ISSUE No. 57

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2023

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MOVING GLOBALLY

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R & D and Manufacturing of Formulations

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Domestic Marketing

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Surgical

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Diagnostic Care @ Home	Chain of Diabetic Clinics	Clinical Research Organisation

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 57th issue of Pharma Web Newsletter for Jan – Mar 2023.

This 57th issue contains the program highlights as well as the following article published by eminent person in Pharma industry.

- **IND & NDA Enabling Preclinical Studies**
  Dr. Nitin M. Shetty, Chief Technical Officer, Bioneeds India Private Limited, Bangalore

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

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

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

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

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

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

IND & NDA Enabling Preclinical Studies

Dr. Nitin M. Shetty
Chief Technical Officer, Bioneeds India Private Limited, Bangalore

Lecture Delivered during Webinar organized by of IPA, Tamilnadu, on 14th March 2023

Drug Development - Strategies

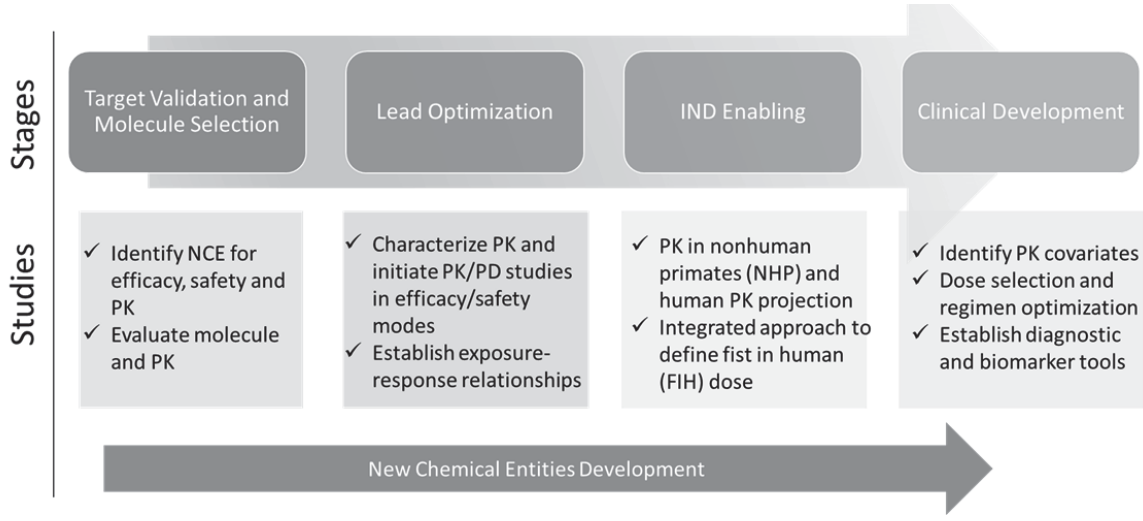
- Planning
- Precise
- Proprietary
- Patience
- Perseverance
- Provision

Stages of Drug Development

- Pre-IND
- IND
- Phase 1 clinical trials
- Phase 2 clinical trials
- Phase 3 clinical trials
- NDA
- Post-marketing

- Early Drug Discover
- Pre-Clinical Phase
- Clinical Phases
- Regulatory Approval

Phases of Drug Discovery & Development



Pre-IND - Before Submitting an IND

- Define chemical properties of the drug
- Conduct nonclinical pharmacology/toxicology studies
- Identify leads or narrow down on HITs thru lead optimization

Pre-IND Drug Discovery Process

Major aspects of early drug discovery

Discovery Phase

- Discovery chemistry
- Discovery biology - In vitro, animal models, in silico
- Often aided by artificial intelligence (AI)

Screening phase

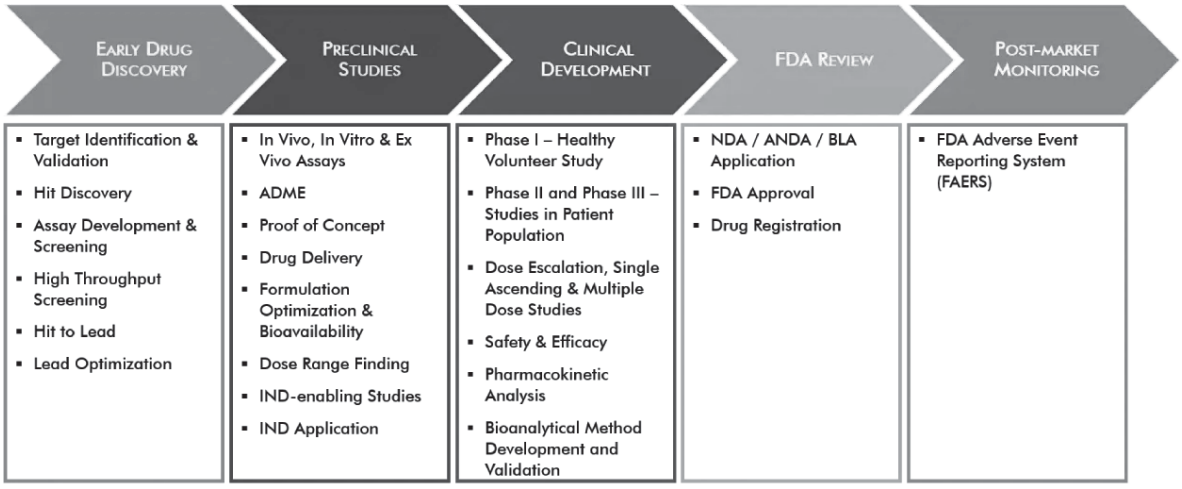
- In vitro pharmacology (test tube, petri dish)
- Ex vivo studies in human tissues
- In vivo pharmacology and efficacy assessment
- Abridged/fast track DMPK & Safety
- Identification of a lead molecule (s)

Pre-IND Drug Discovery Process

PK/PD Studies

- Drugs produce effects by interacting with receptor targets.
- Pharmacokinetics (PK) & pharmacodynamics (PD) are the two main branches of pharmacology that deal with both aspects of this process
- PK/PD helps in assessing how drug molecule begins at its site of administration and travels to the receptor on which it acts.
- Complex biochemical interactions that occur between the body's natural processes and drugs are analyzed and described through PK/PD
- Both of which play a key role in determining the safety and efficacy of drugs.

PK/PD Studies cover all stages of development of pharmacologically relevant species.



New Products Regulated by Regulatory Authorities

- **New entities**
  - Small molecule, Biologic, Nutraceuticals
  - Not previously tested in humans
- **New formulations (re-formulations) for previously tested /approved drugs**
- **Combinations of previously approved drugs**

Investigational new drug (IND)

An investigational new drug (IND) application

- the application is a mandatory requirement to allow FIM studies on unapproved drugs
- is the first step for any pharmaceutical company on their journey to getting a new drug to market.
- Submission to the related regulatory bodies
- Another function of an IND application is to permit shipment of the unapproved drug across state lines,

Investigational new drug (IND)

Two forms of INDs:

- Commercial – businesses filing for marketing approval for a new drug
- Research – businesses filing for investigator IND, emergency use IND, and treatment IND, whereby no standard treatment is available and insufficient time exists to receive approval

Investigational new drug (IND)

Information required IND application (but not limited to):

- Preclinical data to ensure efficacy, kinetics & potential safety in humans
- CMC information such as the controls used for producing the drug substance and product
- Clinical protocols to evaluate whether the initial-phase trials pose any unnecessary risks to research subjects
- Investigator information to evaluate the qualifications of the clinical professionals who are overseeing the trials

Once submitted to DCGI or FDA, the approval process takes around 30-45 days, after which a drug manufacturer "may" send the drug to the investigators for trials.

Investigational new drug (IND)

An Investigational New Drug (IND) application

- is required by the regulators before any clinical studies
- For new drugs or for most follow-on products (besides generics), the results of certain nonclinical studies, known as IND-enabling studies, must be submitted with the IND application to support the investigational drug use in humans.

IND-enabling studies are beneficial because they:

- Predict potential safety concerns
- Allow estimation of safe starting doses for clinical trials
- Identify key parameters for monitoring ADR

IND-enabling Studies

What are IND-enabling Studies?

- IND-enabling studies include in vitro & in vivo assessments to define pharmacological & toxicological properties of a drug.

- To define dose & exposure dependencies, reversibility of toxic effects.

IND-enabling studies allow drug developers to assess:

- PD and safety pharmacology

- PK, including ADME

- Toxicology – Acute, Short & Long term, reproductive & developmental toxicity, and genotoxicity studies

New drug application (NDA)

- **Final** step in a pharmaceutical company's journey to getting their drug to market

- Post IND application approval, clinical trials are initiated

- Following completion of all required phases a formal request to market the drug is made in the form of a NDA

- Application will include all clinical trial data collected through the completed phases carried out following acceptance of the IND.

The NDA is considerably more complex than an IND, this submission will need to encompass a lot more data (approx. 15 sections) including: pharmacokinetic and pharmacodynamic data, ingredient information, CMC, clinical results and quality control.

NDA Enabling Studies

What are NDA-Enabling Studies?

IND-enabling studies are not the end of nonclinical development.

- On the contrary, most development programs require additional studies viz.

  - Multi species long-term, nonclinical studies to assess potential for long-term toxicity

  - Multi segment Reproductive & Development studies

  - Juvenile animal studies may also be required before the drug can be administered to paediatric patients

  - Carcinogenicity studies

IND & NDA Applications

The goal in providing data is to assure the regulator that:

- Benefits of the new drug outweigh the negatives; safeguarding the effectiveness of the drug

- Intended labelling for the drug is correct and appropriate

- Manufacturing process is suitable to preserve the strength and dosage of the drug

Once submitted, the DCGI or FDA may 60 days to decide if it will be filed for further review.

IND & NDA Applications

- Drug development timeline is a complex process

- It starts with an IND submission (after pre-clinical activities are settled to gain approval to cross state lines and start clinical trials)

- and ends with NDA submission to ensure all aspects of the drug are effective and ready to market in the USA.

- It takes around 12-15 yrs & cost $2.6 billion on average (varies on case-case basis)

- Discovery process involves 5,000-10,000 compounds & only 1-5 advances into clinical development (human studies).

- For 5 compounds that make it into clinicals, likelihood of receiving FDA approval is about 3-10%.

Both applications are essential in acquiring market approval & it is a high priority for life science companies to complete it in a quick and compliant way.

IND-Enabling Studies - Drug Metabolism & Pharmacokinetic (DMPK)

Non-GLP

Solubility

- Aqueous solubility assay

- LogP & LogD

Metabolism

- CYP Inhibition & Induction

- Metabolite identification

Metabolite stability

- Microsomal stability/binding studies - Multi species

- Hepatocytes Stability studies (Multi-Species).

IND-Enabling Studies - Drug Metabolism & Pharmacokinetic (DMPK)

Non-GLP

Absorption & Permeability Studies

- Cell permeability (CaCo2, MDCK)
- PAMPA Assay
- MDCK, Efflux (CaCo-2) -Pgp substrate identification

Distribution assay

- Plasma Protein Binding
- Plasma/whole blood stability
- Blood to plasma ratio

GLP

In vivo Pharmacokinetics

- Rat / mice PK
- Tissue distribution assay (cold or radiolabelled)/Immunogenicity
- Dog/Monkey PK

IND-Enabling Studies - Drug Metabolism & Pharmacokinetic (DMPK)

GLP

In vivo Pharmacokinetics

- Rat / mice PK
- Dog/Monkey PK
- Bioavailability/Food effect
- Tissue discrete and uptake studies
- Tissue distribution assay (cold or radiolabelled)/Immunogenicity
- Optimization of suitable formulation, cassette dosing
- Long term studies and multi-study capabilities

IND-Enabling Studies – Safety Assessment

GLP

General Toxicology

- Single dose : 2 route - 2 species (Rat & Mice)
- MTD study with 14-day DRF – Dogs
- Short term toxicity study - 14/28/90-day repeat dose study by intended route
- Rodents - rats & Non-rodents - dogs/monkeys

Genetic toxicity study

- Bacterial Reverse Mutation Test (Ames)
- Mammalian Cell Gene Mutation Test (HPRT Gene, TK Gene)
- Mammalian Chromosome Aberration Test
- Mammalian Cell Micronucleus Assay
- Mouse micronucleus study
- Mouse chromosomal aberration assay

Reproductive Toxicology

- Male & Female Fertility

IND-Enabling Studies – Safety Pharmacology

Undesirable pharmacodynamic effects of drugs on physiological functions in relation to exposure in the therapeutic range and above.

CNS

- General observation
- Modified Irwin test (mice & rats)
- Locomotor activity
- Motor incoordination

CVS

- hERG assay
- Rat, G. pig, Rabbit & Dog CV assessment
- Telemetry with respiratory arm

IND-Enabling Studies – Safety Pharmacology

Respiratory: Whole body plethysmography (Rat)

- Respiratory rate, tidal volume, minute volume, peak inspiratory and expiratory flow, expiration an inspiration time, Penh and EF50

- **GIT**
  - Charcoal meal test

- **Drug – Drug interaction**

NDA-Enabling Studies – Safety Assessment

GLP

General Toxicology

- Chronic Toxicity Studies - 3-19 months repeat dose in rats by intended route
- 3-24 months repeat dose in dogs/monkeys by intended route
- Repeat dose toxicity studies in Juvenile rats & dogs/monkeys

Reproductive & Development Toxicology

- Male & Female Fertility Studies – Segment 1
- Teratology Studies in rats & rabbits – Segment 2
- Pre- and postnatal developmental (PPND) – Segment 3

Carcinogenicity Studies

- 18 months in Mice
- 24 months in rats

Regulatory Authorities – IND-NDA Applications

- **Central Drugs Standard Control Organisation(CDSCO)** - under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India
- **The United States Food and Drug Administration (US FDA)**, Federal agency of the Department of Health and Human Services.
- **The Medicines & Healthcare products Regulatory Agency (MHRA)**, Executive agency of the Department of Health and Social Care in the United Kingdom
- **The Therapeutic Goods Administration (TGA),** Australian Government, Department of Health & Aged Care
- **HEALTH CANADA (Canada)**
- **Medicines Control Council (MCC),** South African Health Products Regulatory Authority (SAHPRA)
- **European Medicines Agency (EMA)** - European Union, Netherlands

QAU Involvement in IND & NDA Studies

Quality Assurance (QA) Programme is a cornerstone in the process of drug discovery & Development

Good Laboratory Practice (GLP) is an integral system created within a test facility. QA constitutes an internal mechanism of continuous monitoring for assuring test facility management (TFM) and regulators of the GLP compliance of the test facility and of the studies conducted therein.

QAU Conducts three types of Inspection

- Study based
- Facility based
- Process based

QUALITY IS EVERYTHING

PHARMACIST IN PATIENT WELFARE

by

Ms. Nihala. M,
Swamy Vivekanandha College of Pharmacy, Tiruchengode

Note: This article was awarded 1st prize in the Essay Competition conducted by our Trust

INTRODUCTION:

A Pharmacist, also known as a Chemist or a Druggist, is a healthcare professional who prepares, controls, formulates, preserves and distributes medicines and advises and guides the public on the correct use of medicines to achieve maximum benefit, minimal side effects and to avoid drug interactions. They also serve as primary care providers in the community. Pharmacists undergo university or graduate-level education to understand the biochemical mechanisms and actions of drugs, drug uses, therapeutic roles, side effects, potential drug interactions, and monitoring parameters. This is mated to anatomy, physiology, and pathophysiology. Pharmacists interpret and communicate this specialized knowledge to patients, physicians, and other health care providers.The most common pharmacist positions are that of a community pharmacist (also referred to as a retail pharmacist, first-line pharmacist or dispensing chemist), or a hospital pharmacist, where they instruct and counsel on the proper use and adverse effects of medically prescribed drugs and medicines. In most countries, the profession is subject to professional regulation. Depending on the legal scope of practice, pharmacists may contribute to prescribing (also referred to as "Pharmacist prescriber") and administering certain medications (e.g., immunizations) in some jurisdictions. Pharmacists may also practice in a variety of other settings, including industry, wholesaling, research, academia, formulary management, military, and government.

PEOPLE TRUST PHARMACIST:

For many years, Pharmacist has consistently been named among the top five most trusted professionals in national surveys. Educators are also consistently in the top five and, according to a recent survey, Pharmacist are the most trusted people in the world. That's our pharmacy profession. Three elements are necessary for trusts are positive relationships, competency/expertise, and consistency. Pharmacists on multidisciplinary teams, the level of trust increase significantly for providing additional health support and disease-specific counselling or for prescribing medications, both acute and chronic meanwhile, pharmacists expect to take on more direct patient care responsibilities in the future and it is assumed to take more role in preventive care measures.

PHARMACEUTICAL CARE:

It is a care to patient-centered, outcome-oriented pharmacy practice in which the pharmacist need to work along with the patients and their healthcare providers to promote health, prevent disease, monitor, initiate, and modify medication use so that safe and effective drug therapy regimens are planned. Pharmaceutical care aimed to optimise the patients' health-related quality of life and achieve positive clinical outcomes within economic expenditures.

PATIENT COUNSELLING:

It is delivery of the medication information to the patients or their representative either orally or in written form regarding how to use the medicine, instruction, on possible side effects, precautionary measures, storage conditions, consumption of diet, and modification of lifestyle if any requires. According to USP, medication counselling is approaches that focus on enhancing the problem-solving skills of the patients for the purpose of improving or monitoring the quality of health and quality of life. During counselling, the pharmacist should assess the patients understanding about his or her illness and treatment and provide individualised advice and effective manner. To provide accurate advice and information, the pharmacist should be familiar with the pathophysiology and therapeutics of the patients' disease. Pharmacist should follow the steps during patient counselling are preparations of the session, opening of the session, counselling content, closing the session with the aim of patient's health care management.

PATIENT MEDICATION HISTORY INTERVIEW:

It is a practice associated with collection and recording of information by reviewing/interviewing of patient related to his/her past and present medication used. Clinical pharmacists are mainly responsible in dealing with such type of activity. Clinical Pharmacists collects detailed, accurate and complete information of all prescribed and non-prescribed medications which patient have taken previously and currently. Patient medication history provides the valuable information on the patient's allergic tendency. Patient compliance and self-medications such type of practice helps the pharmacist to establish with the patient commencing of patient counselling and designing of pharmaceutical care.

COMMUNICATION SKILLS:

Communication skills are the capability to use language in precise and express information in easy way to understand with patients and family members. Effective communication skills are

critical elements for patients, pharmacist and doctors. Communication skill of the pharmacists may be verbal or non-verbal way. The main goals of communication are, to creating good interpersonal relationship, Facilitating exchange of information including patient in decision making. Poor communication skill between pharmacist and patient may leads to following are inaccurate patient medication history, Inappropriate therapeutic decisions which leads to patient confusion, patient disinterest and patient non-compliance.

PHARMACIST GIVE RESPECT FOR THE PATIENT:

Respond to the patient as a person not a prescription or case or room or bed number, avoid exchange personal information and confidences with the patient, pharmacist should arrange adequate time for interaction and minimize interruptions and introduce yourself and explain the patient about the purpose of the interaction and also explain how to use the obtained information, the environment should be clean, neat, and well organized note taking is acceptable but should not control the interaction.

CONCLUSION:

Taking everything into account, the fundamental responsibilities of a pharmacist is to ensure the appropriateness of medication orders. They organize information according to medical problems (disease) helps breakdown a complex situation into its individual parts. A pharmacist serves as a starting point for pharmacy activities like medication counselling, therapeutic drug monitoring, and adverse drug reaction. The certain policies being developed by various countries under which the pharmacist visited certain categories of patients and counsel them about medications as well as supply of the medications as per prescription order. Altogether I conclude that pharmacistplay a very important role in public health through various initiatives which includes health education, health communication, and medication review and medication adherence.

"PHARMACY IS NOT ONLY THE PROFESSION, IT IS PASSION TO SAVE LIFE"

INFORMATION

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

Profile of 1st Rank

PHARMACEUTICS

Name: Mr. Anuj Kumar Singh

Project Title: Development of a safe and effective tetravalent subunit-based vaccine candidate for Dengue Virus and formulating the antigenic protein using the Alumunium hydroxide & Cytosine Phosphoguanine oligonucleotide as adjuvents.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Vasanthraj. P

PHARMACEUTICAL CHEMISTRY

Name: Ms. Jinu Mathew

Project Title: Multi-targeted directed drugs as potential therapeutic agents for Alzheimer's disease modulating GSK-3β, AChE and MAO-B: In silico designing, synthesis and in vitro analysis of novel hybrid marine molecules.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Srikanth Jupudi

PHARMACEUTICAL ANALYSIS

Name: Mr. Vignesh. S

Project Title: Stability-indicating assay method for simultaneous estimation of Dapagliflozin propanediol monohydrate and Vildagliptin in bilayer tablet by RP-HPLC

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Mrs. Kavitha. M

PHARMACOLOGY

Name: Mr. Chandrasekar V

Project Title: Preparation and Evaluation of Sesbania grandiflora (L.) Borax gel on Erectile response in aged rat model.

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Dr. G. Venkatesh.

PHARMACOGNOSY

Name: Mr. R. Padmanaban

Project Title: Pharmacognostical, Phytoformulation and evaluation studies on a novel sparkling water formulation of the leaves of Carica papaya Linn (Caricaceae), therapeutically beneficial in the management of dengue fever

College: Mother Theresa Post Graduate and Research Institute of Health Sciences, Puducherry.

Guide's Name: Prof. Dr. V. Gopal

PHARMACY PRACTICE

Name: Ms. Yuvashri. K

Project Title: Incidence of contrast induced nephropathy post percutaneous coronary intervention

College: KMCH College of Pharmacy, Coimbatore

Guide's Name: Dr. S. Shalini

PHARM D

Name: Mr. K. G. Sandeep, Mr. G. Ramanaprasanth, Ms. S. Tanushree

Project Title: Incidence and Management of Post Covid Complications.

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Dr. R. Kameswaran

NOTIFICATION

F. No. 29/Misc/03/2022-DC (94)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare
****

FDA Bhawan, New Delhi
Dated the April, 2023

CIRCULAR

12 APR 2023

Subject: Licensing regime of Class C & D non-notified medical devices which are currently under mandatory registration, as per GSR 102(E) dated 11.02.2020, under Medical Devices Rules 2017, w.e.f from 01.10.2023 - Regarding.

As you are aware, that the Class C and D non-notified Medical Devices which are currently under mandatory registration, will be under licensing regime w.e.f 01.10.2023, as per GSR 102(E) dated 11.02.2020.

It is pertinent to mention that, as per Medical Devices Rules (MDR) 2017, for grant of manufacturing license of Class C and D medical devices, the inspection needs to be carried out within 60 days from the date of application by the Medical Devices Officers (MDO) of Central Licensing Authority (CLA), to ensure the compliance with Fifth Schedule of MDR 2017.

In order to have smooth transition from mandatory registration to licensing regime, it is suggested that, the manufacturers/importers may apply for grant of manufacturing/import license with all requisite documents and fees as per MDR 2017, through www.cdscomdonline.gov.in portal. The application received will be processed proactively, so that, licensure can be issued within the stipulated time line in order to avoid any disruption of the supply chain of such medical devices and access to the patients.

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

To
All Stakeholders/Associations.

Copy to:
1. All Zonal/Sub-Zonal offices of CDSCO
2. All Port offices.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 25th April, 2023

S.O. 1928(E).— In pursuance of the provisions of sub sub-rule (2) of rule 19 of the Medical Devices Rules, 2017, the Central Government hereby makes the following amendment 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 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, for serial number (1) and the entries relating thereto, the following shall be substituted, namely: —

(1)	(2)	(3)
" 1	The National Institute of Biologicals, Noida	In-Vitro Diagnostics Medical Device for Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus, Syphilis, Blood Grouping, RT-PCR Kits for Diagnosis of Covid-19, Ribonucleic acid (RNA) Extraction Kits for Diagnosis of Covid-19, Viral Transport Medium (VTM) for Diagnosis of Covid-19, RTLAMP Kit for diagnosis of Covid-19, Glucose Test Strip and Fully Automated Analyser Based Glucose Reagent and Glucometer.".

[F. No. : X.11035/22/2018-DR]
ARADHANA PATNAIK, Jt. Secy.

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii) vide notification number S.O.2237 (E), dated the 1st June, 2018.

PARLIAMENT QUESTION AND ANSWERS

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

LOK SABHA
STARRED QUESTION NO.245
TO BE ANSWERED ON THE 17TH MARCH, 2023

ONLINE SALE OF MEDICINES

***245. DR. SUBHASH RAMRAO BHAMRE:**
SHRI SUNIL DATTATRAY TATKARE:

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

(a) whether Drugs Act, Pharmacy Act and other drug related rules do not permit the sale of medicines on the internet and if so, the details thereof;

(b) whether online pharmacies and online platform are indulging in illegal sale of drugs and there is sudden increase in sale of duplicate and spurious drugs, if so, the details thereof;

(c) whether the Government also plans to completely ban online sale of medicines especially abortion pills in the near future, if so, the details thereof and action taken/likely to be taken thereon;

(d) if not, whether the Government has finalized the guidelines for sale and distribution of drugs through e-Pharmacies;

(e) whether illegal e-Pharmacies are also creating their own health data on their portal which is also a threat to personal health data and also against the PM Health data policy of NHRM; and

(f) if so, the corrective steps taken by the Government in this regard?

ANSWER

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

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 245 FOR 17TH MARCH, 2023
****

(a) to (d): In order to regulate the online sale of medicines comprehensively, the Government had published draft rules vide G.S.R. 817 (E) dated 28th August 2018

inviting comments from public/stakeholders 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.

Several court cases are pending in various High Courts in the country on online sale of drugs.

The Hon'ble Madras High Court, vide order dated 17.12.2018, has ordered that as the draft rules are framed by the Central Government, after deliberations including the stakeholders, till the aforesaid rules are notified, the on-line traders are bound not to proceed with their on-line business in drugs and cosmetics. Thereafter, Madras High Court on 02.01.2019 stayed the paragraph containing the above order dated 17.12.2018.

In another case, the Hon'ble High Court of Delhi passed the order that respondents are injuncted from online sale of medicines without licence and the respondents are directed to ensure that the same is prohibited forthwith until further orders.

The said order of the Hon'ble High Court of Delhi was forwarded to all States/UTs Drug Controllers by Central Drugs Standard Control Organisation (CDSCO) on 08.05.2019, 28.11.2019 and 03.02.2023 for necessary action and compliance.

Further, show cause notices were issued by CDSCO to various firms engaged in online/ internet sale of drugs on 08.02.2023 & 09.02.2023.

(e) & (f): CDSCO has informed that no such specific report has been received regarding creation of their own health data by E-Pharmacies on their portal.

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

LOK SABHA
UNSTARRED QUESTION NO.1523
TO BE ANSWERED ON 10TH FEBRUARY, 2023

DRUGS QUALITY CONTROL TEST

1523: SHRI DUSHYANT SINGH:

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

(a) the instances and the details of drugs failing quality-control tests in the last eight years, year-wise;

(b) whether it is a fact that neither the inspectors nor the State Drug Regulatory Authorities (SDRAs) are required to maintain a record of non-compliant and offending drug manufacturers; and

(c) if so, the details thereof along with the reasons therefor?

ANSWER

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

(a) to (c): As per information received from various States/UTs Drugs Controller, year wise data of Not of Standard Quality/Adulterated/Spurious Drugs reported and enforcement action taken thereof in the last eight years (year wise) is annexed.

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

Year (1st April of preceding year to 31st March of following year)	No. of drugs sample s tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of persons arrested	No. of Raids Conducted
2014-15	74,199	3,702	83	152	85	14,042
2015-16	74,586	3,703	234	289	59	3,648
2016-17	76,721	2,780	123	186	106	10,921
2017-18	82,599	2,783	236	131	163	7,067
2018-19	79,604	2,549	205	484	153	33,492
2019-20	81,329	2,497	199	421	220	15,641
2020-21	84,874	2,652	263	236	164	20,922
2021-22	88,844	2,545	379	592	450	15,973

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

LOK SABHA
UNSTARRED QUESTION NO. 2788
TO BE ANSWERED ON 17.03.2023

DOCTOR OF PHARMACY GRADUATE

2788. SHRI ABDUL KHALEQUE:

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

a) whether the Government proposes to permit Doctor of Pharmacy Graduate to prescribe Medicine independently and if so, the details thereof;

b) whether the Government proposes to post Pharma Graduate in Hospital and Community Centres and if so, the intended objective thereof;

c) whether pharmacists have been absorbed in different Government projects for being a technical post and if so, the number of pharmacists absorbed thereof;

d) whether the Government proposes to provide equal work and equal salary to such pharmacist in the country and if so, the details thereof;

e) whether the Government proposes to enhance salary of Tea sector pharmacist and authorize them to perform such duty in absence of Medical Officer and if so, the details thereof; and

f) whether the Government proposes to set up any Drug Testing Laboratory at Assam as functioning of Regional Drug Testing Laboratory is not satisfactory and if so, the details thereof?

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

(a) to (f): The National Medical Commission has informed that writing a prescription is dependent on examining the patients and making a diagnosis and has not agreed to the proposal of Pharmacy Council of India (PCI) for writing of prescription to pharmacist.

The recruitment of Pharmacists in the Government Hospitals including Tea Sector, and their salaries, the eligible qualifications for the posts of pharmacists in the hospitals in any State is governed by the rules of the respective State Government. However, PCI has issued Pharmacy Practice Regulations, 2015 and amendment thereafter, as per which, there is a provision for Pharm.D graduates for working in the hospitals at various positions. Further D Pharm and B Pharm are eligible to work as Community Pharmacists to provide patient care which optimizes the use of medication and promotes health, wellness and disease prevention in collaboration with physicians and other health care professionals.

A Regional Drugs Testing Laboratory (RDTL) is functional at Guwahati, Assam. The RDTL has tested 3285 samples in 2022 as compared to 1133 samples in 2018.

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

LOK SABHA
UNSTARRED QUESTION NO.2984
TO BE ANSWERED ON 17TH MARCH, 2023

QUALITY OF DRUGS

2984: SHRI GAURAV GOGOI:

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

(a) whether WHO has raised an alert over any products of any Indian firm, since 2014;

(b) if so, details of those products and the producer;

(c) whether India's apex drug regulator had undertaken any inspection based on such alert by WHO; and

(d) if so, the details of the result of such inspection?

ANSWER

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

(a) & (b): World Health Organisation (WHO) from time to time issues various Medical products alert with reference to products being manufactured in various countries. Recent such Alerts on Indian products are:-

(i) Four products namely Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup, manufactured by Maiden Pharmaceuticals Limited, Haryana.

(ii) Two products namely DOK 1 Max syrup and Ambronol Syrup manufactured by M/s. Marion Biotech Pvt. Ltd. Uttar Pradesh.

(iii) Tetracycline Hydrochloride Ophthalmic Ointment USP 1%, manufactured by Galentic Pharma (India) Pvt. Ltd., Maharashtra.

(iv) Methotrex (methotrexate) 50mg, manufactured by Celon Laboratories, Pvt. Ltd., Telangana.

(c) & (d): Details of investigation are mentioned as under:

A joint investigation was carried out by Central Drugs Standard Control Organisation (CDSCO) in coordination with State Drug Controller, Haryana at M/s Maiden

Pharmaceuticals Limited 81, HSIDC Industrial Area, Kundli 131028, Dist. Sonepat (Haryana) and control samples of the drugs were drawn and sent for test and analysis to Regional Drug Testing Laboratory, (RDTL) Chandigarh. As per report of the Government Analyst of RDTL Chandigarh, the samples were declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

However, based on violations observed in Good Manufacturing Practices, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022. Further, an order has been issued to M/s Maiden Pharmaceuticals Limited, Sonepat, Haryana on 11.10.2022 stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonepat with immediate effect in public interest.

CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd. B-49, Sector 67, Gautam Budh Nagar, Noida-201301 (U.P.). Drug samples were drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test & analysis. Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023.

In cases of other drugs, the matters are referred to concerned Zonal/subzonal office of CDSCO and investigated in coordination with the State Licensing Authorities (SLAs). Based on the investigations, SLAs take suitable action under the provisions of the Drugs and Cosmetics Act, 1940.

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

LOK SABHA
UNSTARRED QUESTION NO.†3957
TO BE ANSWERED ON 24TH MARCH, 2023

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

†3957: SHRI RAMDAS C. TADAS:

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

(a) whether the new rules for registration of all patented pharmaceutical products including new drugs being marketed in the country have been framed by the Government in coordination with Central Drugs Standard Control Organization;

(b) if so, the mechanism established by the Government for proper enforcement/compliance of the above said provisions/rules in the country;

(c) whether the information regarding incomplete data reported by pharmaceutical companies/importers and registration/marketing of new medicines imported in contravention of the rules have been received;

(d) if so, the details thereof and the action taken/ proposed to be taken by the Government thereon;

(e) whether some multi-national pharma companies have warned the Indian Generic Pharma manufacturers to stop the supply of medicines made for treatment of various chronic diseases; and

(f) if so, the measures taken/proposed to be taken by the Government in this regard?

ANSWER

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

(a) to (f): Regulatory requirements and guidelines for permission to Import and / or Manufacture of new drugs for marketing are specified in the New Drugs and Clinical Trials Rules, 2019.

For grant of permission to Import and/or Manufacture of new drugs for marketing, the applicant is required to submit various information including Chemical and pharmaceutical information's, preclinical & clinical data of safety and efficacy, Regulatory status in other countries etc. depending on category and nature of the new drug as per the provisions of New Drugs and Clinical Trials Rules, 2019.

Such applications for introduction of new drugs first time in the country are examined in consultation with Subject Expert Committees (SEC) of CDSCO and decisions for approval or otherwise are taken considering the recommendations of the Committees.

As communicated by Central Drugs Standard Control Organisation (CDSCO), there is no information that multi-national pharma companies have warned Indian Generic Pharma manufacturers to stop the supply of medicines made for treatment of various chronic diseases.

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

LOK SABHA
UNSTARRED QUESTION NO. 4014
TO BE ANSWERED ON 24th MARCH, 2023

APPOINTMENT OF PHARMACISTS AS MLSP

4014. SHRI V.K. SREEKANDAN:

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

(a) whether it is a fact that the Government provides medicines to patients through district-level mental health and non-communicable disease control schemes and if so, the details thereof;

(b) whether it is also true that the National Health Policy of 2017 provides for the appointment of nurses, pharmacists and ayurvedic doctors as Mid-Level Service Providers (MLSP) and if so, the details thereof;

(c) whether it is also true that the appointment of pharmacists as MLSP has been barred and if so, the details thereof;

(d) whether the Government is reconsidering to appoint them as MLSP and if so, the details thereof; and

(e) whether the Government is considering setting up commissions for pharmacists and nurses in line with the national medical commission and if so, the details thereof?

ANSWER

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

(a) Under NHM financial support is provided to States / UTs for provision of free essential medicines in public health facilities based on the requirements posed by States/UTs in their Programme Implementation Plans (PIPs) within their overall resource envelope. Ministry has recommended facility wise Essential Drugs List (EDL) to be made available at the public healthcare facilities to ensure widespread access to essential medicines which include mental health and non-communicable disease. No of medicines recommended at various facilities are given below. However States have the flexibility to add more.

Sr. No.	Name of Facility	No. of essential Medicine
1	DH	377
2	SDH	313
3	CHC	299
4	HWC-PHC	171
5	HWC-Sub Centre	105

(b) to (e) National health Policy, Para 11.4 -Mid-Level Service Providers: For expansion of primary care from selective care to comprehensive care, complementary human resource strategy is the development of a cadre of mid-level care providers. This can be done through appropriate courses like a B.Sc. in community health and/or through competency-based bridge courses and short courses. These bridge courses admit graduates from different clinical and paramedical backgrounds like AYUSH doctors, B.Sc. Nurses, Pharmacists, GNMs, etc and equip them with skills to provide services at the sub-centre and other peripheral levels. Locale based selection, a special curriculum of training close to the place where they live and work, conditional licensing, enabling legal framework and a positive practice environment

The functions of Community Health Officer (CHO) include provision of primary health care inclusive of clinical, public health and managerial functions. Their role includes early diagnosis, management, care coordination, prevention, control and surveillance of disease conditions. This has to be achieved by providing appropriate and timely treatment and necessary social support.

Nurses and Ayurveda practitioners are serving as CHOs. They not only have an in-depth knowledge of the human body through rigorous clinical experience and training, but also a holistic understanding of public health, which is essential for them to deliver Comprehensive Primary Health Care.

A review of the outline of Bachelor of Pharmacy (B. PHARM) curriculum indicates that a significant component of Pharmacist training is related to Pharmacokinetics, pharmacy, biochemistry, pharmaceutics, bio-technology, drug manufacturing, pharmacology labs, drug interactions etc. Except anatomy and pathophysiology, emphasis on other clinical disciplines such as- General Medicine, General Surgery, Obstetrics/Gynaecology, Paediatrics, Mental Health and Preventive and Social Medicine/Community Health are not covered in the course design. These skills are critical for performing the role of Community Health Officer. Operational guidelines of Comprehensive Primary Healthcare through Ayushman Bharat Health & Wellness Centres approved Nurses and Ayurveda practitioners for the post of Community Health Officer.

The Pharmacy Council of India and the Indian Nursing Council govern the professions of pharmacy and nursing respectively.

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

LOK SABHA
UNSTARRED QUESTION NO.†4027
TO BE ANSWERED ON 24TH MARCH, 2023

PRODUCTION OF SPURIOUS DRUGS

†4027: KUNWAR DANISH ALI:

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

(a) the details of the medicines found harmful to health in the country during the last three years; and

(b) the steps taken/proposed to be taken to check recurrence of incidents similar to that happened in Gambia and Uzbekistan due to India made medicine?

ANSWER

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

(a) & (b): Isolated complaints regarding quality of drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, the matter is referred to State Licensing Authorities (SLAs) for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below:

1. 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. Serious offences have also been made cognizable and non-bailable.

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

3. The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

4. 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.

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

6. 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.

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

LOK SABHA
UNSTARRED QUESTION No-4915
TO BE ANSWERED ON 31.03.2023

E-PRESCRIPTION

4915. SHRI MOHANBHAI KALYANJI KUNDARIYA:
SHRI DIPSINH SHANKARSINH RATHOD:

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

(a) whether it is a fact that due to sloppy and poor handwriting on the prescriptions many a times pharmacists dispense wrong medicines which leads to unwanted events and if so, the details thereof;

(b) whether the Government proposes to take cognizance and introduce e-prescription service to overcome such unwanted events and if so, the details thereof; and

(c) if not, the necessary steps taken by the Government for putting up a mechanism to monitor accuracy and completeness of the prescription?

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

(a) to (c)
Ayushman Bharat Digital Mission enables creation of longitudinal electronic health records for the citizens of the country. Union Health Ministry has notified Electronic Health Record (EHR) Standards which provides guideline for implementation of e-Prescription in EHR Systems. The Ayushman Bharat Digital Mission aims to create the backbone necessary to support integrated digital health infrastructure of the country and has 3 core building blocks, Unique Health IDs (ABHA IDs), Health Professional Registries and Health Facility registries. The health records generated can be linked with the ABHA IDs to facilitate continuity of care across all health facilities.

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

LOK SABHA
UNSTARRED QUESTION NO.4967
TO BE ANSWERED ON 31ST MARCH, 2023

DRUG REGULATORY SYSTEM

4967: SHRI JAI PRAKASH:

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

(a) whether the Government considers it appropriate to work together with States to remove loopholes in the drug regulatory system especially in the aftermath of two recent incidents reported from Uzbekistan and Gambia where it was alleged that medical products exported by two Indian firms to the two countries had certain contaminants which led to adverse reactions and death of some patients; and

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

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

(a) & (b): The Government has taken various regulatory measures to ensure the quality of medicines in the country. These includes notification for affixing Bar Code or Quick Response Code in Active Pharmaceutical Ingredients (APIs) and some drug formulations, increase in sanctioned regulatory posts of CDSCO and notification providing marketers of any drug to be responsible for its quality.

Testing capacities of Central Drugs Testing Laboratories under CDSCO have been strengthened, and Drugs and Cosmetics Rules, 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 product manufacturing license by the Authority, and that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below:

1. 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. Serious offences have also been made cognizable and non-bailable.

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

3. The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

4. 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.

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

6. 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.

The Central Government has provided Rs. 665.05 crores for strengthening the drug regulatory system including upgradation of existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices as part of "Strengthening of State Drug Regulatory System".

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

RAJYA SABHA
STARRED QUESTION NO.*149
TO BE ANSWERED ON 14TH MARCH, 2023

QUALITY OF GENERIC MEDICINES

***149: DR. ASHOK BAJPAI:**

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

(a) whether Government is aware that there is a general public notion that the generic medicines have poor quality;

(b) whether the quality of the generic medicines is being checked by the concerned departments to ensure the correct quantity of its contents; and

(c) the total production, sales and export of generic medicines during the last three years? f incidents similar to that happened in Gambia and Uzbekistan due to India made medicine?

ANSWER

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

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

STATEMENT REFFERRED TO IN REPLY TO RAJYA SABHA
STARRED QUESTION NO.*149 FOR 14TH MARCH, 2023

(a) to (c): Isolated complaints regarding quality of drugs are received from time to time. As and when such complaints are received, the matter is referred to State Licensing Authorities (SLAs) for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945, as the SLAs are empowered to take action in case of any violation to the provisions of the said Act and Rules.

Drugs imported, manufactured and sold in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. There is no definition of 'generic medicines' provided under Drugs & Cosmetics Act. Drug manufactured in the country, irrespective of whether generic medicines or branded medicines, are required to comply with the same standards of quality and safety as prescribed in the Act.

The Drugs inspectors appointed under the said Act are authorized to take samples of any drug which is being manufactured or being sold or is stocked or exhibited or offered for sale or is being distributed and these samples are sent to Govt. Analyst for testing/ analysis to ascertain the quality of drugs. In case the sample is found to be Not of Standard Quality (NSQ)/ Spurious/Adulterated/Misbranded, actions are initiated, based on merit, as per provisions of said Acts & Rules.

As per information received from Medical Stores Organization (MSO), they procure generic medicines under Rate Contract for approximately 1100 registered indenters pan India including CGHS, para-military forces, State & Central prisons, civil institutions etc. All the batches of generic medicines received are subjected to double quality checks before they are supplied to the indenters. Each and every batch of generic medicine received is sent to two NABL accredited registered laboratories for quality check. MSO also ensures that each & every batch of medicine received is also accompanied with an "In House" test report from the manufacturers.

As per information provided by Directorate General of Commercial Intelligence & Statistics under Ministry of Commerce & Industry, the export of pharmaceutical products in last three financial years has shown a year-on-year increase. It was USD 20703.46 million in FY 2019-20, USD 24444.03 million in FY 2020-21 & USD 24618.78 million in FY 2021-22. There is no separate code for 'Generic Medicine' under the 'Principal Commodity Groups' of India's export.

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

RAJYA SABHA
UNSTARRED QUESTION NO.1529
TO BE ANSWERED ON 14TH MARCH, 2023

GOVERNMENT'S STAND ON E-PHARMACIES

1529: SMT. SHANTA CHHETRI:

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

(a) whether Government is aware that Chemists Association threatened to go a strike against e-pharmacies;

(b) the details of laws governing e-pharmacies especially in relation to drug regulation and Government's stand on the issue; and

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

ANSWER

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

(a) to (c): Chemist Association had given an advance notice of nation-wide agitation from 15th February, 2023 against sale of drugs on internet.

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

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

RAJYA SABHA
UNSTARRED QUESTION NO.3120
TO BE ANSWERED ON 28TH MARCH, 2023

SPURIOUS DRUGS IN CIRCULATION

3120: SHRI RAJMANI PATEL:

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

(a) whether it is a fact that spurious and fake drugs and other health care products are available in a large scale in the country;

(b) if so, the percentage of spurious drugs and healthcare products that are in circulation in the country; and

(c) the steps Government has taken or propose take to combat and stop the sale of these drugs in the country?

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

(a) to (c): Isolated complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

The Government has taken various regulatory measures to ensure the quality of medicines in the country. These includes notification for affixing Bar Code or Quick Response Code in Active Pharmaceutical Ingredients (APIs) and some drug formulations, increase in sanctioned regulatory posts of CDSCO and notification providing marketers of any drug to be responsible for its quality.

Further, testing capacities of Central Drugs Testing Laboratories under CDSCO have been strengthened, and Drugs and Cosmetics Rules, 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 product manufacturing license by the Authority, and that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

The Central Government has provided Rs. 665.05 crores for strengthening the drug regulatory system including upgradation of existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices as part of "Strengthening of State Drug Regulatory System".

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

RAJYA SABHA
UNSTARRED QUESTION NO.3153
TO BE ANSWERED ON 28TH MARCH, 2023

REGULATION OF MEDICAL DEVICES AND COSMETICS

3153: SHRI SYED NASIR HUSSAIN:
DR. AMEE YAJNIK:

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

(a) whether Government has taken any steps to amend the laws relating to regulation of medical devices and cosmetics, if so, the status of such amendment and if not, the reasons therefor;

(b) whether Government has received any feedback/comments on the draft Drugs, Medical Devices and Cosmetics Bill,2022, if so, the total number of responses received and a summary thereof; and

(c) whether Government proposed any time limit for introducing the Bill in the Parliament?

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

(a) to (c): Government of India published new Medical Device Rules, 2017 for regulation of manufacture, import, clinical investigation and sale of medical devices on 31.01.2017 which came into effect on 01.01.2018. The Rules contain various provisions for improving transparency and accountability & promote research and development of new medical devices. Further, in order to regulate all the medical devices and phase-wise regulation of the all non-notified medical devices, these Rules have been amended vide notification No. G.S.R. 102(E), dated 11.02.2020.

Additionally, rules pertaining to regulation of cosmetics have been separated from Drugs and Cosmetics Rules, 1945 and a New Cosmetics Rules, 2020 has been published vide notification no. G.S.R. 763(E) dated 15.12.2020.

Comments/suggestions/objections have been received.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 516
TO BE ANSWERED ON 07th February, 2023

MRP of Non-Scheduled Drugs

516 Dr. Ashok Bajpai:

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

(a) whether Government is aware that the non-fixation of the Maximum Retail Price (MRP) of the drugs mentioned in the Schedule of the Drug Price Control Order is leading to exploitation of the poor by over charging the price of such drugs by the drug retailors; and

(b) if so, details of the initiatives taken by Government?

ANSWER

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

(a) & (b): Ministry of Health & Family Welfare (MoH&FW) notifies the National List of Essential Medicines (NLEM), which is incorporated as the Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) by Department of Pharmaceuticals (DoP). National Pharmaceutical Pricing Authority (NPPA), an attached office of DoP, fixed ceiling prices of 890 scheduled formulations across various therapeutic category under NLEM, 2015. Further, MoH&FW notified the NLEM, 2022 on 13.09.2022. Accordingly, DoP notified Revised Schedule-I of DPCO, 2013 on the basis of NLEM, 2022 on 11.11.2022. Under NLEM 2022, NPPA has fixed ceiling prices of 400 scheduled formulations till 03.02.2023. Retail price of 2262 new drugs have also been fixed under DPCO, 2013 till 03.02.2023. The Government monitors the prices of scheduled and non-scheduled drugs and takes action against companies found overcharging the consumers under the relevant provisions of DPCO, 2013.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. 1461
TO BE ANSWERED ON THE 14TH MARCH, 2023

Budgetary allocations to the pharmaceutical industry

1461 Shri B. Parthasaradhi Reddy:

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

(a) the details of the new programmes to promote research and innovation in pharmaceuticals, as announced by the Minister of Finance in her 2023-24 Budget speech;

(b) the details of Government plans to utilise the budgetary allocations made towards the promotion of Bulk Drug Parks; and

(c) the details of Government plans to utilise the budgetary allocations made towards the promotion of Medical Device Parks?

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

(a): In her Budget speech, the Hon'ble Finance Minister had announced that a new Programme to promote research and innovation in pharmaceuticals will be taken up through Centres of Excellence. She had further informed the House that the government shall also encourage industry to invest in research and development in specific priority areas.

Pursuant thereto, the Department of Pharmaceuticals has formulated a Scheme for 'Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)' having two components, viz., strengthening the research infrastructure by establishment of Centres of Excellences (CoEs) at seven existing National Institutes of Pharmaceutical Education & Research (NIPERs) and to provide financial assistance for the companies working with Govt. Institutes and for doing in-house R&D in specified moon-shot areas. The Proposed Scheme has been submitted for appraisal.

(b): A scheme for providing financial support for creation of Common Infrastructure Facilities (CIFs) in three Bulk Drugs parks in the country was approved with a total outlay of Rs. 3,000 cr. @ Rs. 1,000 cr for each selected state. The government has approved the proposals received from the states of Andhra Pradesh, Himachal Pradesh and Gujarat. An amount of Rs. 900 cr. has been allocated for the scheme in BE 2023-24, for second instalment to the three selected states.

(c): A scheme for providing financial support for creation of Common Infrastructure Facilities (CIFs) in four Medical Devices Parks in the country was approved with a total outlay of Rs. 400 cr. @ Rs. 100 cr for each selected state. The government has approved the proposals received from the states of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh. An amount of Rs. 200 cr. has been allocated for the scheme in BE 2023-24, for releasing grant to the selected States.

GOVERNMENT OF INDIA
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DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 3059
TO BE ANSWERED ON THE 28TH MARCH, 2023

Export of substandard medicines

3059 Dr. John Brittas:

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

(a) whether it is a fact that WHO has issued in the recent past alerts and warnings against substandard/contaminated medicines and cough syrups manufactured in India which were exported to Gambia and Uzbekistan;

(b) if so, the details thereof and the actions taken by Government thereon;

(c) whether it is a fact that there are loopholes in the extant regulations governing the quality of medicines manufactured in the country solely for the purpose of export to foreign countries vis-a-vis domestic supply;

(d) if so, the details of extant statues and rules dealing with this; and

(e) the actions proposed to be taken to curb these appalling lapses?

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

(a) & (b): The subject matter pertains to Central Drugs Standard Control Organization (CDSCO) under the Department of Health and Family Welfare. As per the information received from CDSCO, WHO has issued following two Medical Products Alerts w.r.t. cough syrups manufactured in India which were exported to Gambia and Uzbekistan: -

i. WHO Alert dated 05-10-2022 on four products namely Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup and Magrip N Cold Syrup, manufactured by Maiden Pharmaceuticals Limited (Haryana, India), identified in The Gambia.

ii. WHO Alert dated 11-01-2023 on two products namely DOK 1 Max syrup (Paracetamol, Guaiphenesin and Phenylephrine Hydrochloride Cough syrup) and Ambronol Syrup (Ambroxol Syrup), manufactured by M/s. Marion Biotech Pvt. Ltd. Uttar Pradesh, identified in Uzbekistan.

Details of investigation in case of The Gambia and Uzbekistan are mentioned as under:

In the matter of deaths reported in Gambia, a joint investigation was carried out by CDSCO in coordination with State Drug Controller, Haryana at M/s Maiden Pharmaceuticals Limited 81, HSIDC Industrial Area, Kundli 131028, Dist. Sonepat (Haryana) and control samples of the drugs were drawn and sent for test and analysis to Regional Drug Testing

Laboratory, (RDTL) Chandigarh. As per report of the Government Analyst of RDTL Chandigarh, the samples were declared to be of standard quality. The said samples were also found negative for both Diethylene Glycol (DEG) and Ethylene Glycol (EG).

However, based on violations observed in Good Manufacturing Practices, State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma on 7.10.2022. Further, an order has been issued to M/s Maiden Pharmaceuticals Limited, Sonepat, Haryana on 11.10.2022 stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonepat with immediate effect in public interest.

Similarly, in case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd. B-49, Sector 67, Gautam Budh Nagar, Noida-201301 (U.P.) and during the investigation, drug samples were drawn from the manufacturing premises and sent to Regional Drug Testing Laboratory (RDTL) Chandigarh for test and Analysis. Further, manufacturing license of the firm has been suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. RDTL, Chandigarh has forwarded the test reports of 30 drug samples so far, wherein 24 samples of drugs/raw material were declared as "Not of Standard Quality". Out of these 24 samples declared as "Not of Standard Quality", 22 samples fall under the category of adulterated/spurious, which can cause grievous hurt to patients. An FIR has been lodged on 02.03.2023 in the concerned police station and three persons have been arrested.

(c) to (e): So far as manufacture of drugs for export is concerned, the manufacturers are required to obtained license for such manufacturing of drugs for export from the concerned State Licensing Authority (SLA) under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, the manufacturer is required to meet the requirements of importing country.

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RAJYA SABHA
UNSTARRED QUESTION NO. 3065
TO BE ANSWERED ON 28th March, 2023

Price hike of medicines

3065 Dr. Amar Patnaik:

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

(a) whether drug pricing authority has allowed a price hike of 10.7 per cent for scheduled drugs which are under price control on 28th March 2022;

(b) if so, how many drugs have witnessed the hike in the price;

(c) whether the hike in price of scheduled medicines is also applicable for drugs at the Jan Aushadhi Kendras established under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP); and

(d) if not, the measures taken to retain the price of medicines selling in these Kendras under PMBJP after this hike?

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

(a) and (b): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals revised the ceiling price of 898 scheduled formulations upwards by 10.76607%, effective from 01.04.2022, based on Wholesale Price Index (WPI) for all commodities during the calendar year 2021 over the corresponding period in 2020, as per the provisions of Drugs (Prices Control) Order, 2013 (DPCO, 2013). However, increase in the prices of these drugs by the manufacturers is based on commercial consideration and may be lower or same as permissible increase depending on the market dynamics.

(c) and (d): All manufacturers of scheduled medicines, including those sold through Jan Aushadhi Kendras, have to sell the same within the ceiling price (as revised from time to time, including based on WPI). Further, Pharmaceuticals & Medical Devices Bureau of India (PMBI) ensures that the prices of medicines sold through the Kendras are at least 50% cheaper than that of branded medicines available in the open market.

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RAJYA SABHA
UNSTARRED QUESTION No. 3066
TO BE ANSWERED ON THE 28TH MARCH, 2023

Domestic manufacturing of APIs

3066 Shri M. Mohamed Abdulla:

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

(a) whether the Union Government is going to take any new steps to increase the domestic manufacturing of the Active Pharmaceutical Ingredients (APIs) and the details about the country's import of the API for the year 2022-23; and

(b) whether the Union Government is going to introduce a draft of new Quality Control Orders (QCO) to the Active Pharmaceutical Ingredients imported from China and if so, the details thereof?

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

(a): The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22. However, the country also imports various Bulk Drugs/APIs for producing medicines from various countries and most of the imports of the Bulk Drugs/APIs being done in the country are because of economic considerations. India imported Rs. 35,249 crore worth APIs and Bulk drugs in 2021-22. The import value of APIs and Bulk Intermediates from April, 2022 to January, 2023 is Rs 30337 Cr. (source: DGCIS)

The Government of India has taken several measures to encourage domestic manufacturing of Active Pharmaceutical Ingredients (APIs). The Programmatic interventions for the same are as follows;

i. The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for the financial incentive for 41 identified products. A total of 51 applications have been selected under the scheme. Out of these, 22 projects have already been commissioned with the installed capacity of 34,255 MT.

ii. PLI Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. This scheme also covers the APIs, other than those covered under the PLI scheme under Bulk Drugs as mentioned at Point (I).

iii. Under the Scheme for Promotion of Bulk Drug Parks, proposals of Andhra Pradesh, Gujarat and Himachal Pradesh have been approved for financial support to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.

(b): As per the inputs received from Central Drug Standard Control Organization (CDSCO) under the Department of Health and Family Welfare, the import of Active Pharmaceutical Ingredients (APIs) is already regulated under the Drugs and Cosmetics Act, 1940 and Rules.

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LOK SABHA
UNSTARRED QUESTION NO. 4953
TO BE ANSWERED ON THE 31st MARCH, 2023

Faculty Vacancies in NIPER Institutes

4953. SHRI MAGUNTA SREENIVASULU REDDY:

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

(a) the total number of faculty positions in National Institute of Pharmaceutical Education and Research (NIPER) across the country;
(b) the number of faculty positions that are filled and vacant as of date;
(c) whether the Government has taken any steps to fill the faculty vacancies in NIPER; and
(d) if so, the details thereof and if not, the reasons therefor?

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

(a) to (d): Seven National Institutes of Pharmaceutical Education & Research (NIPERs), autonomous institutes of national importance, at Mohali, Ahmedabad, Guwahati, Hyderabad, Hajipur, Kolkata, and Raebareli have been set up under the aegis of the Department of Pharmaceuticals. The recruitment to various posts is done by the respective institutes under supervision of their Board of Governors on an ongoing basis. As per information obtained, out of total 217 sanctioned faculty posts, 126 posts have presently been filled up on regular basis by these institutes.

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LOK SABHA
UNSTARRED QUESTION No. 4108
TO BE ANSWERED ON THE 24th March, 2023

Bulk Drug Park in Andhra Pradesh

4108. SHRI BALASHOWRY VALLABHANENI:

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

(a) whether the Government has approved the proposal for setting up of a bulk drug park in Andhra Pradesh;

(b) if so, the details thereof;

(c) whether it is true that the said park is expected to be completed in two years;

(d) if so, the details thereof and the current status of the said park and whether it is on course to complete the park within the stipulated time; and

(e) if so, the details thereof along with the details of funds sanctioned, approved, released and spent so far on setting up of the above mentioned park?

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

(a) to (e): The Scheme for Promotion of Bulk Drug Parks aims to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.

After evaluation of proposals received from 13 states, Government has approved the proposal of setting up Bulk Drug park in Andhra Pradesh, Gujarat and Himachal Pradesh.

The Andhra Pradesh Bulk Drug Infrastructure Corporation Limited (APBDICL) /State Implementing Agency (SIA) has indicated completion of the project within next 24-28 months.

An amount of Rs. 225 crore as 1st Instalment was released on 07.03.2023 to SIA.

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LOK SABHA
UNSTARRED QUESTION No. 333
TO BE ANSWERED ON THE 3rd February, 2023

Domestic Pharmaceutical Companies

333. SHRI S. JAGATHRAKSHAKAN:

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

(a) whether the domestic pharmaceutical companies are expected to report steady revenue growth of 6-8 per cent in FY2023 and FY2024; and

(b) if so, the details thereof alongwith the initiatives that are proposed to be taken by the Government keeping in view the fact that the domestic pharmaceutical industry continues to grapple with cost inflation and pricing pressures?

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

(a): The department does not maintain projections of annual revenues of pharmaceutical companies. However, the growth in average annual turnover of Pharmaceuticals for the last three years is estimated to be about 9%.

(b): The Department of Pharmaceuticals is implementing the following schemes to support domestic manufacturing of pharmaceuticals in the country:

i. Under the Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, the financial incentives are to be provided for 41 identified products. Out of these, 21 projects have already been commissioned.

ii. Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentives to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products.

iii. Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance for creation of common infrastructure facilities to three States which have been selected under the scheme viz Gujarat,

Himachal Pradesh and Andhra Pradesh. The industrial units setting up plants for APIs in these Parks will get benefitted from the common infrastructure developed under the scheme, which will decrease the manufacturing cost and increase their competitiveness.

iv. The Department is implementing the scheme of Strengthening of Pharmaceutical Industry (SPI), with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26 to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs

Further, the National Pharmaceutical Pricing Authority (NPPA) revises the ceiling prices of scheduled medicines annually on the basis of Wholesale Price Index (WPI) for preceding calendar year on or before 1st April of every year, which is notified by the Government on the 1st day of April every year (The WPI increase is the maximum increase permissible and may or may not be availed by the manufacturers). It is further clarified that prices are increased or decreased by the manufacturers based on market dynamics. In case of non-scheduled formulations, the manufacturer can increase the MRP upto 10% during the preceding twelve months.

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LOK SABHA
UNSTARRED QUESTION No. 1430
TO BE ANSWERED ON THE 10th February, 2023

PLI for Neutraceuticals and Dietary Supplements

1430. SHRI VINCENT H. PALA:
SHRI JAGDAMBIKA PAL:

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

(a) whether the Government has plans to introduce a PLI (Production Linked Incentive) scheme or Research Linked Incentive scheme for nutraceuticals and dietary supplements;

(b) if so, the details thereof;

(c) the details on the status of the progress made by the Task Force on Nutraceuticals under the Principal Scientific Advisor;

(d) whether the Government has plans to introduce any other support for the domestic manufacturing of Active Pharmaceutical Ingredients (APIs) besides the existing PLI scheme; and

(e) if so, the details thereof?

ANSWER

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

(a) and (b): The Department of Pharmaceuticals is not handling the subject of nutraceuticals and dietary supplements.

(c): As per information received from Office of Principle Scientific Advisor, a Task Force on Nutraceutical Sector under the Chairmanship of the Principal Scientific Adviser to GoI (PSA to GoI) was constituted in December, 2021 to evolve a road map to provide a thrust to Nutraceutical Sector and facilitate unlocking the sectors' growth potential by addressing the challenges the industry is facing. So far, three meetings of Task Force have been held and formation of the Nutraceutical Panel has been done under the Department of Commerce

(d) & (e): The Department of Pharmaceuticals Department implements various programmes to minimize country's dependence on imports and to give fillip to indigenous manufacturing of Active Pharmaceutical Ingredients (APIs) / Bulk Drugs and the details are as follows :

i. Production Linked Incentive (PLI) Scheme for Bulk Drugs, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for financial incentive for 41 identified products. Out of these, 21 projects have already been commissioned with the installed capacity of 33,895 MT.

ii. The Production Linked Incentive Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six year. The eligible drugs under this scheme also include APIs.

iii. Scheme for Promotion of Bulk Drug Parks, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance of Rs 1000 crore each to the State of Himachal Pradesh, Andhra Pradesh and Gujarat for establishing Bulk Drug Parks. The financial assistance will be given for creation of common infrastructure facilities which will be used by the industrial units which will get established in these Parks.

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LOK SABHA
UNSTARRED QUESTION NO. 1456
TO BE ANSWERED ON THE 10th February, 2023

Research and Development in Pharma Sector

†1456. DR. RAMESH POKHRIYAL "NISHANK":

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

(a) the steps taken by the Government to promote Research and Development in pharmaceutical sector of the country during the last five years; and
(b) the steps taken/proposed to be taken by the Government to promote the private sector participation in the R&D?

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

(a) and (b): Department of Pharmaceuticals (DoP) has been assigned the responsibility of promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector. DoP has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance to nurture and promote quality and excellence in pharmaceutical education and research in India, which besides imparting postgraduate and doctorate education, conduct high end research in various pharma specializations.

Research and Development (R&D) in pharma sector is also undertaken by number of institutions and organizations under various scientific ministries/ departments.Council of Scientific and Industrial Research (CSIR) through its constituent laboratories has been pursuing R&D activities for drug discovery and development. CSIR-CDRI has built a unique model for drug research in India – having everything under one roof, from synthesis, screening, development studies, process up-scaling to clinical studies for the development of drugs. Department of Biotechnology (DBT), along with its Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC) has facilitated implementation of R&D projects for drug discovery in the areas of Tuberculosis (TB), Anti-Microbial Resistance (AMR), Diabetes, Cancer, Rare Diseases, etc., through its regular schemes. Department of Scientific & Technology (DST) has also invited proposals for research in rare diseases with focus to bring generic drugs which are off-patent and to develop process chemistry for drugs under patent to make it affordable once patent expires.

During budget 2023-24, Hon'ble Finance Minister has announced about a new Programme to promote research and innovation in pharmaceuticals to taken up through centres of excellence. It was also mentioned that the government will encourage industry to invest in research and development in specific priority areas.

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LOK SABHA
UNSTARRED QUESTION NO. †1572
TO BE ANSWERED ON 10th February, 2023

Essential Drugs under DPCO

†1572. SHRI DINESH CHANDRA YADAV:

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

(a) whether the Government has notified 93 more essential drugs to be covered under Drug Price Control Orders (DPCO) recently;

(b) whether 120 essential drugs were included under DPCO in the previous month before such notification and if so, the details thereof;

(c) the total number of drugs included under DPCO till date;

(d) whether the Government proposes to create awareness/publicity with regard to such drugs for the common people;

(e) whether the rates of drugs under DPCO list have been increased by 25 to 30 percent annually, an example of which is Timolet eye drops and if so, the details thereof;

(f) whether the Government has set up any criteria for hiking the prices of such drugs and if so, the details thereof;

(g) whether there is any mechanism set up by the Government in DPCO to monitor the rates of such drugs; and

(h) the details of grievance redressal mechanism established by the Government for public in this regard?

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

(a) to (c): Department of Pharmaceuticals (DoP) notified Revised Schedule-I of Drugs (Prices Control) Order (DPCO) on 11.11.2022 incorporating the National List of Essential Medicines (NLEM) notified by the Ministry of Health and Family Welfare on 13.09.2022. There are 388 medicines (including 2 animal vaccines and 2 stents) consisting of approximately 954 formulations in the Revised Schedule-I of the DPCO, 2013. National Pharmaceutical Pricing Authority (NPPA) under the DoP has fixed ceiling prices of 400 scheduled formulations under NLEM, 2022 till 06.02.2023 as per the provisions of DPCO, 2013.

(d): Consumer awareness/publicity with regard to such drugs is undertaken through a Central Sector Scheme namely, Consumer Awareness, Publicity and Price Monitoring (CAPPM) and is implemented at the Central level by NPPA and at the State/UT level by Price Monitoring and Resource Units (PMRUs) jointly set up by NPPA and the respective State/UT Government. PMRUs, inter alia, undertake consumer awareness programmes through print and electronic media by organizing seminars, webinars, etc.

(e) & (f): As per the extant provisions of DPCO, 2013, the ceiling prices of scheduled medicines (including Timolol Eye Drops 0.25% and 0.5%) are revised annually by the Government on the basis of increase in Wholesale Price Index (WPI) (all commodities) over the preceding calendar year and notified by the Government on the 1st day of April every year. The compound annual growth rate (CAGR) of WPI for the period 2015-22 is 2.94 per cent. Further, the WPI increase provides for the maximum increase permissible and may or may not be availed by manufacturers. In addition, the prices of 400 scheduled formulations have been refixed under NLEM, 2022 till 06.02.2023. This has led to an average reduction of 15.39 % in the ceiling prices. Specifically, in the case of Timolol Eye drops 0.50% there is a reduction of 9.74% over its price under NLEM, 2015.

(g) & (h): The NPPA monitors the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 and takes action against companies found overcharging the consumers based on the references received from PMRUs, the State Drugs Controllers; individuals; samples purchased from the open market; reports from market based data; and complaints reported through the grievance redressal websites/digital platform viz., 'Pharma Jan Samadhan', Mobile App 'Pharma Sahi Daam', and 'Centralized Public Grievance Redress and Monitoring System (CPGRAMS)'. In addition, NPPA has a Helpline 1800-111-255/email: monitoring-nppa@gov.in, on which complaints on shortage, overcharging of drugs are received from consumers across the country. The Government takes action against companies found overcharging the consumers under the relevant provisions of DPCO, 2013.

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LOK SABHA
UNSTARRED QUESTION NO. 1603
TO BE ANSWERED ON 10th February, 2023

License for Software Medical Devices

1603. SHRIMATI KANIMOZHI KARUNANIDHI:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:
(a) the number of licences issued by the Central Drugs Standard Control Organisation (CDSCO) for software medical devices;
(b) the data on the licences to import, sell, manufacture and clinically investigate, software medical devices, State-wise specially in Tamil Nadu;
(c) the details on the types of software that have been granted medical devices' licences, based on speciality;
(d) whether the use of software is regulated keeping in view the protection of digital medical data of the citizens; and
(e) if so, the details thereof?

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

(a) to (b): Central Drugs Standard Control Organization (CDSCO) under the Department of Health and Family Welfare has granted import / manufacturing licences for Medical Devices and In Vitro Diagnostic medical devices that either incorporate electronic programmable systems, including software, or standalone software that are devices in themselves. Details may be seen at Annexure.

(c): The licenses granted for the medical devices either incorporate electronic programmable systems, including software, or standalone software that are devices in themselves such as.

i. Blood Pressure Monitoring Devices,
ii. Glucometer,
iii. Digital Thermometer,
iv. CT Scan Equipment,
v. MRI Equipment,
vi. PET Equipment,
vii. X-ray Machine,
viii. Dialysis Machine,
ix. Defibrillators,
x. Ultrasound Equipment,
xi. Electrocardiograph,
xii. Ablation devices,
xiii. Bone Marrow Cell Separator, etc.

(d) to (e): Software Medical Devices, including In Vitro Diagnostic software, fall under the definition of a medical device as per S.O. 648(E) dated 11.02.2020, and are regulated under the provisions of Medical Devices Rules, 2017.

Import/manufacturing licences granted as on 07.02.2023

Licence (Form Type)	No. of Approvals	
	India	Tamil Nadu
Import licences (Form MD-15)	661	97
Manufacturing licences (Form MD-9 / MD-10)	34	03
Manufacturing licences granted by State Licensing Authority (Form MD-5 / MD-6)	118	04
For clinical investigation, the clinical investigation protocols are permitted rather than issuing the license. (Form MD-23)	03	00

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LOK SABHA
UNSTARRED QUESTION NO. 2946
TO BE ANSWERED ON THE 17TH MARCH, 2023

Indian Pharmaceutical Industry

2946. DR. AMAR SINGH:

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

(a) whether the Government agrees with the view that Research-Linked Incentives (RLIs) can provide an impetus for the Indian pharmaceutical industry to increase R&D investments, as well as encourage it to forge much-needed linkages with academia to coinnovate;

(b) if so, the details thereof;

(c) whether the Government has taken note that despite the availability of several Government instruments, many brilliant ideas from entrepreneurs often do not come to fruition because of their inability to access adequate funding from the Government; and

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

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

(a) and (b): Pursuant to Budget announcement 2023-24 about a new Programme to promote research and innovation in pharmaceutical sector, the Department of Pharmaceuticals has formulated a Scheme for 'Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)' having two components, viz., strengthening the research infrastructure by establishment of Centres of Excellences (CoEs) at seven existing National Institutes of Pharmaceutical Education & Research (NIPERs) and to provide financial assistance for the companies working with Govt. Institutes and for doing in-house R&D in specified moon-shot areas.

(c) and (d): Department of Science & Technology has launched a National Initiative for Developing and Harnessing Innovations (NIDHI) program to convert knowledge-based and technology-driven innovative ideas into successful start-ups. Further, Biotechnology Industry Research Assistance Council (BIRAC) under the Department of Biotechnology has created a Biotech Ignition Grant to promote biotech entrepreneurs, with Rs. 50 lakhs in grant-in-aid support per biotech entrepreneur.

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MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 2969
TO BE ANSWERED ON THE 17th MARCH, 2023

Self-reliance in Pharmaceuticals and Biopharma

2969. SHRI T.R. BAALU:

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

(a) whether the Government agrees to the view that India need to make exponential investments in Research and Development (R&D), manufacturing, and digital transformations to become a global pharmaceutical innovation hub as well as achieve its vision of self-reliance in pharmaceuticals and biopharma;

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

(c) the steps taken/proposed to be taken by the Government keeping in view the fact that India's current public expenditure on R&D remains low, at less than one percent of Gross Domestic Product (GDP) of the country?

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

(a) to (c): Yes Sir. Realizing the importance of Pharma innovation, the Hon'ble Finance Minister in her Budget speech 2023-24 has announced that a new Programme to promote research and innovation in pharmaceuticals will be taken up through Centres of Excellence. She had further informed the House that the government shall also encourage industry to invest in research and development in specific priority areas.

Pursuant thereto, the Department of Pharmaceuticals has formulated a Scheme for 'Promotion of Research and Innovation in Pharma MedTech Sector (PRIP)' having two components, viz., strengthening the research infrastructure by establishment of Centres of Excellences (CoEs) at seven existing National Institutes of Pharmaceutical Education & Research (NIPERs) and to provide financial assistance for the companies working with Govt. Institutes and for doing in-house R&D in specified moon-shot areas.

In addition, the Department of Pharmaceuticals has already set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) all over the country to run postgraduate and doctorate courses and undertake high-end research in the pharma sector. An amount of Rs. 1,500 cr has been approved for implementation of the scheme of NIPER during the period 2021-22 to 2025-26.

Further, in order to encourage domestic manufacturing, reduce import dependence and ensure technology up-gradation, the Department is implementing the following schemes:

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

ii. Production Linked Incentive Scheme for Pharmaceuticals with a financial outlay of Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29;

iii. Scheme for Promotion of Bulk Drug Parks with a financial outlay of Rs. 3,000 crores and tenure from FY 2020-2021 to FY 2024-25; and

iv. Scheme of Strengthening of Pharmaceutical Industry (SPI) with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2973
TO BE ANSWERED ON THE 17th March, 2023

Promotion of Bulk Drug Park

2973. DR. VISHNU PRASAD M.K.:
SHRI T.R.V.S. RAMESH:

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 for the past two years and if so, the details thereof;
(b) the current status of implementation of the Scheme for Promotion of Bulk Drug Parks in the State of Tamil Nadu; and
(c) the details of the funds allocated, disbursed and utilized for setting up of a new Bulk Drug Park in Tamil Nadu?

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

(a) and (b): The Scheme for Promotion of Bulk Drug Parks aims to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs. 1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.

After evaluation of proposals received from 13 states, the proposals of Andhra Pradesh, Gujarat and Himachal Pradesh were selected in October-November 2022. The State Implementing agencies (SIA) of the three respective States have indicated completion of these projects within next 24-28 months. The proposal of Tamil Nadu has not been selected under the scheme.

(c): In view of the above, the question does not arise.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. †2978
TO BE ANSWERED ON 17th March, 2023

Sale of Antiretroviral Drugs

2978. SHRI ANUMULA REVANTH REDDY:

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

(a) whether it is a fact that the antiretroviral drug is being sold at high prices due to shortage/insufficient supply of drugs in the country;

(b) if so, the details thereof;

(c) the quantum of antiretroviral drugs produced in the country in the last five years, year-wise, Statewise;

(d) the quantum of antiretroviral drugs imported and amount of funds utilized for the same in the last five years, year-wise, country-wise; and

(e) the steps taken/proposed to be taken by the Government for ensuring the supply/production of antiretroviral drugs in adequate quantity to meet the demand in the country in the last five years, year-wise?

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

(a) & (b): No such complaint of shortage/ price violation of antiretroviral drug has been received in the Department of Pharmaceuticals (DoP).

(c) & (d): The data on production and import of antiretroviral drugs is not readily available with CDSCO and DGCIS.

(e): National Pharmaceutical Pricing Authority (NPPA) under DoP takes remedial steps for ensuring availability of drugs by impressing upon concerned companies to rush the stocks to the places of reported shortage of any drug as and when reported by the State Drug Controllers (SDC) or through references received from Ministry of Health or individual complaints or through Pharma Jan Samadhan.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 4002
TO BE ANSWERED ON THE 24TH MARCH, 2023

Research and Innovation in Pharmaceutical Sector

†4002. SHRIMATI JASKAUR MEENA:
SHRI KRIPANATH MALLAH:

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

(a) whether the Government is planning to set up centres of excellence for research and innovation in pharmaceutical sector across the country;

(b) if so, the details thereof, State-wise including Assam;

(c) the details of the target set and funds estimated for this purpose;

(d) the details of the number of States including the districts in Rajasthan likely to be covered for this purpose; and

(e) the time by which such project is likely to be implemented?

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

(a) to (e): Yes Sir. Pursuant to the Budget Announcement 2023–2024 about launch of a new programme to promote research and innovation in the pharmaceutical sector, the Department of Pharmaceuticals has prepared a Scheme for 'Promotion of Research and Innovation in the Pharma MedTech Sector (PRIP)' which includes a component for strengthening the research infrastructure by establishment of Centres of Excellences (CoEs) at seven existing National Institutes of Pharmaceutical Education & Research (NIPERs) at Mohali (Punjab), Ahmedabad (Gujarat), Hyderabad (Telangana), Guwahati (Assam), Kolkata (West Bengal), Hajipur (Bihar) and Raebareli (Uttar Pradesh) at an estimated cost of Rs 700 crore. No state-wise or district-wise targets have been fixed for this purpose.

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 4975
TO BE ANSWERED ON THE 31st MARCH, 2023

PLI Scheme for Pharmaceutical Sector

4975. SHRI THIRUNAVUKKARASAR SU:

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

(a) the number of projects commissioned for various products so far under the Product Linked Incentive (PLI) scheme;

(b) whether the Government has taken steps to boost domestic production of high value formulations, critical APIs and High-End Medical Devices under the PLI Scheme;

(c) if so, the details thereof and the extent to which it would promote Aatmanirbharta; and

(d) if not, the reasons therefor?

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

(a) to (d): The Government of India has taken several measures to encourage domestic manufacturing of Pharmaceutical drugs including bulk drugs and high end medical devices to reduce import dependence and to boost domestic manufacturing. The Programmatic interventions to support domestic manufacturing of APIs are as follows;

i. The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India, with a financial outlay of Rs. 6,940 crores and the tenure from FY 2020-2021 to FY 2029-30, provides for the financial incentive for 41 identified products. A total of 51 applications have been selected under the scheme. Out of these, 22 projects have already been commissioned with the installed capacity of 34,255 MT

ii. PLI Scheme for Pharmaceuticals, with a financial outlay Rs. 15,000 crores and the tenure from FY 2020- 2021 to FY 2028-29, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years. This scheme also covers the APIs, other than those covered under the PLI scheme under Bulk Drugs as mentioned at Point (i). Projects have been commissioned in 261 manufacturing locations, out of total 309 manufacturing locations.

iii. PLI Scheme for Promoting Domestic Manufacturing of Medical Devices with total financial outlay of Rs. 3,420 crore and tenure from FY 2020-2021 to FY 2027-28, provides 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. Under the scheme, 26 applications have been approved and 14 projects have been commissioned. Under the scheme, domestic manufacturing of high-end medical devices has started which include Linear Accelerator, MRI Scan, CT-Scan, Mammogram, C- Arm, MRI Coils, high end X-ray tubes, etc

iv. Under the *Scheme for Promotion of Bulk Drug Parks,* proposals of Andhra Pradesh, Gujarat and Himachal Pradesh have been approved for financial support to facilitate setting up of three (3) Bulk Drug Parks in the country. The total financial outlay of the scheme is Rs. 3000 crore and the tenure of the Scheme is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 Crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less.

v. Under the major non-schematic intervention, in order to attract investments in Pharma sector including for APIs, the Government has allowed 100% FDI in pharma sector for greenfield projects under automatic route. For the brownfield projects, upto 74%, FDI investments are allowed under automatic route and beyond 74% to 100%, FDI investments are allowed under government approval route. Similarly, the Government has allowed 100% FDI in medical devices sector under automatic route.

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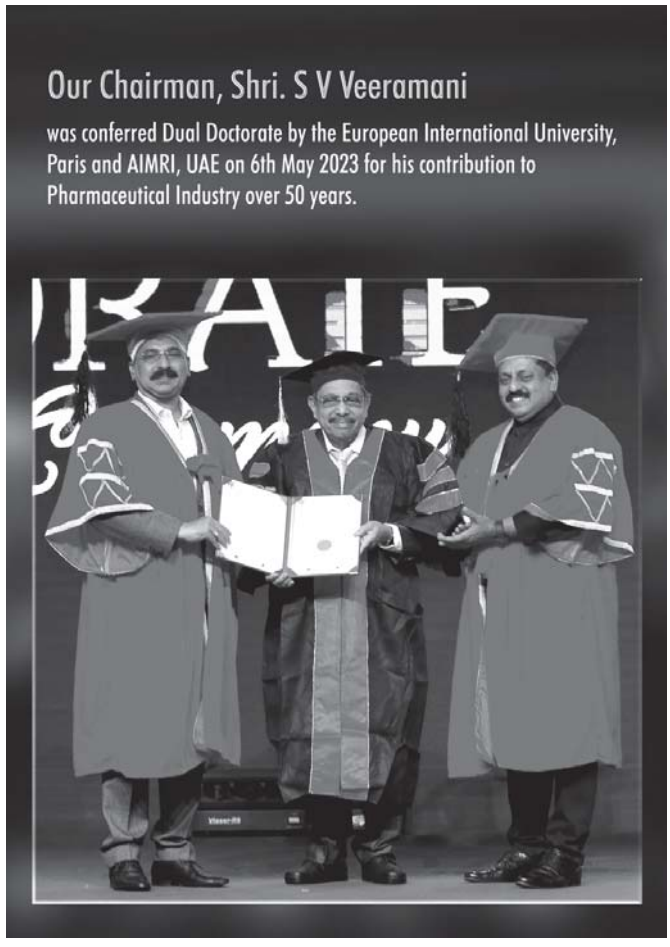
This issue of Pharma Web is also available online at the Trust website : www.pictrust.com

Congratulation to Shri. S. V. Veerramani



Congratulation to Dr. S. Manivannan

We congratulate **Dr. S. Manivannan, M. Pharm, Ph. D**, promoted to Joint Drugs Controller (India), Central Drugs Standard Control Organization, Ministry of Health & Family Welfare, Government of India.

- In the year 1998, joined as Drugs Inspector, CDSCO, Govt. of India, Ministry of Health and Family Welfare, at Chennai.
- Got an assignment of setting up a new office of CDSCO at Bangalore as ADC(I) In-Charge in 2009
- In the year 2010, got promoted as Assistant Drugs Controller (India)
- In the year 2011, directly selected through UPSC as Deputy Drugs Controller (India)

NEWS

New-Age Tech Platforms Set to Revolutionise Drug Research as India Gets its Act Together

India has so much going for it to stamp its mark on the global Pharmaceutical Industry and the key to it lies in value creation through cutting-edge R&D. With a thrust on firming up research capabilities by creating an ecosystem that fosters innovation, we can garner a significant market share through our pioneering solutions and make our way to the top as a global Pharma superpower.

Drug discovery and development, in particular, can play an instrumental role in catapulting India to the Big League if the regulatory guidelines for clinical trials are realigned with global standards. Aided by factors like the globalisation of clinical trials, the rising trend of outsourcing the process to Indian organisations owing to substantially lower costs and the adoption of new-age technologies for clinical research, the Indian clinical trials market is expected to grow at a compounded annual growth rate of 8.2% in the next eight years to reach US $3.88 billion by 2030.

Realising this immense potential, the government proposed a policy in October last year to reduce the time required for approval of innovative products by at least 50% in the next two years to boost clinical research. The digitalisation of clinical trials, backed by alternative technology platforms, is poised to act as a critical differentiator by streamlining regulatory compliance and expediting the process through real-time data acquisition on drug safety.

Taking this ahead, the Union Health Ministry recently issued a draft notification to pave the way for using alternative technology platforms to establish the safety and efficacy of investigational drugs, which comes as a shot in the arm for Indian researchers engaged in drug development and research.

Once the amendments to the New Drugs and Clinical Trials Rules 2019 are approved to this effect, the duration of research and the costs of developing novel drugs and effective therapies will be considerably reduced as preclinical trials can then be done on human tissues and cells grown in laboratories through alternative technology platforms like human organ-on-chips, micro-physiological systems and other in vitro or cell-based assays. The US has already set a precedent by bringing a legislation that no longer necessitates animal testing for FDA approval on new drugs, thus signifying a fundamental shift towards computer modelling, organ chips and other technology platforms for preclinical trials.

In the Indian context, this landmark decision is aimed at establishing the country as a clinical research hub. Clinical trials through cutting-edge technologies can improve the success rate of experimental drugs by 70-80%, and organ-on-chips are a case in point. It can revolutionise medical research and drug discovery by enabling an understanding of the drug action mechanism on human organs in ways that were never possible before.

Designed to create miniaturised biological testing systems that mimic human organs on small chips, organ-on-a-chip technologies are advanced cell culture models that accurately reflect human physiology. Unlike cells grown in 2D mono-layered laboratory dishes, the three-dimensional microfluidic devices representing these technologies can simulate the functions and physiology of living organs. By dramatically improving the accuracy and efficiency of preclinical drug testing, this technology enables researchers to filter out in the earliest drug development stage itself those drug candidates that are highly unlikely to make the grade. This, in turn, can improve the success rate of the experimental drugs entering clinical trials.

To enhance the ability to find better solutions for patients and caregivers, organ-on-a-chip labs can help improve the mechanistic understanding of drug toxicities and facilitate the process of developing personalised medicine by assessing the genetic variations between patients and also influencing the way the body reacts to a drug.

As this ahead-of-its-time technology evolves, patient-derived stem cells can be used to create personalised organ-on-a-chip models. Coupled with other new-age technology platforms, this milestone in biomedical engineering is ready to redefine the future of drug research, and we are excited about it.

Source: *ET Healthworld,* 16th February 2023

PCI to Introduce Medical Devices Manufacturing in Revised Pharmacy Curriculum

The Pharmacy Council of India (PCI) is working to modify the existing curriculum of Pharmacy education to make it more focused on modernizing the Pharma industry.

PCI will introduce full-time degree programmes in the manufacturing of medical devices and students will get internship opportunities in hospitals for hands-on training.

The revised curriculum would be implemented once PCI gets full control over Pharmacy education from the AICTE, which is in the final stages. PCI will get complete control over the curriculum in a year once the formality and other processes are completed. PCI introduced attractive scholarships to meritorious Graduate Pharmacy Aptitude Test (GPAT) qualifiers, which currently are available only to students from AICTE-approved Pharma colleges.

Speaking to Education Times, a source in PCI on the condition of anonymity says, “As soon as we get the entire control of Pharmacy education, we would work on changing the curriculum to make it in consonance with the demands of the industry.”

“The main thrust would be to introduce full-time degree courses in the manufacturing of medical instruments the provision for which is not there in the existing curricula. There

also be some aspects related to engineering that the students would need to study while pursuing these full-time degree courses as there are plans to increase the number of pharmacy colleges. Besides, teachers would be updated about the industrial manufacturing process of medical devices," adds the source.

There are discussions to introduce Pharmaceutical ethics, vaccination training similar to that offered to nurses and increasing awareness of social pharmacy in the new curriculum.

Source: *ET Healthworld,* 16th February 2023

Indians' Medical Bills Set to Swell, Here's Why

The medical bills for consumers are all set to rise as India's Pharma Industry continues to bear the brunt of high prices of raw materials.

The industry has witnessed a steep price increase of over 100 per cent from pre-pandemic levels of certain raw materials for essential drugs called active pharmaceutical ingredients (API), reported TOI.

Earlier, the Pharma industry was considering the hike to be a transitory phenomenon. However, the increasing price of raw materials, even after improvement in supply chain and logistics, has created a troublesome situation in the industry.

The sharp increase has been witnessed in high-volume key antibiotics including azithromycin and amoxicillin imported from China. "These are also the products where India has near or complete dependence on China. As against this, prices of most vitamins, including vitamin B and D, also imported from China, are at an all-time low," stated the TOI report.

Besides APIs for key antibiotics, anti-TB rifampicin and anti-diabetes metformin have also doubled from the pre-pandemic level, the industry experts highlighted. Antibiotics including Azithro, Clav and Amoxicillin are high-volume products, the production of which is dependent on imports from the neighbouring country.

Reasons for the hike

The sharp hike can be attributed to increase in prices of key constituents, materials and solvents used for making these drugs. The supply-chain disruptions caused by Russia-Ukraine war led also contributed to the price. rise as it led to surge in the freight cost.

Another significant reason could be inflation. "Further, few agents have been controlling the imports of certain products, which has led to a cartelisation of sorts. The government should break the monopoly and prevent sole agents from controlling the market," said an executive with a firm manufacturing APIs.

According to the TOI report, a Mumbai-based trader stated, “It's more about Chinese fleecing as we are dependent on them, coupled with some registration agents pushing them to form unholy cartels for their own benefits.”

It may be noted that cost has gone up for only those drugs for which raw materials are imported from China. Once the pandemic spread, API prices of certain drugs like fever and pain relief medication, paracetamol, life-saving antibiotic Meropenem (also used for Covid), and anti-diabetic metformin, jumped by over 200 per cent, putting the spotlight back on India's near total-dependence on China. Since 2020, prices have been increasing due to the pandemic-induced supply disruption and logistics challenges, pinching the industry hard.

“API prices have remained inflated due to the lockdown in China for the past two-three years, logistics and high energy prices. So far, companies have been managing API prices by being efficient with operations. Also, the government had allowed some price revisions a couple of years ago,” said Sujay Shetty, global health industries advisory leader at PwC India.

For essential drugs, prices undergo a change — either increase or decrease — in line with the annual wholesale price index (WPI) in April each year. Non-scheduled drugs (those outside price control) are allowed an annual increase of 10 per cent every year, according to Pharma policy.

Source: *ET Healthworld,* 28th February 2023

Second Time in A Month, Indian Firm Recalls Eye Medicine From US

In a second recall within a month, Global Pharma Healthcare has recalled artificial eye ointment lubricant due to possible contamination in the US market. The ointment is used as an eye lubricant and to relieve dryness of eyes. Early February, the Chennai-headquartered pharmaceutical company had announced recalling of artificial tears lubricant eye drops.

Global Pharma Healthcare, however, said when the artificial tears lubricant eye drops were subjected to investigations, results proved there was no evidence of contamination to date.

While the announcement said the use of contaminated eye ointment may cause adverse events, including infection in the eye that could lead to blindness, the company has not received any reports of adverse events related to this product.

Further, the company has notified the brand owner and importer of this product, Delsam Pharma, about the recall and urged wholesalers, retailers and customers, who have the recalled product, to stop any use and discard the product safely and appropriately.

When contacted, Global Pharma Healthcare told TOI, "Early in February 2023, a

voluntary product recall of Ezricare/Delsam eyedrops (which were contract manufactured) was issued based on claims by the USDFDA/CDC regarding possible contamination of products. These claims were based solely on testing opened bottles from various healthcare settings; in numerous cases, patients had, in fact, been using multiple brands of eyedrops. Despite there being nil complaints against Delsam eye ointment, Global Pharma Healthcare initiated a voluntary product recall out of abundance caution."

Source: *The Times of India*, 1st March 2023

Drug Combo Regimen Can Treat Fatal Scrub Typhus Cases Better, Say Indian Researchers

Researchers have identified a better drug treatment for 'severe scrub typhus,' a life-threatening bacterial infection, which may lead to more lives being saved among those who get infected. Scrub typhus is transmitted to humans through tick bites. Agricultural labourers are at a major risk of infections due to exposure to shrubs where the ticks breed.

A multi-centre clinical trial conducted by Indian researchers which involved 800 patients found that administering a combination of antibiotic drugs is more effective for treating severe scrub typhus than single-drug therapies. The study has been published in New England Journal of Medicine.

"The trial demonstrated that treatment with intravenous doxycycline and azithromycin is more effective than using either drug on its own. The combination of the two drugs may have resulted in a more complete blockade of protein synthesis and consequently reduced bacterial growth and multiplication," said Prof. George M. Varghese, Department of Infectious Diseases, Christian Medical College, Vellore, Tamil Nadu.

The patients were split in three groups through a randomisation process to receive intravenous doxycycline, intravenous azithromycin, or a combination of both intravenous doxycycline and azithromycin, respectively, for a week's duration.

The trial found that combination therapy was superior to therapy with intravenous doxycycline or azithromycin alone. Patients who were treated with combination antibiotics had fewer complications from the infection on the seventh day. In line with other studies, this study also found that there was no difference in the outcome between using doxycycline or azithromycin alone. Also, up to 96 (12%) of the 800 patients died.

Mr. Varghese said, "The implication of this study is that when using a combination of azithromycin and doxycycline to treat severe scrub typhus, more patients can be discharged from the hospital by the seventh day as they

would have fewer persisting complications, such as respiratory distress syndrome (ARDS), hepatitis, hypotension or shock, meningoencephalitis, and kidney failure.

About 6% of patients infected with scrub typhus could die in spite of diagnosis and treatment. The new evidence is expected to change treatment guidelines which will lead to better salvaging of patients.

Mr. Varghese added, "Scrub typhus typically presents as a fever that may be associated with headaches, coughs, shortness of breath, and brain symptoms, like confusion and disorientation. One-third of patients develop severe disease that affects multiple organs in the body and leads to lethally low blood pressure. Death rates in severe disease can reach up to 70% without treatment and 24% with treatment."

Scrub typhus is a major public health threat in India and other South Asian countries. It is estimated that in endemic regions, about a billion people are at risk of contracting the infection, while a million people get infected and 1.5 lakh people die from it every year. The trial was funded by Department of Biotechnology and Wellcome India Trust.

Source: *The Hindu,* 2nd March 2023

U.S.-CDC Probe into Cough Syrup Deaths in the Gambia Pins Blame on Indian Manufacturer

A probe report by the top public health body of the U.S., Centre for Disease Control, into the death of children in The Gambia due to kidney injury, has suggested a strong link between these deaths and consumption of allegedly contaminated cough syrup manufactured by India-based Maiden Pharmaceuticals.

A CDC report released on Friday said, "This investigation strongly suggests that medications contaminated with Diethylene Glycol [DEG] or Ethylene Glycol [EG] imported into The Gambia led to this Acute Kidney Injury (AKI) cluster among children."

The CDC report is the third such evidence to link cough syrups manufactured in India to the deaths. Earlier, the World Health Organization (WHO) in the same case had stated that it had found DEG and EG, two industrial chemicals in tested samples in the range of 1% to 21.3%. Before this, an investigation by The Gambian parliament had said Maiden Pharma 'should be held accountable.'

India's claim

The Indian government, however, maintains that when it collected control samples from the pharma company of the same batch that was exported to The Gambia it found no contamination. "We had also requested that a team of Indian officials go to The Gambia to investigate the case, but we have been disallowed by The Gambia from conducting the probe," a senior Health Ministry official told The Hindu.

Between July and Septmber last year, The Gambian Ministry of Health had identified that 78 children developed sudden kidney failure and up to 66 (85%) of them died. The Gambia had requested help from CDC experts to help investigate the situation.

The CDC report states that June 21 was chosen as a start date for the investigation because medications (allegedly contaminated cough syrup) suspected to cause the deaths were imported in The Gambia on that day. Up to 56 patients met the criteria for investigation and were included in the CDC analysis.

These children had developed fever, vomiting, diarrhoea, loss of appetite and an inability to pass urine. The report said that most children died within 11 days of experiencing symptoms.

Caregivers interviewed

The CDC team of experts interviewed caregivers of affected children who said they had given the affected children a prescription or over-the-counter cough syrup-based medication before their kids were unable to pass urine.

The CDC report pointed out that a single international manufacturer (Maiden Pharma) that produced a syrup-based medication was reported in 8 of 14 interviews in which caregivers identified the manufacturer name or at least one medication administered to their child before hospitalisation.

The report further added that lab analysis of 23 medication samples conducted by The Gambia's Ministry of Health and the WHO confirmed that four products from Maiden Pharmaceuticals in Haryana contained DEG and EG.

Based on records from The Gambia's Medicines Control Agency, all medications that tested positive for DEG and EG were imported into The Gambia on June 21, 2022, shortly before the occurrence of the first AKI cases.

The report says that in past DEG outbreaks, manufacturers have been suspected of substituting DEG in the place of more expensive, pharmaceutical-grade solvents, adding that testing of lab samples has supported the fact that contaminated medical syrups led to a cluster outbreak of AKI cases.

It adds, “Further support for a toxic etiology includes the wide geographic distribution of cases in the country (six of seven health regions), a common pharmaceutical manufacturer of medications reported to have been used by many patients... This intoxication appears to have only affected children, likely because medications in syrup form are most commonly used for children in The Gambia.”

This likely poisoning event highlights the potential public health risks posed by the inadequate quality management of pharmaceutical exports, highlights the CDC report. It warns against the risks of inadequate regulatory structures which make the sale of medicines from international markets a high-risk activity especially in low-resource settings like The Gambia.

"Medications for export might be subject to less rigorous regulatory standards than those for domestic use. Simultaneously, low-resource countries might not have the human and financial resources to monitor and test imported drugs," the CDC report stated.

Source: *The Hindu,* 3rd March 2023

Fake Drug Rackets Spread Across Six States

A spurious drugs racket, first detected in Bargarh and Jharsuguda districts of Odisha in January, is spread across Uttar Pradesh, Haryana, Himachal Pradesh, Bihar, West Bengal and Telangana, investigators have found. Following the arrest of a Bulandshahr native by UP police on Thursday, it has come to light that the fake medicines were being manufactured mainly in Baddi area of Solan district in Himachal Pradesh and were supplied to other parts of the country.

As per the FIR filed by police at Sigra police station in Varanasi, the drugs were manufacture mainly in Himachal Pradesh besides in Haryana and transported to UP. The suppliers pasted GST invoices of other goods on the spurious medicines so that checks by tax officials don't come in the way during inter-state transport, police have found out.

The medicines were supplied to various parts of UP, Bihar, Odisha besides Kolkata, Hyderabad and Ahmadabad. They pasted labels of various manufacturing units of known brands having units in Chandigarh, Guwahati, Sikkim, Haridwar and Baddi.

While Odisha Police have registered cases against five persons including two UP natives, the Uttar Pradesh police have registered FIR against 16 persons at Sigra police station in Varanasi (UP). The spurious medicines sold include many popular antibiotics and medicines for acidity. Ashok Kumar, the UP supplier who has been arrested, have told police that he bought the consignments from a supplier in Panchkula in Haryana and two persons from Himachal Pradesh. The Panchakula supplier has drugs licence to manufacture certain generic medicines. He, however, sold fake medicines of popular brands, police have found out.

Odisha's drugs controller Subodh Nayak said the fake medicines first came to light in Bargarh after the officials started checking on why some retailers were purchasing medicines from suppliers from UP though the same were available with stockists locally. "It didn't match with brand. These were then put to laboratory test and found of substandard quality," he said, adding since it had interstate ramifications authorities in UP were alerted.

The Odisha authorities have found the spurious drugs, an antibiotic, the same UP supply, was also sold in Cuttack and Bhubaneswar. After the brands were found fake, the authorities are planning to take action against the dealers in the twin cities as well,

another senior health department officer said.

The state government, meanwhile, has added two more members to its special squad to probe the fake drugs' outstate links. Drugs inspectors Sashmita Dehury (Jharsuguda) and Sunita Nag (Bargarh), who spilled the bins on the racket first, have been included in the squad which earlier had assistant drugs controllers Sudarsan Biswal, Tushar Ranjan Panigrahi and Dharmadev Puhan..

Source: *The Times of India,* 5th March 2023

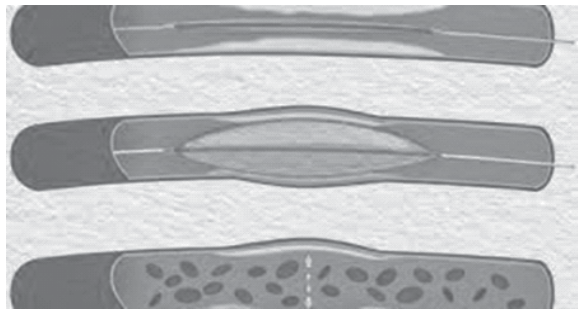
Drug-Coated Balloons Better Than Stents: Doctors

Using drug-coated balloons improves outcomes, reduces complications, and the need for a permanent metal inside the body when used in the right cases, said senior interventional cardiologist Dr Antonio Colombo from Italy.

While it may take some time to show long-term studies to say if it can replace drug-eluting stents, experience from doctors, who have been using these shows encouraging results, he said.

The cardiologist, who delivered a lecture and performed a live surgery at the Sri Ramachandra Medical Centre, interacted with journalists at Kauvery Hospitals.

During a coronary angioplasty, doctors use a balloon to stretch open a narrowed or blocked artery. This is followed by inserting a short wire mesh tube, called a stent, into the artery. The stent, coated with a drug, is left in place permanently to allow blood to flow more freely. But stents come with certain problems and cannot be used in some patients with narrow vessels.



"The decision to use a drug coated balloon or drug eluting stent is made by the cardiologist in the cath lab. After dilating the vessel, the decision to use a stent or balloon is made. If the vessel looks good, the patient may just need a balloon. An inflated balloon can be placed for 60 seconds and removed after the drug is delivered," he said. However, it will take time to evaluate long term results of the drug coated balloon, he said. Over the last two to three years, doctors have found the risk of restenosis (blocks) is around 10 to 15%, almost like that of drug eluting stents.

Kauvery Hospital's chief cardiologist Dr K P Suresh Kumar said the hospital has been offering balloon angioplasty to patients. "Many people with diabetes have diffused arteries. The blood vessels are too small, or the clot is too long. In both these conditions

chances of relapse are very high when using a stent," he said. Most of these patients are given drug coated balloons to deliver drugs. "Unlike in the west, the cost of a drug coated balloon in India is equal to the price of a stent, which is around 32,000. We have Indian manufacturers who make these drug eluting balloons," he said. The balloons are used in smaller blood vessels when there are multiple blocks.

The balloons, he said, are not a replacement for stents. "As of now, each of them have a purpose," he said.

Source: *The Times of India,* 15th March 2023

Govt Shuts Down 18 Cos Making Spurious Drugs

In a major crackdown on pharmaceutical companies selling substandard or spurious drugs, the Centre has cancelled the licences of 18 firms across the country, health ministry sources said.

These firms were found to be violating the Good Manufacturing Practices (GMP) and, the sources said, in some cases, the samples of drugs being manufactured by them were found to be spurious or not-of-standard quality, leading to the government action.

The crackdown comes in the wake of two recent incidents reported from Uzbekistan and Gambia, where it was alleged medical products exported by two Indian firms to the two countries had certain contaminants that led to adverse reactions and the death of some patients.

The sources said a joint inspection was carried out in 20 states across the country by the Central Drug Standards Control Organisation (CDSCO) and the state drug control administration.

"We identified 203 drug manufacturing units for potential violation of GMP. In phase-I of nationwide crackdown, action has been initiated against 76 units," said a health ministry official.

Source: *The Times of India,* 29th March 2023

Rs 800 Crore Spent on Non-Starter Vaccine Complex at Chengalpet

The Centre has spent 804 crore on the integrated vaccine centre at Chengalpet, Union minister of state for health and family welfare Bharati Pravin Pawar told Parliament. The complex, built on 100 acres, is yet to start manufacturing vaccines.

The minister was replying to questions raised by DMP MP P Wilson about the status of reopening the integrated vaccine complex by HLL Biotech at Chengalpet and the upgradation of Pasteur Institute at Coonoor. He also wanted to know if the ministry was aware that the Chengalpet vaccine complex was established in 2012 at an estimated cost of 594 crore.

The minister did not reply to the status of the complex, planned as the nodal centre for research, manufacture and supply of vaccines at affordable prices for the Union government's Universal Immunisation Program (UIP). The complex, which has the capacity to make 585 million doses of vaccines, was to make manufacture pentavalent combination (DPT + HEP B + Hib), BCG, Measles, hepatitis B, anti-rabies, Hib and JE vaccines, but it remains unutilised.

On Pasteur Institute of India, the health minister said the Centre has spent 115.78 crore for the upgradation of the institute in Coonoor, which is carrying out trial runs of equipment in the upgraded current good manufacturing practice.

It is also working on seed characterisation of vaccines and qualification of vaccines. On Wednesday, Wilson tweeted the Union minister's reply, and wondered why Tamil Nadu is not allowed to use the complex to manufacture Covid-19 vaccines.

Source: *The Times of India,* 30th March 2023

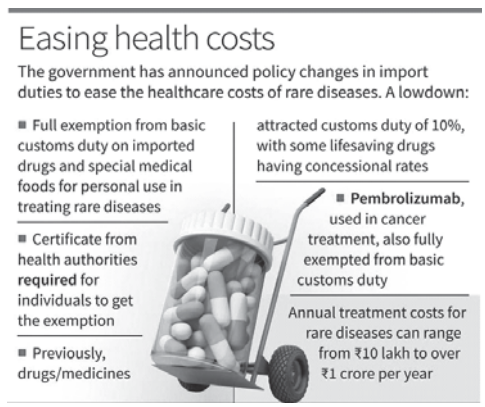
Drugs for Rare Diseases Get Customs Duty Relief

Centre issues waiver to offer substantial cost savings for those in need of such treatments; pembrolizumab (Keytruda) used in treatment of various cancers also gets the same concession.

The Central Government has given full exemption from basic customs duty on all drugs and food for special medical purposes imported for personal use for treatment of all Rare Diseases listed under the National Policy for Rare Diseases 2021 through a general exemption notification.

In order to avail this exemption, the individual importer has to produce a certificate from Central or State Director Health Services or District Medical Officer/Civil Surgeon of the district. Drugs/Medicines generally attract basic customs duty of 10%, while some categories of lifesaving drugs/vaccines attract concessional rate of 5% or Nil.

According to a release issued by the Central Government while exemptions have already been provided to specified drugs for treatment of Spinal Muscular Atrophy or Duchenne Muscular Dystrophy, the Government has been receiving many representations seeking customs duty relief for drugs and medicines used in treatment of other Rare Diseases.



Drugs or Special Foods required for the treatment of these diseases are expensive and need to be imported.

It is estimated that for a child weighing 10 kg, the annual cost of treatment for some rare diseases, may vary from ₹10 lakh to more than ₹1 crore per year with treatment being lifelong and drug dose and cost, increasing with age and weight.

This exemption will result in substantial cost savings and provide much needed relief to the patients, said the release.

The Government has also fully exempted Pembrolizumab (Keytruda) used in treatment of various cancers from basic customs duty.

Source: *The Hindu,* 30th March 2023

Drugmakers Get More Time to Join 'Track and Trace System' for Exports

Drugmakers have got another extension, this time up to August 1, to help implement the Track and Trace system for export of pharmaceuticals consignments.

On the cards for at least eight years, the system was mooted as a measure to address counterfeit and product recall challenges. The latest extension, from the earlier March 31 deadline, came in the backdrop of pharma exporters' body Pharmexcil's representation to the Commerce Department citing members' difficulties in joining the system.

"The date for implementation of Track and Trace system for export of drug formulations with respect to maintaining the parent-child relationship in packaging levels and its uploading on central portal has been extended upto 1.08.2023 for both SSI and non SSI manufactured drugs," the Directorate General of Foreign Trade (DGFT) said in a recent notification.

Pharmaceuticals Export Promotion Council of India (Pharmexcil) Director General Ravi Udaya Bhaskar ruled out the likelihood of any further delay in the system's roll out. "We have already paid C-DAC who is working on this [project], thus no further postponement will be there," he said, highlighting how product traceability was a part of good manufacturing practices.

All manufacturing data is based on traceability and the barcode, under the system, on the packaging can help identify the source as well as serve to prevent sabotage. Asserting that the Track and Trace system is the need of the hour, he said the extensions had been necessitated on account of other issues facing the industry, including those triggered by the pandemic. As a facilitation measure, the Centre had made available a ₹25 lakh grant, for the barcode machinery, to SSI units.

Initially, secondary and tertiary packing will get covered under the system, the primary packing will be included at a later stage, Mr. Bhaskar added.

India's pharmaceutical exports for the first 11 months of FY23, rose more than 3% to $22.90 billion amid challenges, including a rise in raw material prices. The exports are estimated to have ended the fiscal at about $25 billion, better than the previous year but missing the $27 billion target.

Source: *The Hindu,* 7th April 2023

Your Medical Device Could be Spying on You; Industry Demands Protective Laws

After ransomware attacks at major hospitals expose the risk to medical records, experts warn that personal medical devices with software components are also hazards that can leak health data

Common medical devices such as oximeters, hearing aids, glucometers, and pacemakers can be turned into spyware and malware, say experts, warning that such devices can even leak your medical data if not layered with adequate cyber protection. Industry experts are now seeking urgent Central government intervention to recognise this threat and immediately put in place measures to plug any possible drain.

Their warning comes close on the heels of the ransomware attacks suffered by India's top tertiary care hospitals, leading to the siege of millions of medical records and vast amounts of health data at Delhi's All India Institute of Medical Sciences, Safdarjung Hospital and Lady Hardinge Medical College and Hospitals. A ransomware attack is a computer virus that encrypts one's essential files and renders them inaccessible unless the hacker is paid for the key to open them.

Health Records at Risk

Indian multinational pharmaceutical company Sun Pharma, the world's fourth largest generic pharma firm, was also among the establishments that recently took a hit. These attacks ran parallel to the series of failed attempts to hack into India's top medical research organisation, the Indian Council of Medical Research (ICMR).

"What these attacks indicate is our vulnerability," said Shuchin Bajaj, founder director of the Ujala Cygnus Group of Hospitals, adding that these electronic health records contain one of the most valuable databases of knowledge: sensitive patient information.

Medical Devices to Malware

Now, experts are warning that it is not only large healthcare establishments that are under threat. Many personal use medical technology devices — including oximeters, hearing aids, glucometers, medical monitoring watches, and implants such as pacemakers and insertable loop recorders meant for long-term monitoring and recording of electrical activity of the heart — all contain software as medical device (SaMD) and software in medical devices (SiMD) and are usually connected to the internet, mobile phones, servers, and the cloud.

"If not given adequate cyber protection, these devices can be turned into spyware and

malware and can even breach data. Currently, there are no guidelines on the regulation of SaMD and SiMD. Therefore, we suggest that the government should consult with industry experts to identify the challenges that could pose a risk to national security," warned Pavan Choudary, chairman, Medical Technology Association of India (MTaI), adding that the biggest challenge with medical devices was their small size.

Vulnerable Population

India has one of the world's top 20 markets for medical devices and the fourth-largest in Asia. The medical devices sector in India is projected to reach $50 billion by 2025, according to the India Brand Equity Foundation. According to statistics from the Commerce Ministry analysed by the Association of Indian Medical Device Industry (AiMeD), medical device imports rose by a record 41% to ₹63,200 crore ($ 7.91 billion) in 2021-22 from ₹44,708 crore ($5.59 billion) in 2020-21.

The Indian population is growing at a rate of 1.6% per year and has an elderly population of over 100 million. Rapid economic growth, rising middle class incomes, and the increased market penetration of medical devices has left the population vulnerable, experts say.

Inadequate Systems

India currently lacks any centralised data collection mechanism which gives an exact cost of data corruption for the healthcare industry. However, it is clear that data -- now called the new oil -- is seeing a threat that has become rampant, sophisticated, and severe, said Arushi Jain, director, Akums Drugs and Pharmaceuticals. As pharmaceutical companies continue to embrace digital transformation, their highly sensitive, valuable information becomes even more at risk for cyberattacks, she said.

"Pharma companies face their IT environment being landed with legacy hardware and software. In particular, operational technology devices, networks and systems that support business did not have IT security in mind when built. These networks and systems need to connect with IT networks, which exposes them to an organisation's entire threat landscape and creates new opportunities for cyber criminals," she explained.

Data Governance Needed

While the Central government is currently pushing to digitise health records, data protection and cyber-security are governed by the Information Technology Act and the Contract Act. The government has also introduced the Digital Personal Data Protection Bill, which is currently pending before the Parliament.

Data protection is not rocket science, but requires legal and technical artisanship, the allocation of adequate resources and the training of all professionals involved in the processing of personal data, says the World Health Organisation (Europe) in its paper, titled "The protection of personal data in health information systems – principles and processes for public health". It advocates for continuous effort that is based on an institutional vision, a governance concept and a willingness to be accountable.

Source: *The Hindu,* 7th April 2023

Pharma Exports Grew A Shade Better to $25.39 bn in FY 23

Growth came despite increase in raw material and freight cost, aid agencies continuing to maintain focus on COVID: Pharmexcil Director General

India's pharmaceutical exports totalled $25.39 billion in FY23, a shade better than the previous fiscal but short of the $27 billion target as headwinds, including impact of the Russia-Ukraine war, hampered the pace of growth.

Compared to $24.6 billion in 2021-22, this was a more than a 3% increase and came in the face of higher raw material prices, more outgo on freight and the continued focus of global aid agencies on COVID, Pharmexcil Director General Ravi Udaya Bhaskar said.

Export of vaccines, in value terms, showed a decline of about 80% with non-governmental and aid agencies which procure medicines and vaccines for distribution to beneficiaries in low-income countries channelling most funds for COVID work. This translated into a lower off take of other vaccines, especially those used as part of universal inoculation programme, and drugs, including those for HIV and tuberculosis he said.

Negative growth in the important market of Africa, on account of an economic slowdown, as well as in the CIS countries, primarily in Russia on account of the war and sanctions, were key factors that weighed in on the performance. An increase in raw material costs and withdrawal of GST exemption on ocean and air freight charges were among the headwinds despite which Pharma exporters clocked year on year growth.

North America, especially the U.S., continued to be the top market with the latter contributing to more than one-third of the total exports, followed by Belgium, South Africa, U.K., Brazil and Russia, Mr.Bhaskar said, adding that granular details for the full fiscal are yet awaited. In terms of total vaccine exports, it was $334 million for the 11 months till February. In FY22, vaccine exports were at $532 million.

Source: *The Hindu,* 14th April 2023

Safety Concerns Over E-Pharma Put Centre in A Spot

The misuse of online pharmacies is a major concern against granting permission to platforms, says a parliamentary panel

Central Health Ministry sources say that they are in no mood to give the e-pharma platforms a “free run", calling the move far too angerous.

“Consumer safety is our primary focus. Unlimited accessibility to medicines through e-pharmacy, sale of sub-standard, habit-forming medicines [like sedatives, mood-altering drugs], profiling of patients and buyers, and illegal data collection are the main concerns," said the source, adding that this dynamic industry must be handled with care.

A cautious Health Ministry has maintained this despite a rap-on-its-knuckle by a parliamentary panel asking it to finalise the draft e-pharmacy rules and implement them without further delay. “Vigilance wins over the perceived convenience and economics of the e-pharma market."

The parliamentary panel also expressed concern over the possible misuse of online pharmacies in the absence of regulation and mentioned that there are concerns over the distribution of illegal or unethical medicines, or outdated, substituted, or counterfeit medications.

According to a report – E-pharmacy Market in India 2022-2027 – compared to its physical counterparts, e-pharmacy has emerged in recent years as a superior and more practical strategy for addressing consumer problems and delivering excellent customer solutions.

“In 2021, the market for online pharmacies was worth ₹25.50 bilion. It is anticipated to expand at a compound annual growth rate (CAGR) of 22.20% from 2022 to 2027 when it is expected to reach ₹89.47 billion," it added.

While there are talks in the Health Ministry about a complete ban on e-pharmacy in the industry, earlier this year the Drug Controller General of India (DCGI) sent show-cause notices to 20-odd e-pharmacies including Tata 1mg, NetMeds, Practo etc. stating that there was sale of drugs that weren't allowed for retail sale and lack of proper prescription. The Hindu contacted some of the e-pharma businesses, but no response was received.

In India, the Drugs and Cosmetics Act of 1940 regulates the import, manufacturing and distribution of drugs in India. E-pharma business insiders maintain that shutting down business doesn't help. “Stringent laws and strong e-pharmacy code of conduct will help this market," they say.

Indian Medical Association (IMA) in its white paper on online pharmacies said that drug abuse, misuse, self-medication, access to children, no place or system to evaluate adverse drug reactions, no clarity on drug storage conditions and no system of immediate recall in case of drugs are problems that the industry comes with. ”These need to be addressed," it advised.

Source: *The Hindu,* 30th April 2023

CDSCO Confirms WHO Alert on Contaminants In Punjab-Made Cough Syrup

The cough syrup manufactured in Punjab's Derabassi, which had been flagged in a 'product alert' by the World Health Organisation on April 25, has been found to contain unacceptable amounts of toxic contaminants - diethylene glycol and ethylene glycol.

The Central Drugs Standard Control Organisation (CDSCO) at Baddi in Himachal Pradesh on Tuesday confirmed the presence of toxic contaminants in the cough syrup, as was highlighted by WHO a week ago.

“The samples were tested in our Chandigarh laboratory where it was found that

diethylene glycol and ethylene glycol were present in more than permitted levels and hence substandard. The investigation will continue and the DCGI has been updated on the matter," said a CDSCO official.

The cough syrup is manufactured by Punjab's QP Pharmachem Ltd and is marketed by Haryana-based Trillium Pharma.

Punjab's food and drug administration (FDA) has cancelled the manufacturer's licence for liquid drugs after the CDSCO confirmed the cough syrup was substandard. In fact, diethylene glycol and ethylene glycol were found in excess amounts in another Indian-made cough syrup that has been blamed for the death of 66 children in Gambia.

A lot of 18,336 bottles of cough mixture, Guaifenesin syrup TG, manufactured by QP Pharmachem Ltd was exported to Cambodia in 2020.

However, the WHO has not received any information on the adverse effects of the drug in that country. The WHO alert was sounded when samples of the cough syrup from Micronesia and Marshall Islands were analysed by quality control laboratories of Therapeutic Goods Administration (TGA), Australia.

The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol. WHO reached out to QP Pharmachem Ltd on April 12, 2023 and contacted Trillium to understand their involvement and countries where they had distributed the product.

Alleging that the drug meant only to be exported to Cambodia had somehow been routed to the Islands without approval, QP Pharmachem managing director Sudhir Pathak said, "I will challenge sample analysis report in the court and also lodge an FIR against the trader-Telpha, who had exported the syrup elsewhere."

CDSCO Baddi is expected to issue a show-cause notice on the issue to the manufacturer, and the firm at this point can contest the report. Accordingly, another sample analysis of the drug can be conducted at CDSCO Kolkata laboratory, which is the final authority for the decision. WHO had alerted CDSCO to the situation as a routine practice.

"We do not have reports of the product being found in other countries. But, if the alert needs to be updated beyond Micronesia and the Marshall Islands, then we will do so," said WHO's official spokesperson. "Our correspondence continues and we await details of the actions from CDSCO," she added.

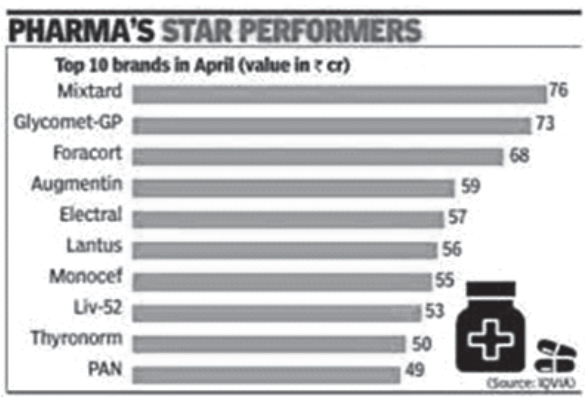
Sources in CDSCO pointed out that whenever traders are engaged in the export of drugs, they enjoy huge profit margins and offer low margins to the manufacturer. To cut corners, the manufacturers affect the quality of the drugs, they alleged.

Source: *The Times of India,* 3rd May 2023

Virals Beaten Back? Diabetic Medicines' Sales Rebound in April

It seems we shrugged off flu as well as virals in April pretty well, as anti-diabetic therapies have started to bounce back, dethroning antibiotics from their pole position. Anti-diabetic therapies Mixtard and Glycomet-GP made a comeback into the top five selling brands' list in the over Rs 2-lakh-crore pharma retail market, overtaking popular antibiotic Augmentin. Over the last few months, as the country was suffering from flu and Covid, the antibiotic had registered substantial growth and even emerged as the largest-selling brand in February. It had overtaken the established market leader for several years now - antidiabetic therapy Human Mixtard.

Last month, Mixtard resumed the top rank, followed by Glycomet-GP, registering sales of Rs 76 crore and Rs 73 crore respectively. Overall, April witnessed an 11% growth with sales of Rs 17,799 crore, according to latest data culled from market research firm IQVIA.



Antibiotic Augmentin had been witnessing a growth in sales since January, and assumed the top slot in February and March, coinciding with the flu and viral season in the country. It may be noted Augmentin, a combination of amoxicillin and clavulanic acid, is believed to work against various types of bacteria, but is being popped in for viral infections too. Respiratory issues seem to have troubled a few people, with Foracort taking the third slot (Rs 68-crore sales), while antibiotic Augmentin slipped to the fourth place with Rs 59-crore sales.

Among therapies, respiratory, anti-infectives, vaccines and pain medicines were the major market drivers. In fact, respiratory and anti-infectives posted the highest growth of 29% and 25% respectively during the month, dipping from the previous levels of 50% each for both in March, the data showed. Besides Augmentin, others that had recorded highest growth include Calpol and Monocef during March.

Domestic companies hold a majority share of 83% in the pharma retail market, while the remaining 17% is held by multi-nationals. Domestic companies have consistently outperformed MNCs for the past 12 months, an analyst from Motilal Oswal said. Among the top 20 corporates, Mankind (up 19% year-on-year, or YoY), Alembic (18% YoY), JB Chemicals (18% YoY), Macleods (16% YoY), Cipla (15% YoY), Alkem (14% YoY), and Ajanta (up 14% YoY) all outperformed the pharma retail market, he added.

Source: *The Times of India,* 15th May 2023

Company Deregistered for Smuggling Psychotropic Drug to Sudan

Guntur-based pharmaceutical firm, Safe Formulations Limited, was stripped of its registration by the Pharmaceuticals Exports Promotion Council of India (Pharmexcil) for smuggling Tramadol drugs to Sudan.

The fighters use the drug to stay awake in war zones. In the suspension letter to Safe Formulations, Pharmexcil director general R Uday Bhaskar, said, "On April 25, we sought details of licensees to whom Tramadol was supplied and details of importers and other documents. The firm responded on April 27, stating they will send a reply by April 28. However, the firm failed to provide the information within the deadline. Due to this, the membership of Safe Pharma with Pharmexcil has been cancelled with immediate effect."

In an earlier notice, the director general said, "It has come to our notice that central intelligence unit of Mumbai customs intercepted a consignment on February 27, and seized around 10 lakh Tramadol tablets on way to a pharmacy firm in JUBA, South Sudan. The shipment was examined at the air cargo complex in Sahar."

Source: *The Times of India,* 1st May 2023

HEARTFELT CONDOLENCES

Shri. Vijay A. Metha

DOB: 25.05.1941
DOD: 31.03.2023

Shri. Vijay A. Metha founder and Managing Director of M/s. Retort Pharmaceuticals Pvt. Ltd., Chennai. He is one of the trustee of our trust and actively participated in IPA and IPCA conferences

A senior Pharma Industry person, Shri Vijay A Metha, held various positions in several Pharmaceutical Industry associations including Indian Pharmaceutical Association (IPA), Indian Drug Manufacturers' Association (IDMA) and Tamil Nadu Pharmaceutical Manufacturers Association (TN PMA), Founder Director of Tamil Nadu Ayurveda, Siddha, Unani Drugs Manufacturers Association (TASUDMA) and Trustee of Tamilnadu Pharmaceutical Sciences Welfare Trust.

We lost an active trustee and pray for his soul rest in peace. We extend our condolences to his family.

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