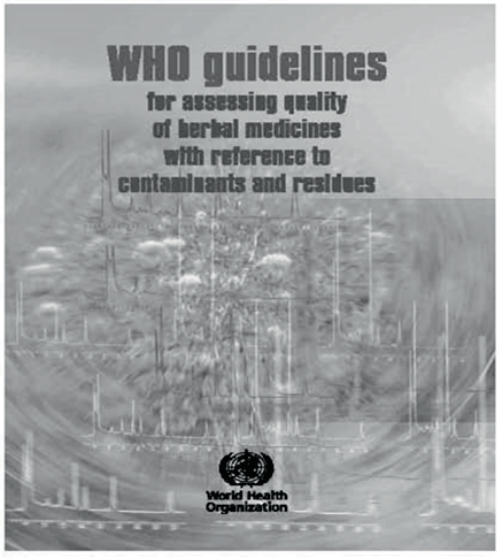




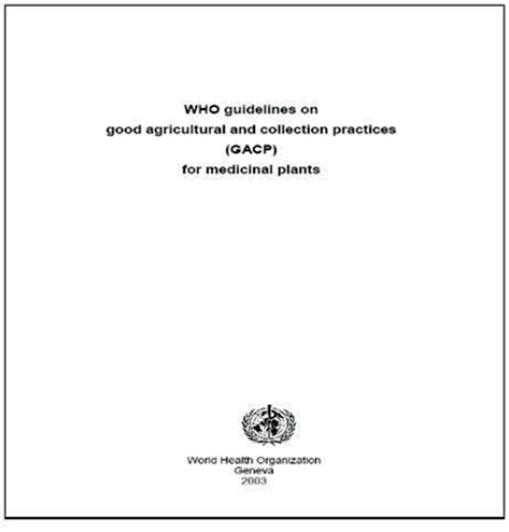


Quality Assurance

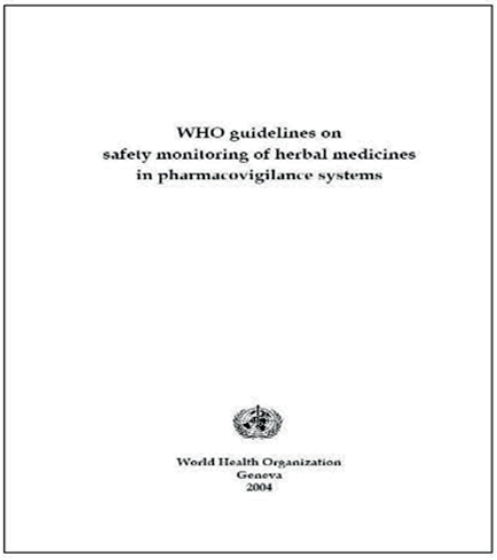


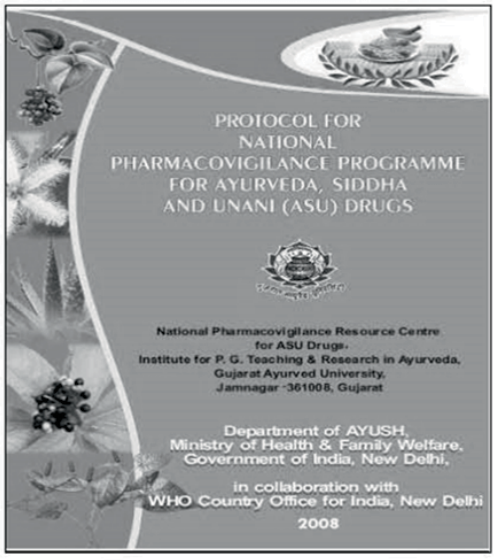


Quality of Raw Materials

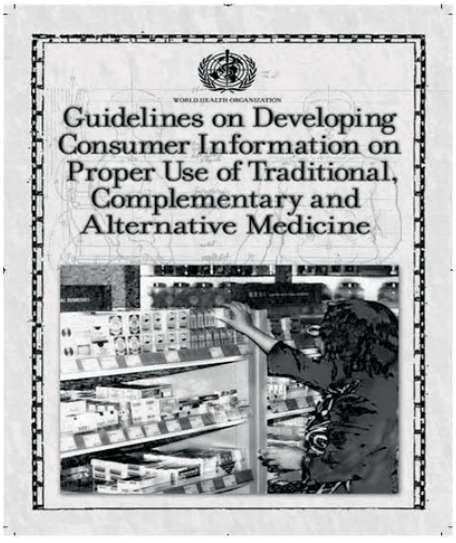


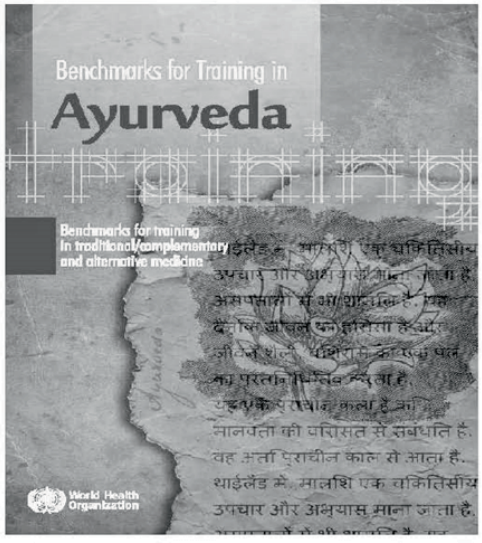
Safety Monitoring





Rational Use and Training





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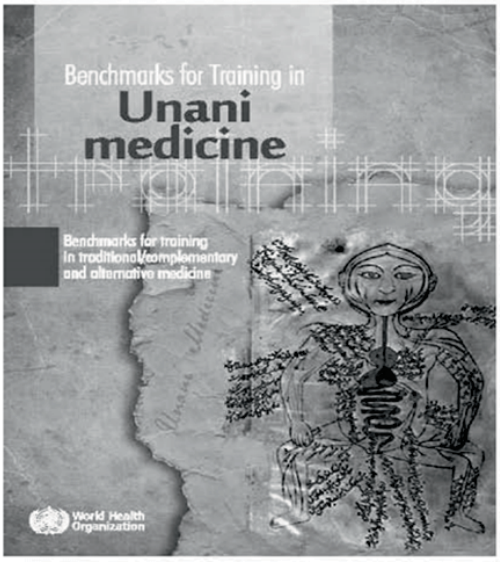

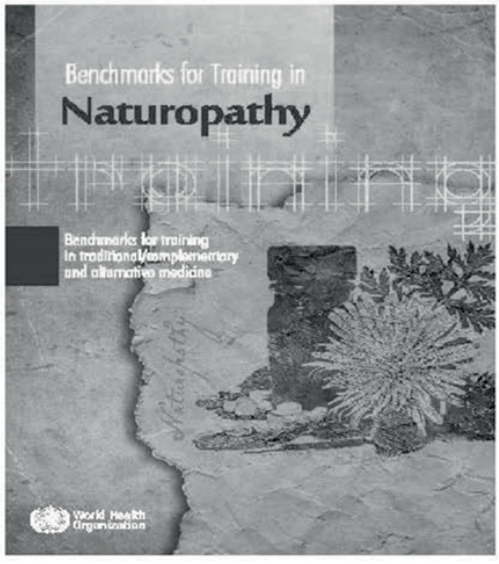

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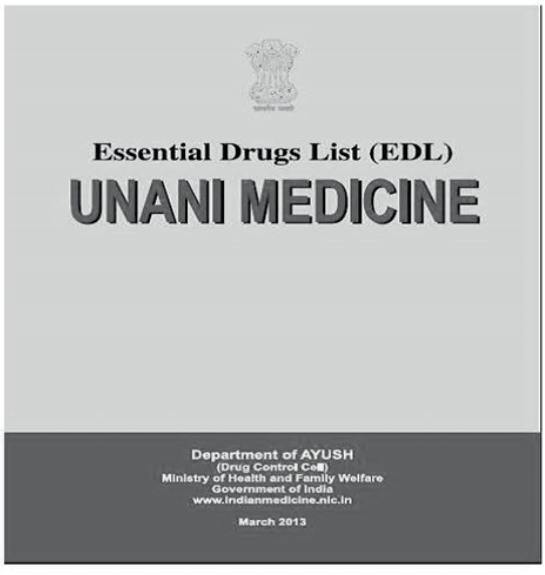

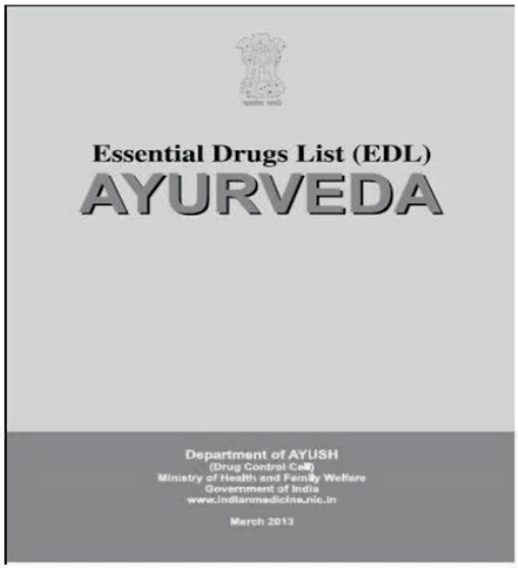

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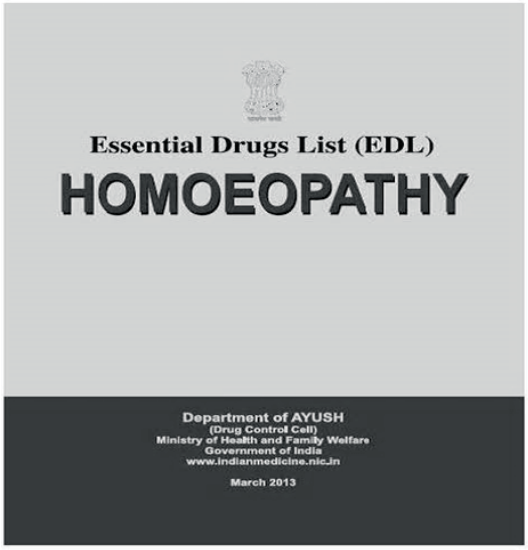
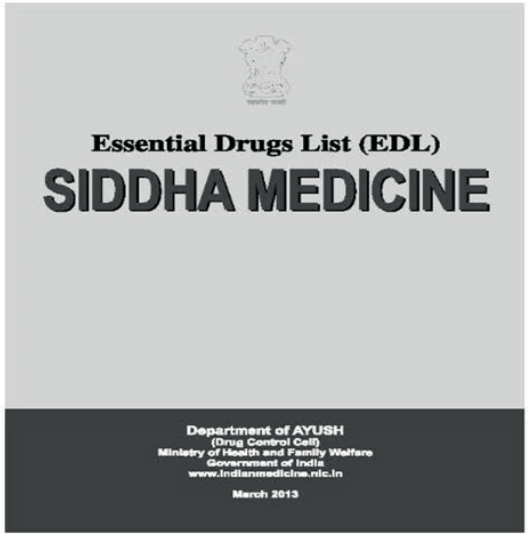
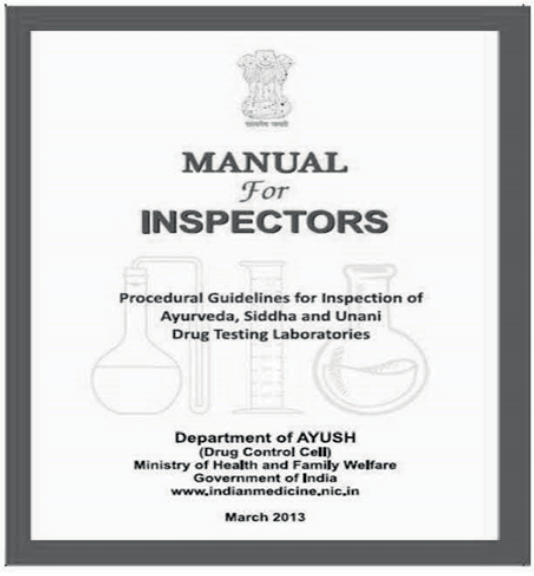
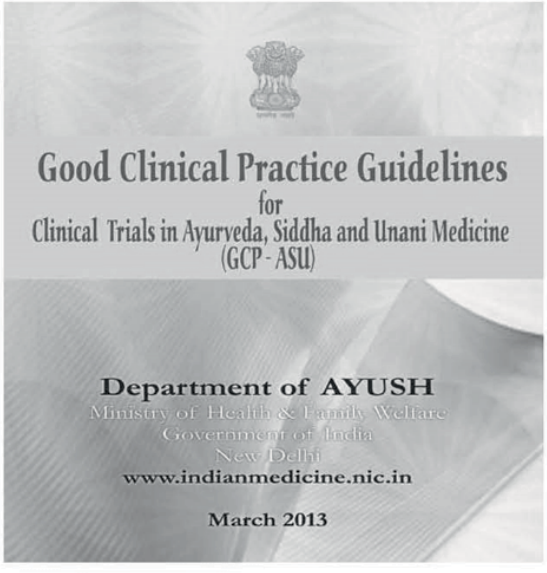




Safety, Efficacy, Quality





INFORMATION

G. Rangachari Memorial (PG Pharmacy Fellowship) Awards 2024

Tamilnadu Pharmaceutical Sciences Welfare Trust, is a subsidiary of IPA (Tamilnadu Branch) started in 1989 and has been doing service to profession of Pharmacy in assisting the students as well as the industry. We have a small library and also provide abstracts and text articles to under graduate and post graduate students and supporting to the IPA Tamilnadu Branch activities like seminars, conferences etc.

Apart from above, from year 1998, we initiated Research fellowship award to selected M.Pharm and latter Pharm D (2013) final year students from various colleges in Tamilnadu, for their ongoing project work. Every year, in September we call for synopses of their projects from students, codify the synopses and sent to an evaluator outside the state of Tamilnadu for evaluation. Based on the report we make cash awards for the first, second and third ranks.

This is now in its 27th year, has received a total of 195 applications, comprising 138 from M.Pharm comprising six different branches and 57 from Pharm D from 22 Institutions.

All synopses were sent to **Dr. L. Sathiyanarayanan**, Vice Principal, Poona College of Pharmacy, Bharathi Vidyapeeth University, Pune – 411038, and his team for evaluation. Based on the ranking, 21 students have been selected for Awards as per the following details:

PHARMACEUTICS			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Mr. Jawathu. A	PSG College of **Pharmacy, Coimbatore**	12,000
2nd	Ms. Aeiysha. B	JSS College of **Pharmacy, Ooty**	10,000
3rd	Mr. Pranam Prabhu. G	JSS College of **Pharmacy, Ooty**	8,000

PHARMACEUTICAL CHEMISTRY			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Ms. D. Melphiya	JSS College of Pharmacy, Ooty	12,000
2nd	Ms. G. Gishmi	COP, Madras Medical College, Chennai	10,000
3rd	Mr. Sagarkanta Mohanty	JSS College of Pharmacy, Ooty	8,000

PHARMACEUTICAL ANALYSIS			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Mr. H. Mohammed Idrees	COP, Madras Medical College, Chennai	12,000
2nd	Mr. R. Jawaharsamuvel	COP, Madras Medical College, Chennai	10,000
3rd	Mrs. Meera Gomathi. M	COP, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	8,000

PHARMACOLOGY			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Mr. Raghul L R V	JSS College of Pharmacy, Ooty	12,000
2nd	Ms. Devadharuna V M	JSS College of Pharmacy, Ooty	10,000
3rd	Ms. Rashi Jain	JSS College of Pharmacy, Ooty	8,000

PHARMACOGNOSY			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Ms. T. Tanamani Jenifer	COP, Madras Medical College, Chennai	12,000
2nd	Ms. Mounika A.R	Sri Ramachandra Faculty of Pharmacy, SRIHER, Chennai	10,000
3rd	Mr. Ponmadasamy. M	College of Pharmacy, Maduria Medical College, Madurai	8,000

PHARMACY PRACTICE			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Ms. Sneha. R	Sri Ramachandra Faculty of Pharmacy, SRIHER, Chennai	12,000
2nd	Mr. M. Jegatheeswaran	SRM College of Pharmacy, SRMIST	10,000
3rd	Ms. Pavithra. S	Sri Ramachandra Faculty of Pharmacy, SRIHER, Chennai	8,000

Pharm D			
Rank	**Name**	**College**	**Prize Amount (Rs.)**
1st	Ms. Jaishree. M, Mr. Abishek. M, Mr. Sri Harish Kumar. S	SRM College of Pharmacy, SRMIST, Chennai	15,000
2nd	Ms. A. Arshada Fathin, Mr.Adarsh. S	PSG College of Pharmacy, Coimbatore	12,000
3rd	Ms. Nila. P, Ms. Nimmy Mariam John, Ms. Pooja. R , Ms. Seema Bhegam. M. R.	KMCH College of Pharmacy, Coimbatore	10,000

Shri. G. Swaminthan Memorial Award - Essay Competition 2024

TNPSWT imitated a new activity from 2011 for Essay competition and this year subject being **"Pharmacists: Meeting Global Health Needs"**. This awarded is in the name of **"Shri. G. Swaminthan Memorial Award"** -- Sponsored by M/s. Pharm Product Pvt Ltd. Thanjavur.

This year we have received 124 applications from 27 Colleges and this was evaluated by **Dr. A. Ramesh**, Principal, Vishnu Institute of Pharmaceutical Education & Research, Vishnupur, Telangana.

Based on the rating -- 3 students have been awarded as below

Rank	Name	College	Prize Amount (Rs.)
1st	Ms. Saranya Devi. C S	PSG College of Pharmacy, Coimbatore	10,000
2nd	Ms. Mohamed Raashith	Sir ISSAC Newton College of Pharmacy, Pappakovil, Nagapattinam	8,000
3rd	Mr. Surya. K	PSG College of Pharmacy, Coimbatore	7,000

The above awards were sponsored by **Mr. T. Ravichandran, M/s. Pharma Products Pvt Ltd**, Thanjavur for the above awards.

Fourrts University Merit Award 2024

From year 2015 M/s. Fourrts India ltd sponsored university merit award for topper candidates, who have secured high marks in B.Pharm examinations passed during September 2023, examinations held in December 2023 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Rank	Name	College	Prize Amount (Rs.)
1st	Ms. Fathima Neha. H (561972034)	K.M.C.H. College of Pharmacy, Coimbatore.	10,000
2nd	Ms. Menaka. M (561990047)	Aadhi Bhagawan College of Pharmacy, Cheyyar.	8,000
3rd	Ms. Sandhiya. S (561990065	Aadhi Bhagawan College of Pharmacy, Cheyyar.	7,000

The above awards were sponsored by **Dr. S. V. Veerramnai**, Chairman & Managing Director, **M/s. Fourrts (India) Laboratories Pvt Ltd**, Chennai, for the above awards

EVENTS

National Conference & NPW Valedictory

The Indian Pharmaceutical Association (IPA), Tamil Nadu State Branch, hosted a landmark event on December 23, 2024, at the Silver Jubilee Auditorium of The Tamil Nadu Dr. M.G.R Medical University, Guindy, Chennai. The event combined the **National Conference on Current Trends in Pharmaceuticals** with the valedictory function of the 63rd National Pharmacy Week, theme **"Think Health, Think Pharmacy."**

The Chief Guest, **Thiru. Ma. Subramanian,** Honourable Minister for Health & Family Welfare, Government of Tamil Nadu, highlighted the vital contributions of the pharmaceutical sector to healthcare and praised the integration of cutting-edge technologies within the industry. The Vice Chancellor of The Tamil Nadu Dr. M.G.R Medical University, **Dr. K. Narayanaswami,** delivered a special guest address, emphasizing the evolving role of pharmacy professionals.

Key Sessions

The conference featured insightful technical sessions delivered by eminent speakers, including:

- **Artificial Intelligence Transforming the Pharma Industry** by Shri. Duraisamy Rajan Palani, Founder & CEO, Archimedis Digital.
- **Regulation and Opportunities in Medical Devices** by Shri. NG Badari Narayan, S3V Vascular Technologies Ltd., Mysuru.
- **Current Technological Developments of AYUSH Drugs** by Dr. R. Ilavarasan, Retired Assistant Director, CSMCARI, Ministry of Ayush, Govt. of India, Chennai.

Felicitations and Awards

The IPA-TN recognized excellence through its prestigious award function:

- Best Pharmacist Award 2024: Mr. K. Pandiyan, General Manager, Saimirra Innopharm Pvt. Ltd., Chennai.

·**Special Recognition Awards:**

- **Pharmacy Education**: Prof. Dr. A. Shantha, Former Joint Director (Pharmacy), DME.
- **Regulatory Affairs Award:** P. Veluswamy, Former Deputy Drug Controller, TN DCA.
- **Industrial Pharmacist Award:** T. Muniswamy Naidu, Restech Formulations Pvt. Ltd., Pondicherry.
- **Hospital Pharmacist Award:** Dr. K.T. Mani Senthilkumar, COO, Royal Care Hospital, Coimbatore.
- **Best Community Pharmacist Award**: T. Natarajan, Proprietor, Janaki Pharmacy, Adyar, Chennai.

Shri. M.N. Srindhar, Director of Drugs Control, was felicitated for his newly assigned position.

Contributions of TNPSWT

The Tamil Nadu Pharmaceutical Sciences Welfare Trust (TNPSWT), a subsidiary of IPA-TN, has supported the profession since 1989 by assisting pharmacy students and the industry.

- **Research Fellowships**: This year, 21 students from a pool of 195 applicants received awards.
- **Essay Competitions:** With the theme **"Pharmacists – Meeting Global Health Needs,"** the G. Swaminathan Memorial Award recognized three winners out of 124 entries from 27 colleges.
- **Fourrts University Merit Award 2024**: Sponsored by M/s. Fourrts India Laboratories, this award honored students with the highest B.Pharm marks from Tamil Nadu Dr. M.G.R Medical University

All awards were presented by the Honourable Minister for Health & Family Welfare.

Closing Remarks

The event concluded with a heartfelt vote of thanks from Shri. T. Sathish, Secretary, IPA-TN. Attended by over 1,500 pharmaceutical professionals from across Tamil Nadu, the conference served as a vibrant platform to explore innovations, address challenges, and reinforce the pharmaceutical sector's commitment to public health and collaboration.

World Pharmacist Day 2024 Celebrations at Mother Terasa College of Pharmacy

Mother Terasa College of Pharmacy, Illuppur, Pudukkottai, celebrated World Pharmacist Day on September 25, 2024, with great enthusiasm. The event featured Dr. Balakumar Pitchai, Professor & Director of Research Training & Publications at Periyar Maniammai Institute of Science & Technology, Thanjavur, as the Chief Guest. In his inspiring address, Dr. Balakumar emphasized the pivotal role of pharmacists in global healthcare and urged students to uphold ethical values in their profession.

Mr. R. C. Uthaya Kumar, Chairman of the Mother Terasa Group of Institutions, extended his support and encouragement. The celebrations began with a welcome address by Principal Dr. T. Shri Vijaya Kirubha, highlighting the significance of the day in honoring pharmacists' contributions.

The event featured engaging competitions like poster presentations, essay writing, and sports, showcasing students' talents and teamwork. Winners were recognized during a special award ceremony. The programme concluded with a vote of thanks by Mrs. A. Gayathri, Assistant Professor, leaving attendees inspired and motivated to contribute to public health and society.

A Seminar on “Bridging the Gap: From Bachelors of Pharmacy to Industry Professionals

The Department of Pharmaceutics, Periyar College of Pharmaceutical Sciences, Tiruchirappalli, Tamil Nadu organised a Seminar on the topic “Bridging the Gap: From Bachelor of Pharmacy to Industrial Professional. Totally 80 participants took part in this seminar. The event began with a welcome address by Professor Dr. R. Rajagopalan, Head Department of Pharmaceutics the organizer of this Seminar.

It was felicitated by the Principal Prof. Dr. R. Senthamarai and the session was handed over to the guest speaker Mr. B. Venkatesh, Drugs Inspector of Madurai South Zone under Tamil Nadu Drugs Control Administration, Government of Tamil Nadu. He has provided with valuable insights and information's on a topic that is essential to the Students Education and Future Careers in pharma industry. Especially he has shared his thoughts of knowledge and preparation strategies to crack the GPAT, Drugs Inspector exams etc. The session was ended with a interaction session. Finally vote of Thanks was proposed by Mrs. S. Priya Dharshini, Assistant Professor, Department of Pharmaceutics, followed by a warm and enthusiastic applause, marking the successful end of the event.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th August, 2024

S.O. 3284(E).— Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Etodolac + Paracetamol vide notification number S.O. 4706 (E), dated the 7th September, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii), dated the 7th September, 2018;

And Whereas, the said notification was challenged by M/s. Emcure Pharmaceuticals Ltd. in W.P. (C) No. 10098/2018 before the High Court of Delhi, claiming that fixed dose combination of S(+) Etodolac + Paracetamol is not covered under the notification;

And Whereas, the Hon'ble High Court of Delhi has passed judgement dated 22nd January, 2020, the operative part of the which is reproduced below:-

"This court is of the view that the Impugned Notification, in so far as it is stated to be applicable to the FDC of S(+) Etodolac + Paracetamol cannot be sustained. The same is set aside. The matter is remanded back to DTAB/Sub-committee constituted by it to examine the issue regarding the said FDC in accordance with the directions issued by the Supreme Court in Pfizer Limited and others (Supra). The DTAB/Sub- Committee shall submit its report to the Central Government who may act thereon in accordance with law.";

And Whereas, the Drugs Technical Advisory Board in its 88th meeting held on 26th September, 2022 deliberated the issue and recommended for constitution of a DTAB Sub- committee to examine the matter in light of the judgement passed by the Hon'ble Delhi High Court;

And where as, the DTAB Sub-Committee considered the said fixed dose combination as irrational and recommended for its prohibition in public interest under section 26A of Drugs and Cosmetics Act, 1940; And Whereas, based on the recommendation of DTAB Sub- committee, matter was further deliberated in 90th meeting of Drugs Technical Advisory Board held on dated 25th January, 2024 and made recommendation for prohibiting the manufacture, sale and distribution for human use of fixed dose combination of S(+) Etodolac + Paracetamol;

Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug fixed dose combination of S(+) Etodolac + Paracetamol with immediate effect as the said drug is found to have no therapeutic justification and may involve risk to the human beings.

[F.No. X.11035/485/2017-DRS]
RAJIV WADHAWAN, Advisor (Cost)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 25th September, 2024

S.O. 4197 (E).— In exercise of the powers conferred by sub-section (2) of section 20 ofthe Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby makes the following amendment further to amend the notification of the Ministry of Health and Family Welfare (Department of Health and Family Welfare) vide number S.O. 2177(E), dated the 11th May, 2023, published in Gazette of India, Extraordinary Part II, Section 3, Sub-section (ii), namely:—

In the said notification, for item numbers (ii), (iv), (viii) and (ix) and the entries relating thereto, the following shall be substituted, namely:—

" (ii) Dr. Anjan Pal, Senior Scientific Officer (Microbiology)

(iv) Dr. Dilip Kumar Panda, Technical Officer (Pharmacology)

(viii) Dr. Dipak Shivaji Harel, Junior Scientific Officer (Pharmaceutical Chemistry)

(ix) Shri Inder Singh Rawat, Technical Officer (Bacteriology)".

[F.No. X.11035/101/2024-DRS]
RAJIV WADHAWAN, Adviser (Cost).st)

MINISTRY OF HEALTH AND FAMILY WELFARE

CORRIGENDUM

New Delhi, the 25th October, 2024

G.S.R. 666(E).—In the notification of the Government of India, Ministry of Health and Family Welfare, published in the Gazette of India, Extraordinary Part II, Section 3, Sub-Section(I) vide G.S.R. 922(E) dated the 28th December, 2023-

(1) Under Short title and commencement for the words "(1) These rules may be called the Drugs (….. Amendment) Rules, 2023" the following shall be substituted as, :- (1) These rules may be called the Drugs (Second Amendment) Rules, 2023.

(2) in the Note for the words "notification number G.S.R (E), dated……" the following shall be substituted as, :- "notification number G.S.R 410 (E), dated 2nd June, 2023".

[F. No. X-11014/2/2017-DRS]
RAJIV WADHAWAN, Adviser (Cost).

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th December, 2024

S.O. 5330(E).— In exercise of the powers conferred by sub-rule (2) of rule 19 of the Medical Devices Rules, 2017, 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) number S.O. 2237(E), dated the 1st June, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), namely:-

In the said notification, in the table,

(i) in serial number (2), in column (3), after the word, "Condoms", the following shall be inserted, namely: -

", Surgical Gloves and Medical examination Gloves";

(ii) in serial number (3), in column (3) after the word, "Disinfectant", the following word shall be inserted, namely:-

", Surgical Gloves and Medical examination Gloves";

(iii) in serial number (5), in column (3) after the word, "and Falope Rings", the following shall be inserted, namely:-

", Surgical Gloves, Medical examination Gloves, Cotton Bandages, Anticoagulant Solutions used in blood bags and Disposable syringes".

[F.No. X. 11035/29/2024-DRS]
RAJIV WADHAWAN, Advisor (Cost).

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 2237(E), dated the 1st June, 2018 and last amended vide notification number S.O. 1928(E), dated the 25th April, 2023.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th December, 2024

S.O. 5633(E).—WHEREAS the Central Government is satisfied that the use of drug formulations containing Nimesulide 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 all formulations of Nimesulide for animal use;

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

"Nimesulide and its formulation for animal use"

[F. No. X. 11035/100/2024-DRS]
RAJIV WADHAWAN, Adviser (Cost)

NOTIFICATION

New Delhi, the 10th December, 2024

S.O. 5331(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with sub-rule (1) of rule 18 of the Medical Devices Rules 2017, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 3739(E), dated, the 2nd August, 2022 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), dated the 8th August, 2022 except as respects things done or omitted to be done before such supersession, the Central Government hereby designates the following Government Analysts specified in column (2) of the Table given below as Medical Device Testing Officers in respect of the Medical Devices as specified against their names in column (4) of the said table, namely :-

Serial No.	Name of Government Analyst	Name of Laboratory	Medical Device (s)
(1)	(2)	(3)	(4)
1.	Dr. Saroj Kumar Ghosh	The Central Drugs Laboratory, Kolkata	Sterile and Single use Medical Devices, Non-sterile Medical Devices, Surgical dressings, Gloves for Medical purposes, Disinfectant.
2.	Dr. Rakesh Kumar Rishi		
3.	Dr. Anjan Pal		
4.	Dr. Dilip Kumar Panda		
5.	Smt. Suparna Maitra		
6.	Smt. C. Vijayalakshmi	The Central Drugs Testing Laboratory, Chennai	Mechanical Contraceptives, Gloves for Medical purposes.
7.	Smt. G. Sasikala		
8.	Shri Kishor Gembali		
9.	Shri. C. Hariharan	The Central Drugs Testing Laboratory, Mumbai	Mechanical Contraceptives, Gloves for Medical purposes.
10.	Smt. Sayali U. Warde		
11.	Smt. Akshata S. Paranjpe		
12.	Smt. Sujata S. Kaisare		
13.	Dr. Vijayakumar Munipalli		
14.	Smt. Sukhada A Navaratne		
15.	Shri. Amar Jyoti Chamuah	The Regional Drugs Testing Laboratory, Guwahati, Assam	Sterile and Single Use Medical Devices, Non-sterile Medical Devices, Gloves for Medical purposes.
16.	Shri. Dilip Kr. Sarkar		
17.	Smt. Rinku Kalita		
18.	Shri. Hitesh Kumar Khare	The Regional Drugs Testing Laboratory, Chandigarh	Sterile and Single Use Medical Devices, Non-sterile Medical Devices, Surgical dressings, Gloves for Medical purposes.
19.	Dr. Debasis Maiti		

Serial No.	Name of Government Analyst	Name of Laboratory	Medical Device (s)
(1)	(2)	(3)	(4)
20.	Dr. Rajesh Kumar Sharma	The National Institute of Biologicals, Noida	In-vitro Diagnostic Medical Devices.
21.	Ms. Kanchan Ahuja		
22.	Ms. Ajanta Sircar		
23.	Dr. Richa Baranwal		
24.	Dr. Pankaj Kumar Sharma		
25.	Dr. Varun Singh		
26.	Dr. Gauri Misra		
27.	Dr. Ashwani Kumar Dubey		

[F.No. X. 11035/29/2024-DRS]
RAJIV WADHAWAN, Advisor (Cost).

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Order

File No. DC-DT-15011(11)/85/2024 **Date** 07 AUG 2024

Subject: Specifying names of countries under the Rule 101 of New Drugs and Clinical Trial Rules, 2019 related to new drug approval – Regarding

As per Rule 101 of New Drugs and Clinical Trials Rules, 2019 the Central Licensing Authority, with the approval of the Central Government, may specify, by an order, the name of the countries, from time to time, for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V of the said rules.

In exercise of the powers conferred under Rule 101 of the said rules with the approval of the Central Government, the countries namely; **USA, UK, Japan, Australia, Canada and EU** are hereby specified for following categories of new drugs:-

- Orphan Drugs for rare diseases
- Gene and cellular therapy products
- New drugs used in pandemic situation
- New drugs used for special defense purpose
- New Drugs having significant therapeutic advance over the current standard care.

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

To,

1. CDSCO Website

CC to:

1. PS to Adviser Cost, MoHFW, Nirman Bhawan, New Delhi

File No. DCGI/Legal/Misc-41/2020-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Legal Cell)

FDA Bhawan, Kotla Road,
New Delhi – 110 002
Date: 02-12-2024

Public Notice

Sub: Reconstitution of "Central Expert Committee" to determine the quantum of compensation in respect of faulty ASR Hip Implants manufactured by M/s. DePuy International Limited, U.K. (now M/s. Johnson & Johnson Private Limited) implanted in India - reg.

The Ministry of Health & Family Welfare, Govt. of India (New Delhi) has reconstituted a Central Expert Committee to examine issues related to the faulty ASR Hip Implants manufactured by M/s. DePuy International Limited, U.K. (now M/s. Johnson & Johnson Private Limited) and imported by M/s. DePuy Medical Private Limited, Mumbai (now Johnson & Johnson Private Limited).

The Central Expert Committee is reconstituted under the chairmanship of Dr. Ajay Kumar Shukla, Professor of Orthopaedics, RML Hospital (New Delhi) to determine the quantum of compensation as admissible and medical management for the affected patients who were implanted with faulty ASR Hip implant.

The affected patients who were implanted with faulty ASR Hip Implant and are suffering from disability and other losses may approach either Central Expert Committee or State Level Committee as per their convenience. In case the affected patients intend to approach the Central Expert Committee, they may write an e-mail or send the hard copy by post / by hand to Legal Cell, CDSCO (HQ), FDA Bhawan, Kotla Road, New Delhi – 110 002, Email ID: legalcell@cdsco.nic.in

The ASR patients who have already submitted their claim application before the State / UT Level Committee or Central Expert Committee, need not file any fresh claim application.

In case the affected patients intend to approach State Level Committee, they may write to concerned State / UT Drugs Controllers, who will be the Member Secretary of State Level Committee.

(**Dr. Rajeev Singh Raghuvanshi**)
Drugs Controller General (India)

F.No. IC/36/2024 (E-office)
Government of India,
Ministry of Health and Family Welfare,
Directorate General of Health Services,
Central Drugs Standard Control Organization (HQ),
(International cell)

Date:
09 DEC 2024

CIRCULAR

Subject: Shipment of Drug samples sent by foreign National Regulatory Authorities into India for test, examination, or analysis-regarding

This office has received communications from foreign National Regulatory Authorities (NRAs) requesting to facilitate the clearance of shipments of drug samples sent to India for testing at the authorized drug testing laboratories, to ascertain that only safe, efficacious, and quality drugs are released for their population. It is further informed that any delays in clearing such shipments by Indian port offices will affect the testing & release, and may lead to delayed access of such lifesaving drugs.

In this regard, all port offices of CDSCO are hereby directed that such drug shipments sent by any NRAs of foreign nations are required to be released on a fast-track basis, subject to the fulfilment of the following conditions-

1. The Drug samples shall be sent only by the concerned National Regulatory Authority
2. Drug Samples shall be accompanied by an undertaking stating that the samples have NIL commercial values, and are exclusively used for test, examination, or analysis only
3. The analysis shall be carried out at a testing laboratory possessing valid permission in Form-37
4. The residual samples shall not be returned and shall be disposed of by the testing laboratory as per applicable procedures

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

To:

1. All zonal and sub-zonal offices of CDSCO
2. All port offices (Air/Sea) of CDSCO
3. All stakeholders through CDSCO website (for information)

F.No.10171/DCGI/10/2024-eoffice
Government of India
Directorate General of Health Service
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road,
New Delhi-110002

26 DEC 2024

NOTICE

Sub: Submission of Clinical Trial Site Addition and change of Principal Investigator applications through SUGAM Portal-Reg.

In order to streamline the regulatory submission procedure, the submission of applications for addition of Clinical Trial Site and change of Principal Investigator are functional on online system of SUGAM Portal (www.cdscoonline.gov.in) for Global Clinical Trials, Clinical trials of New Drugs, Subsequent New Drugs, Investigational New Drugs, Fixed Dose Combinations and Bioavailability & Bioequivalence studies. Applicants seeking for approval of Clinical Trial Site Addition and change of Principal Investigator applications may apply through the online portal.

The applicant should submit application through SUGAM along with the checklist of documents along with the approval of the ethics committee. The proposed addition of the clinical trial sites is deemed to be approved if no objection is received from the CDSCO within 30days of the receipt of the application and the proposed change of Principal Investigator is deemed to be approved by the CDSCO from the date of receipt of application subject to the condition that application is complete as per the checklist.

Rajeev

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

To,

1. All stakeholders through CDSCO website

2. CDAC Team

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION NO. 90
TO BE ANSWERED ON THE 30TH JULY, 2024

Startups scheme in Pharma sector

90 # Smt. Geeta alias Chandraprabha:

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

(a) whether any special scheme is being run by Government to encourage startups in the Pharma sector of the country;

(b) if so, the total number of new industries established in the Pharma sector of the country through startups during the last three years;

(c) whether financial assistance is provided by Government in setting up of these industries;

(d) if so, the total amount of financial assistance provided by Government to such established industries; and

(e) the total number of new industries established under Pharma sector in Uttar Pradesh during the last three years and the details thereof?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI. JAGAT PRAKASH NADDA)

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

Statement referred to in reply to the RAJYA SABHA STARRED Q. No. 90 (15TH POSITION) for answer on 30.07.2024 raised by Smt. Geeta Alias Chandraprabha regarding "Startups Scheme in Pharma Sector"

(a): The Government of India has implemented several schemes to encourage startups across various sectors including the pharmaceutical sector. These include:

Startup India Initiative, launched on January 16, 2016, which aims to foster innovation and encourage investments across various industries, including the pharmaceutical sector. The initiative includes three flagship schemes viz., Fund of Funds for Startups (FFS); Startup India Seed Fund Scheme (SISFS); and Credit Guarantee Scheme for Startups (CGSS).

Biotechnology Industry Research Assistance Council (BIRAC) under Department of Biotechnologies offers funding assistance through initiatives such as the Biotechnology Ignition Grant (BIG), Sustainable Entrepreneurship and Enterprise Development (SEED), and Launching

Entrepreneurial Driven Affordable Products (LEAP) schemes. The funding ranges from INR 30 Lakhs to INR 100 Lakhs per startup, enabling them to refine their ideas, establish proof-of-concepts, pilot, and commercialize their products and technologies. BIRAC also promotes innovation and research in biotechnology through the i4 programme and the PACE programme.

It is also pertinent to mention that Department of Pharmaceuticals has launched a Scheme for Promotion of Research and Innovation in Pharma-MedTech sector (PRIP). Under Component BIII of the PRIP scheme, 50 of 125 research projects in the identified six priority areas are for the startups in the pharmaceuticals sector.

(b): As of 30th June 2024, the Department for Promotion of Industry and Internal Trade (DPIIT) has recognized a total of 1,40,803 entities as startups, of which 2,127 are from the pharmaceutical sector. During the last three years, 1397 DPIIT-recognized start-ups were set up in the pharmaceutical sector details of which are as follows:

Sector	2021	2022	2023	Total
Pharmaceutical	283	451	663	1,397

© & (d): Under the Startup India initiative, the Government is implementing flagship schemes, namely, the Fund of Funds for Startups (FFS); the Startup India Seed Fund Scheme (SISFS); and, the Credit Guarantee Scheme for Startups (CGSS). Under these Schemes support is extended to startups across all sectors and industries at various stages of their business cycle. SISFS provides financial assistance to seed-stage startups through incubators. The scheme was launched in FY 2021-22 for a period of 4 years with a corpus of Rs. 945 Cr. As of 30th June 2024, under SISFS, Rs. 862.84 crore has been approved for 205 incubators. FFS has been established to catalyse venture capital investments and is operationalized by the Small Industries Development Bank of India (SIDBI). SIDBI provides capital to Alternative Investment Funds (AIFs) registered with Securities and Exchange Board of India (SEBI), which in turn invest in startups. As of 30th June 2024, under FFS, Rs. 10,804.7 crore has been committed to 138 AIFs. CGSS is implemented to enable collateral-free loans to DPIIT recognized startups through eligible financial institutions (Member Institutes - MIs). The scheme is operationalized by the National Credit Guarantee Trustee Company (NCGTC)

Limited and has been operational on a pilot basis from 1st April 2023. As of 30th June 2024, 182 loans amounting to Rs. 426.09 crore have been guaranteed to beneficiary startups. These initiatives demonstrate the Government's commitment to fostering a robust startup ecosystem in India.

(e): The number of new industries established under Pharma Sector in Uttar Pradesh during last three years is 214, of which 176 units are in medical devices and 38 units are in drugs and formulations.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 833
TO BE ANSWERED ON THE 30TH JULY, 2024

Use of AI in drug development

833 Shri B. Parthasaradhi Reddy:

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

(a) whether Government is planning to integrate the use of Artificial Intelligence (AI) in drug development;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether Government has taken any initiatives to support the development and deployment of AI technologies in the pharmaceutical sector;

(d) if so, the details thereof and if not, the reasons therefor; and

(e) whether Government is planning to take any measures to train professionals in the pharmaceutical sector for the use of AI in drug development?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (MS. ANUPRIYA PATEL)

(a) to (e): Yes. Department of Pharmaceuticals has taken steps to promote R&D in the sector including in the areas of Artificial Intelligence and Machine Learning through the Promotion of Research and Innovation in the Pharma-Medtech Sector (PRIP) Scheme. Further, NIPERs under the aegis of Department of Pharmaceuticals have introduced topics related to Artificial Intelligence in their courses and they provide training to students in AI-based tools to build human resource capacities in these areas for the pharmaceutical sector. In addition, the Department of Biotechnology (DBT) also supports Artificial Intelligence-based research activities in the biotech sector, particularly in the healthcare and agriculture areas, in order to leverage emerging technologies for these sectors.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1622
TO BE ANSWERED ON THE 06TH AUGUST, 2024

Guidelines to control essential drugs

1622 # Shri Narhari Amin:

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

(a) whether Government has issued any guidelines to control essential drugs in the country;

(b) if so, the details of such guidelines issued in this regard;

(c) whether Government has prepared a list of essential drugs;

(d) if so, the number of such drugs included in the list along with their names; and

(e) the details of the action proposed to be taken against those who violate the guidelines issued by Government?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (MS. ANUPRIYA PATEL)

(a) to (e): The Essential Commodities Act, 1955 under the Section 2(A) defines 'essential commodity' as commodity specified in the Schedule of the Act. 'Drugs' is listed as first item in the Schedule of the Act. Although all drugs are essential, however, Ministry of Health and Family Welfare notifies the National list of Essential Medicine (NLEM) from time to time to serve purposes like promoting the rational use of medicines; guiding safe and effective treatment of priority disease conditions of a population; and, optimizing the available health resources of the country etc. In the current NLEM - 2022, 384 drugs are included and may be seen at https://cdsco.gov.in/opencms/opencms/en/consumer/Essential-Medicines/.

Under the Drugs and Cosmetics Act, 1940 and Rules thereunder, manufacturers of drugs are required to comply with conditions of manufacturing licence and the requirements of Good Manufacturing Practices (GMP). As per the Drugs Rules, 1945, the manufacturing, testing, labelling, packaging, storage and distribution are required to be carried out in compliance with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. In case of violation, the Licensing Authority is empowered to take the action as per the said Act and Rules.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3057
TO BE ANSWERED ON 9th AUGUST, 2024

Bulk Drug Parks

3057 Shri Manoj Tiwari:

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

(a) whether the Scheme for Promotion of Bulk Drug Parks has significantly reduced the country's import of bulk drugs during the last two years;

(b) if so, the details thereof, year-wise;

(c) the current status of the implementation of the Scheme for Promotion of Bulk Drug Parks in the country, State-wise including NCT of Delhi; and

(d) the amount of funds allocated, disbursed and utilized for setting up of new Bulk Drug Parks in the country, State-wise?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (d): The scheme "Promotion of Bulk Drug Parks" was approved on 20th March, 2020 for providing easy access to world class Common Infrastructure Facilities (CIF) to prospective bulk drug units located in the parks. The total financial outlay of the scheme is Rs. 3000 crore for the Scheme tenure from FY 2020-2021 to FY 2024-2025. The Scheme is being implemented through the State Implementing Agencies (SIAs).

Establishment of Bulk Drug Parks has been approved in the States of Gujarat on 08.10.2022, Himachal Pradesh on 11.10.2022 and Andhra Pradesh initially on 07.11.2022 (Kakinada) and to new location (Nakkapalli). on 07.12.2023. Financial assistance of Rs.1000 crore each has been approved for the States of Andhra Pradesh, Gujarat and Himachal Pradesh for the creation of CIF in the Bulk Drug Parks. First instalment amount has been released to the three States in F.Y. 2022-23.

The work of CIF in all three approved Parks is under progress.

The amount of funds allocated, disbursed and utilized for setting up of Bulk Drug Parks in the three States is as under:

Approved State	Release Date of 1st Installment of Central Grant	Central Grant released (Rs. Crore)	State fund (Rs. crore)	Fund Utilised till 30th June 2024 (Rs. crore)
Gujarat	14/10/2022	300	137.10	129.17
Himachal Pradesh	20/02/2023	225	35.54	21.37
Andhra Pradesh	13/03/2023	225	132.30	-

The Scheme Steering Committee (SSC) in its meeting held on 09.07.2024, approved the extension of Scheme tenure by one year from F.Y. 2024-25 to F.Y. 2025-26 for completion and implementation of the Bulk Drug Parks in the States.

As the Bulk Drugs projects in all the three States are likely to be completed in F.Y. 2025-26, any impact on country's import of bulk drugs can only be analysed after the operationalization of these Bulk Drug Parks.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 3113
TO BE ANSWERED ON THE 13th DECEMBER, 2024

Pharmaceuticals Import from China

3113. Smt. Mala Roy:

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

(a) the details of Import of raw materials for manufacture of medicine for Pharmaceutical Industry from China; and

(b) the import details of quantity and value of imports from China during the last five years?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) & (b): The details of quantity and value of import of raw material for manufacture of medicines, i.e. Active Pharmaceutical Ingredient (API)/ bulk drugs and Drugs Intermediates from China during the last five years is as per Annexure.

Annexure

Annexure referred to in reply to part (a) and (b) of Lok Sabha Unstarred Question No. 3113 for answer on 13.12.2024

Import of APIs/bulk drugs, Drugs Intermediates from China 2019-20 To 2023-24 in terms of Value and Quantity				
S. No.	Description	FY	Quantity (Kgs)	Value (INR Cr)
1	Bulk drugs, Drug Intermediates	2019-20	220875185	16443
2		2020-21	256608708	19403
3.		2021-22	264582478	23273
4		2022-23	300120194	25551
5		2023-24	344152814	27055

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 831
TO BE ANSWERED ON THE 03rd DECEMBER 2024

Current size of the Indian pharmaceutical industry

831 Shri Sandosh Kumar P:

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

(a) the current size of the Indian pharmaceutical industry and the total profit of the same for the last three years;

(b) the details of the export of pharmaceutical products for the previous three years; and

(c) the State-wise list of the export of pharmaceutical products for the last three years?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a): India's pharmaceutical market currently valued at USD 50 billion with domestic consumption valued at USD 23.5 billion and export valued at USD 26.5 billion is the world's third-largest by volume. With an extremely diversified product base covering generic drugs, bulk drugs, over-the-counter drugs, vaccines, biosimilars, and biologics, the Indian pharmaceutical industry has a strong presence at the global level. "Pharmacy of the world" as it is called offers around 60,000 generic brands across 60 therapeutic categories, accounting for 20 per cent of global generic drug exports by volume.

(b): The export of pharmaceutical products for the previous three years are:

Export of Pharmaceutical products in terms of Value USD Mn			
Description	**2021-22**	**2022-23**	**2023-24**
Drug formulations, biologicals	19001.09	19458.62	21714.29
Bulk drugs, drug intermediates	4468.53	4709.22	4786.52

(c): The state-wise export of pharmaceutical products for the last three years is as per Annexure.

Annexure referred to in reply to part (c) of Rajya Sabha Unstarred Question No. 231 for answer on 03.12.2024

State-wise list of the export of pharmaceutical for the last three years in terms of Value INR Cr			
State wise	**FY 2021-22**	**FY 2022-23**	**FY 2023-24**
Andaman & Nicobar	n.a	n.a	0.01
Andhra Pradesh	5744.84	8607.28	11390.05
Arunachal Pradesh	0.13	0.95	0.00
Assam	66.40	136.04	143.18
Bihar	216.22	233.81	210.76
Chandigarh	40.39	89.25	71.73
Chattisgarh	0.16	0.38	1.18
Dadra & Nagar Haveli	1136.79	2019.18	2723.89
Daman & Diu	836.10	705.15	103.15
Delhi	564.39	212.58	529.62
Goa	5022.18	5329.24	6527.08
Gujarat	15586.60	16480.18	18297.14
Haryana	22.70	100.25	224.1863901
Himachal Pradesh	7461.24	8400.07	9155.92
Jammu & Kashmir	383.47	348.35	367.96
Jharkhand	0.01	0.01	n.a
Karnataka	3008.37	4293.76	5917.91
Kerala	35.73	22.64	48.75
Ladakh	n.a	n.a	n.a
Lakshadweep	n.a	n.a	n.a
Madhya Pradesh	8947.26	8517.40	10615.05
Maharashtra	5700.31	10614.11	11219.09
Manipur	0.39	0.03	0.50
Meghalaya	0.00	0.00	0.01
Mizoram	0.08	n.a	n.a
Nagaland	0.00	0.00	n.a
Odisha	4.18	2.64	0.97
Puducherry	694.19	802.74	1114.20
Punjab	2583.81	3406.75	3037.38
Rajasthan	667.30	944.71	924.63
Sikkim	96.88	92.25	89.61
Tamil Nadu	142.45	957.89	1531.25
Telangana	21219.45	25681.07	29148.90
Tripura	0.00	0.0381544	0.02
Uttar Pradesh	648.06	926.16	777.23
Uttarakhand	1208.30	1145.93	1463.14
West Bengal	84.30	75.02	164.05
Total	**82122.66**	**100145.85**	**115798.55**

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 824
TO BE ANSWERED ON 03rd DECEMBER, 2024

Promotion of domestic manufacturing of medicines

824 Dr. Dharmasthala Veerendra Heggade:

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

(a) whether Government is making efforts to promote domestic manufacturing of medicines such as bio-pharmaceuticals, complex generics, gene therapy drugs, complex excipients, orphan drugs etc., considering their scarce availability and prohibitive cost in the country; and

(b) if so, the details of the efforts made and outcomes achieved in this regard?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (b): The Department of Pharmaceuticals is implementing the Production Linked Incentive (PLI) Scheme for Pharmaceuticals with a total financial outlay of Rs. 15,000 crore and scheme tenure up to FY 2027-28. The scheme provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. Product "Category- 1" contains generally high value pharmaceuticals products. The product categories approved under the scheme include as below:

1. Bio-pharmaceuticals
2. Complex generic drugs
3. Patented drugs or drugs going off patent during the scheme tenure
4. Orphan drugs
5. Complex excipients

Details/numbers of Category 1 products (sub-category wise) are as under:

Product Sub-Category	No. of eligible products approved for manufacturing under the scheme
Bio-Pharmaceuticals	68
Patented drugs or drugs going off patent during the scheme tenure	157
Complex Generic Drugs	158
Complex excipients	17
Orphan drugs	8
Total	**408**

The scheme provides for incentives on incremental sales to selected participants for a period of 6 years at the rate of 10% for FY 2022-23 to FY 2025-26, 8% for FY 2026-27 and 6% for FY 2027-28.

Total sales of approved eligible Category- 1 products under the PLI Scheme for Pharmaceuticals is given below:

Financial Year	Sales (Rs. in crore)
FY 2022-23	17,931.18
FY 2023-24	23,228.40
FY 2024-25 (up to Sept 2024)	11,853.11

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 841
TO BE ANSWERED ON 03rd DECEMBER, 2024

Pharmaceutical companies in Puducherry

841 Shri S. Selvaganabathy:

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

(a) the stringent conditions and measures enforced by Government in granting new licences for starting a pharmaceutical manufacturing in Puducherry;

(b) the number of pharmaceutical manufacturing companies presently running in Puducherry;

(c) whether periodical inspection of the companies are conducted, if so, the details thereof; and

(d) the action taken by Government of Puducherry for violation of procedures in the last three years?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a): (i) Manufacturing licenses are issued by Department of Drugs control, Puducherry, based on the other statutory approvals viz, (A) Puducherry Pollution Control Committee, (B) Inspectorate of Factories and Boilers, (C) Department of Electricity & (D) Puducherry Commune Panchayat and followed by inspection of the manufacturing units jointly by the Drug Inspectors of Central Drugs Standard Control Organization (CDSCO), South Zone, Chennai with the Drug Inspectors of Department of Drugs Control, Puducherry as per the GSR-1337 dated 27.10.2017 by Ministry of Health and Family Welfare.

(ii) Grant of fresh manufacturing licenses of Ayurveda, Siddha & Homeopathy were issued by the inspection followed by the Good Manufacturing Practices (GMP) Compliance and approval from Indian Systems of Medicine (ISM) Expert Committee as per GSR 716(E) dated 01.10.2021 by Ministry of Health and Family Welfare.

(iii) Grant of fresh manufacturing licenses of Cosmetics were issued as per the Cosmetic Rules 2020, Issuance of License followed by inspection and self-compliance by the manufacturer in Form Cos-7 as per GSR 763(E) dated 15.12.2020 by Ministry of Health and Family Welfare.

(iv) Grant of fresh manufacturing Medical Device licenses were issued online (mdonline portal) after inspection and verification by the Notified Body for Medical Devices for Class A & B as per the GSR 78(E) dated 31.01.2017 by Ministry of Health and Family Welfare.

(b): As per the information provided by the Government of Puducherry, number of pharmaceutical manufacturing companies presently running in Puducherry is as below:

Category	No. of Units
Allopathic	71
Cosmetics	33
Ayush	54
Medical Device	04

(c): As per the information provided by the Government of Puducherry, details of periodical inspection of the companies conducted is as below:

Details of Inspection	Year - wise		
	2024	2023	2022
Risk Based Inspection	2	3	-
Joint Inspection	28	41	27
Surprise Inspection	2	-	-
Regular Inspection	76	102	65
Other Agencies (Police Dept.)	14	1	-

(d): The action taken by Government of Puducherry for violation of procedures in the last three years is as follows:

Details of Action Taken	Year - wise		
	2024	2023	2022
Not of Standard Quality (NSQ) Product Manufacturing approval suspension	27	27	25
Suspension of Drug Manufacturing License	4	1	-
Stop Production of Drug Manufacturing License	3	6	-
Cancellation of Drug Manufacturing License	-	3	-

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 890
TO BE ANSWERED ON 03rd DECEMBER, 2024

Medical devices manufacturing in the country

890 Shri Anil Kumar Yadav Mandadi:

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

(a) whether it is a fact that India is dependent on imports of medical devices for its domestic requirement;

(b) if so, the details of the medical devices that are being imported from other countries;

(c) whether Government has made any plan/policy to produce medical devices locally; and

(d) if so, the details thereof and if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) &(b): India both exports and imports Medical devices. The medical devices Imported from other countries in last three years is given below:

(USD Million)

S. No	Segment	FY 2021-22	FY 2022-23	FY 2023-24
1	Consumables & Disposables	1624	1091	1185
2	Surgical Instruments	169	210	205
3	Electronics Equipment	5441	4884	5408
4	Implants	423	540	586
5	IVD Reagents	883	767	804
	TOTAL	**8540**	**7492**	**8188**

Source: DGCIS, Ministry of Commerce and Industry

The medical devices exported to other countries in last three years is given below: -

(USD Million)

S. No	Segment	FY 2021-22	FY 2022-23	FY 2023-24
1	Consumables & Disposables	1378	1605	1752
2	Surgical Instruments	71	72	79
3	Electronics Equipment	1163	1335	1472
4	Implants	135	188	266
5	IVD Reagents	176	191	216
	TOTAL	**2923**	**3391**	**3785**

Source: DGCIS, Ministry of Commerce and Industry

(c) & (d): Government of India has taken several measures to encourage domestic manufacturing of medical devices to reduce import dependence and to boost domestic manufacturing and attract large investments. The major schematic interventions are as follows:-

(i) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD): The Union Cabinet approved proposal on 20.03.2020 with the objective of the Scheme to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The production tenure of the scheme is from FY 2020-2021 to FY 2027-28 with total financial outlay of Rs. 3,420 crore. The scheme provides for financial incentive to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the four target segments of the scheme, for a period of five (5) years. 32 applicants have been selected under the scheme. The cumulative sales made by the applicants under the scheme is Rs 8039.63 crore (which includes exports worth Rs 3,844.01 crore) up to September, 2024.

(ii) Production Linked Incentive (PLI) Scheme for Pharmaceuticals, with a financial outlay of Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, also covers In-Vitro Diagnostic (IVD) medical devices among other pharmaceutical goods. The scheme provides for financial incentive to 55 selected applicants including 5 applicants of In-Vitro Diagnostic (IVD) for production of identified products under three categories for a period of six years. Against committed investment of Rs 163.86 crores, investment worth Rs 216.58 crores have been realized by the IVD applicants. The employment has been generated by IVD applicants are 1702 persons. Total 248 IVD products are approved so far.

(iii) Scheme for Promotion of Medical Devices Parks: The scheme "Promotion of Medical Device Parks" was approved on 20th March, 2020 for providing easy access to world class common infrastructure facilities to medical device units located in the parks. The total financial outlay of the

scheme is Rs. 400 crore and the implementation period is from FY 2020-2021 to FY 2024-2025. Under the scheme, Department had received proposals from 16 States. After evaluation of the proposals, Govt. of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were conveyed final approval for creation of common infrastructure facilities in the proposed medical device parks in these four states. Civil works in all the other three parks (except Himachal Pradesh) has progressed well with most of the structures for housing equipment for Common Infrastructure Facility (CIF) constructed, while procurement of equipment is in progress.

Medical Device park at Himachal Pradesh was facing funding issues from the state government side. It appears that due to cost overrun it did not remain feasible for the state government to implement the park within the framework of the scheme guidelines of the department, despite all support available from the department and Rs. 30 crores already released to the state. Hence, the proposal for setting up of the Medical Device Park at Nalagarh has been withdrawn by the State Government.

(iv) New scheme for Strengthening Medical Device Industry launched on 8.11.2024:

In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched on 8.11.2024 with financial outlay of Rs. 500 crore. Sub-scheme of the scheme is as given below:-

(i) Common Facilities for Medical Devices Clusters

(ii) Marginal Investment Scheme for Reducing Import Dependence

(iii) Capacity Building and Skill Development for Medical Devices

(iv) Medical Device Clinical Studies Support Scheme

(v) Medical Device Promotion Scheme

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

RAJYA SABHA
UNSTARRED QUESTION NO.934
TO BE ANSWERED ON 03RD DECEMBER, 2024

ENSURING QUALITY AND SAFETY OF PHARMACEUTICALS

934: SHRI K.R.N. RAJESHKUMAR:

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

(a) the measures being taken by Government to ensure that drugs produced by pharmaceutical companies meet the required safety and efficacy standards;

(b) whether Government has conducted any review of the Drugs and Cosmetics Act to strengthen quality control regulations for pharmaceuticals; and

(c) the steps taken to improve the functioning and capacity of the Central Drugs Standard Control Organization (CDSCO) to address quality control lapses?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (c): Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act, 1940, advises the Government on technical matters for administration of the Act. Based on the recommendations of the Expert Committees / DTAB, advice from State Drugs Controllers in Drugs Consultative Committee (DCC) meetings and comments from stakeholders, the Government considers amendments in the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure that the drugs produced in the country meet the required safety and efficacy standards and to improve the functioning and capacity of CDSCO, as stated below:

(i). In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) had initiated risk-based inspections of Drug manufacturing firms from Dec 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections more than 400 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses / product licenses etc.,

have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

(ii).Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good ManufacturingPractices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover>250 crores from 29.06.2024.

(iii). On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(iv). On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(v). On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi). 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 nonbailable.

(vii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(viii). To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(ix). 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.

(x). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(xi). Central government is providing regular Residential, regional training and workshops to CDSCO, State Drug Regulatory Authorities on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22,854 persons while in F.Y 2024-25 so far 13,007 persons have been trained.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 1613
TO BE ANSWERED ON 10th DECEMBER, 2024

Scheme to strengthen medical devices industry

1613 Dr. Parmar Jashvantsinh Salamsinh:
Shri Mithlesh Kumar:

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

(a) whether Government has launched any scheme for strengthening the medical devices industry of the country in order to enhance the healthcare system; and

(b) if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) & (b): In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched on 8.11.2024. The scheme has an outlay of Rs. 500 crore and tenure of the Scheme is 3 years from Financial Year 2024-25 to FY 2026-27. Objective of the sub-schemes under the scheme are as follows: -

(i) Common Facilities for Medical Device Clusters: To strengthen existing infrastructure by providing financial assistance to medical device clusters for creating Common Infrastructure Facilities, boosting domestic manufacturing capacity and improving cluster quality and to strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices.

(ii) Marginal Investment Scheme for Reducing Import Dependence: To promote domestic production of key components, raw materials and accessories used in manufacturing of medical devices, including in-vitro diagnostic devices, in order to reduce dependence of Indian medical device manufacturers on imported key components and raw materials and increase the depth of our value chains.

(iii) Capacity Building and Skill Development in Medical Device Sector: The main objective of the component is to fill the gap existing in the education and research in medical devices sector and to ensure quality teaching, training and nurturing excellence in Medical Technology education for generating critical mass of trained human resource to meet the requirements of rapidly innovating multidisciplinary areas of Medical Technology and create R&D ecosystem for the sector.

(iv) Medical Device Clinical Studies Support Scheme: To support the medical device industry by fostering development of devices supported by clinical evidence and generation of clinical data that demonstrates the safety and efficacy of the devices manufactured in India. This will promote manufacturing of quality products with better efficacy and safety. It will also enhance credibility of domestic manufacturers to produce high quality products, opening up opportunities for them in markets outside the country.

(v) Medical Device Promotion Scheme: To promote Medical Device Industry by bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sector as well as to facilitate growth and development of the sector through conducting studies, organizing awareness programs, creation of databases and promotion of industry.

The scheme will provide the much needed thrust to address the unmet needs of the industry. The scheme is expected to have a multiplier effect in augmenting the domestic manufacturing capacities with significant reduction in imports, and promote - quality, human resource development, safety and efficacy of medical devices, and also enhance the depth of medical device value chains in the country.

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

RAJYA SABHA
UNSTARRED QUESTION No. 1713
TO BE ANSWERED ON 10th DECEMBER, 2024

PRESCRIPTION OF GENERIC MEDICINES

1713. SHRI SHAKTISINH GOHIL:

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

(a) whether Government is aware that the regulation requiring registered medical practitioners (RMPs) to prescribe medicines by generic names is ignored in 99 per cent of cases, limiting access for marginalized communities;

(b) if so, the details of actions taken, including the number of disciplinary proceedings and penalties against RMPs in the past five years;

(c) the details of directions issued by Government, National Medical Commission, Medical Council of India and other authorities regarding generic prescriptions; and

(d) the details of Government hospitals complying with the regulation to prescribe medicines by generic names?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (d): Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is rational prescription and use of drug. Further, the erstwhile Medical Council of India(MCI) had issued Circulars dated 22.11.2012, 18.01.2013 and 21.04.2017 vide which all Registered Medical Practitioners have been directed to comply with the aforesaid provisions.

The National Medical Commission Act, 2019, empowers the appropriate State Medical Councils or the Ethics and Medical Registration Board (EMRB) of the National Medical Commission to take disciplinary action against a doctor for violation of the provision of the aforesaid Regulations. No data related to number of disciplinary proceedings and penalties against RMPs in the past five years is maintained centrally by the Ministry. Further, States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
STARRED QUESTION NO. 276
TO BE ANSWERED ON THE 13th DECEMBER, 2024

Role of Artificial Intelligence in Boosting Pharmaceutical Sector

***276. Shri Dhairyasheel Sambhajirao Mane:**

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

(a) whether the Government has taken note of the importance of advanced technologies such as Artificial Intelligence, Block Chains etc. which can play a major role in boosting the pharmaceutical sector in the country;

(b) if so, the details in this regard and the various steps taken by the Government to leverage such technological developments to the sector's advantage in the country; and

(c) the steps taken by the Government to boost the pharmaceutical sector in the country?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

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

Statement referred to in reply to the Lok Sabha Starred Q. No. 276 (16th POSITION) for answer on 13.12.2024 raised by Shri Dhairyasheel Sambhajirao Mane regarding the *"Role of Artificial Intelligence in Boosting Pharmaceutical Sector"*

(a) & (b): Yes, Department of Pharmaceuticals has taken steps to promote R&D in the sector including in the areas of Artificial Intelligence and Machine Learning through the Promotion of Research and Innovation in the Pharma-Meditech Sector (PRIP) Scheme. Further, NIPERs under the aegis of Dept. of Pharmaceuticals have introduced courses that cover topics related to Artificial Intelligence, Machine Learning and Blockchain Technology and they also provide training to students in AI-based tools to build human resource capacities in these areas for the pharmaceutical sector. In addition, the Department of Biotechnology also supports the projects for application of Artificial Intelligence for Affordable and Accessible Healthcare.

(c): The Government of India has undertaken several measures to boost the pharmaceutical and medical device sectors, including the implementation of PLI Scheme for critical Key Starting Materials, Drug Intermediates & Active Pharmaceutical Ingredients; the PLI Scheme for Pharmaceuticals; the PLI Scheme for Medical Devices; the Medical Device Parks Scheme; the Bulk Drug Park Scheme; Strengthening Medical Device Industry Scheme and PRIP Scheme.

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

RAJYA SABHA
UNSTARRED QUESTION NO. 1695
TO BE ANSWERED ON 10TH DECEMBER, 2024

REGULATION OF E-PHARMACIES

1695: SHRI S NIRANJAN REDDY:

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

(a) the regulations currently governing the online sale of medicines by e-pharmacies and the details thereof;

(b) whether Government makes a regulatory distinction between the different models of online pharmacies and the details thereof; and

(c) the status of the draft policy on the online sale of medicines and the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (c): In order to regulate the online sale of medicines comprehensively, the Government had published draft Rules vide G.S.R. 817 (E) dated 28.08.2018 for amendment to the Drugs and Cosmetics Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy.

The draft Rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e-pharmacy, complaint redressal mechanism, monitoring of e -pharmacy, etc.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. †3161
TO BE ANSWERED ON THE 13th DECEMBER, 2024

Prices of Medicines and Surgical Equipments

†3161. Shri Daroga Prasad Saroj:

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

(a) whether there is 5 to 100 times difference between wholesale price and selling price of most medical or surgical equipments like Vigo, IV set, fixator, vicryl thread, waist belt as well as medicines in India;

(b) whether the Government has any control over pricing of medicines and surgical equipments;

(c) if so, the details thereof alongwith the details of the authority who has been instilled for the same;

(d) if not, the reasons therefor;

(e) whether the Government is making any plan to print the MRP two to three times the actual price at whatever price fixed by the drugs companies to supply the medicines and surgical equipments to the dealers; and

(f) whether the Government proposes to control the arbitrary and indiscriminate collection of consultation fees in Private hospitals and by doctors in the country?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (e): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP), fixes the ceiling price of medicines included in Scheduled-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). All manufactures of scheduled medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. In case of non-scheduled formulations, a manufacturer is at liberty to fix the Maximum Retail Price (MRP) of the drugs launched by it. However, as per the DPCO 2013, no manufacturer can increase MRP of non-scheduled drug by more than 10% of the MRP during preceding 12 months. Further, NPPA also fixes the retail price of new drug, as defined in DPCO 2013. NPPA monitors the prices and initiates action against the defaulting companies as per the extant provisions of DPCO, 2013 as and when any violation is reported/notices. However, the business practices including margins and discounts offered to various stakeholders in the supply chain at different stages are not within the purview of DPCO, 2013. The surgical equipment like Vigo, IV set, fixator, vicryl thread, waist belt, are non-scheduled items as per the DPCO, 2013. Accordingly, their prices are monitored for any violation in terms of increase in prices in accordance with law.

(f): As per the information provided by the Ministry of Health & Family Welfare, the Government enacted the Clinical Establishments (Registration and Regulation) Act, 2010 (CE Act) with a view to prescribe minimum standards of facilities and services as may be provided by them. CE Act is applicable to all types of Clinical Establishments including clinics, hospitals, diagnostic centres in both government and private health facilities (except those of Armed Forces), if the same is adopted and implemented by the States/ Union Territories. As per the Clinical Establishments (Central Government) Rules, 2012 every clinical establishment shall display the details of charges, facilities available prominently at a conspicuous place to maintain transparency. The States/ Union Territories which have adopted CE Act are primarily responsible for regulating their hospitals including private hospitals as per provisions of the Act and Rules made thereunder so as to ensure the provision of affordable and quality healthcare to patients.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
STARRED QUESTION NO. *236
TO BE ANSWERED ON 17th DECEMBER, 2024

Pharma Jan Samadhan Web System

236 # Smt. Geeta alias Chandraprabha:

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

(a) whether the Pharma Jan Samadhan Web System has been established to redress consumer complaints regarding pricing and availability of medicines;

(b) if so, the features of this web system; and

(c) the manner in which consumers can get their problems resolved through this web system and the details thereof?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

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

Statement referred to in reply to the Rajya Sabha Starred Question No. *236# (11th POSITION) for answer on 17.12.2024 raised by Smt. Geeta alias Chandraprabha regarding "Pharma Jan Samadhan Web System".

(a) to (c): Yes, National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) launched Pharma Jan Samadhan (PJS) with an objective to provide complaint redressal system. Any stakeholder can lodge an on-line complaint relating to non-availability of medicines; overpricing of medicines; sale of drugs without prior price approval; and, refusal of supply or sale of medicines to NPPA through PJS. The complaint can be lodged in the PJS through the NPPA's website on the URL:
https://nppaipdms.gov.in/NPPA/PharmaJanSamadhan/registration.

Action on the complaint received through PJS with the complete information is initiated within 48 hours by the NPPA. As soon as the complaint is lodged on PJS portal, an acknowledgement regarding receipt of complaint along with the registration number is sent to the complainant's mobile/ Email ID. The complainant can track the status of his/her complaint by using that reference number on the portal. In case of overcharging and selling of medicines without price approval etc., further action is taken after detailed examination of documents provided by the complainant as per provisions of the Drugs (Prices Control) Order, 2013.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 2422
TO BE ANSWERED ON THE 17TH DECEMBER, 2024

Domestic medical device industry

2422 Smt. Ranjeet Ranjan:

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

(a) the details of import of various high-end medical devices in the country in the past five years, country-wise ;

(b) the measures taken by Government to promote domestic manufacturing of high-end medical devices;

(c) whether Government has considered increasing the customs duty on finished medical devices as recommended by the Standing Committee to encourage local production; and

(d) whether Government plans to establish additional central medical device testing laboratories to address the current shortfall?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a): Department of Revenue has informed that there is no classification under the heading of "High End Medical Devices". However, Import-Export data in respect of five segments (Consumables & Disposables, Electro-Medical Equip, Implants, In-Vitro Diagnostics, Surgical Instruments) of medical devices for last five years is as follows: -

(USD Million)

	F.Y. 2019-20	F.Y. 2020-21	F.Y. 2021-22	F.Y. 2022-23	F.Y. 2023-24
Export	2293	2532	2923	3391	3785
Import	5845	6242	8540	7492	8188

Source: DGCI&S, Ministry of Commerce and Industry

Between FY 2019-20 and FY 2023-24, the CAGR of imports in the said five segments is 8.79% and CAGR of exports is 13.35% which indicates that growth of exports during this period has been more compared to imports.

Country-wise imports and exports figures in respect of major countries as follows: -

Exports

(USD Million)

Major Country	F.Y. 2019-20	F.Y. 2020-21	F.Y. 2021-22	F.Y. 2022-23	F.Y. 2023-24
USA	521.85	600.01	631.48	714.12	714.30
Germany	123.74	133.7	127.29	176.63	199
China	130.27	133	146.94	144.574	166
Netherlands	33.78	43.87	93.68	110.44	145
Japan	30.63	27.21	31.84	38	42.17

Source: DGCI&S, Ministry of Commerce and Industry

Imports

(USD Million)

Major Country	F.Y. 2019-20	F.Y. 2020-21	F.Y. 2021-22	F.Y. 2022-23	F.Y. 2023-24
USA	1190.08	984.08	1464.73	1418	1519
China	622.2	1110.92	1657.67	1246.82	1332
Germany	732.07	668.5	782.35	797.49	908
Netherlands	347.51	228.51	398	416	460
Japan	280.08	236.99	343.08	321.77	372

Source: DGCI&S, Ministry of Commerce and Industry

(b): Government of India has taken several measures to encourage domestic manufacturing of medical devices to reduce import dependence and to boost domestic manufacturing and attract large investments.

(i) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD): The Union Cabinet approved proposal on 20.03.2020 with the objective of the Scheme to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The production tenure of the scheme is from FY 2022-2023 to FY 2026-27 with total financial outlay of Rs. 3,420 crore. The scheme provides for financial incentive to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the four target segments of the scheme, for a period of five (5) years. The cumulative sales made by the applicants under the scheme is Rs 8039.63 crore (which includes exports worth Rs 3,844.01 crore) up to September, 2024.

(ii) Scheme for Promotion of Medical Devices Parks: The scheme "Promotion of Medical Device Parks" was approved on 20th March, 2020 for providing easy access to world class common infrastructure facilities to medical device units located in the parks. The total financial outlay of the scheme is Rs. 400 crore and the implementation period is from FY 2020-2021 to FY 2024-2025. Under the scheme, Department had received proposals from 16 States. After evaluation of the proposals, Govt. of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh were conveyed final approval for creation of common infrastructure facilities in the proposed medical device parks in these four states.

(iii) Scheme for Strengthening Medical Device Industry: In order to provide support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion, a new scheme "Strengthening of Medical Device Industry" with five sub-schemes has been launched on 8.11.2024 with financial outlay of Rs. 500 crore. Sub-scheme of the scheme is as given below: -

(i) Common Facilities for Medical Devices Clusters
(ii) Marginal Investment Scheme for Reducing Import Dependence
(iii) Capacity Building and Skill Development for Medical Devices
(iv) Medical Device Clinical Studies Support Scheme
(v) Medical Device Promotion Scheme

(c) Department of Pharmaceuticals had recommended to increase the basic custom duty on 40 finished medical devices to Department of Revenue (DoR) but recommendation was not considered by DoR.

(d) As per information provided by Ministry of Health and Family Welfare, as on date they have notified six central medical device testing laboratories for testing of certain medical devices. In order to strengthen the government medical testing facilities in the country, Medical Device Rules, 2017 has been amended vide G.S.R 409E dated 02//06/2023 incorporating provisions for State Governments to notifying State Medical Device testing laboratories.

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

RAJYA SABHA
STARRED QUESTION NO. 239
TO BE ANSWERED ON THE 17TH DECEMBER, 2024

DGUIDELINES OF DCGI ON RECALL OF DRUGS, GOOD DISTRIBUTION PRACTICE AND AGAINST CONFUSING BRANDS

239 SHRI A. D. SINGH:

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

(a) whether guidelines issued by Drug Controller General of India (DCGI) on recall of drugs, good distribution practice and against confusing brands are having no force of law;

(b) if so, the details thereof;

(c) whether these guidelines have not been incorporated in the rules;

(d) if so, the reasons therefor;

(e) whether Government will incorporate these guidelines in the rules, so that their enforceability can be ensured; and

(f) if not, the reasons therefor?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO. 239 * FOR 17 TH DECEMBER, 2024

(a) to (f) Central Drugs Standard Control Organization (CDSCO) has issued guidelines on "Recall and Rapid Alert System for Drugs" (including Biologicals & Vaccines). Further, Draft Guidelines on Good Distribution Practices for Pharmaceutical Products is also published for ensuring quality of Drugs in the supply chain. These guidelines are available on website of CDSCO (www.cdsco.gov.in).

On 06.11.2019, the Drugs and Cosmetics Rules, 1945 were amended vide G.S.R 828 (E) making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

Further, Central Government has also amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. These contain specific reference for product recalls.

In case of drug samples declared as Not of Standard Quality by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the Not of standard quality Drugs in the market.

Under the Drugs and Cosmetics Act, 1940 and Rules thereunder, manufacturers of drugs are required to comply with conditions of manufacturing licence and the requirements of Good Manufacturing Practices (GMP). As per the Drugs Rules, 1945, the manufacturing, testing, labelling, packaging, storage and distribution are required to be carried out in compliance with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. In case of violation, the Licensing Authority is empowered to take the action as per the said Act and Rules.

Further on need basis, various guidelines/regulatory procedures are considered and incorporated in the Rules through amendment as per the procedures prescribed in the Drugs and Cosmetic Act, 1940.

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

RAJYA SABHA
UNSTARRED QUESTION NO. 2499 #
TO BE ANSWERED ON 17TH DECEMBER, 2024

PHARMACEUTICAL COMPANIES FAILING ON QUALITY STANDARDS

2499 #: SHRI NEERAJ DANGI:

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

(a) whether the medicines by the pharmaceutical companies of the country are not meeting the quality standards, if so, the details of such medicines and companies;

(b) the company-wise details of medicines banned by Government;

(c) the appropriate action taken by Government to ensure that these pharmaceutical companies maintain high quality of medicines; and

(d) the details of action taken by Government to deal strictly with companies manufacturing spurious medicine?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 239 * FOR 17 TH DECEMBER, 2024

(a) & (b): List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). In case the sample is found to be Not of Standard Quality (NSQ)/ Spurious/Adulterated/Misbranded, actions are initiated as per provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder.

© & (d): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure that the drugs produced in the country meet the required safety and efficacy standards, as stated below:

(I). In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) had initiated risk-based inspections of Drug manufacturing firms from Dec 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard

Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 400 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

(ii). Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover>250 crores from 29.06.2024.

(iii). On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(iv). On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(v). On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi). 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 nonbailable.

(vii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(viii). To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(ix). 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.

(x). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(xi). Central regulator 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.

(xii). Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25 so far 13007 persons have been trained.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
STARRED QUESTION No. *373
TO BE ANSWERED ON THE 20th DECEMBER, 2024

Ban on FDC Medicines

***373. Shri S Venkatesan:**

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

(a) whether the Government has banned 156 Fixed Dose Combination (FDC) medicines which included commonly used antibiotics, painkillers and multivitamins;

(b) if so, the details thereof;

(c) the number of FDCs identified by the Kokate Committee as irrational and under production without licences; and

(d) the measures taken/proposed to be taken by the Government to protect people from risks associated with these irrational drugs?

ANSWER

THE MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI JAGAT PRAKASH NADDA)

(a) to (d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO THE LOK SABHA STARRED QUESTION NO. *373 (13TH POSITION) FOR ANSWER ON 20.12.2024 RAISED BY SHRI S VENKATESAN REGARDING "BAN ON FDC MEDICINES".

(a) to (d): As per the information provided by M/o Health & Family Welfare, there are provisions under the Drugs and Cosmetics Act, 1940, under which Central Government may regulate, restrict or prohibit manufacture, etc of any drug including Fixed Dose Combination (FDCs) drugs in public interest if the use of drugs is likely to involve any risk to human beings or animals or there is no therapeutic justification for the ingredients contained in FDCs. based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard

Whenever, any such concerns on any drug including FDCs are reported, the matter is examined in consultation with expert committee/ Drugs Technical Advisory Board (DTAB) and appropriate action is taken for prohibition of such drugs.

Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, Central Government prohibited several FDCs. List of such banned FDCs including 156 banned FDCs in the month of August, 2024 is available on the website of Central Drugs Standard Control Organisation (CDSCO) i.e www.cdsco.gov.in.

Under the provision of Drugs & Cosmetics Act and Rules, manufacture/ sale/ distribution of any banned drug is a punishable offence. State Licencing Authorities are empowered to take action in case of manufacture, sale of such unapproved FDCs.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4285
TO BE ANSWERED ON THE 20th DECEMBER, 2024

Production of Medicine

†4285. Smt. Sanjna Jatav:

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

(a) whether the Government is aware of the news item published in Dainik Jagran Delhi news dated 23.07.2024 pointing out that five medicines manufactured in Uttarakhand failed the sample test;

(b) if so, the details thereof;

(c) the names of the medicines of various pharmaceutical companies which have been tested in different States by the Government through Central Drugs Standards Control Organisation (CDSCO) during the last three years;

(d) the names of the medicines along with the details of their manufacturing companies which have failed the sample tests; and

(e) the action taken/Licenses of pharmaceutical companies cancelled by the Government in this regard?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (e): List of drugs of various companies, which are declared Not of Standard Quality(NSQ)/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and is available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). These drug alerts contain complete information regarding the name of the drug, its batch number, manufacturing and expiry date, name of manufacturer, NSQ results from CDSCO lab etc.

With regard to quality and safety of drugs, action is taken as and when the cases of relating to quality or safety are reported, by the state licensing authorities concerned against the manufacturer/producer of Not of Standard Quality (NSQ)/ Spurious/ Misbranded/ Adulterated medicines as per the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in the appropriate Court of law.

Further, in order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) had initiated risk-based inspections of drug manufacturing firms from December, 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 400 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules, 1945.

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GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4365
TO BE ANSWERED ON THE 20th DECEMBER, 2024

Domestic Production of Generic Medicines

4365. Shri Selvam G:

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

(a) the details on the current production levels of generic medicines in the country;

(b) the percentage of the total pharmaceutical market in the country is comprised of generic medicines, and manner in which the Government plan to increase this percentage to improve affordability;

(c) the incentives or schemes that are in place to support the establishment and growth of manufacturing units dedicated to producing generic medicines;

(d) the data on the estimated savings to patients as a result of increased generic medicine usage, particularly for chronic diseases; and

(e) the percentage of domestically produced generic medicines is exported, and the manner in which the Government balances domestic demand with export opportunities?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (e): India's pharmaceutical market for FY 2023-24 is valued at USD 50 billion with domestic consumption valued at USD 23.5 billion and export valued at USD 26.5 billion. India's pharma industry is considered to be the world's third largest by volume and 14th in terms of value of production. With an extremely diversified product base covering generic drugs, bulk drugs, over-the-counter drugs, vaccines, biosimilars, and biologics, the Indian pharmaceutical industry has a strong presence at the global level. According to National Accounts Statistics 2024, published by the Ministry of Statistics and Programme Implementation, total output for industry i.e. Pharmaceuticals, medicinal and botanical products is Rs. 4,56,246 crores for FY 2022-23 at constant prices, of which value added is Rs. 1,75,583 crores. The production level of generic medicines is not available separately.

The Government launched Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) with an objective of making quality generic medicines available at affordable prices to all. Under this scheme, dedicated outlets known as Jan Aushadhi Kendras (JAKs) are opened across the country to provide medicines at 50%-80% cheaper rates than branded medicines. A total of 14,320 JAKs have been opened across the country till 30.11.2024. Under PMBJP, 2047 medicines and 300 surgicals/devices are part of the product basket, covering all major therapeutic groups such as cardiovascular drugs, anti-cancers, anti-diabetics, anti-infectives, anti-allergic, gastro-intestinal medicines, nutraceuticals, etc. It is estimated that on a daily basis 10-12 lakhs consumers buy medicines from more than 14300 Jan Aushadhi Kendras spread across the country. In last 10 years, sales of medicines worth Rs. 6,462 crore have been made through JAKs. This has led to estimated savings of Rs. 30,000 crore for citizens, compared with spending on branded medicines.

Also, Government of India has taken several measures to encourage domestic manufacturing in Pharmaceutical Sector to reduce import dependence, boost domestic manufacturing and attract large investments. The Production Linked Incentive (PLI) scheme for Pharmaceuticals has been launched in FY 2020-21, with a financial outlay of Rs. 15,000 crores and the production tenure from FY 2022-2023 to FY 2027-28, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. Under this scheme, apart from patented drugs, biopharmaceuticals, bulk drugs, In Vitro Diagnostic (IVD) devices and excipients (used in production of medicines), generic medicines of various categories such as - complex generics, auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs are produced and incentivised under the scheme.

National Pharmaceutical Pricing Authority (NPPA) is an attached office of the Department of Pharmaceuticals and is entrusted to implement and enforce the provisions of the Drugs Price Control Order (DPCO), 2013, in accordance with the powers delegated to it. NPPA is entrusted with the function of monitoring the availability of drugs in the country, identify shortages, if any, and to take remedial steps, in accordance with the provisions of the Drugs (Prices Control) Order, 2013.

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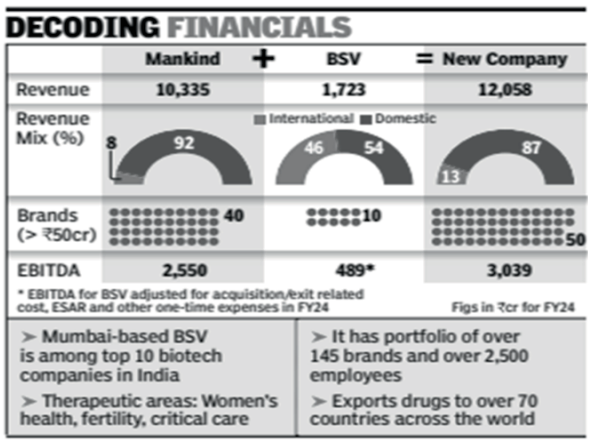
NEWS

Mankind to Acquire Biotech Co BSV from Advent for 13.6k Crore

Mankind Pharma is acquiring biotech company BSV Group, (formerly Bharat Serum & Vaccines) from PE firm Advent International for an enterprise value of around Rs 13,630 crore, subject to closing related adjustments. The deal marks a significant leap for Mankind Pharma, positioning it as a market leader in India's women's health and fertility drug market, alongside access to other high-entry barrier products in critical care, with established complex R&D tech platforms. It will potentially establish Mankind as the number one player in the Rs 11,000 cr gynaecology market, with a 13% share. At present, Mankind is ranked third, and has a 7% market share, while BSV 6%.

The deal will be funded through internal accruals and a mix of debt and equity, sources told TOI.



BSV has an in-house manufacturing and R&D platform with a track record of multiple firsts in the country and globally, says a company statement. The deal was in the making for the last few months with Europe's largest buyout group EQT with Abu Dhabi Investment Authority (ADIA) as other bidders.

BSV has developed recombinant and niche biologic products in-house, demonstrating its strong R&D capabilities and boasts of a robust branded product portfolio across women's health, fertility and critical care. It reported revenues of Rs 1,723 crore in FY24, delivering a 20% y-o-y growth. The company has a niche portfolio offering in women's health, encompassing the entire lifecycle - from fertility to post-pregnancy.

Advent had acquired a majority stake in Bharat Serum & Vaccines in November 2019 from Orbimed Asia and Kotak PE for $500 million and remaining was acquired a year later in 2020 for an undisclosed sum, thereby giving its erstwhile promoters the Daftary family an exit.

Rajeev Juneja, vice-chairman and MD, Mankind Pharma said, "BSV acquisition represents a pivotal milestone in the Mankind's journey, establishing us as a market leader in Indian women's health and fertility segment."

Source: *The Times of India,* 26th July 2024

Clinical Trial: Government Announces Waiver for Several Drugs Approved from Select Countries

In a decision that would make drugs manufactured outside India more accessible and affordable in the local market the Central government has decided to waive the requirement for clinical trials in India if the drugs are approved in the United States, United Kingdom, Japan, Australia, Canada and European Union.

The Central Government has specified a set of five categories for new drugs that will be considered for the Indian market. “Drugs including vaccines that fall in the category -- orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes, and new drugs having significant therapeutic advances over the current standard care – will be considered under the waiver,” said a senior Health Ministry official, adding that names of the countries on the current list can be added or taken off.

According to an order issued on August 7 by India's drug regulatory agency, Central Drugs Standard Control Organisation (CDSCO), the Central Government has authorised the exemption of local clinical trials for approval of new drugs, 'as per Rule 101'.

“As per Rule 101 of New Drugs and Clinical Trial Rules, 2019 the Central Licensing Authority, with approval of the Central Government, may specify by an order, the name of the countries from time to time for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V of the said rules," reads the order.

Meanwhile, another official at the Health Ministry noted that the order has been a long standing demand of the pharmaceutical companies and health experts who have been advocating for enhanced drug accessibility for patients and for research.

Anil Matai, director general, Organisation of Pharmaceutical Producers of India (OPPI) reacting to the announcement said that this a welcome and progressive move that will significantly benefit both domestic and foreign drug manufacturers by expediting the approval process and facilitating faster access to essential medications for Indian patients.

“OPPI has been advocating for this notification, recognising its potential to transform both the pharmaceuticals, and the healthcare landscape in India. The inclusion of specific categories such as orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, those for special defense purposes and new drugs with significant therapeutic advance over the current standard care would address critical and unmet medical needs.

This strategic alignment is particularly crucial for accelerating access to innovative therapies to the patients in India," he said.

The group has, however, maintained that extending these waivers to a broader range of therapeutic categories will further enhance access to cutting-edge treatments. It has asked the Central Government to consider additional therapeutic areas where similar waivers could significantly impact patient access.

Source: *The Hindu,* 8th August 2024

ICMR Signs MoAs to Advance First-in-human Clinical Trials for Four Promising Molecules

The Indian Council of Medical Research (ICMR) has formalised Memorandums of Agreement (MoAs) with multiple sponsors under its 'Network for Phase 1 Clinical Trials'. The agreements mark an entry into first-in-human clinical trials for four promising molecules, the council saidThese include collaborative research over a small molecule for multiple myeloma with Aurigene Oncology Limited; partnering for Zika vaccine development with Indian Immunologicals Limited; coordinating a seasonal influenza virus vaccine trial with Mynvax Private Limited; and CAR-T cell therapy advancement study for a new indication of chronic lymphocytic leukaemia with Immuno ACT.

"This initiative is a crucial step towards establishing India as a leader in the clinical development of pharmaceutical agents," the council said.

Union Health Minister J.P. Nadda said that the collaboration between ICMR and prominent industry and academic partners is a key milestone in the pursuit of affordable and accessible cutting edge treatments for all citizens. He noted that the initiative positioned India to emerge as a global leader in healthcare innovation.

Rajiv Bahl, Director General, ICMR, said that establishing the first phase of clinical trial infrastructure is a key component in fostering the development of indigenous molecules and cutting edge treatments.

The ICMR's 'Network for Phase 1 Clinical Trials' comprises four strategically located institutions across India — the King Edward Memorial Hospital and Seth Gordhandas Sunderdas Medical College, Mumbai; the Advanced Centre for Treatment, Research and Education in Cancer, Navi Mumbai; the SRM Medical College Hospital and Research Centre, Kattankulathur; and the Postgraduate Institute of Medical Education and Research, Chandigarh. They are supported by the Central Coordinating Unit at the ICMR's headquarters in New Delhi.

The network is designed to enhance India's capacity to conduct early phase clinical trials, supported by robust infrastructure and dedicated manpower at each trial site, ensuring smooth and effective operations.

Source: *The Hindu,* 14th September 2024

Biosimilars Can be a Boon for Autoimmune, Cancer Patients

Biological drugs — or biologics made from bacteria or living cells — are a boon for many kinds of autoimmune diseases and even cancer. But very few people in India have a clear idea about them. Umesh Isalkar speaks to Dr Syamasis Bandyopadhyay, senior consultant rheumatologist at Kolkata's Apollo Multispecialty Hospital, to know the basics.

How do biological drugs work to cure disease?

They target specific components responsible for overactive immune response seen in autoimmune diseases to stop disease progression without suppressing the immune system as a whole. As with many chronic illnesses, biologics are usually a long-term treatment. But the dosage and duration may vary depending on the patient's response. These drugs are licensed by competent authorities worldwide, just like conventional medicines, with hundreds of studies supporting their effectiveness.

Can biologics be used for all kinds of diseases?

No. Biologics have specific scientific criteria for each medical condition. Often, these drugs are used along with conventional treatments to achieve better results.

Why don't Indian patients have a fair idea about them?

That's because biologics are under utilized in India compared to the developed world as they are more expensive. Only specialist doctors are authorized to prescribe them, following established guidelines and indications. The higher cost is largely due to the drug's complex development process and manufacturing. But India has started producing biosimilars — affordable versions of biological drugs — over the past seven years. Biosimilars are about one-third the cost, making treatment more accessible. Biosimilars have also led to a reduction in the prices of biologics. However, typically, alternatives are tried first before biologics are considered.

What are JAK inhibitors and what do they treat?

They are a newer class of drugs used to treat ankylosing spondylitis (AS), and are now produced by Indian companies at lower costs. These inhibitors are also effective for conditions like IBD-associated arthritis and psoriatic arthritis.

What side effects do these medicines have?

Many avoid biological drugs due to misconceptions about their side effects. They fear these drugs will compromise the immune system, leading to further health issues. Biologics don't harm the immune system, they correct its response instead. But JAK inhibitors may not be suitable for older individuals with ischemic heart disease or those with very low white blood cell and platelet counts. And, like biological drugs, JAK inhibitors can also reactivate dormant tuberculosis. Patients must make informed decisions.

Source: *The Times of India,* 18th September 2024

To Curb Antimicrobial Resistance, Government May Include Antibiotics in Definition of New Drug

The Drugs Technical Advisory Board (DTAB), the highest statutory decision-making body on technical matters related to drugs in the country, has recommended the inclusion of all antibiotics in the definition of new drugs in the New Drugs and Clinical Trial (NDCT) Rules, 2019.

The recommendation to the Drugs Consultative Committee (DCC) is aimed at curbing the growing antimicrobial resistance which is now recognized as a public health threat globally.

According to Rule 122 E of the Drug and Cosmetic Rules 1945, a new drug can be one which has not been used in the country and has not been recognised as effective and safe by the licensing authority for the proposed claims. It could also be an approved drug with modified or new claims including indications, dosage, and new route of administration.

If brought into the new drug bracket, the manufacturing, marketing, and sale of antibiotics will be documented. Also, the manufacturing and marketing clearance will have to be obtained from the Central government instead of State drug administration, and patients will be able to buy antibiotics only on prescription.

The board is also looking at amending the labelling requirements under the Drugs Rules, 1945 and adding a blue strip or box for antimicrobial products. It has recommended that no antimicrobials should be sold by the traders to the non-pharmaceutical industries who do not hold requisite licences.

A recently released report by the Indian Council of Medical Research's Antimicrobial Resistance Surveillance Network said that drug-resistant and difficult to treat urinary tract infections, blood stream infections, pneumonia, and typhoid are among the diseases that are showing resistance to commonly used antibiotics in India.

Meanwhile, in a recent meeting, DTAB was apprised that antimicrobial resistance has been recognised as a serious and growing threat to public health globally.

"The problem of antimicrobial resistance has been highlighted as a global health priority in multiple high-level platforms and in view of this it was proposed to include all antibiotics in the definition of "new drug" in New Drugs and Clinical Trial Rules, 2019," noted the minutes of the meeting.

DTAB added that antimicrobial resistance can be caused due to misuse of antibiotic, antiviral, antifungal, etc. and accordingly recommended that the matter may be deliberated in the DCC initially.

Source: *The Hindu,* 17th October 2024

Medical Device Sector Welcomes Centre's ₹500 Crore Outlay

Despite government assistance, the medical device manufacturing sector in India faces several challenges, principally a lack of infrastructure, Union Minister for Chemicals and Fertilizers J.P. Nadda admitted while recently launching the Central Scheme for Strengthening the Medical Device Industry.

The move has been welcomed by the industry with the government allocating a total outlay of ₹500 crore. “The comprehensive scheme targets critical areas of the medical device industry covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure, and industry promotion," the Ministry said.

Calling it a game changer that will not only help the industry but will also help make India self-reliant, the Centre noted that medical device industry is an essential pillar of healthcare delivery. From diagnostic machines to surgical instruments, and from stents to prosthetics, medical devices are critical for the prevention, diagnosis, and treatment of diseases. India's medical device market is valued at approximately $14 billion and is expected to grow to $30 billion by 2030, according to the Ministry.

Welcoming the announcement. Himanshu Baid, managing director, Poly Medicure said that the new scheme for medical devices marks a significant milestone for India's MedTech sector, fostering both growth and export potential.

Key initiatives such as the identification of common facilities for medical device clusters will encourage collaboration, innovation, and cost efficiency. Capacity building and skill development programs are crucial to bridge talent gaps, ensuring high standards of manufacturing and clinical expertise," he said.

He added that the medical devices clinical studies support scheme will boost the development of high-quality, globally competitive products, enhancing India's presence in international markets, while the marginal investment scheme to reduce import dependence will stimulate domestic manufacturing, promote self-reliance, and drive down import costs.

Industry experts note that these measures will accelerate sectoral growth, reduce import reliance, and enhance India's position as a leading exporter of medical devices. The comprehensive approach is expected to benefit the industry and strengthen the country's healthcare infrastructure.

The new scheme consists of five sub-schemes including - Common Facilities for Medical Devices Clusters, Marginal Investment Scheme for Reducing Import Dependence and Capacity Building and Skill Development for Medical Devices.

Anish Bafna, CEO and MD, Healthium Medtech, said, “The government's recent ₹500 crore scheme for the medical device industry marks a major advancement toward boosting domestic manufacturing and reducing import reliance. With ₹180 crore dedicated to the marginal investment scheme, there is a significant push to develop a robust local supply chain, thereby lowering costs and spurring innovation. Additionally, ₹100 crore for clinical study support will help companies generate critical evidence for regulatory compliance, facilitating market expansion. For the medical device industry, these initiatives provide a strong foundation to drive innovation, enhance self-reliance, and position India as a global leader in medical technology.”

The Central government through the sub-scheme for common facilities for medical devices clusters, will provide financial assistance to medical device clusters for creating common infrastructure facilities including - design and testing centre, animal labs etc. for the manufacturers located in the cluster. The additional schemes aim to reduce dependence on imported components.

“Currently, most raw materials and key components are imported, making Indian manufacturers reliant on external supplies for medical device production. This sub-scheme offers a one-time capital subsidy of 10-20%, with a maximum cap of ₹10 crore per project," a release issued by the Ministry noted.

Meanwhile, under the other schemes the Central government will offer financial support for running various Masters' and short-term courses. Under the sub-scheme, support up to ₹21 crore for masters' courses in central government institutions; and ₹10,000 per candidate for short-term courses along with ₹25,000 per candidate for Diploma courses to National Council of Vocational Education and Training approved institutes will be available.

Source: *The Hindu,* 9th November 2024

Pharma Sector Must Grow Beyond Making Generic Drugs, Says Rajeev Singh

Business in the pharmaceutical sector in India can reach the projected value of US$130 billion – a two and a half times growth – in six years only if it expands beyond manufacturing generic drugs, according to drugs controller general Rajeev Singh Raghuvanshi. He said India needs to replicate its success in generic medicine manufacturing across biological drugs, research and manufacturing, medical devices, digital health and drug discovery research.

Raghuvanshi said this while delivering the SSK Marthandam endowment oration at Sri Ramachandra Institute of Higher Education and Research. He said India supplies medicines to more than 200 countries worldwide, provides 40% of generic medicines consumed in the US, 25% of the total medicines consumed in the UK and 60% of

global vaccines. Nearly 90% of the medicines consumed by low- and middle-income countries globally are manufactured by Indian producers.

"We have achieved this position with considerable effort, but maintaining this position is more challenging than reaching the top," he said. India's successful generic business stemmed from its strength in chemistry. "We were so proficient in replicating innovators' work that we discovered new synthesis routes for APIs to reduce costs by half or even more. This success held us back," he said, urging manufacturers to innovate new molecules for drug research.

The journey towards this destination has commenced, he added. Three years ago, just three countries recognised Indian pharmacopeia, but now a dozen countries have joined the list. "By the end of the financial year, we anticipate increasing it to 20. Some Indian companies have begun demonstrating to the world their progression from volumes to values," he said.

The advantage India possesses over other countries is that companies here have service embedded in their core culture. "During Covid, India manufactured and distributed vaccines free of cost while some major countries were pursuing profits," he said.

Source: *The Times of India,* 16th November 2024

Health Secretary Seeks Ban on Websites Selling Habit-Forming Drugs

Health Secretary Supriya Sahu has written to the Drugs Controller General of India urging him to expedite the formulation of regulations governing the online sale of pharmaceuticals and sought his intervention to ban websites that sell habit-forming drugs in violation of existing laws.

Presently, States were not empowered to block such websites under current provisions of law, she observed.

In a letter to Rajeev Singh Raghuvanshi, Drugs Controller General of India, the Health Secretary raised the availability of certain habit-forming drugs, particularly tapentadol, on e-commerce platforms. The Government of Tamil Nadu, she said, has been proactive in combating drug abuse through stringent measures including law enforcement and involving all stakeholders including educational institutions. Despite these efforts, there are significant challenges with the online sale of certain drugs.

The Tamil Nadu Police and the Drugs Control Department have reported a troubling trend of offenders procuring habit-forming drugs through online platforms. “These platforms operate without geographical restrictions, complicating our investigations due to the minimal or misleading information

available about sellers. This situation undermines our ongoing initiatives aimed at preventing drug abuse among students and the general public," Ms. Sahu said, in the letter.

She noted that the sale of Schedule H and H1 medicines without a prescription from a registered medical practitioner and without the supervision of registered pharmacists is a clear violation of Section 18 (c) of the Drugs and Cosmetics Act, 1940 read with rules 65 (9) (a) and 65 (2) of the Drugs Rules, 1945 respectively. The lack of transparency on the sellers' licenses exacerbates this issue, making it difficult to trace and monitor illegal transactions.

While rampant misuse of these drugs poses a serious threat to people's health, officers face challenges in controlling the flow of these substances through online channels that often evade regulatory scrutiny.

Noting that the Drugs and Cosmetics Act, 1940 was a Central Act, she urged the official to expedite formulation of regulations governing the online sale of pharmaceuticals as it was essential to safeguard public health and ensure that drug sales are conducted legally and responsibly.

Source: *The Hindu,* 19th November 2024

Indian Pharma Industry Set to Grow 58% to $130 Billion by 2030

The pharma industry expects to grow 58 per cent to $130 billion in the next five years from its current market value of $55 billion, driven by innovations, increasing exports, and a strong focus on affordability and efficiency.

Dr Veeramani, Chairman of Pharmexcil said the pharmaceutical industry stands as a global leader, exporting to over 200 countries and providing comprehensive solutions across APIs, finished dosages, clinical research and pharmacovigilance.

He said at the CPHI and PMEC India, a three-day expo, that the sector is poised for transformative growth from its current $55 billion to a projected $130 billion by 2030 and $450 billion by 2047 with innovations in biologics and specialty generics.

The impact of policies such as the US Biosecure Act will underline the industry's potential to redefine healthcare solutions worldwide, he added.

With exports currently contributing $27.85 billion, India is solidifying its position as the 'Pharmacy of the World.'

The industry's advancements in biologics, specialty generics, and AI-driven technologies are redefining healthcare solutions worldwide.

India's pharmaceutical sector is expected to continue its upward trajectory, with a target of a $1 trillion industry by 2047.

The expo has brought together over 2,000 exhibitors and 50,000 visitors from over

120 countries, including the USA, UAE, South Korea, Japan, and the UK.

Yogesh Mudras, Managing Director, Informa Markets in India said the pharmaceutical industry ranks third globally in pharmaceutical production by volume and 14th by value, contributing about 2 per cent to the nation's GDP.

India is among the top 12 global biotechnology destinations and the third largest in the Asia-Pacific region, he said.

The leadership stems from key advantages such as a low manufacturing cost, which is 30-35 per cent lower than in the US and Europe, cost-efficient R&D at 87 per cent less than developed markets and an abundant pool of skilled labour, he added.

Source: *The Hindu Businessline,* 27th November 2024

AstraZeneca Asthma Drug More Effective than Steroids During Attacks: Study

AstraZeneca's Fasenra, an injectable treatment for severe asthma, is more effective during attacks than the oral steroid that has been the standard of care for 50 years, cutting the need for further treatment by 30 per cent, according to a study published.

The antibody drug known chemically as benralizumab was approved by U.S. and EU regulators in 2017 as a treatment for a severe form of the breathing disorder called eosinophilic asthma that targets a type of white blood cell associated with lung inflammation.

The new study, led by King's College London researchers, involved 158 patients in Britain who were at high risk of an asthma or chronic obstructive pulmonary disease (COPD) attack.

The researchers found that Fasenra can be more effective than the oral corticosteroid prednisolone when injected during an attack, also called an exacerbation, which can involve symptoms such as wheezing, coughing and chest tightness.

Steroids such as prednisolone can reduce inflammation in the lungs but also may cause severe side effects.

The exacerbations account for 30 per cent of COPD flare-ups and nearly half of all asthma attacks, and can become more frequent as the disease progresses.

Many patients who suffer these attacks need repeated courses of steroids, re-hospitalisation or die within 90 days, the researchers said.

In the study, after 28 days of treatment respiratory symptoms were found to be better with benralizumab. After 90 days, there were four times fewer people in the AstraZeneca drug group that failed treatment compared to standard of care with prednisolone.

The findings show that the AstraZeneca drug can also be used during the emergency of a life-threatening attack, at a hospital or potentially even at home, to reduce the need for further treatment and hospitalisations, researchers said.

"This could be a game-changer for people with asthma and COPD," Professor Mona Bafadhel from King's College London, who led the trial, said in a statement.

Asthma and COPD exacerbations cause nearly four million deaths worldwide each year, but treatment for the chronic conditions has not changed in five decades, she noted.

Fasenra is AstraZeneca's second-best selling drug from its respiratory and immunology portfolio. It brought in $436 million in sales in the third quarter, up 13 per cent from a year earlier.

The study was sponsored by the University of Oxford and the research received funding from the Anglo-Swedish drugmaker. The findings were published in The Lancet Respiratory Medicine journal.

Source: *Business Standard,* 28th November 2024

Eli Lilly to Launch Diabetes, Obesity Drug in India Next Year

Eli Lilly, the US pharmaceutical giant that gained widespread attention globally with its weight-loss treatments, plans to launch its blockbuster drug - Tirzepatide - in India in 2025."India presents a promising market, with a large and growing population, rising disease burden from obesity, diabetes, and cancer, and an increasing health expenditure ... A combination of all of this makes us very optimistic about the India opportunity. We are committed to bringing our next line of innovations to the country, starting with our obesity pipeline and Tirzepatide in 2025," Vineet Gupta, associate VP - MD, Eli Lilly (India) told TOI in an exclusive interview.

In India, the drug will be introduced under the brand name Mounjaro, targeting both type 2 diabetes and obesity. The company received marketing authorisation for the drug earlier in July, and is working to get the additional approvals, ahead of its 2025 launch.

Sales of Mounjaro globally for Q3 2024, stood at over $3.1 billion. Meanwhile, its Danish rival, Novo Nordisk with the ground-breaking Wegovy, has reportedly said it plans to get the drug in 2026 to India.

Soaring global demand for weight-loss drugs has propelled drug biggies Lilly and Novo Nordisk among the world's most valuable companies as they aggressively compete in the obesity market that analysts predict could cross $100 billion in the next decade. The surge in demand has led firms to scramble to scale up production capacity globally.

In the US, the price of Mounjaro is around $1,000 per fill, but the amount a patient pays depends on factors like insurance. A huge demand for weight loss among affluent Indians, particularly celebs, has led to them being imported through unofficial channels, sidestepping regulatory checks. These are available at a fraction of the US price, majorly in the grey market.

Gupta said that the company has not decided on the pricing of Tirzepatide for India, but it "will be priced competitively and appropriately which will reflect the efficacy of this medicine and also the value that it will bring in reducing the overall health and economic burden of type 2 diabetes and obesity".

Through the launch of Mounjaro, the company will widen its key diabetes portfolio in the country. In diabetes, it has distribution partnerships with two domestic pharma companies: for Huminsulin range of products with Lupin, and for Humalog and Trulicity with Cipla.

"Our strategy in India has been a mix since we set up shop in 1993. We have some strategic partnerships which are specifically for our diabetes portfolio, and our non diabetes portfolio in India, we continue to promote through our own team. We are expanding our commercial operations in the country, in preparation of bringing these innovations," he stated.

Eli Lilly also has a contract manufacturing collaboration with Gland Pharma to manufacture human insulin vials in the country.

Source: *The Times of India,* 9th December 2024

Indian Scientists Develop Novel Gene Therapy Treatment for Haemophilia

Scientists in India have reported success with using gene therapy to treat severe haemophilia A, a rare hereditary condition resulting from a faulty gene which triggers severe, spontaneous, and potentially fatal bleeding episodes.

Though only tested on five patients in Tamil Nadu so far, none of them have reported bleeding episodes over an average follow-up period of 14 months. It is not unusual for those afflicted by haemophilia to have weekly bleeding episodes, requiring frequent treatment. The results of the study were reported in the peer-reviewed New England Journal of Medicine (NEJM) earlier this week.

The trial was led by Alok Srivastava of the Centre for Stem Cell Research (CSCR) at Christian Medical College, Vellore, and financially supported by the Union Department of Biotechnology.

One-time solution

The typical treatment for the condition requires injections at frequent intervals, with infusions of a 'clotting factor' to prevent

bleeding. Gene therapy treatments, however, promise to be a one-time solution. A gene introduced into the body teaches it to create enough of the clotting factor that can prevent such haemorrhage.

Haemophilia can be classified as minor or severe depending on the percentage of clotting factor present in those afflicted. Haemophilia A, the more common version of the condition, is caused by the absence of a blood-clotting factor called Factor VIII. Even though haemophilia is a rare disorder, India has the world's second largest patient pool, with an estimated 40,000 to 100,000 patients.

Those with Severe Hemophilia A have less than 1% of the clotting factor, and manage the condition with repeated Factor VIII replacement, monoclonal antibodies, or injecting substances that mimic Factor VIII to stop or prevent bleeding. Because of the nature of the condition and the relatively low numbers of patients, treatment can be expensive. A March 2024 research study in the journal Heliyon estimates the per patient cost of treating a haemophiliac in India to be $300,000 (or ₹2.54 crore) over a 10-year period.

Safer, more effective treatment

There is only one gene therapy — Roctavian — which was approved by the U.S. Food and Drug Administration for commercial use in 2023. Its effectiveness was established based on results from a cohort of 112 patients followed up for at least 3 years after Roctavian treatment. Following the infusion, the average bleeding incidents decreased from 5.4 bleeds per year at baseline to 2.6 bleeds per year. The majority of patients who received Roctavian also received corticosteroids to suppress their immune systems for the gene therapy to be effective and safe, according to the U.S. FDA.

Roctavian works by transporting the therapeutic gene into the body by using an adenovirus as a carrier or vector and involves the liver in producing Factor VIII. In the CMC trial, stem cells from the patients were fused with the clotting factor gene using another kind of vector, called a lentivirus.

'Ground-breaking'

This approach, the authors say in their paper, is safer than using an adenovirus, and potentially opens up the gene therapy treatment to children.

An independent expert described the study as "ground-breaking."

"This ground-breaking study is notable for several reasons. First, it establishes that initiating and executing studies involving new gene therapy is possible even in resource-constrained settings such as India," said Johny Mahlangu, in an editorial in the NEJM. "[There is] the potential to localise the manufacture of gene therapy in India, resulting in reduced cost and increased gene therapy access beyond India. This breakthrough could remove other barriers, such as liver health and maturity, and the need for immunosuppressive therapy," Dr. Mahlangu added.

Source: *The Hindu,* 12th December 2024

Pharma Market Rebounds, Asthma Drug top Seller

After months of sluggish sales, strong demand for derma and cardiac drugs drove the organised pharma retail market to double-digit growth in Nov, with heavy pollution in several parts of the country boosting Foracort sales.

The medication, used for asthma and respiratory issues, topped the market in Nov with sales of Rs 82 crore, according to the latest data culled by TOI from IQVIA.

Foracort assumed the top slot in Nov with a growth of 2%, while antibiotic Augmentin ranked second with a growth of 9% registering Rs 76 crore sales, and antidiabetic therapy Glycomet GP, ranked third, was almost flat at Rs 69 crore.

In terms of therapies, urology led the growth with 18% rise, while the derma, cardiac, and pain-relief segments followed with growth rates of 16%, 13%, and 13%, respectively.

Further, pain-relief medication Zerodol SP posted a growth of 22%, while others which grew over 20% month-on-month include Ryzodeg, Rosuvas, Cilacar, Rybelsus and Duphalac.

Sun Pharma continued to lead the pack with a share of 8% in the overall pharma retail market valued at Rs 2,28,059 crore. Cipla and Dr Reddy's also increased their share month on month.

During the month, both acute - mainly painkillers and anti-infectives - and chronic medication, those prescribed for long-term ailments, posted a double-digit growth of 11% each.

"After a lull for the last three months, industry volumes reported positive growth of 3.5%. Rebound in growth for anti-infectives was led by key molecules like amoxicillin + clavulanic acid and ceftriaxone, pantoprazole + domperidone combination was main growth driver for gastro-intestinal therapy, cough syrups, formoteral + budesonide and levocetirizine+montelukast drove growth in respiratory therapies," an analyst from ICICI said.

Domestic companies registered growth of nearly 11%, whereas MNCs grew just over 10%.

In 2025, the market will continue to grow by high-single digits, led by price increase and new launches, while volume growth remains muted, an analyst from HSBC told TOI. "In 2025, we assume Indian companies will start their journey in GLP-1 (Glucagon-like peptide-1) drugs with the launch of generic liraglutide," he added.

GLP-1 is a hormone that helps control blood sugar levels and plays a role in weight management. Globally, MNCs including Novo Nordisk and Eli Lilly have launched blockbuster drugs for obesity and diabetes, which are expected to be launched in India over the next few years.

Source: *The Times of India,* 14th December 2024

Pharma Units Get 12-Month Extension to Implement Revised Schedule M of Drugs and Cosmetics Act

The Union Health Ministry on Saturday (January 4, 2025) revised the date of implementation of the revised standards of Schedule M of the Drugs and Cosmetics Act to give pharmaceutical manufacturing industry 12 more months to comply.

Pharmaceutical firms must now comply with the improved manufacturing practices by December 31, 2025. The extension follows a request from the manufacturing units for time to upgrade their facilities.

Schedule M is a part of the Drugs and Cosmetics Act of 1945 that outlines Good Manufacturing Practices (GMP) for pharmaceutical products in India. It covers the requirements for premises, plants, and equipment used in the manufacturing process.

To keep pace with the fast changing pharmaceutical manufacturing and quality, the government revised the GMP mentioned in current Schedule 'M' of the Act.

Time for smooth transition

The new Schedule M was notified in December 2023. In order to have a smooth transition from the present Schedule M to the revised one, it was decided to provide a transition period of six months for large manufacturers (>₹250 crore turnover) and 12 months for Micro Small and Medium Enterprises (MSMEs) (<₹250 crore turnover) respectively. The notification was published on January 5, 2024.

As per the notification, units with annual turnover of more than ₹250 crore were to comply with the revised Scheduled M standards from July 1, 2023. For units with annual turnover of less than ₹250 crore (MSMEs), the date of implementation was January 1, 2025.

However, following representations from various industry associations representing pharma MSMEs seeking extension of this deadline, a draft notification has been issued by the Department of Health and Family Welfare giving them three months' time to register with Central Drugs Standard Control Organisation (CDSCO) as well as share their plans of upgradation with it.

“Total twelve months' extension will be provided for such units i.e. until end of the year. After 3 months, an audit of these facilities will be conducted and depending on the status of implementation of the plan, action will be taken if the upgradation which has been committed is not being executed,'' said a release issued by the Health Ministry.

“The main reasons for seeking extension are arranging finances for upgradation and time for implementation of the required changes. The issue of providing extension in the implementation date has been discussed in detail,'' the Ministry added.

Revision to improve manufacturing standards

The revision of Schedule M was done to bring India's manufacturing standards on a par with global standards, especially to those of World Health Organisation (WHO), and ensure production of globally acceptable quality of drugs.

Good Manufacturing Practices are being implemented in the country to build and bring quality into products by way of control on materials, methods, machines, processes, personnel and facility/environment, etc.

There are around 10,500 manufacturing units in the country, of which around 8,500 fall under the MSME category. India is a major exporter of medicines to Low and Middle-Income Countries (LMIC) which require WHO GMP certification. Currently, there are around 2,000 units in the MSME category in the country having WHO GMP certification.

The Department of Pharmaceuticals (DoP) launched a scheme, Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS), to provide financial support for upgradation of MSME units.

Till date, CDSCO has inspected more than 800 manufacturing units and 252 public testing labs.

"The observations from the units being audited and the feedback coming from stakeholders clearly show the improvement on ground towards implementation of GMP standards by MSMEs. There is awareness and sensitization all around and there are a good number of units which have initiated the upgradation process," noted the release.

Source: *The Hindu , 5*th January 2025

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