ISSUE No. 49

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

e-NewsLetter

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2021

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Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 49th issue of Pharma Web Newsletter for **Jan– Mar 2020.**

We are publishing this issue also e-newsletter, and this issue is delayed, due to non-availability of suitable articles and other information. We are sending this issue to all our Pharma professionals through email and What's app. This newsletter will also be available in our website.

This 49th issue contains the following articles,

- **Advances in Controlled Release Drug Delivery System** by Deveswaran R*, Bharath S Department of Pharmaceutics, Faculty of Pharmacy, M. S. Ramaiah University of Applied Sciences, Bangalore- 560 054, Karnataka
- **Pharmacists: The Vital Link Between Prescribers Vs Patients** by Ms. Priya Choudhary, JSS College of Pharmacy, Ooty.

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

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue. We also published the parliament question answers related to pharmacy profession, discussed in Lok Sabha and Rajya Sabha.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., M/s. Acid 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

ADVANCES IN CONTROLLED RELEASE DRUG DELIVERY SYSTEM

by

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Abstract:

Controlled drug delivery systems have been developed to improve the effectiveness of drug delivery in the body. It plays a significant role in achieving slow release of drug over a period of time as well as targeting the drug to organ or tissue. CRDDS have some advantages over traditional drug delivery system. This review underlines the methodology of controlled drug delivery system preparation, their significance, formulation challenges, advantages and disadvantages, detailed classification, development strategies and the future innovations of controlled release technologies.

Keywords: Controlled drug delivery, dose, efficacy, development strategies, regulatory

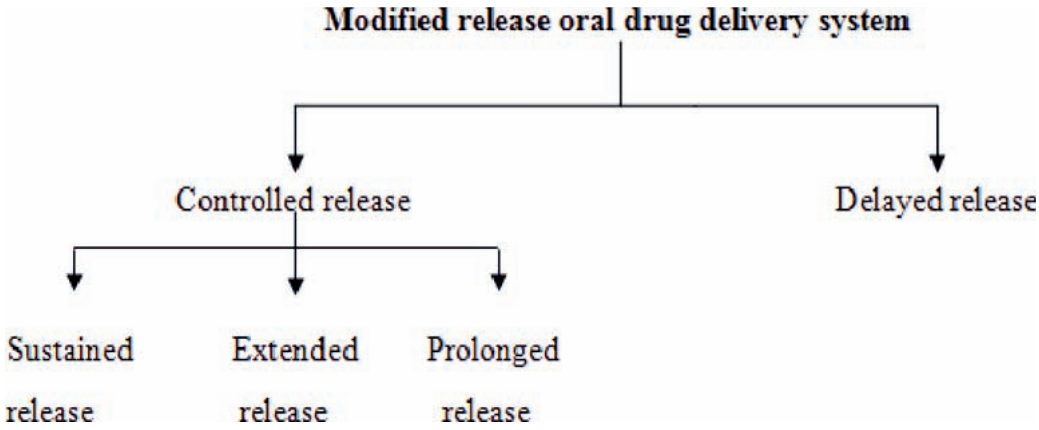
Introduction

The term controlled release (CR) implies the predictability and reproducibility in the drug release kinetics which means the drug release from the delivery system proceed at the rate profile not only expected kinetically but also reproducible from one division to another. Controlled release drug delivery systems (CRDDS) alter the drug distribution along with a reduction in drug toxicity. CRDDS intended to exercise control drug release in the body this may be temporal or spatial nature or both. These dosage forms aims to retard the release of drugs in such a way that its appearance in the systemic circulation is delayed or prolonged and plasma drug concentration sustained, onset of drug action delayed and duration of therapeutic effect is maintained. The science of controlled release was first originated from the development of oral sustained release products in the early 1940s. The development of the pharmacology and pharmacokinetics demonstrated the importance of drug release rate in determining therapeutic effectiveness of this therapy. This becomes the reason behind the development of controlled release. Over the past decades as the complication involves in the marketing of new drugs increased and various advantages of CRDDS are recognized, greater attention is being paid in this field. Today the oral controlled drug delivery system becomes major drug delivery systems mainly drugs with high water solubility and short biological half-life. Other than oral, routes like transdermal, ocular, vaginal and parenteral were also established for controlled release of various drugs.

Formulation Challenges of CR Delivery Systems: The major challenges in the development of CR formulations are

1. Intersection of market expectations for once-daily dosing and the prevalence of lower-solubility, higher-dose compounds for the development of oral solid CR products
2. Increasing need for pediatric CR dosage forms
3. APIs with short half-life and the need for high-dose delivery
4. Most polymers need to be solubilized in organic solvents before coating the CR formulations
5. Increased complexity of patient-to-patient variability and IVIVC in the formulations
6. Enhanced scrutiny and regulatory requirements of CR formulations.

Many compounds do not have sufficient colonic absorption for conventional CR formulations. Absorption technologies such as nanoparticles, amorphous-drug, and lipid-formulation technologies are needed to provide sufficient driving force for adequate absorption, especially in the lower part of the gastrointestinal tract. These absorption technologies have developed over the past decades for immediate-release dosage forms, but substantial research is still required to couple them with the processing technologies in case of controlled release dosage forms. Also in case of opioids and othercontrolled substances development of CR dosage forms imparts abuse resistance. An effective approach should be designed to counter this. These approaches have been novel and vary greatly in physical, chemical, and pharmacological approaches. Formulation scientists have devised an array of approaches that facilitate meeting target pharmacokinetic profiles while providing abuse resistance using waxy excipients, high melting point and viscosity modifiers etc. The other challenge is the urgent and increasing need for pediatric CR dosage forms. This is because fewer excipients are deemed acceptable for pediatric use by regulatory agencies. Dosage forms for infants and children are challenging because these patients may not be able to swallow a solid-dosage capsule or tablet, and also concern for dose dumping is of crucial importance.



Advantages of Controlled Drug Delivery

- Improved the patient compliance especially with long-term treatments for chronic diseases
- Conventional dosages form produce fluctuation in plasma drug concentration. These fluctuations depend on the drug kinetics within the body like ADME process. Controlled release eliminates this type of fluctuation in plasma drug concentration
- Reduction in dose and dosing frequencies
- Maintenance of required drug concentration in plasma thus eliminates the failure of drug therapy and improved the efficiency of treatment
- Suitable for drugs which having a short biological half-life (3-4 hrs) and drugs rapidly eliminate from the body

Disadvantages

- Dose dumping wherein rapid release of a relatively large quantity of drug from a controlled release formulation. This phenomenon becomes hazardous with potent drugs
- Poor in-vivo & in-vitro correlations
- Difficult to optimize the accurate dose and dosing interval
- Patient variability affects the release rate like GI emptying rate, residential time, fasting or non-fasting condition

Classification of Controlled Release Systems: The controlled release system divided into following major classes based on release pattern.

1. Rate pre-programmed drug delivery system: The release of drug from the delivery system is pre-planned with particular flow rate. The system controls the molecular diffusion of drug molecules across the barrier medium within or surrounding the delivery system.
2. Osmotic pressure activated system: Osmotic pressure is used as the driving force for the release of drug in a controlled manner.

3. **Polymer membrane permeation controlled system:** Drug is completely or partially encapsulated in a drug reservoir cubicle whose drug-releasing surface is covered by rate controlling polymeric membrane. In drug reservoir, the drug can be solid or dispersion of drug particle or concentrated drug solution in a liquid.

4. **Activated modulated drug delivery system:** The release of drugs from the delivery system is controlled or activated by physical, chemical and biological process. Drug release is controlled by the energy input or any applied process.

5. **Hydrodynamic pressure activated system:** Drug is placed into the collapsible impermeable compartment which contains liquid drugs and forms drugs reservoir from which the drug releases slowly over a period of time.

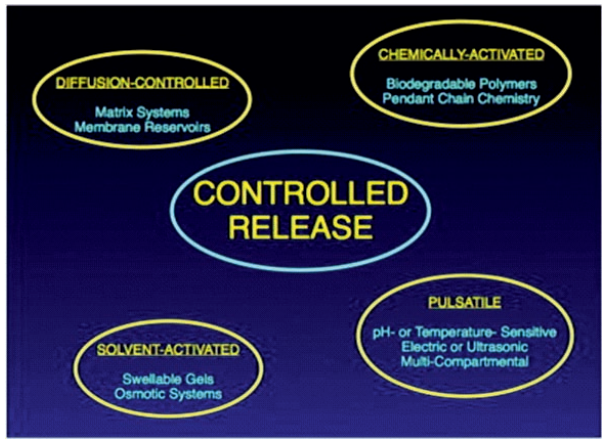
6. **Polymer matrix diffusion-controlled system:** The reservoir is prepared by homogeneously dispersing drug particles in the rate controlling hydrophilic or lipophilic polymer matrix. The resultant medicated polymer matrix provides the medicated disk with defined surface area and controlled thickness.

7. **Vapour pressured activated system:** Liquid exists in equilibrium with its vapour phase and pressure of the independent volume of fluid. The device consist of two chambers, one contains the drug solution and second with a vaporizable fluid such as fluorocarbon. After shooting of drug, volatile liquid vaporizes at the body temperature and creates a vapour pressure that compresses the below chamber, which releases the drug in a controlled way.

8. **Magnetically activated system:** Drug reservoir is made-up of peptide or protein powder in a polymer matrix. These reservoirs contain the macromolecule drug which is magnetically controlled and delivered the drug. In some cases, electromagnetically vibration mechanism is also used.

9. **Site targeting drug delivery system:** Delivery of drugs to the targeted tissue is complex, and it is consists of multiple steps of diffusion and partitioning. It is an uncontrolled release of drugs from the drug delivery system, but the path of drug release should be in control. To get rid of uncontrolled drug release, drug delivery system should be site targeting specific.

10. **Mechanically activated system:** Drug reservoir is equipped with a mechanically activated pumping system. A controlled amount drug is delivered into the body cavity, such as nose or mouth, through a spray system which works on mechanically drug delivery pumping system. The spray volume of delivered drug is fixed in each pumped spray.

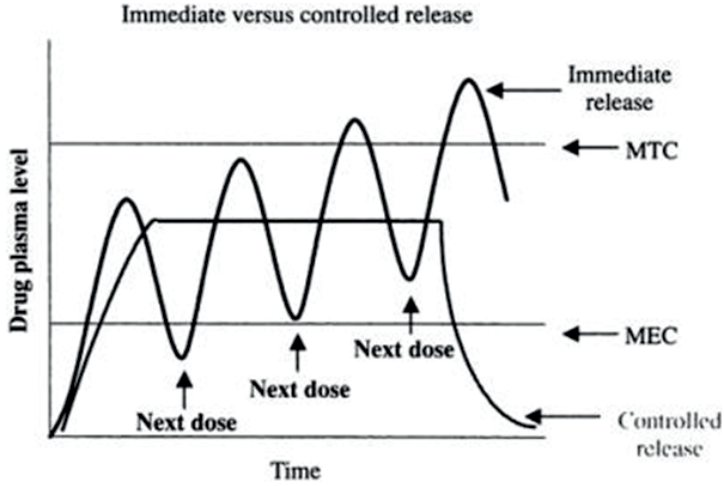


Development Strategies in CRDDS

The development of CR formulations is usually undertaken as a lifecycle management strategy. At this stage of the development program, the pharmacokinetic parameters such as peak concentration (Cmax), time to peak concentration (Tmax), half-life (T1/2), area under the curve (AUC), and the absorption, distribution, metabolism, and excretion (ADME) profile of an IR dosage form of the drug are well defined. The dosing interval required to obtain the required plasma levels of the drug that result in a therapeutic effect should be well understood. These data are crucial in defining the range of dose required to be administered over a defined period of time. The plasma levels that may cause undesirable side effects would also be known. It is, therefore, important to ensure that the drug is released from the dosage form in a controlled rate and not to an extent that it causes side effects. Realizing the potential clinical advantages of CR products it has refined the treatment approach to certain conditions such as cardiovascular and central nervous system diseases. In addition, these apparoches have helped formulation scientists to design CR dosage forms in a way that are most closely related to the therapeutic challenges and needs of disease conditions. Various CR platform technologies, such as hydrophilic matrices, multiparticulate reservoir-type systems, and push-pull osmotic pumps, have been commonly used to effectively deliver drugs over time. These approaches have enhanced patient experience and compliance, as well as enabling challenging drugs to be formulated and successfully marketed.

Improved understanding has also led to the development of more complex formulations, such as fixed-dose combinations, in which two or more drugs with the same or different release profiles are formulated into one dosage form. The success of oral, parenteral, ocular, and topical routes has been established through several marketed CR systems such as osmotic CR tablets, coated granules/beads/particulates for release over time, poly(lactic-co-glycolic acid) microparticles, liposomes, matrix or reservoir transdermal delivery, iontophoresis patches, and ocular inserts. During the past few years, significant advances have been made in the area of targeted drug-delivery systems, in which drugs are targeted to specific organs and tissues. Examples include dendrimers, polymeric nanoparticles, solid lipid nanoparticles, nanoemulsions, and vesicular systems such as liposomes and virosomes. Another advancing field is the combination of regenerative medicines and tissue/genetic engineering including the

use of DNA or siRNA in CR systems for regeneration of bone and cartilage. Also advances in polymer chemistry, specifically pH-dependent and pH-independent release from polymer systems and the availability of specific grades of the polymers; advances in in-vitro and in-vivo models to understand the release mechanism of the API from the formulation; the co-delivery of IR and CR systems; advancement in engineering of manufacturing equipment to support scale up of CR formulations; and the development of targeted delivery systems or delivery of medications directly to the affected area as opposed to systemic delivery. Targeted drug delivery has been made possible by use of novel polymers, formulation, and analytical techniques, such as imaging to control the level of coating to obtain the required performance of the dosage form. Advances in polymer systems to control drug delivery and techniques to identify critical material properties that can impact drug product quality and dosage form performance have resulted in the development of better controlled systems.



The concept of risk assessment and use of QbD principles have helped in developing robust drug formulations for controlled release. Further areas that have matured are pulsatile-release approaches and chronotherapeutic delivery. The extension of this concept sets the stage for the personalized medicine genre, an area that appears poised for substantial growth, and enabling technologies integrated into the pharmaceutical development area. Nanotechnologies are enabling the development of new drug-delivery approaches in many areas. For example, the development of high surface area mesoporous silica substrates, which offer the ability to provide bioavailability enhancement and deliver a high drug payload, may have broad utility in the development of oral CR formulations of poorly soluble compounds. Nanorobots can either be MEMS based (microelectromechanical systems) or biochemically based (e.g., DNA nanobots) and can offer the ability to deliver specific, complex release profiles, and/or target specific cells. This technology may enable customization of dose regimens for a specific patient and disease state. Nanotechnology offers both diagnostic and therapeutic advantages. The assimilation of biomarkers into delivery systems focuses on tailored therapy for a patient based on gene sequencing, metabolites, and proteins. Activatable CR systems are based on the concept of activating the specific biomarker once the drug reaches the therapeutic site. This approach decreases the toxicity associated with potent drugs.

Future Innovations in CRDDS

More work in pharmacokinetic modeling and simulation techniques are needed to predict the drug-release performance in the development phase of CR formulations. The use of advanced medical devices to administer drugs for controlled delivery via transdermal, subcutaneous, ocular, and parenteral routes will be foreseen in near future. Public health areas for oral CR innovation are pediatric and abuse-deterrent CR dosage forms. There are a number of abuse-resistant formulation approaches available today, and these approaches will continue to be refined and expanded. Pediatric studies are now required for product approval and are crucially important because dosing challenges, flexibility, GI transit, and ADME are often different for pediatric patients than for adults. Similarly, the need for innovation to better serve the growing geriatric population is strong. Despite significant efforts over the past decades, oral delivery of high molecular-weight molecules, peptides, and proteins using immediate-release or modified-/delayed-release approaches remains an ongoing challenge. This problem is exacerbated by a growing percentage of molecules in this category and the growing importance of such molecules to the pharmaceutical industry. While exceptions exist, this area remains almost entirely an unmet need. Innovation in new materials and associated dosage forms is an ongoing area of research to address this need. While early in development, orally delivered microelectronics and devices show promise to assist in the protection, absorption, and controlled-release delivery of pharmaceuticals. In the manufacturing arenathat requires innovation to meet increasing economic and environmental health and safety are continuous manufacturing processes and improved and new approaches for containing high-potency actives.

A potential area for future innovation is research into complex release profiles for one or more drugs with biologically responsive delivery platforms in combination with biomarkers. Although oral drug delivery is the most desired route of administration, some of the new molecules are only available through injection or implant. Significant innovation is also possible in customized/personalized delivery technologies for diseases affecting daily life of patients and conditions requiring frequent dose adjustment depending on stage of the disease (e.g., Parkinson's and Alzheimer's), chrono-pharmacokinetic delivery systems, use of newer and better controlled-release polymers, and improved targeting leading to site-specific controlled-release delivery of pharmaceuticals and biologics.

Conclusion: It can be concluded that by thorough understanding of controlled-release mechanisms and improved development of technologies, it is possible to design an appropriate method for efficient drug delivery system at the particular site. These formulations will be helpful in increasing the efficiency of the treatment by decreasing the dose. A controlled release drug delivery system can be a significant progress towards solving problems regarding the targeting of a drug to a particular organ or tissue and controlling the rate of drug delivery to the target site. These unmet technologies needs create great opportunity designed for research, development,

and innovation. Breakthroughs into controlled oral delivery designed for water insoluble drugs and biopharmaceuticals are probable toward contain momentous impact on the pharmaceutical and biotechnology industries. On the other hand, the constant development of present delivery technology is too important when it comes to decreasing cost and increasing efficiency.

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PHARMACIST - THE VITAL LINK BETWEEN PRESCRIBERS AND PATIENTS

by
Ms. Priya Choudhary
JSS College of Pharmacy, Ooty

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

Being a budding pharmacist, I feel proud writing this essay and justifying my profession as a vital link between prescribers and patients.

We live in a society where we all are dependent upon pharmacists but unfortunately in eyes of the public, the role of Pharmacy profession and its contributions to health care are often not duly recognized and even misunderstood. This is possibly because both the public and the policymakers believe that pharmacist role is restricted to merely buying and selling of medicine but in realitythere is lot more to add to it.

The role of the pharmacist is very diverse. From working in healthcare setting to pharmaceutical industries, from carrying out tasks in R&D to manufacturing, from quality control to packing,from quality assurance to practice setting,from academics to regulatory affairs and clinical research. The role doesn't end here there's so much more to add. The most important job being the healthcare professional, whole responsibility is to ensure that people drive maximum therapeutic benefit from their treatments with medicines. This makes them a important bridge between doctors and patients. They prove as asset for both the doctors and patients. This requires them to keep abreast of developments and advances in knowledge and technology related to manufacture and use of medicines. There are around 5 lakhs Pharmacist in India in almost every nook and corner of the country. These friendly neighbourhood pharmacies are doing yeomen services to the nation by providing quick services and medicines to the public through the day and even at odd hours. The pharmacies are often the first port of call for many common health related problems. People find it conveniently located in the neighbourhood. There is no need of appointment. The Pharmacist behind the counter is friendly, knows their clients well and is ever ready to help. The clients look upon the pharmacist to give them advice on various health related matters, diagnose their condition and even recommend medicine. People have lot of faith and trust in them. They guide the client and if its needed advice them to consult a doctor.

The clinical pharmacist work in liaison with physicians and attend ward rounds and contributes towards ADR monitoring, treatment chart reviews, making suggestions in therapy, taking medication histories, providing drugs and poison information etc. Pharmacist contributes

to healthcare development and develops new ways to support patient in their use of medicine and as a part of clinical decision making. A Pharmacist is expert in medicine and has always been known as accessible and trusted source of advice and treatment.

There's very special relationship between pharmacist and the patient. It is a bond of trust. People listen to their advice and trust them completely. Pharmacist is an important link which joins prescribers and patients. A doctor only recognizes the disease and illness, he prescribes the medicines by diagnosis but a pharmacist counsel the patient's right from receiving the prescription to dispensing, from answering queries to proper guiding, from making them feel comfortable to refilling the prescription. It is no wrongly said that,"A doctor gives lives to the patient through medicines. A pharmacist gives life to medicines through knowledge and skills."

Its pharmacist who knows A-Z about the medicine, uses, side effects ADR and everything else. How magical it is that a small pill is capable of improving and curing various diseases and illnesses. There's so much power in a pill that is can provide therapeutic effects within few minutes. All this knowledge is absorbed by the pharmacist. Doctor alone cannot prevent, diagnose, care for and treat patients with illness, disease and injury. A pharmacist is equally responsible for the diagnose, care and treatment of the patient. Pharmacist is the bridge between doctors and patients who counsels and advice the patients to maximize the desired effect of the drugs and minimizes ADR and side effects. After receiving prescription from the doctors, the patients comes to the pharmacist, now it is the responsibility of the pharmacist to make sure that the patient is well aware of the medicines, how to use it, the side effects, how to prevent side effects, when to take the medication, the food which should be avoided, to know the history of the patient, all the risks associated with a particular medicine and if required a pharmacist can change the medicine after with the doctor keeping in mind the patient's medical history. For all these things to happen, a pharmacist should be well educated and should have knowledge about everything. Effective communication is one of them. Communication with patients is essential to improve the use of medication by patients and ensure optimal therapeutic outcomes. Pharmacist can improve patient adherence to drug therapy through appropriate strategies, including patient counselling and education. Through knowledge and skills a pharmacist gives life to the patients.

In the end I would like to say that,
I'm a specialist in medication
I'm a companion of the physician
I'm a counsellor to the patients
I'm a guardian of public health
This is my calling. This is my pride.

Congratulations to Dr. M. Ramanathan

We are happy to share that, Dr. M. Ramanathan, Principal, PSG College of Pharmacy conferred with D.Sc. degree through research on the title "Inflammatory pathway studies in neuro degenerative conditions with reference to cerebral ischemia" in the 33rd convocation of The Tamil Nadu Dr. MGR Medical University, Chennai.

The Honorable Prime Minister, Shri. Narendra Modi was the Chief Guest and delivered the convocation address through video conference.

The Honorable Governor of Tamil Nadu, Shri. Banwarilal Purohit gave the award and Dr. J. Radhakrishnan, IAS declared the award. Dr. C. Vijayabaskar, Minister for Health and Family Welfare, Government of Tamil Nadu and Dr. Sudha Seshayyan, Vice-Chancellor were present to grace the occasion.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 4th February, 2021.

S.O. 529(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs and Cosmetics Rules, 1945, the Central Government hereby appoints the persons specified in column (2) of the Table below as Government Analysts for the whole of India in respect of the classes of drugs specified against their names in column (3) of the said Table, namely:—

Serial number	Name, designation and address of the Government Analyst	Class of drugs
(1)	(2)	(3)
1.	Dr. Sandeep Kumar Singh, Joint Director, Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh.	(i) Haemorrhagic Septicaemia vaccine; (ii) Ranikhet Disease vaccine.
2.	Dr. Sweta Raghuvanshi, Joint Director, Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh.	(i) Haemorrhagic Septicaemia vaccine; (ii) Ranikhet Disease vaccine.

2. This order shall come into force from the date of its publication in the Official Gazette.

[F.No. X.11035/285/2018-DRS]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 26th February, 2021.

G.S.R. 140(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under sub-section(1) of section 12 and sub-section(1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 827(E), dated the 6th November, 2019, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of fortyfive days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on 6th November, 2019;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) Short title and commencement.—These rules may be called the Drugs and Cosmetics (Amendment) Rules, 2021.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, against serial number 23, in the entries under the column "Class of Drugs", for the words, brackets and figures "and (iv) Anganwadi Workers", the following words, brackets and figures shall be substituted, namely:—

"(iv) Anganwadi Workers; and (v) Community Health Officers at Ayushman Bharat Health and Wellness Centres.''.

[F.No.X.11014/13/2019-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification number F.28-0/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 763(E), dated the 15th December, 2020.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th March, 2021

S.O. 1170 (E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs and Cosmetics Rules, 1945, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare number S.O. 282(E), dated the 28th February, 2005, except as respects things done or omitted to be done before such supersession, the Central Government hereby appoints—

(1) Shri Amar Jyoti Chamuah - Junior Scientific Assistant;
(2) Shri Dilip Kr. Sarkar - Junior Scientific Assistant;
(3) Smt. Rinku Kalita - Junior Scientific Assistant; and
(4) Shri Arun Kumar Das - Junior Scientific Assistant,

at the Regional Drugs Testing Laboratory, Guwahati as Government Analysts for the whole of India in respect of all classes of drugs except the classes of drugs mentioned below, namely:—

(i) Sera;
(ii) Solution of Serum Proteins intended for injection;
(iii) Vaccines (parenteral and Oral);
(iv) Toxins;
(v) Antigens;
(vi) Anti-toxins;
(vii) Sterilized Surgical Ligature and Sterilized Surgical Sutures;
(viii) Bacteriophages;
(ix) Anti-sera for veterinary use;
(x) Vaccine for veterinary use;
(xi) Toxoid for veterinary use;
(xii) Diagnostic Antigens for veterinary use;
(xiii) VDRL Antigen;
(xiv) Human Blood and Human Blood Products including components, to test for freedom for HIV antibodies;
(xv) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus; and
(xvi) Condom.

[F.No. X.11014/13/2020-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th March, 2021

S.O. 1260(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby appoints,—

Serial number	Name	Designation
1.	Shri Hitesh Kumar Khare	Senior Scientific Officer-II
2.	Dr. Debasis Maiti	Senior Scientific Officer-II

at Regional Drugs Testing Laboratory, Chandigarh, to be the Government Analysts for the whole of India in respect of all classes of drugs, except the classes of drugs mentioned below, namely:—

(i) Sera;
(ii) Solution of Serum Proteins intended for injection;
(iii) Vaccines (parenteral and Oral);
(iv) Toxins;
(v) Antigens;
(vi) Anti-toxins;
(vii) Sterilized Surgical Ligature and Sterilized Surgical Sutures;
(viii) Bacteriophages;
(ix) Anti-sera for veterinary use;
(x) Vaccine for veterinary use;
(xi) Toxoid for veterinary use;
(xii) Diagnostic Antigens for veterinary use;
(xiii) VDRL Antigen;
(xiv) Intra-Utrine Devices and Falope Rings;
(xv) Human Blood and Human Blood Products;
(xvi) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus; and
(xvii) Condom

[F.No. X.11014/4/2020-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th April, 2021

G.S.R. 255(E).—Whereas the Central Government, on being satisfied that the Fixed Dose Combination (hereinafter referred as the FDC) of corticosteroid with any other drug for systemic use is likely to involve certain risk to human beings, vide its notification number G.S.R. 578(E), dated the 23rd July, 1983, inter alia prohibited the manufacture and sale of FDCs of Steroids for internal use except combination of Steroids with other drugs for the treatment of Asthma;

And whereas, the Central Government vide notification number G.S.R. 738(E), dated the 9th October, 2009 further amended the said notification number G.S.R. 578(E), dated the 23rd July, 1983 and substituted item 14 and the entries relating thereto with the entry "Fixed Dose combination of corticosteroid with any other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers";

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was examined by Prof. Kokate Committee constituted by the Central Government for examining the safety and efficacy of FDCs which were licensed prior to 1st October, 2012 without prior approval of the Central Licensing Authority and therefore, Prof. Kokate committee examined the said FDC in current scenario based on the available documents and scientific literature and considered this FDC as rational and accordingly, the FDC of Tamsulosin HCl 0.4mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was approved;

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was also referred to Drugs Technical Advisory Board and upon examination, the Drugs Technical Advisory Board had now recommended to exclude the FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule from the prohibition made vide notification number G.S.R. 738(E), dated the 9th October, 2009.

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following amendments further to amend the notification number G.S.R. 578(E), dated the 23rd July, 1983, namely:—

In the notification, in the Table, for item 14 and the entries relating thereto, the following item and entries shall be substituted, namely:—

"14. Fixed Dose Combination of corticosteroid with any other drug [excluding Fixed Dose Combination of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30mg in hard gelatin capsule] for internal use except for preparations meant for meter dose inhalers and dry powder inhalers.".

[F. No. X.11014/8/2020-DR]
DR. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Subsection (i) vide notification number G.S.R. 578(E), dated the 23rd July, 1983 and lastly amended vide notification number G.S.R. 738(E), dated the 9th October, 2009.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th April, 2021

G.S.R. 258(E).— Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (1) of sections 12 and sub-section (1) of 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 656(E), dated the 20th October, 2020, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 21st October, 2020;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

(1) (1)These rules may be called the Drugs (3rd Amendment) Rules, 2021.

(2) They shall come into force with effect from the 1st day of November, 2021.

(2) In the Drugs Rules, 1945, in Schedule H1, after serial number 47 and the entry relating thereto, the following serial number and entry shall be inserted, namely:—
"48. Tapentadol".

[F.No. X.11035/519/2019-DRS]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 202(E), dated the 22nd March, 2021.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th April, 2021

S.O. 1520(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby appoints Dr. Raghuram Reddy Adidala at Central Drugs Testing Laboratory, Hyderabad to be the Government Analyst for the whole of India in respect of all classes of drugs, except the classes of drugs mentioned below, namely:—

(1) Sera;
(2) Solution of Serum Proteins intended for injection;
(3) Vaccines (parenteral and Oral);
(4) Toxins;
(5) Antigens;
(6) Anti-toxins;
(7) Sterilized Surgical Ligature and Sterilized Surgical Sutures;
(8) Bacteriophages;
(9) Anti-sera for veterinary use;
(10) Vaccine for veterinary use;
(11) Toxoid for veterinary use;
(12) Diagnostic Antigens for veterinary use;
(13) VDRL Antigen;
(14) Human Blood and Human Blood Products including components, to test for freedom for HIV antibodies;
(15) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus;
(16) Condoms.

[F. No. X.11014/11/2020-DR]
DR. MANDEEP K. BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 8th April, 2021

S.O. 1521(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) number S.O. 2808(E), dated 30th November, 2012 published in Part II - Section 3 - Sub-section (ii) of the Gazette of India, Extraordinary, namely,—

In the said notification, for item number (i) and (ii), the following items shall be substituted, namely:—

"(i) Smt. Sayali Umesh Warde, Senior Scientific Officer Grade-II;

(ii) Smt. Sujata Sudesh Kaisare, Senior Scientific Assistant;

(iii) Smt. Sukhada Ajay Navaratne, Senior Scientific Assistant;

(iv) Dr. Vijaya Kumar Munipalli, Senior Scientific Assistant; and

(v) Smt. Akshata Sandeep Paranjpe, Senior Scientific Assistant.".

[F.No. X.11014/12/2020-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 2808(E), dated the 30th November, 2012.

NEWS

CBI Books Cases Against Six Current and Former Office-bearers of Indian Red Cross

The Anti-Corruption Bureau of the Central Bureau of Investigation (CBI) Chennai has booked a corruption case against former and current office-bearers of the Indian Red Cross Society.

Following a complaint from T. Sengottaiyan, deputy secretary to Tamil Nadu Governor Banwarilal Purohit, the CBI registered a first information report (FIR) on December 29 citing criminal conspiracy, criminal breach of trust and criminal misconduct to cause pecuniary advantage to themselves and causing wrongful loss to Indian Red Cross Society from 2011 to 2020. In FIR, names of the six accused were given as Harish L. Mehta, chairman of the Indian Red Cross Society, Tamil Nadu Branch; M.S.M. Nasruddin, general secretary; C. Indernath, treasurer; Senthilnathan, former treasurer; Manish Choudhary, Deputy/Joint secretary of Indian Red Cross Society at its national headquarters in New Delhi; and V. Vadivel Mugundhan, former chairman of the TN branch. The CBI said other unknown public servants and private persons also committed the offences. The FIR was forwarded to the Principal Court for CBI cases.

Source: *The Hindu*, 10th January 2021

Govt has Decided to Shut 2 Pharma PSUs, Disinvest other 3: Govt Tells LS

The government has decided to close two pharma public sector undertakings and disinvest the other three, Parliament was informed.

"The Department of Pharmaceuticals has five public sector undertakings (PSUs). Out of the five PSUs, the government has taken a decision to close two pharma PSUs, namely Indian Drugs & Pharmaceuticals Ltd (IDPL) and Rajasthan Drugs & Pharmaceuticals Ltd (RDPL)," Minister of Chemicals and Fertilisers D V Sadananda Gowda said in response to a question in the Lok Sabha.

The government has also decided to strategically disinvest the other three -- Hindustan Antibiotics Ltd (HAL), Bengal Chemicals & Pharmaceuticals Ltd (BCPL), and Karnataka Antibiotics & Pharmaceutical Ltd (KAPL), he added.

The government has offered voluntary retirement benefits to all employees of IDPL and RDPL, Gowda said.

"However, the Committee of Ministers constituted on September 9, 2019, will take necessary decisions pertaining to closure/strategic sale of the pharma public sector undertakings, including the sale of assets and clearance of outstanding liabilities," he added.

Source: *Business Standard*, 9th February 2021

Andhra Pradesh: Woman SI Carries Body of Homeless Man for 1km

A woman sub-inspector, carried the body of an 80-year-old homeless person on her shoulders for over one kilometre after no one came forward to shift it. The incident took place at Adavi Kottutu, a village on the outskirts of Sampangipuram in Kasibugga Palasa, an area known for its cashew industries, in Andhra Pradesh's Srikakulam district.

After Kasibugga police received information about the death of an unknown person in the fields in Adavikotturu, sub-inspector Kotturu Sirisha reached there along with constables.

“We noticed the body of an unknown person, aged around 80 years, who locals said was a beggar. But bringing the body from the fields to the vehicle was difficult as there was no path to the road. We requested the villagers but no one came forward,” Sirisha told TOI.

The sub-inspector, who is a native of Vizag city and holds an pharmacy degree, said it was not a case of suspicious death as there were no injuries on the body

It is likely the man died due to starvation as he was very frail and weak,” the SI said. When no one came forward to help shift the body, Sirisha took the initiative and carried the body on a makeshift stretcher with the help of a member from Lalitha Trust.

It took them about 25 minutes to reach the police vehicle. After seeing the woman police officer carrying the body, some villagers stepped forward and extended help to cremate the body.

Sirisha, who is the mother of a 12-year-old, told TOI she preferred a police job as her mason father wanted to see one of his four daughters join the force. She also worked in the prohibition and excise department.

She said she did not have any fear or sentiment when she decided to carry the body. “I joined the police force to serve people and extend my services to the society. The dead deserve dignity too. I only did my duty,” she said. DGP Gautam Sawang also lauded the humanitarian gesture of Sirisha.

Source: *The Times of India*, 2nd February 2021

Pharma Exports up 12.43% During April-December 2020-21

India's exports of pharmaceutical products during April-December 2020-21 grew by 12.43 per cent to USD 17.57 billion, Parliament was informed on Friday. India's exports of pharmaceutical products have not declined and they are growing consistently, Minister of State for Commerce and Industry Hardeep Singh Puri said in a written reply to the Rajya Sabha.

"During 2019-20, India's exports of pharmaceuticals were USD 20.58 billion with a growth rate of 7.57 per cent over the previous year. Total pharma exports during April-December 2020-21 were at USD 17.57 billion, registering a growth rate of 12.43 per cent over the same period of the previous year," he said.

Replying to a question on FDI, Minister of State for Commerce and Industry

Som Parkash said that during the last three years, the Foreign Direct Investment (FDI) equity inflow increased from USD 44.85 billion in 2017-18 to USD 49.97 billion in 2019-20.

According to the data, FDI in defence industries stood at USD 0.63 million. It was USD 2.20 million in 2019-20.

The retail trading sector attracted USD 1.26 billion in April-November 2020-21 period, while telecommunications received USD 19.65 million.

In reply to a separate query, Parkash said total FDI inflow in terms of percentage of GDP has increased from 2.21 per cent (2009-10 to 2013-14) to 2.41 per cent (2014-15 to 2018-19).

On a question about single window approval system for industry, Parkash said the central government is working on setting up a Single Window System for clearances and approvals of industry in the country.

Despite the presence of several IT platforms for investing in India such as in departments of the Government of India and State Single Window Clearances, investors need to visit multiple platforms to gather information and obtain clearances from different stakeholders, he said.

"To address this, the creation of a Centralized Investment Clearance Cell, which would provide end-to-end facilitation support, including pre-investment advisory, information related to land banks and facilitating clearances at central and state level was proposed," Parkash added.

The cell, he said, is being planned as a one-stop digital platform to obtain all requisite central and state clearances/ approvals required to start business operations in India.

The cell "will be a National portal that integrates the existing clearance systems of the various ministries/ departments of Government of India and of state governments without disruption to the existing IT portals of ministries and will have a single, unified application form," the minister added.

This will eliminate the need for investors to visit multiple platforms/ offices to gather information and obtain clearances from different stakeholders and provide time-bound approvals and real time status update to investors, Parkash informed.

Source: *ET Healthworld,* 5th February 2021

Sun Pharma Recalls 36,275 Cartons of Testosterone Injection in the US for Labelling Error

Sun Pharmaceutical Industries is recalling 36,275 cartons of a drug used to treat low testosterone levels in the US market for incorrect labelling. The US arm of the domestic pharma major is recalling Testosterone Cypionate Injection in the American market, according to the latest enforcement report of the US Food and Drug Administration.

The affected lot of the intramuscular injections was manufactured by the drug maker in India and distributed in the US by Princeton, New Jersey-based Sun Pharmaceutical Industries Inc, it said.

Elaborating on the reasons for the Class III recall, the USFDA said: “Incorrect Labelling: Incorrect lot number on secondary packaging.”

As per the USFDA, a class III recall is initiated in a "situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences".

The company initiated the nationwide recall on January 11, 2021.

Last year in October, Sun Pharma had recalled 747 bottles of generic diabetes drug in the US due to the possibility of the affected lot containing cancer-causing nitrosodimethylamine above the acceptable intake limit.

The company had recalled RIOMET ER (metformin hydrochloride for extended-release oral suspension) due to deviation from the current good manufacturing practices -- detection of N-nitrosodimethylamine impurity in finished drug product.

The US, the world's largest pharmaceuticals market, is also the biggest market for Mumbai-based Sun Pharma. The company has presence in the country since 1996 with a focus on generics, branded generics and over-the-counter (OTC) products.

Source: *ET Healthworld,* 7th February 2021

Glenmark Launches Kidney Cancer Treatment Drug in India Priced 96% Lower Than Innovator Brand

Glenmark Pharma launched a generic kidney cancer treatment drug 'Sunitinib oral capsules' in India priced 96 per cent lower compared to the innovator brand.

In a regulatory filing, Glenmark Pharma said it launched "SUTIB, the generic version of Sunitinib oral capsules to treat kidney cancer in India. The drug is launched at a MRP that is approximately 96 per cent lower than the MRP (maximum retail price) compared to the innovator brand, priced at Rs 7,000 (50 mg), Rs 3,600 (25 mg) and Rs 1,840 (12.5 mg) per month".

Sunitinib is also approved by the US Food and Drug Administration (USFDA).

Kidney cancer (renal cell carcinoma) is a disease of uncontrolled cell growth in the lining of small tubes in the kidney.

Quoting Globocan 2020 report, Glenmark said there are close to 40,000 patients with renal cancer in India.

Alok Malik, Group Vice President and Business Head, India Formulations, said, “Oncology is an important focus area for Glenmark. We recognise that advanced kidney cancer is a complex disease and patients in India are faced with limited treatment options. Glenmark is committed to bringing targeted and effective medicines at an affordable cost to physicians and their patients.”

Source: *ET Healthworld,* 16th February 2021

Indian Pharma Market Expected to Hit USD 130 Billion by 2030: Sadananda Gowda

The Indian pharmaceutical industry has proved to be a dependable supplier of quality drugs in a time of global need on account of the Covid-19 pandemic, and is expected to reach a size of USD 130 billion by 2030, Chemical and Fertiliser Minister D V Sadananda Gowda said on Monday. Following the onset of the pandemic, the Indian pharma industry has shown its role as a reliable supplier of drugs and medical devices in a time of need, he added.

"The total market size of the Indian pharma industry is expected to reach USD 130 billion by 2030. The medical devices industry in India has the potential to grow at 28 per cent per annum to reach USD 50 billion by 2025," Gowda said.

He was addressing the curtain-raiser press conference on the 6th edition of 'Indian Pharma & India Medical Device 2021'.

"India has been serving more than 200 countries with its pharma products and will continue to discharge its responsibilities. We intend to continue formulating plans that are based on sound science, technology, business sense, and ethics," Gowda said.

Pharmaceuticals are one of the top-10 attractive sectors for foreign investment in India. FDI inflows in the pharmaceuticals sector reached Rs 3,650 crore in 2019-20, recording a growth of 98 per cent year-on-year, he added.

"While India will continue to strive to achieve and maintain a leadership position in the manufacturing and supply of high-quality generic medicines and medical devices, we also need to look at how to improve access to medical care," Gowda said.

At this year's edition, "we would like to deliberate upon strategies to help us innovate and bring newer and affordable therapies to the market and cement India's position as a truly world-class favoured investment destination," he added.

Emphasising the importance of India for the inoculation against Covid-19 globally, Minister of State for Chemicals and Fertilisers Mansukh Mandaviya said India has already made two Covid-19 vaccines and has supplied them to 12 countries.

India has also launched the world's largest Covid-19 vaccination programme, he added.

The international conference will also provide an opportunity for showcasing how the Covid-19 crisis can be transformed into an opportunity for India, Mandaviya said.

Source: *ET Healthworld,* 8th February 2021

Indian Drugmaker to Pay $50mn in Fine for Destroying Records before FDA Inspection

An Indian drug manufacturer has agreed to plead guilty to concealing and destroying records prior to a 2013 US Food and Drug Administration's inspection of its plant and pay USD 50 million in fines and forfeiture, the Department of Justice has announced.

In a criminal information filed in federal court in the District of Nevada and unsealed on Tuesday, Fresenius Kabi Oncology Limited (FKOL) was charged with violating the Federal Food, Drug and Cosmetic Act by failing to provide certain records to Food and Drug Administration's (FDA) investigators.

As part of a criminal resolution, FKOL agreed to plead guilty to the misdemeanour offense, pay a criminal fine of USD 30 million, and forfeit an additional USD 20 million.

FKOL also agreed to implement a compliance and ethics programme designed to prevent, detect, and correct violations of US law relating to FKOL's manufacture of cancer drugs intended for terminally ill patients, a media release said.

"By hiding and deleting manufacturing records, FKOL sought to obstruct the FDA's regulatory authority and prevent the FDA from doing its job of ensuring the purity and potency of drugs intended for US consumers," said Acting Assistant Attorney General Brian Boynton of the Justice Department's Civil Division.

"FKOL's conduct put vulnerable patients at risk. The Department of Justice will continue to work with FDA to prosecute drug manufacturers who obstruct these inspections," the statement said.

"Pharmaceutical companies that obstruct FDA inspections jeopardise patient safety," said US Attorney Nicholas A. Trutanich for the District of Nevada.

According to court documents, FKOL owned and operated a manufacturing plant in Kalyani, West Bengal, that manufactured active pharmaceutical ingredients (APIs) used in various cancer drug products distributed to the United States.

The government alleges that prior to a January 2013 FDA inspection of the Kalyani facility, FKOL plant management directed employees to remove certain records from the premises and delete other records from computers that would have revealed FKOL was manufacturing drug ingredients in contravention of FDA requirements.

Kalyani plant employees removed computers, hardcopy documents, and other materials from the premises and deleted spreadsheets that contained evidence of the plant's violative practices, the Department of Justice alleged.

Source: *ET Healthworld,* 11th February 2021

Gujarat Pharma Co Raided for Falsely Branding Drugs

The Gujarat Food and Drugs Control Administration (FDCA) on Thursday raided a pharmaceutical company in Gandhinagar district and allegedly found them manufacturing drugs while falsely branding them with names of other pharma companies.

Sunlovis Pharmaceuticals LLP and one of its five partners Pravin Ramsang Chaudhari were booked for the offence after falsely branded drugs, raw materials, export packaging and finished products were seized in the raids.

The unit of Sunlovis Pharmaceuticals LLP at Hajipur village of Kalol in Gandhinagar was beset by officials who found EXCLAV 625, an antibiotic drug, being branded as those from Finecure Pharmaceuticals Limited of Uttarakhand.

Officials said they seized 4.3 lakh tablets worth Rs63 lakh from the premises. While Sunlovis does have a drug manufacturing license since the past three years, it is not for this particular antibiotic.

The smart move here, said FDCA Commissioner Dr Hemant Koshia, was to allegedly use the name of a well-known brand that also manufactured Exaclav-625 Co-Amoxiclav Tablet B.P, and then allegedly export it to Nigeria.

Further, the company was found falsifying the manufacturing date as January 2021 on products that were being manufactured in February.

While busting this one scam, officials also found another medicine, Exatil Dry Syrup, being falsely branded in the name of Brussels Pharmaceuticals Limited, registered in Changodhar.

Source: *ET Healthworld,* 12th February 2021

Pharma Exports to Arab Nations Cumbersome, says Sanjay Bhattacharyya

India for trade beyond hydrocarbons

India has urged Arab countries to make it easier to export pharmaceutical products to the region and asked them to tap Indian farms to secure food supplies, as it seeks to diversify the $160 billion trade basket with the Arab bloc beyond hydrocarbons.

“Indian pharma products enjoy great credibility around the world, [but] we do not have the same kind of recognition in most of the Arab world, because the process through which medicines are brought into your countries are very elaborate and cumbersome at times,” said Ambassador Sanjay Bhattacharyya, Secretary (Arab, OIA & CPV), Ministry of External Affairs.

Mr. Bhattacharya said market access to Indian pharma goods could be an 'early harvest' idea ahead of the India-Arab Partnership forum scheduled in the first week of December, after a gap of five years.

"We should look for an early harvest here by looking at the USFDA and GMP [Good Manufacturing Practice]-approved drugs that can come in as a first step. India is a large producer of generics, but we also go beyond that," he said at a meeting hosted by FICCI with Ambassadors of several Arab countries on economic opportunities between India and the Arab nations.

India-Arab trade accounts for 20% of India's overall trade, but is still concentrated in hydrocarbons, the secretary said, mooting agriculture, technology and tourism as potential areas for diversification.

Agriculture reforms

"Food security is important for India as well as the Arab world, particularly the Gulf region. With the new agricultural reforms in India, there are huge opportunity for many companies in the Arab world to set up base in India where you could have farming and then the produce could go back home," Mr. Bhattacharya said. "This could be a win-win situation for both sides," he added.

Source: *The Hindu,* 23rd February 2021

Indian Pharmaceutical Firms Go Local for APIs, Seeking to End Reliance on China

Indian drug companies are looking to local makers of so-called active pharmaceutical ingredients (API) or trying to make them in-house in a bid to end their reliance on China as ties between the two countries soured after a deadly border clash last June.

Though India is known as the pharmacy of the world for its massive production capacities of both generic drugs and vaccines, China accounted for half of its API needs in 2019 from nearly nothing three decades ago, industry data shows.

Executives at India's Cadila Healthcare, Cipla, Sun Pharmaceutical, and? Biocon said on Tuesday they were aggressively working on reducing the dependence on the richer rival for raw materials.

Disruption to supplies from China due to the Covid-19 pandemic was also a major factor, they said, as early last year many of them had to scramble for ingredients to make important drugs sold worldwide.

"Because of the anti-China sentiment ... most of the companies are working towards de-risking themselves in terms of making it clear that their supply chain linkages with China are limited," Gaurav Suchak, supply head of Cadila, told the BioAsia conference organised by the southern state of Telangana.

"For the critical API molecules, the idea is to go for a backward integration where you are in control of that pie which is going to make the most impact on your business, and also to make sure that the entire value chain is secure."

Companies are also eyeing reliable local vendors who can promise consistency and competitive prices, he said.

Cipla's supply chief Swapn Malpani said it had launched an "API re-imagination" programme to possibly expand its own manufacturing capacities using recent government incentives https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=1685432 such as production subsidies, apart from working with local suppliers.

Biocon's supply head Prasad Deshpande said the company had a target on "how much percent of revenue is independent of China".

"We are happy to say that by the last quarter, we were almost 50% completely independent of China," Deshpande said. "That does not mean we will not source from China, but we are not dependent on China anymore."

But he also said India would have to improve its infrastructure and accelerate approval processes to take on the scale and speed of China.

Source: *ET Healthworld,* 23rd February 2021

Cabinet Approves Production Linked Incentive Scheme for Pharmaceuticals

The Union Cabinet, chaired by Prime Minister Narendra Modi on Wednesday approved the Production Linked Incentive (PLI) Scheme for Pharmaceuticals over a period of Financial Year 2020-21 to 2028-29.

The scheme will be part of the umbrella scheme for the Development of the Pharmaceutical Industry. The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector.

The PLI scheme is aimed to benefit domestic manufacturers, help in generating employment and is expected to contribute to the availability of a wider range of affordable medicines for consumers.

The scheme is expected to promote the production of high-value products in the country and increase the value addition in exports. Total incremental sales of Rs.2,94,000 crore and total incremental exports of Rs.1,96,000 crore are estimated during six years from 2022-23 to 2027-28.

It is expected to promote innovation for the development of complex and high-tech products including products of emerging therapies and in-vitro diagnostic devices as also self-reliance in important drugs. It is also expected to improve the accessibility and affordability of medical products including orphan drugs to the Indian population. The Scheme is also expected to bring in investment of Rs.15,000 crore in the pharmaceutical sector.

One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

The salient features of the Scheme are as follows:-

Target Groups:
The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR) to ensure wider applicability of the scheme across the pharmaceutical industry and at the same time meet the objectives of the scheme. The qualifying criteria for the three groups of applicants will be as follows-

(a) Group A: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods more than or equal to Rs 5,000 crore.

(b) Group B: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods between Rs 500 (inclusive) crore and Rs 5,000 crore.

(c) Group C: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods less than Rs 500 crore. A sub-group for MSME industry will be made within this group, given their specific challenges and circumstances.

Quantum of Incentive:
The total quantum of incentive (inclusive of administrative expenditure) under the scheme is about Rs 15,000 crore. The incentive allocation among the Target Groups is as follows:

(a) Group A: Rs 11,000 crore.
(b) Group B: Rs 2,250 crore.
(c) Group C: Rs 1,750 crore.

The incentive allocation for Group A and Group C applicants shall not be moved to any-other category. However, incentive allocated to Group B applicants, if left underutilized can be moved to Group A applicants.

Financial Year 2019-20 shall be treated as the base year for computation of incremental sales of manufactured goods.

Category of Goods:
The scheme shall cover pharmaceutical goods under three categories as mentioned below:

a. Category 1
Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals: Other drugs as approved.

b. Category 2
Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates.
Source: *ET Healthworld,* 23rd February 2021

c. Category 3 (Drugs not covered under Category 1 and Category 2)
Repurposed drugs; Autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

Rate of incentive will be 10% (of incremental sales value) for Category 1 and Category 2 products for first four years, 8% for the fifth year and 6% for the sixth year of production under the scheme.

Rate of incentive will be 5% (of incremental sales value) for Category 3 products for first four years, 4% for the fifth year and 3% for the sixth year of production under the scheme.

The duration of the scheme will be from FY 2020-21 to FY 2028-29. This will include the period for processing of applications (FY 2020-21), optional gestation period of one year (FY 2021-22), incentive for 6 years and FY 2028-29 for disbursal of incentive for sales of FY 2027-28.

Source: *ET Healthworld,* 24th February 2021

J Jayaseelan of TN IDMA Nominated to Executive Committee of NBA

The president of the Tamil Nadu State Pharmacy Council (TNSPC) and chairman of the Tamil Nadu, Kerala and Pondicherry board of the Indian Drug Manufacturers Association (TN IDMA), J Jayaseelan has been nominated as a member to the executive committee of the National Board of Accreditation (NBA), the autonomous agency to assess and accredit technical education programmes and institutions.

NBA has been reconstituted with 16 EC members and it will operate with immediate effect for a period of three years, a communiqué issued by the NBA member secretary says.

This is the first time a person representing pharmaceutical side becomes a member to the NBA. Jayaseelan is the managing director of three pharmaceutical companies engaged in formulation development, API production and marketing.

A passionate pharma industry professional with 30 years experience, Jayaseelan became an authentic leader of the pharmaceutical space, both in industry and in education side, and he is loved and admired by all stakeholders. With his entrepreneurial bug to become a successful entrepreneur, he became an undisputed industry leader early in his life.

Since the quality of the pharmacy educational institutions need to be checked by the NBA, the nomination of Jayaseelan as an EC member will be an asset to the accreditation board to assess the quality of the pharmacy colleges in the country, hopes the academic community. The executive committee consists of 16 members out of which three members are senior IAS officers holding secretary ranks in the department of higher education and two members of chief secretary ranks from Uttar Pradesh and Maharashtra.

In addition to the chairman of the All India Council of Technical Education (AICTE), vice chancellors of eminent universities, directors of technical education board of various universities, directors of corporate affairs of multinational companies and head of education and innovation of the Confederation of Indian Industry (CII) have been made members to the NBA executive committee.

Commenting on his nomination to the NBA, the former president of the IDMA, S V Veeramani said, "The entire pharmaceutical sector in Tamil Nadu takes pride in, and the accreditation board can utilize his potential for the quality assurance of the pharma industry and pharmacy education institutions."

Source: *Pharmabiz,* 6th March 2021

Covid-19: Import Licences for Foreign Vaccine In 3 Days, says Government

In order to fast track availability of Covid-19 vaccines in the country, the drug controller will process import licences and registration certificate applications of foreign-made jabs in three working days after grant of emergency use approval, according to guidelines issued by the health ministry.

"The CDSCO (Central Drugs Standard Control Organisation) will process applications for registration certificate (registration of oversees manufacturing site and product: in this case Covid-19 vaccine) and import licence, within three working days from the date of approval of restricted use in emergency situation," the ministry said.

The government on Tuesday waived the pre-condition of bridging studies in local population for grant of EUA for foreign-made vaccines that have already been approved for use in the US, the UK, the European Union and Japan or are on WHO lists.

However, such vaccines will be required to carry out parallel bridging studies once launched in India.

"Applications for restricted use in emergency situation for such vaccines may be accompanied by bridging trial protocol, application for import registration certificate and application for import licence," the ministry said.

An application can be made by a foreign manufacturer through its Indian subsidiary. It can also be filed through an authorised agent in India in case a company does not have an Indian subsidiary.

The Drugs Controller General of India (DCGI) will issue permission for restricted use with following conditions: vaccine shall be used as per the guidelines prescribed under National Covid-19 Vaccination Programme; first 100 beneficiaries of such vaccines shall be assessed for seven days; and applicant shall initiate conduct of post-approval bridging clinical trials within 30 days of such approval," the guidelines said.

Each vaccine batch will be released by the Central Drugs Laboratory (CDL), Kasauli, before it can be used as per guidelines prescribed under the National Covid-19 Vaccination Programme.

After receiving approval from the CDL, an applicant will use the Covid-19 vaccine only on 100 people initially and submit the safety data to CDSCO. The company concerned will be allowed to use the vaccine only after the safety data of the 100 recipients submitted by it

is reviewed by subject experts in the CDSCO and found to be satisfactory.

The regulator will approve the protocol for the bridging trial in consultation with its subject expert panel within seven days of the receipt of the proposal, the guidelines said.

The government expects the move to facilitate quicker access to foreign vaccines by India and encourage imports, including that of bulk drug material, optimal utilisation of domestic fill-and-finish capacity etc, which will, in turn, provide a fillip to vaccine manufacturing capacity and vaccine availability within the country.

Source: *The Times of India,* 16th April 2021

India's Reputation as Pharmacy of World Reinforced; Made-In-India Vaccines Supplied to 72 Nations: Jaishankar

External Affairs Minister S Jaishankar told Rajya Sabha Wednesday that India's reputation as "pharmacy of the world" stands reinforced the way it reached out to nations in the midst of a global crisis and supplied vaccines to 72 nations.

Making a statement on "Vaccine Maitri" initative, he said the supply of 'Made-in-India' vaccine to 72 nations after the world was reeling under COVID-19 pandemic prompted global leaders and world citizens extend warmth to India and its citizens.

Even as the COVID pandemic was in full fury, there were already global demands of India's pharmaceutical and medical capabilities which could be met largely due to the extraordinary ramp up of India's COVID-related capabilities, Jaishankar said.

Talking about low fatality rates and the high recovery rates, he said: "Our reputation as the 'pharmacy of the world' has been reinforced. So indeed has the faith in 'Make in India'. But more than the vaccines, our policies and conduct have emerged as a source of strength for the stressed and vulnerable nations of the world. They can see that there is at least one major nation that truly believes in making vaccines accessible and affordable to others in dire need."

He said Vaccine Maitri began in the immediate neighbourhood, starting with the Maldives, Bhutan, Bangladesh, Nepal, Sri Lanka and Myanmar, as also Mauritius and Seychelles and thereafter to the Gulf.

"Supplying smaller and more vulnerable nations was then the logic of reaching out to regions from Africa to the CARICOM. There was also contracts that our producers have entered into with other nations, either bilaterally or through the Covax initiative. To date, we have supplied 'Made in India' vaccines to 72 nations across geographies," the minister said.

He said the House should recognise the enormous feeling for India that its initiative has generated.

Jaishankar said there was an external beneficial impact of India's capabilities and it could meet the spiking requirements of hydroxychloroquine, paracetamol and other relevant drugs across the world and added that India's domestic vaccination programme started in January and within a few days, it also started assisting our immediate neighbours.

"In fact, we supplied 150 nations with medicines, 82 of them as grants by India. As our own production of masks, PPEs and diagnostic kits grew, we made them available to other nationsl. This generous approach... was also extended to the Vande Bharat Mission. Starting from Wuhan, we brought back nationals of other countries while looking after our own," he said.

He said as Indians, "we are all naturally internationalist by virtue of our culture, traditions, heritage and history" and PM Modi's vision has provided an over-arching framework to make India's goodwill meaningful in terms of practical initiatives and activities that reflected in its humanitarian assistance and disaster responses, whether in Yemen, Nepal, Mozambique or Fiji.

"In the last few years, India has developed a reputation of being the first and reliable responder in the region," the minister said.

"When it came to Africa, we raised the level of our cooperation very substantially ... Our projects, training and presence has today spread widely across that continent. From the Caribbean to the Pacific Islands, the message has been clear that the Prime Minister of India not only has the willingness to engage them personally, but to back that up with concrete development programmes. It is this outlook of human-centric global cooperation that is the driving force of Vaccine Maitri," he said.

Jaishankar said the prime minister in his virtual address to the UN General Assembly in September 2020 had declared that India's vaccine production and delivery capacity will be used to help all humanity in fighting this crisis.

"We also offered to enhance cold chain and storage capacities for the delivery of vaccines. This approach is not only in keeping with our age-old tradition of Vasudhaiva Kutumbakam.... As a prominent nation in an increasingly multi-polar world, the international community has greater expectations of us, and we, in turn, are prepared to demonstrate our willingness to shoulder greater responsibilities," he said.

He said as early as 15 March 2020, prime minister took the initiative to hold a meeting of SAARC heads of government to fashion a regional response resulting in SAARC COVID-19 Fund that supported the early exchanges on this issue.

"The Ministry of External Affairs conducted 14 e-ITEC courses in partnership with premier institutions like AIIMS and PGI Chandigarh" with 1,131 professional participants in it from 47 countries.

Jairam Ramesh (Cong) said he expected the government to recognise the roots of 2014 success to the previous year adding that the FERA was set up in 1973 while there were huge investments in science and technology in public institutes.

He said Bharat Biotech's Covaxin was developed in an institute in Hyderabad set up 16 years ago by public funds.

Binoy Viswam of CPI said: "We did not become pharmacy of India recently question about vaccine reach to the poor.

Anand Sharma (Cong) echoed "We must place the contribution of our institutes built over decades such as ICMR."

To these, Jaishankar replied: "You will recall the saying, success has many fathers. Too many fathers claiming success today. All of us know the enormous efforts of government in getting vaccine prices lowered, lowest in the world"

He also said that he was proud to have taken Covaxin.

Source: *The Economic Times,* 17th March 2021

Solara Active Pharma and Aurore Life Sciences Merge to Create Pure-play API/CRAMs Company

The Board of Directors of Solara Active Pharma Sciences accepted the recommendations of the Committee of Independent Directors and Audit Committee and approved the amalgamation of Aurore, Empyrean and Hydra with Solara.

"The combination creates a pure-play API company of scale with strong presence in Regulated Markets, Emerging Markets, a broad product portfolio, robust operations infrastructure, excellent R&D capabilities and clear synergies to further accelerate growth for the combined entity.," informed a statement from the company.

It added, "The merger is EPS accretive to Solara and will enhance other important financial ratios for Solara. The merger is in line with Solara's strategy of accelerating growth via appropriate inorganic actions. The combined entity will have the scale of market presence and product portfolio combined with robust manufacturing and R&D infrastructure to grow into a leading global pure play API and CRAMS company."

Commenting on the performance, Bharath Sesha, the MD & CEO of Solara stated, "As Solara continues its journey towards accelerated growth, the combination with Aurore is a significant boost. The two entities complement each other on product portfolio, geographical presence and customers while amplifying the strengths of world-class quality systems, strong R&D capabilities and robust manufacturing infrastructure. The combination will provide a compelling value proposition for both our generic APIs and CRAMS customers and exciting opportunities for the talented teams to grow with the company."

Rajender Rao Juvvadi, the MD of Aurore, stated, "In a very short span of time Aurore has reached a critical size and an inflection point and needs additional capacity and capital to grow to the next level being an important API player. The merger with Solara creates an opportunity to meet these aspirations and helps in achieving the desire of being one of the most dominant API players.

The merged entity provides a platform to combine the advantages of scale with a lean and cost-efficient unique product development ability. Aurore's R&D ability and speed of validations, filings and continuing product portfolio creation would enable the merged entity substantially scale up and underpin its pure-play presence."

Source: *Express Pharma,* 11th April 2021

Indian Pharma Exports Grow at 18 Percent to 24.44 bn in FY 21

Pharma exports from India witnessed over 18 percent growth to USD 24.44 billion during the last financial year against USD 20.58 billion in FY20, Pharmaceuticals Export Promotion Council of India (Pharmexcil) said on Saturday. "We have observed a big leap in our exports in the month of March 2021 which is USD 2.3 billion (figures for March are provisional) and is highest among the exports of all the months of this financial year, the growth rate for this month is 48.5 percent against the exports in March 2020 (USD 1.54 billion)," Udaya Bhaskar, Director General of Pharmexcil said in a release.

Growth rate seems relatively big as the exports of March 2020 were crunched due to lockdown across the world and supply chain disruption, he was quoted as saying.

When the global pharma market is negatively grown by 1-2 percent in 2020, there is a big surge in demand for Indian-made generics owing to its quality and affordability, the official said adding Drug formulations and Biologicals is the second largest Principal commodity being exported by India.

The Pharma exports body is expecting big growth in Indian vaccine exports in the coming years and the government policy on PLI (production Linked Incentive) scheme will also help the domestic pharma to grow by reducing import dependence and develop export potential in the days to come as most of the countries are looking at India for APIs (active pharmaceutical ingredient) he said. North America is the largest exporting region for Indian pharmaceuticals with more than 34 percent share.

Country-wise exports to the US, Canada and Mexico have recorded a growth of 12.6, 30 and 21.4 percent respectively. South Africa being the second largest exporting country, recorded a big jump of 28 percent growth while Europe was the third largest exporting region which has recorded approximately 11 percent growth over the previous year.

Source: *ET Healthworld,* 17th April 2021

Happy Hypoxia' Among Youngsters New Threat

While an increasing number of youngsters are being admitted in hospitals with moderate to severe symptoms of Covid-19 during the current wave, doctors sounded an alert about 'happy hypoxia' among youngsters.

Happy hypoxia refers to the condition where the patient has low oxygen saturation, but does not feel any symptoms of low saturation. As a result, they do not get alarmed until the disease has progressed and there is severe damage to the lungs.

“Younger patients often experience 'happy hypoxia' in which they do not feel any breathlessness or related symptoms till oxygen saturation levels fall below 80. Usually symptoms like breathlessness and discomfort in the chest are experienced when oxygen levels fall below 90 saturation. But in cases of happy hypoxia patients get alarmed late. We are getting a lot of cases of youngsters coming with happy hypoxia. They suddenly deteriorate and often there is little time for treatment,” said Dr Rahul Agarwal, consultant, internal medicine, Medicover Hospitals.

Explaining, Dr Kiran Madala, in-charge, head of department of critical care, Nizamabad Medical College, said, “The phenomenon is particularly seen in younger people because their immunity is high, because of which they can withstand some amount of hypoxia. They are comfortable even at 81 saturation level, whereas in older people symptoms appear at 92 saturation too. This is a reason for late admissions.”

Madala added that young adults are also exposed to the virus more, as they are economically active. “All of these factors add to the risk of severe infection among younger patients. However, the most vulnerable continue to be the elderly and immune compromised people,” he said.

The fact that more younger patients are getting affected and seek medical help late also means more deaths among youngsters. Doctors are now suggesting for 'alerts on symptoms' at various stages of the disease. “Covid can be mild in 85%, moderate in 15% and 2% cases can be fatal. Alert signs are needed for the patients going from mild to moderate to critical. The government should form a scientific committee of doctors from govt and private hospitals to issue detailed daily alerts of symptoms to look out for to the public. There are newer symptoms like rash, diarrhoea, conjunctivitis, joint pains, but these are not mentioned in state or central protocol for RT-PCR testing. Further, many cases RT-PCR results are coming negative due to mutant variant. Including these alerts in daily medical bulletin can cut down cases of sudden deterioration and deaths,” said Dr M Karuna, a paediatrician treating Covid cases.

Source: *The Times of India,* 24th April 2021

Apex Laboratories Gets Approval for Clevira as Covid Supportive Drug

City based pharma company Apex Laboratories will take the doctor's prescription route for its oral antiviral CleVira tablet that got the Central government's approval as a supporting measure for mild to moderate condition of Covid-19, a senior official said.

Apex Laboratories said it has got the approval from the Ministry of Ayush for its antiviral drug Clevira as a supporting measure for mild to moderate condition of Covid-19.

The company said this is the first of its kind approval in India through various stages of scrutiny at The Central Council for Research in Ayurvedic Sciences and Interdisciplinary Technical Review Committee.

According to the official, the company will position this as a doctor prescribed drug and not as an over-the-counter sales drug.

The company said a phase III Clinical trial was carried out in Government Medical College Omandurar Government Estate Chennai with Tamil Nadu government's approval.

The trial outcomes revealed that Clevira has shown 86 per cent recovery rate on fifty day of treatment in mild to moderate Covid-19 cases.

The official said enquiries from the medical practitioner world have started for CleVira as a medicine for Covid-19 following the approval from the Ministry of Ayush.

The company's flagship product is Zincovit which is in good demand from corporate hospitals for Covid-19. Apex Laboratories is also into dermatology, pain management, anti-infectives, anti-viral, nutraceuticals and herbal products.

Source: *ET Healthworld,* 24th April 2021

Drugs Tag on Medical Devices Causing A Short Supply Line, says Manufacturers and Suppliers

A new rule in January classifying medical devices such as nebulisers, blood-pressure monitors, digital thermometers and glucometers as drugs is causing a short supply of these products, their manufacturers and suppliers said.

These devices are widely used in the home treatment of Covid-19 patients and are facing high demand amid the second wave of the pandemic sweeping across the country. But companies dealing in these said they are facing hurdles in scaling up production, import and retail of the products as every process now needs government approval and licenses under the Drugs Act. Ecommerce companies said there are fewer sellers of these devices on their platforms compared with last year.

The government hasn't put oxygen concentrators under the Drugs Act yet — these portable machines to produce oxygen can be sold under voluntary license registration till September. But manufacturers and sellers are already facing harassment from drug inspectors, who ask them to take government approvals and follow the drug rules, two senior industry executives said.

Clampdown by Authorities

These medical devices were previously not covered under any specific regulations.

The industry is not opposed to regulation, but wants that to be specific to medical devices and not under the Drug Act which is for medicines.

"Companies need to take approval and undergo inspection even if they want to expand production capacities, set up a new line or a warehouse for any medical electronics regulated as a drug now," said Rajiv Nath, forum coordinator of the Association of Indian Medical Device Industry. These are measures that can be adopted during peacetime and not when it is a war-like situation, said Nath, who is also managing director of Hindustan Syringes & Medical Devices. "The government needs to allow relaxations on regulatory compliance for medical electronics for a few months till the second wave is controlled."

States such as Maharashtra that have imposed restrictions on the sale of non-essentials have not made oxygen concentrators an essential, which has further impacted availability, manufacturers said.

A few sellers and retailers have some stock but are unable to sell, they said.

A senior executive at a leading medical device manufacturer said drug authorities in Maharashtra had clamped down on online sellers and retailers of oxygen concentrators in the last two-three days, saying that they needed to supply to state governments instead of directly selling them since the product came under the Drugs Act.

"Drug inspectors say we have to comply with them. While the intention may be good as they want to prevent hoarding, but it reduces retail availability," he said.

A drug license is required to even stock these medical devices and sell them. Hence, the number of sellers on ecommerce platforms has reduced drastically so has individual stores selling them, since now only pharmacies in brick-and-mortar retail can sell such products.

"The entire process of licensing to sell them has increased the shortage as compared to last year," a senior ecommerce industry executive said.

Despite facing these regulatory issues, companies such as BPL Medical Technologies and Philips are working on increasing the supplies of oxygen concentrators and other devices.

"Oxygen concentrators should be considered as an essential product to ensure wider availability through retail stores and ecommerce even as we are sourcing units and trying to ramp up local production," a BPL Medical spokesperson said.

Nath of the medical device industry association said currently there was demand for almost 2,000 units of oxygen concentrators daily since hospital beds were not available.

"The whole process of taking approval, undergoing inspection to scale up supplies will take days, which will delay availability of these products if covered under compulsory manufacturing license as required under Drugs Act. Also, it is not the best time to bring in these devices under the enforcement of the Act," he said.

Last week, the union health ministry extended the timeline by six months to classify eight critical medical equipment including CT scans, MRI machines, defibrillators, dialysis units and X-ray machines as drugs for existing manufacturers and importers. It also allowed voluntary drug licensing for manufacturers and importers of pulse oximeter till August 2022. But there was no relaxation of the rules for nebulisers, BP machines, digital thermometers, glucometers and oxygen concentrators, despite requests from the industry.

Source: *The Times of India,* 24th April 2021

PARLIAMENT QUESTION – ANSWERS

RAJYA SABHA
UNSTARRED QUESTION NO.908
TO BE ANSWERED ON 9TH FEBRUARY, 2021

ADVERSE EFFECTS FOLLOWING IMMUNISATION

908 SHRI PARTAP SINGH BAJWA:

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

(a) whether the Ministry has observed any Adverse Effects Following Immunisation (AEFI) arising from the use of COVAXIN and, if so, the details thereof;

(b) whether the Ministry has observed any AEFI arising from the use of COVISHIELD and if so, the details thereof;

(c) whether any COVID-19 vaccine currently under clinical trials in the country have led to any AEFI, if so, the details thereof; and

d) the details of the common side effects of all vaccines currently being used or undergoing clinical trials in India?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): As on 4th February 2021, a total of 81 Adverse Event Following Immunisation (AEFIs) i.e. 0.096% AEFIs cases have been reported out of total beneficiaries vaccinated with Covaxin vaccine. For Covishield vaccine, a total of 8,402 AEFIs, i.e. 0.192% AEFI cases have been reported out of total beneficiaries vaccinated.

Most of these are minor AEFIs like anxiety, vertigo, giddiness, dizziness, fever, pain, rashes, and headache which are self-limiting and all people have recovered.

(c): As per New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act,1940 and in light of urgent need due to COVID pandemic in the country, Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI) has granted permission to manufacture two COVID-19 vaccines based on the prescribed procedure and due evaluation of pre-clinical and clinical trial data. The details of the AEFI reported after introduction of these two vaccines is given at reply at (a) & (b) above.

(d): The common side effects of vaccines under country's immunization programme include pain, swelling, redness at injection site, local abscess, fever, malaise etc.

The adverse events which have been reported from COVID-19 vaccines which are approved for restricted use in emergency situation includes headache, rash, chills, myalgia, fatigue, fever, dizziness, inflammation and pain, swelling or redness at the site of injection, vaccination site, erythema, pruritus etc.

RAJYA SABHA
UNSTARRED QUESTION NO.1704
TO BE ANSWERED ON 9TH MARCH, 2021

IMPORT OF DRUGS FROM CHINA

1704 DR. C.M. RAMESH:

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

(a) whether bulk of the drugs to manufacture medicines in the country are imported from China, if so, the details thereof for the last three years;

(b) the manner in which Government is going to protect the pharma industry in view of the recent steps taken by Government ; and

(c) whether Government has considered any alternative arrangement so that there is no scarcity of medicines in the country, if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

((a): Yes, As per data available with Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, the details of the percentage of raw materials imported from China are as under:

Year	Percentage (in terms of value)
2018	66.53%
2019	72.40%
2020	72.15%

(b): Department of Pharmaceuticals has launched following three schemes for promoting domestic manufacturing of critical Key Starting Materials/Drug Intermediates and Active Pharmaceutical Ingredients (API) by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence:

(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) In India:
(II) Scheme for Promotion of Bulk Drug Parks:
(III) Production Linked Incentive Scheme for Pharmaceuticals:

(c): Under the provisions of the Drugs and Cosmetics Rules, 1945 various sites of different countries are registered by the CDSCO for import of various Active Pharmaceutical Ingredients (API) which are used for manufacture of drug formulations in the country. CDSCO reviews all such applications for import of APIs in an expeditious manner.

RAJYA SABHA
UNSTARRED QUESTION NO.2339
TO BE ANSWERED ON 16TH MARCH, 2021

USE OF OPIOID-RELATED MEDICATION IN THE COUNTRY

2339 SHRI PARTAP SINGH BAJWA:

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

(a) whether any opioids being sold as medicines in India can be purchased without a prescription;

(b) whether Government has taken any action to prevent the sale or access to medical opioids to those with illegitimate prescriptions;

(c) if so, whether there is a monitoring mechanism to prevent such sales;

d) whether the opioid tramadol is prescribed in India for medical use;

(e) whether the Ministry has conducted any research on the potential addiction to tramadolbased medication; and

(f) whether the Ministry has taken any proactive measures to regulate the export of tramadol?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (c): Sale and distribution of drugs is regulated in terms of the provisions of the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 made thereunder through a system of licensing and inspection. As per the provisions of the Act and Rules, various drugs including drugs of Opioid category are included in Schedule H and Schedule H1 of Drugs & Cosmetic Rules, 1945 and such drugs are required to be sold by retail only on the prescription of Registered Medical Practitioners (RMP). The State Licensing Authorities are empowered to take action on any violation of the conditions of sale license. In order to check illegal sale of drugs, the State Drug Controllers are sensitized from time to time in the matter.

(d): Various formulations of Tramadol are approved in the country under the provisions of Drugs & Cosmetic Act, 1940 and Rules made thereunder for medicinal use.

(e): As per the report of National Survey conducted by National Drug Dependence Treatment Centre, AIIMS, New Delhi funded by the Ministry of Social Justice and empowerment, the prevalence of overall opioid use in India was 2.06%. Further, pharmaceutical opioids (Tramadol comes under pharmaceuticals opioids) were the second most common type of opioids used in India (0.96%). Drugs Treatment Clinics have been set up in different parts of the country to help those who have problems due to use of these drugs.

(f): Under Drugs & Cosmetic Act 1940 and rules, made thereunder, provisions applicable for export of drugs are also applicable for export of Tramadol.

RAJYA SABHA
UNSTARRED QUESTION NO.3123
TO BE ANSWERED ON 23rdMARCH, 2021

RISING PROBLEM OF MULTI-DRUG RESISTANT DEATHS

3123 SHRI HARSHVARDHAN SINGH DUNGARPUR:

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

(a) whether Government is aware that there is a rising problem of multi-drug resistant deaths in the country; and

(b) if so, the steps Government plans to take to reduce the overuse and unsupervised use of antibiotics by patients?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) & (b): Government of India has given due cognizance to the problem of Antimicrobial Resistance (AMR). Ministry of Health and Family Welfare (MoHFW) has initiated various activities for containment of AMR, as under :-

I. The State Drugs Controllers have been sensitized from time to time for taking policy measures including stringent regulatory action over the counter sale of antibiotics. Since March 2014, a separate Schedule H-1 has been incorporated in Drug and Cosmetic Rules to regulate the sale of antimicrobials in the country. About 24 antimicrobials belonging to third/fourth generation cephalosporins and carbapenems are covered in the schedule. These antimicrobials cannot be sold without a proper medical prescription and their drug packaging requires the specific labelling along with red border

II. National Action Plan for containment of Antimicrobial Resistance (NAP-AMR) was launched on 19th April, 2017, involving stakeholders from various ministries / sectors.

III. National Programme on Containment of AMR was initiated during the 12th Five Year Plan. National Centre for Disease Control (NCDC) coordinates this programme. Under the programme National AMR surveillance network of state medical colleges, labs(NARS-Net) have been established in order to generate quality data on AMR for seven priority bacterial pathogens of public health importance using WHONET software. NCDC conducts AMR surveillance through a network of 30 state medical college laboratories in 25 states.

IV. National Guidelines on Infection, Prevention and Control in Healthcare facilities were released in Jan, 2020. These guidelines have been shared with various stakeholders across the country to be used in training modules for country-wide trainings in a systematic manner.

V. Antimicrobial stewardship (AMSP) activities: In order to promote rational use of antibiotics among the healthcare providers, a series of sensitization and training workshops have been organized in different healthcare facilities in the country for the benefit of the practicing clinicians. Standard treatment guidelines developed by NCDC for rational use of antibiotics have been made available to clinicians across the country.

VI. To create awareness among the public about AMR, several Information, Education and Communication (IEC) activities have been coordinated by NCDC along with other partners to raise awareness about AMR among different stakeholders by way of organizing Public lectures, participating in Live programmes on Lok Sabha Television, Doordarshan, organizing AMR programmes in schools and colleges, etc.

RAJYA SABHA
UNSTARRED QUESTION No. 533
TO BE ANSWERED ON THE 5th FEBRUARY, 2021

Production linked incentive scheme for API production

533 Shri K.C. Ramamurthy:

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

(a) the details of production-linked incentive scheme being implemented for manufacture of Active Pharmaceutial Ingredients (APIs) in the country;

(b) whether the Ministry has made any request to the Ministry of Finance or GST Council to bring down 18 per cent GST on the manufacture of APIs to 5 per cent as requested by the pharma industry; and

(c) if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a): This Department runs a scheme namely 'Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India' which intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The financial incentive under the scheme is provided on sales of 41 identified products in four different Target Segments for a period of six (06) years. The tenure of the scheme is from financial year 2020-21 to 2029-30 with the total financial outlay of Rs.6,940 crore. The Government has already approved five applications under Target Segment-1.

(b) to (c): All the suggestions received from Pharma and Medical Device industry Associations in respect of direct and indirect taxes are duly sent to Ministry of Finance for their consideration.

RAJYA SABHA
UNSTARRED QUESTION No. 1319
TO BE ANSWERED ON THE 12th February, 2021

Steps to reduce dependence on imports for APIs and intermediaries

1319 Dr. Vinay P. Sahasrabuddhe:

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

(a) the steps taken by the Ministry to reduce dependence on imports for Active Pharmaceutical Ingredients (APIs) and intermediaries in Indian pharmaceutical industry during the last three quarters; and

(b) the steps taken by or the plans prepared by the Ministry and the concerned Departments to engage with the relevant stakeholders to achieve self dependency in this sector?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): The Department of Pharmaceuticals has recently launched following two schemes for promoting domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs after series of consultations with the relevant stakeholders: -

(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) In India: Under the scheme, financial incentive is given for manufacturing of 41 eligible products under the four Target Segments viz.:

(i) Fermentation based KSMs/Drug Intermediates.
(ii) Fermentation based niche KSMs/Drug Intermediates /APIs.
(iii) Key Chemical Synthesis based KSMs/Drug Intermediates.
(iv) Other Chemical Synthesis based KSMs/Drug Intermediates/APIs.

Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940.

(II) Scheme for Promotion of Bulk Drug Parks: To provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs. 1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

RAJYA SABHA
UNSTARRED QUESTION No. 1321
TO BE ANSWERED ON THE 12th February, 2021

India's share in global trade of generic pharmaceuticals

1321 Dr. Fauzia Khan:

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

(a) the details of India's share in the global trade of generic pharmaceuticals;

(b) the total quantity and value of the production of generic pharmaceuticals along with the quantity and value of such products exported and imported during the last three years and the current year, category-wise; and

(c) the share of generic and non-generic medicines in the total sales of medicines in the country, including Government hospitals?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): As per Pharmexcil, the global Generic market in 2019 is estimated at $ 360 billion. The domestic Generic market size in 2019 was $ 20.87 Billion. India has exported Generics during 2019 worth around $ 15.63 billion. India's share of generics in the global exports is around 4.6%.

[Source: IQVIA report (data provided is of the calendar year]

(b): The details of generics exports are as follows:

India's Generic Pharma exports $ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-December)
Drug Formulations (Generics)	12900.28	14368.65	15811.24	13966.85

The details of India's pharma imports are as follows:

India's imports of Pharmaceutials $ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-December)
Drug Formulations	1767.74	1927.67	2156.05	1859.40

[Source: DGCIS]

(c): Data pertaining to sales of generic and non-generic medicines is not maintained by this department.

RAJYA SABHA
UNSTARRED QUESTION NO. 2766
TO BE ANSWERED ON 19th March, 2021

Free of cost generic drugs to hospitals

2766 Smt. Priyanka Chaturvedi:

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

(a) whether it is a fact that Government is planning to supply generic drugs free of cost in the hospitals soon;

(b) if so, the details thereof; and

© whether Government has taken any steps to keep a check on over prescription and wastage of drugs by the hospitals and if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): The Ministry of Health and Family Welfare under its National Health Mission has taken up with all the States regarding provision of free essential drugs in all public health facilities. In order to nudge the State towards adoption of policy to provide free essential generic drugs in public health facilities, up to 5% additional funding (over and above the normal allocation of the state) under the National Health Mission (NHM) was introduced as an incentive. Accordingly, all the States/UTs have reported to have notified policy to provide free drugs in public health facilities. The support under the NHM is provided not only for drugs but also for various components necessary for effective implementation of Free Drug Service Initiative, viz., strengthening/setting up robust systems of procurement, quality assurance, IT backed supply chain management systems, etc.

The Department of Pharmaceuticals also implements the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) through which quality generic medicines are provided to the citizens at an affordable price in more than 7,500 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) functioning in all the districts of the country.

(c) The subject of public health, hospitals and dispensaries falls in the State List as per the Seventh Schedule of the Constitution. However, Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drug. Further, the erstwhile Medical Council of India (MCI) had issued Circular dated 21.04.2017 vide which all the Registered Medical Practitioners have been directed to comply with the aforesaid provisions. As and when complaints are received against the violation of code of ethics for doctors, such complaints are now referred by the National Medical Commission (NMC) to the concerned State Medical Commissions where the doctors/medical practitioners are registered. States have been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities. Practice of prescription audit is one of the prerequisites for getting certified under the National Quality Assurance Standards (NQAS).

RAJYA SABHA
UNSTARRED QUESTION NO. 1969
TO BE ANSWERED ON 12th March, 2021

New drug policy

1969 Shri P. Bhattacharya:

(a) whether Government has formulated a new drug policy;

(b) if so, the details thereof;

(c) by when it is likely to be announced;

(d) from which date it is being implemented;

(e) the steps taken in that regard;

(f) whether any safeguards have been provided therein to control the rising prices of medicines and pharmaceutical products, particularly life-saving drugs; and

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

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) : No, Sir.

(b) to (g): In view of the reply (a) above, the question does not arise.

RAJYA SABHA
UNSTARRED QUESTION NO. 2767
TO BE ANSWERED ON 19th March, 2021

Cancer drugs

2767 Dr. Narendra Jadhav:

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

(a) whether Government is aware of the fact that the cancer burden is increasing and has taken steps to ensure affordable pricing and availability of treatment drugs for the same;

(b) whether price control for cancer medicines has been introduced; and

(c) the price comparison from 2015-2020 for the same?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) to (c): As per the latest National Cancer Registry Programme Report (NCRP) of the Indian Council of Medical Research (ICMR) under the Ministry of Health & Family Welfare for the year 2020, the annual figures of estimated incidence and mortality of cancer cases are as under:

Year	2017	2018	2019
Estimated incidence of cancer cases	12,92,534	13,25,232	13,58,415
Estimated Mortality of cancer cases	7,15,010	7,33,139	7,51,517

Further, the projected number of incidences of cancer cases in the country is 15.7 lakhs for the year 2025.

The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed the ceiling prices of 86 anti-cancer scheduled formulations under the National List of Essential Medicines, 2015 (NLEM, 2015). Further, the NPPA, vide order S.O. 1041(E) dated 27th February, 2019 put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalisation' approach. By this approach, the Maximum Retail Price (MRP) of 526 brands of these medicines have been reduced by up to 90%. This move resulted in annual savings of around Rs. 984 crore to the patients. The details of revised prices are available on website of NPPA, i.e., nppaindia.nic.in.

A list showing the ceiling price of scheduled anti-cancer medicines as in 2020 and its price (same/other dosage & strength) as in 2015 is enclosed as **Annexure.**

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
1	5-Fluorouracil	Injection 250 mg/5 ml	1 ml	2.33	Injection 250 mg/5 ml	1 ml	2.3
2	6-Mercaptopurime	Tablet 50mg	1 tablet	6.44	Tablet 50mg	1 tablet	9.86
3	Actinomycin D	Powder for Injection 0.5mg	Each Pack	316.2	Injection 0.5mg	Each Pack	584.65
4	All-trans Retinoic Acid	Capsule 10mg	1 capsule	81.56	#		
5	Arsenic Trioxide	Injection 1mg/ml	1 ml	54.14	#		
6	Bleomycin	Powder for Injection 15 Units	Each Pack	618.94	Injection 15 mg	1 ml	680.2
7	Bortezomib	Powder for Injection 2 mg	Each Pack	12263.1	#		
8	Calcium folinate	Tablet 15 mg	1 Tablet	40.67	#		
9	Capecitabine	Tablet 500 mg	1 Tablet	126.01	#		
10	Carboplatin	Injection 10 mg/ml	1 ml	53.06	#		
		*			Injection 450 mg/vial	Each Pack	2677.42
		*			Injection 150 mg/vial	Each Pack	871.17
11	Chlorambucil	Tablet 2 mg	1 Tablet	36.8	Tablet 2 mg	1 Tablet	49.93
		Tablet 5 mg	1 Tablet	82.7	#		

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
12	Cisplatin	Injection 1 mg/ml	1 ml	6.87	#		
		*			Injection 10mg	Each Pack	93.67
		*			Injection 50mg/vial	Each Pack	332.63
13	Cyclophosphamide	Tablet 50mg	1 Tablet	4.04	Tablet 50mg	1 Tablet	4.14
		Powder for Injection 500mg	Each Pack	79.58	Injection 500mg	1 injectable	80.29
14	Cytosine arabinoside	Injection 100 mg/ml	Each Pack	198.09	Injection 100 mg/vial	Each Pack	263.27
		Powder for Injection 1000 mg	Each Pack	1068.41	Injection 1000 mg/vial	Each Pack	1292.5
		Powder for Injection 500 mg	Each Pack	510.65	Injection 500 mg/vial	Each Pack	569.21
15	Dacarbazine	Powder for Injection 200 mg	Each Pack	438.03	#		
		Powder for Injection 500 mg	Each Pack	988.15	Injection 500 mg	Each Pack	1136.24
16	Daunorubicin	Powder for I.V. Injection 20 mg(5 mg/ml)	Each Pack	242.47	Injection 20 mg vial/pack	Each Pack	390.51
17	Docetaxel	Powder for Injection 20 mg	Each Pack	2984.59	#		
		Powder for Injection 80 mg	Each Pack	11347.62	#		

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
18	Doxorubicin	Injection 2 mg/ml	1 ml	35.8	#		
		*			Injection 10 mg vial/pack	Each Pack	216.94
		*			Injection 50 mg	Each Pack	1264.44
19	Etoposide	Capsule 50mg	1 capsule	54.21	#		
		*			Capsule 100 mg	1 Capusle	57.75
		Injection 20 mg/ml	1 ml	35.75	Injection 100 mg/5ml vial	Each Pack	212.42
20	Gefitinib	Tablet 250 mg	1 Tablet	427.35	#		
21	Gemcitabine	Powder for Injection 1 gm	Each Pack	5289.73	Injection 1 gm	Each Pack	6590.68
		Powder for Injection 200mg	Each Pack	1168.23	Injection 200 mg	Each Pack	1440.73
22	Ifosfamide	Powder for Injection 1 g	Each Pack	360.78	Injection 1 gm/2ml vial	Each Pack	380.79
		Powder for Injection 2 g	Each Pack	947.01	#		
23	Imatinib	Capsule 100mg	1 Capsule	77.4	#		
		Capsule 400mg	1 Capsule	254.67	#		
		Tablet 100mg	1 Tablet	79.19	Tablet 100mg	1 Tablet	96.71
		Tablet 400mg	1 Tablet	229.24	Tablet 400mg	1 Tablet	296.27

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
24	L-Asparaginase	Powder for Injection 10000 Ku	Each Pack	1600.63	#		
		Powder for Injection 5000 Ku	Each Pack	1033.19	Powder for Injection 5000 Ku	Each Pack	1307.19
25	Melphalan	Tablet 2 mg	1 Tablet	97.82	Tablet 2 mg	1 Tablet	119.83
		Tablet 5 mg	1 Tablet	167.77	Tablet 5 mg	1 Tablet	201.02
26	Mesna	Injection 100 mg/ml	1 ml	16.72	#		
		*			Injection 200 mg	1 ml	27.13
27	Methotrexate	Injection 50 mg/ml	1 ml	39.94	Injection 50 mg/ml	1 ml	36.64
		Tablet 10 mg	1 Tablet	12.11	Tablet 10 mg	1 Tablet	15.4
		Tablet 2.5 mg	1 Tablet	4.77	Tablet 2.5 mg	1 Tablet	5.21
		Tablet 5 mg	1 Tablet	8.35	Tablet 5 mg	1 Tablet	8.39
		*			Tablet 7.5mg	1 Tablet	12.44
28	Oxaliplatin	Injection 100mg (as licensed)	Each Pack	4455.9	#		
		Injection 50mg (as licensed)	Each Pack	2591.45	Injection 50 mg vial	1 injecta ble	3304.92
29	Paclitaxel	Injection 100mg/16.7ml	1 ml	222.53	#		
		Injection 30mg/5ml	1 ml	222.53	Injection 30mg/5ml	1 ml	332.61

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
30	Procarbazine	Capsule 50mg	1 Capsule	34.47	Capsule 50mg	1 Capsule	34.93
		Tablet 50mg	1 tablet	46.97	#		
31	Rituximab	Injection 10mg/ml	1 ml	756.26	#		
32	Temozolomide	Capsule 100mg	1 capsule	2077.53	#		
		Capsule 20mg	1 Capsule	594.68	#		
		Capsule 250mg	1 Capsule	4672.75	#		
		Tablet 100mg	1 Tablet	1542.12	#		
		Tablet 20 mg	1 Tablet	373.62	#		
		Tablet 250 mg	1 Tablet	3816.9	#		
33	Thalidomide	Capsule 100mg	1 Capsule	60.92	#		
		Capsule 50mg	1 Capsule	35.19	#		
34	Trastuzumab	Injection 440 mg/50ml	Each Pack	59976.96	#		
35	Vinblastine	Injection 1mg/ml	1 ml	20.46	Vinblastine sulphate Injection 10 mg/pack	Each Pack	314.57
36	Vincristine	Injection 1mg/ml	1 ml	51.96	Injection 1mg/ml	1 ml	55.87
37	Bicalutamide	Tablet 50 mg	1 Tablet	68.41	#		
38	Letrozole	Tablet 2.5 mg	1 Tablet	40.65	#		

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price(Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
39	Prednisolone	Injection 20 mg/2 ml	1 ml	3.57	Injection 20 mg Vial/pack (as sodium Phosphate or Succinate	1 ml	4.58
		Oral Liquid 15 mg/5ml	1 ml	0.75	Prednisolone Acetate Drop 1%	1 ml	3.49
		Oral Liquid 5 mg/5ml	1 ml	0.43	#		
		Tablet 10 mg	1 Tablet	0.97	Tablet 10 mg	1 Tablet	1.02
		Tablet 20 mg	1 Tablet	1.95	Tablet 20 mg	1 Tablet	1.9
		*			Tablet 5 mg	1 Tablet	0.6
		Tablet 40 mg	1 Tablet	2.8	#		
40	Tamoxifen	Tablet 10 mg	1 Tablet	2.57	Tablet 10 mg	1 Tablet	4.8
		Tablet 20 mg	1 Tablet	2.9	Tablet 20 mg	1 Tablet	3.06
41	Azathioprine	Tablet 50 mg	1 Tablet	10.12	Tablet 50 mg	1 Tablet	10.92
42	Cyclosporine	Capsule 100mg	1 Capsule	102.2	Capsule 100 mg	1 Capsule	117.36
		Capsule 25 mg	1 Capsule	27.43	Capsule 25,mg	1 Capsule	27.32
		Capsule 50 mg	1 Capsule	52.49	Capsule 50 mg	1 Capsule	53.28
		Injection 50 mg/ml	1 ml	268.93	#		
		*			Injection 100 mg/ml	1 ml	131
		Oral Liquid 100 mg/ml	1 ml	94.24	#		

		Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2020			Ceiling price of Scheduled formulation after allowing Wholesale Price Index (WPI) for 2015		
Sl No	Medicines	Dosage form and Strength	Unit	Ceiling price (Rs.)	Dosage form and Strength	Unit	Ceiling price (Rs.)
43	Mycophenolate mofetil	Tablet 250 mg	1 Tablet	41.4	#		
		Tablet 500mg	1 Tablet	81.89	#		
44	Tacrolimus	Capsule 0.5 mg	1 Capsule	22.05	#		
		Capsule 1 mg	1 Capsule	38.95	#		
		Capsule 2 mg	1 Capsule	76.3	#		
		Tablet 0.5 mg	1 Tablet	18.68	#		
		Tablet 1 mg	1 Tablet	34.31	#		
		Tablet 2 mg	1 Tablet	67.77	#		

* Not in Schedule-I during 2020

Not in Schedule-I during 2015

LOK SABHA
STARRED QUESTION NO. 346
TO BE ANSWERED ON THE 19TH MARCH, 2021

FIXED DOSE COMBINATIONS

***346. SHRI RAVNEET SINGH BITTU:**

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

(a) whether the Government is aware that several unscientific combinations of drugs have flooded the markets as Fixed Dose Combinations (FDCs) and if so, the details thereof;

(b) whether a lax regulatory framework has led to this situation in the country and if so, the reaction of the Government thereto;

(c) whether the National Pharmaceutical Pricing Authority (NPPA) has raised some concerns on drug cocktails and has flagged the issue to the Indian Council of Medical Research (ICMR) and if so, the details thereof;

(d) the details of FDC drugs banned during the last three years;

(e) whether the Government has taken any measures to fix the prices of new drugs which were FDC medicines or drug cocktails; and

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

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO.346* FOR 19TH MARCH, 2021

(a) to (d): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Under the said Rules, Fixed Does Combinations is a new Drugs. For the manufacture of any FDC falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organsiation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority.

Under the afore-said Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments not to issue such licenses to FDCs falling under definition of new Drugs without approval of DCG(I), the Central Government constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further, the Central Government also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to prohibition of the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the Hon'ble High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Hon'ble Delhi High Court before the Hon'ble Supreme Court by way of filing Special Leave Petition (SLP). Further, about 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Supreme Court. Hon'ble Supreme Court, vide its order dated 15.12.2017, directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Accordingly, a Sub-Committee of DTAB was constituted which after providing hearing to all the petitioners/appellants, submitted its report to DTAB which was accepted by DTAB.

Based on the recommendations of DTAB, the Central Government, vide notifications dated 07.09.2018, prohibited 328 FDCs for manufacture, sale or distribution. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writ petitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

Earlier, in 2007, CDSCO had received complaints from consumer association regarding rationality of certain Fixed Dose Combinations (FDC) marketed in the country. As follow up action, CDSCO prepared a list of 294 FDCs and communicated to State Drugs Controllers vide letter dated 14.08.2007. A writ petition was filed in the Hon'ble High Court of Madras and the Hon'ble Court granted stay order. However, DTAB in its meeting held on 16.1.2008 constituted asub-committee to examine these FDCs. The recommendations of the subcommittee was referred to Hon'ble Supreme Court. The Hon'ble Supreme Court in its judgment, dated 15.12.2017, accepted the recommendations of DTAB and ordered for disposal of these petitions. Accordingly, Central Government vide notifications S.O. 180(E) to S.O.259 (E), dated 11.01.2019, prohibited 80 FDCs for manufacture, sale or distribution.

National Pharmaceutical Pricing Authority (NPPA), under the Ministry of Chemical & Fertilizers, flagged the following to Indian Council of Medical Research (ICMR), New Delhi. The detail is as below:

"The Authority noted that the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. The Authority deliberated upon the matter in detail and expressed its concern that approval of these FDCs may compromise the rationale in the usage of the drugs and may lead to over medication. The Authority also apprehended that fixation of retail price of these FDCs may lead to a higher price being fixed than the sum of the price of their individual components resulting in profiteering by the companies. The Authority is of the view that guidelines in the usage of these FDCs needs to be looked into. Accordingly, the Authority requested that matter may be highlighted to Indian Council of Medical research (ICMR), New Delhi."

(e) & (f): NPPA which is mandated with the task of dealing with pricing issues of drugs fixes the retail price of only those new drugs which have been approved/No Objection Certificate (NOC) issued by CDSCO. Further, NPPA has extended retail price to 1495 FDCs under DPCO 2013.

LOK SABHA
STARRED QUESTION NO. 354
TO BE ANSWERED ON THE 19TH MARCH, 2021

IMPORT OF MEDICINES

†*354. DR. VIRENDRA KUMAR:

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

(a) whether the Government imports medicines from other countries;

(b) if so, the details thereof;

(c) whether the Government has any provision to send drug inspectors to these countries to ensure adherence to the norms related to quality; and

(d) if so, the details thereof?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO.354* FOR 19TH MARCH, 2021

(a) & (b): Import of "Drugs" as defined under the Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder is regulated under the Chapter III of the said Act and Rules. For import of drugs, the foreign manufacturing site and the drugs to be imported are required to be registered and import licence is required to be obtained from Central Drugs Standard Control Organisation (CDSCO).

CDSCO has granted Registration Certificate and Import Licence for import of various medicines manufactured in China, Germany, United States of America, Italy, Singapore, Japan, Switzerland, Spain, United Kingdom, etc.

© & (d): There is a provision under Rule 24(A)(5) of the Drugs and Cosmetics Rules, 1945, for inspection or visit of the manufacturing premises of drugs, by the licensing authority or by any persons to whom powers have been delegated in this behalf by the Licensing Authority under Rule 22 of the said rules.

LOK SABHA
UNSTARRED QUESTION NO.3923
TO BE ANSWERED ON 19TH March, 2021

BANNED MEDICINES

3923. KUNWAR DANISH ALI:

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

(a) whether Government is aware that a number of medicines are being prescribed in the country which are banned in foreign countries;

(b) if so, the details thereof and reasons therefor; and

(c) the steps being taken by the Government to curb such practices?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a) to (c): Import, Manufacture, Sale and Distribution of Drugs are regulated under the Drugs & Cosmetic Act 1940 and Rules made thereunder.

There are side effects of all drugs. Therefore, all drugs are approved and allowed to be manufactured and marketed in India based on their risk-benefit analysis.

A drug banned/restricted in one country may continue to be marketed in other countries as the respective Governments examine the usage, doses, indications permitted etc. and overall risk benefit ratio and take decisions on the continued marketing of any drug in that country.

Safety issues of drug formulations, as and when reported, are assessed in consultation with the Expert Committees / Drugs Technical Advisory Board (DTAB). Based on the recommendations of the Expert Committees/DTAB, the Government considers to take appropriate action to regulate/restrict/prohibit the manufacture, sale and distribution of such drugs in the country under the provisions of Drugs and Cosmetics Act, 1940.

LOK SABHA
UNSTARRED QUESTION NO.3975
TO BE ANSWERED ON 19TH March, 2021

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

3975. SHRI SHANTANU THAKUR:

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

(a) the main objectives and salient features of the functioning of Central Drugs Standard Control Organisation (CDSO);

(b) whether CDSO is responsible for approval of new drugs in the country; and

(c) if so, the details thereof along with the drugs approved during the last three years?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945, Medical Devices Rules, 2017 and New Drugs and Clinical Trials Rules, 2019 made thereunder.

The main functions of the Central Licensing Authority in Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare are as under: -

1. Approval of New Drugs including vaccine, biotech products under New Drugs and Clinical Trials (ND&CT) Rules, 2019 to ensure their quality, safety and efficacy;

2. Grant of Permission to conduct clinical trials to ensure that clinical trial is conducted as per the ND&CT Rules, 2019 and Good Clinical Practices guidelines;

3. Registration and control on the quality of imported drugs under Drugs and Cosmetics Rules, 1945; Cosmetics under Cosmetic Rules, 2020 and notified medical devices under Medical Devices Rules, 2017;

4. Grant of License to Manufacture Class C and Class D Medical Devices under Medical Devices Rules,2017;

5. Participating in the meeting of Drugs Consultative Committee (DCC) & Drugs Technical Advisory Board (DTAB) under Drugs & Cosmetic Act.

6. Approval of License for manufacture of large volume parenteral, vaccines and biotechnology products and operation of blood banks and also of such drugs as may be notified by Government from time to time under the provisions of Drugs and Cosmetics Rules in the country as Approving Authority.

(b) & (c): Central Licensing Authority in CDSCO approves import/manufacture and marketing of new drugs under New Drugs and Clinical Trials (ND&CT) Rules, 2019.

For manufacture/ import of new drug in the country, the manufacturer/ importer is required to obtain new drug permission from CDSCO before obtaining the manufacturing license/ import license. Details of such permissions granted during the last three years are as below:

Year	Number of Permissions
2018	239
2019	208
2020	415
Total	862

LOK SABHA
STARRED QUESTION No. †*388
TO BE ANSWERED ON 23rd March, 2021

Jan Aushadhi Kendras at Panchayat and Block Level

†*388. SADHVI PRAGYA SINGH THAKUR:

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

(a) the norms laid down for the opening of Jan Aushadhi Kendras in the country;

(b) Whether the Government proposes to open Jan Aushadhi Kendras at Panchayat and Block levels in the country, particularly in Bhopal, Madhya Pradesh;

(c) if so, the details thereof; and

(d) if not, the reasons therefor?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

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

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (d) OF THE LOK SABHA STARRED Q.NO. 388 FOR ANSWER ON 23.03.2021 REGARDING JAN AUSHADHI KENDRAS AT PANCHAYAT AND BLOCK LEVEL

(a) As per internal guidelines framed by the Bureau of Pharma PSU of India (BPPI), the Implementing Agency of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), any individual possessing D. Pharma/B. Pharma qualifications or any individual/organization that has employed a person with D. Pharma/B. Pharma qualifications for getting drug license from the State Government concerned is eligible to open Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK). The basic requirements which an applicant need to fulfill for applying to open PMBJK are as follows:

i. Minimum 120 sq. ft. space duly supported by proper documents.
ii. Registration details of the pharmacist with the State Pharmacy Council.
iii. Certificate/proof from the authorities concerned along with undertaking for applicants under category of Divyang, SC and ST entrepreneurs.

(b) (c) & (d) More than 7,520 PMBJKs are presently functional in all the Districts in the country. The opening of PMBJKs in the country, including in Block and Gram Panchayat areas, depends on receipt of applications from the individual entrepreneur and availability of pharmacist. BPPI accords preference to applications received for opening PMBJKs in Block and Gram Panchayat areas and process them on priority basis.

LOK SABHA
UNSTARRED QUESTION No. 178
TO BE ANSWERED ON THE 2nd FEBRUARY, 2021

PLI Scheme for Bulk Drugs

178. SHRI P.V. MIDHUN REDDY:
SHRI MAGUNTA SREENIVASULU REDDY:
SHRI ADALA PRABHAKARA REDDY:

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

(a) whether the Government has received a favourable response from the Pharmaceutical sector for the Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices;

(b) if so, the details thereof;

(c) the details of applications received in this regard; and

(d) whether the Government has appointed a Project Management Agency for this scheme and if so, the details thereof.

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a) to (c): Yes, Sir. The Department has received a favourable response to the Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices. In total 215 applications have been received for the 4 Target Segments for the PLI schemes for Bulk Drugs and 28 applications for the 4 Target Segments for the PLI Scheme for Medical Devices.

(d): The Department has appointed M/s IFCI Limited, a public sector non-Banking Finance Company as the Project Management Agency (PMA) for smooth implementation and functioning of the Scheme.

LOK SABHA
UNSTARRED QUESTION No. 1376
TO BE ANSWERED ON THE 9th February, 2021

Domestic Pharma Manufacturing

1376. SHRI ARVIND GANPAT SAWANT:

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

(a) whether the Government is planning to support the increase in domestic pharmaceutical manufacturing capacity amid COVID-19 outbreak;

(b) if so, the details thereof;

(c) whether any steps have been taken by the Government to curb large dependency on other countries for Pharmaceutical products; and

(d) if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a) to (d): The Department of Pharmaceuticals has recently launched following two schemes for promoting domestic manufacturing of critical KSMs/Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs:

(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) In India: Under the scheme, financial incentive is given for manufacturing of 41 eligible products under the four Target Segments viz.:

(i) Fermentation based KSMs/Drug Intermediates.
(ii) Fermentation based niche KSMs/Drug Intermediates /APIs.
(iii) Key Chemical Synthesis based KSMs/Drug Intermediates.
(iv) Other Chemical Synthesis based KSMs/Drug Intermediates/APIs.

Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940.

(II) Scheme for Promotion of Bulk Drug Parks: To provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

LOK SABHA
UNSTARRED QUESTION No. 3335
TO BE ANSWERED ON THE 16th March, 2021

Pharmaceutical and Medical Device Industry

3335. SHRI BHAGWANTH KHUBA:

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

(a) whether the Government has launched any new initiative to support the pharmaceutical and medical devices manufacturing industry to reach their potential in the coming years;

(b) if so, the details thereof; and

(c) the fresh steps taken by the Government for promoting domestic manufacturing of bulk drugs and medical devices in the country?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a) to (c): The Department of Pharmaceuticals has recently launched following five schemes for promoting domestic manufacturing of Pharmaceutical drugs including bulk drugs and medical devices by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

(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) In India: Under the scheme, financial incentive will be given for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Incentives for incremental sales will be given to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

(II) Scheme for Promotion of Bulk Drug Parks: This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

(III) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices: Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is Rs. 3,420 crore.

(IV) Promotion of Medical Device Parks: This scheme provides for grant-in-aid to 4 Medical Device Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.100 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 400 crore and the tenure of the Scheme is from FY 2020-21 to FY 2024-25.

The above four schemes were notified on 21.07.2020 in the Gazette of India and the detailed guidelines of these schemes are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

(V) Production Linked Incentive Scheme for Pharmaceuticals: The Union Cabinet recently approved Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The total financial outlay of the scheme is Rs. 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme has been notified on 3.3.2021 in the Gazette of India.

LOK SABHA
UNSTARRED QUESTION No. 4395
TO BE ANSWERED ON THE 23rd March, 2021

Production and Import of APIs

4395. SHRI P.P. CHAUDHARY:
SHRI FEROZE VARUN GANDHI:
SHRI KAUSHAL KISHORE:

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

(a) the details of Chemicals and their ingredients, like APIs, which are produced in India and which are imported;

(b) the details of Indian currency spent on the import of these chemicals and ingredients;

(c) the details of Indian manufacturers which were affected due to disruption caused by the global pandemic in the logistics and supply chains;

(d) whether any policy/scheme has been formulated to increase or facilitate production of the imported chemicals and their ingredients in the country to ensure safety of chemical products and adequate quantity for Indian market consumption; and

(e) if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a): As per Central Drugs Standard Control Organisation (CDSCO), the manufacture, sale and distribution of the drugs is regulated under Drugs and Cosmetics Act and rules there under. As per the said rules, the manufacturing licence for manufacturing of drugs is issued by state licensing authorities. CDSCO has no data regarding details of APIs manufactured in India. So far as import is concerned, as per the data available from port offices of CDSCO more than 700 APIs of various therapeutic categories such as Antibiotics, Vitamins, Hormones, Antiviral, Anti-TB, Anticonvulsant, Analgesic, Antipyretic, Antidiabetic, Cardiovascular etc. have been imported into country.

(b): As per the available data received from the various port offices of CDSCO, the details of value imports of various Bulk Drugs / Active Pharmaceutical Ingredients (APIs) during the last three years is as under:

Year	Value (in Cr.)
2018	7066
2019	8247
2020	8857

(c): As per National Pharmaceutical Pricing Authority (NPPA), at the onset of the pandemic there was an apprehension that supplies of essential APIs/KSMs from China might be disrupted. However, the NPPA did not receive any reference regarding shortage of medicines in the country in the ongoing pandemic.

(d) & (e): The Department of Pharmaceuticals has recently launched following three schemes for promoting domestic manufacturing of Pharmaceutical drugs including bulk drugs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

(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) In India: Under the scheme, financial incentive will be given for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Incentives for incremental sales will be given to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

(II) Scheme for Promotion of Bulk Drug Parks: This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

The above two schemes were notified on 21.07.2020 in the Gazette of India and the detailed guidelines of these schemes are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

(III) Production Linked Incentive Scheme for Pharmaceuticals: The Union Cabinet recently approved Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The total financial outlay of the scheme is Rs. 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme has been notified on 3.3.2021 in the Gazette of India.

LOK SABHA
UNSTARRED QUESTION No. 4405
TO BE ANSWERED ON THE 23rd March, 2021

Promotion of Pharma Manufacturing

†4405. SHRI DILESHWAR KAMAIT:
SHRI JUGAL KISHORE SHARMA:
SHRIMATI GEETA KORA:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:
(a) the details of the schemes implemented to promote domestic pharmaceutical manufacturing;

(b) whether indigenous pharmaceutical companies have reduced the country's dependence on foreign pharmaceutical products by manufacturing the same; and

(c) if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a): The Department of Pharmaceuticals has recently launched following three schemes for promoting domestic manufacturing of Pharmaceutical drugs including bulk drugs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries:-

(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) In India: Under the scheme, financial incentive will be given for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Incentives for incremental sales will be given to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

(II) Scheme for Promotion of Bulk Drug Parks: This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

The above two schemes were notified on 21.07.2020 in the Gazette of India and the detailed guidelines of these schemes are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in.

(III) Production Linked Incentive Scheme for Pharmaceuticals: The Union Cabinet recently approved Production Linked Incentive scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The total financial outlay of the scheme is Rs. 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme is from FY 2020-2021 to 2028-29. The scheme has been notified on 3.3.2021 in the Gazette of India.

(b) & ©: The schemes have been launched recently. The result of the schemes in terms of reduced dependence on foreign pharmaceutical products will be visible after 2-3 years.

LOK SABHA
UNSTARRED QUESTION No. †4509
TO BE ANSWERED ON 23rd March, 2021

Generic Medicines

†4509. SHRI BHANU PRATAP SINGH VERMA:

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

(a) whether the generic medicines are helpful for all especially for the poor and the deprived ones as they bring down the health care cost and if so, the details thereof;

(b) whether the Government has taken adequate measures to manufacture quality medicines in the name of generic medicines and to ensure their availability to the common people at affordable rates;

(c) if so, the details thereof;

(d) whether a legal framework is required to be developed to ensure quality in the testing of generic medicines;

(e) if so, whether the Government is taking any measure in this regard; and

(f) if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a) Yes Sir. As per the 71st Round (January-June 2014) of the National Sample Survey Office (NSSO) on Health in India, the purchase of medicines account for around 72% in rural sector and 68% in urban sector, of the total expenditure on non-hospitalized treatment of ailments. As such, with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP) was launched by the Department of Pharmaceuticals. Under the scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJK) are opened all over the country to provide generic medicines to the masses. As on 17.03.2021, 7523 PMBJKs are functional across the country. At present, the product basket of PMBJP comprises of 1450 drugs and 204 surgical instruments.

A medicine under PMBJP is priced on the principle of a maximum of 50% of the average price of top three branded medicines. Therefore, the cost of the Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. During the financial year 2019-20, PMBJP has achieved sales of Rs. 433.61 crores (at MRP). This has led to savings of approximately Rs. 2500 crores of the common citizens of the country. During the current financial 2020-21, sale of Rs. 613.23 crore has been made till 13.03.2021, which has led to savings of about Rs. 3700 crore to the citizens.

(b) & (c) The manufacturing, sale and distribution of Drugs in the country are regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection developed by the Ministry of Health & Family Welfare. The license for manufacturing, sale and distribution of Drugs are granted by State Licensing Authorities appointed by respective State Governments. The manufacturers are required to comply with the conditions of license and follow Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are of standard quality. All drugs manufactured in the country are required to comply with the standards prescribed under the said Act and Rules. The State Licensing Authorities are empowered to take action in case of any violation of above requirements. Further, Central Drugs Standard Control Organisation (CDSCO) & Ministry of Health & Family Welfare have taken various steps to ensure the quality of drugs including generic drugs manufactured/ marketed in the country.

In order to ensure the adequate availability of medicines at the PMBJKs under the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP), the logistics systems have been strengthened. At present, three **warehouses are functional** at Gurugram, Chennai and Guwahati and fourth one is under construction at Surat. Further, 37 distributors have been appointed across the country to support the supply of medicines to remote and rural areas.

(d) (e) & (f) The Government is committed to ensure that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening of legal provisions, organizing workshops and training programmes for manufacturers and regulatory officials and conducting risk-based inspections. As regard the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP), the medicines listed in the product list are procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products. Apart from this, each batch of drug is tested at laboratories accredited by the 'National Accreditation Board for Testing and Calibration Laboratories' (NABL). Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras.

LOK SABHA
UNSTARRED QUESTION NO. 4551
TO BE ANSWERED ON 23rd March, 2021

Monitoring Mechanism for Drug Supply

4551. SHRIMATI SAJDA AHMED:

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

(a) whether the Government has adopted any monitoring mechanism with real-time drug production and supply in domestic market and if so, the details thereof;

(b) whether the Government has taken note that during the pandemic, supply chain of essential drug was broken in rural areas and if so, the details thereof;

(c) whether the Government proposes any policy to ensure nationwide sufficient access of drugs including rural areas in view of future pandemic situation and if so, the details thereof; and

(d) whether there is any existing mechanism to monitor medicine outlets to confirm the availability of drugs and if so, the details thereof?

ANSWER
MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D.V. SADANANADA GOWDA)

(a): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) implements and enforce the provisions of the Drugs (Prices Control) Orders in accordance with the powers delegated to it. There is a mechanism of monitoring the production and availability of the essential drugs/ scheduled drugs under para 21 (1) the Drugs (Prices Control) Order, 2013 (DPCO, 2013) that provides for submission of quarterly return in respect of production/ import and sales of scheduled medicines and Active Pharmaceutical Ingredients (APIs) contained in scheduled formulations as stated in Form-III of Schedule-II of the DPCO, 2013 by a manufacturer/ importer/ marketer. Further, any manufacturer/importer wanting to discontinue manufacture / import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule-II of the DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production / import up to one year.

NPPA monitors shortage & non-availability of drugs on the basis of reports received from the State Drugs Controllers and complaints, if any, received from individuals. On receipt of such reports, NPPA immediately takes up the matter with the concerned manufacturer and advise them to rush the stock in the affected area. NPPA under the Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has set up Price Monitoring and Resource Units (PMRUs) in the State/ Union Territories. Till now, PMRUs have been set up in seventeen (17) States. Under the CAPPM Scheme advertising & publicity campaign/ seminars/ workshops/ webinars etc. are organised from time to time. Apart from this, consumers are made aware about the price fixation and availability of medicines.

(b): As per information provided by the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare, the CDSCO has not received any report that supply chain of essential drugs was broken in rural areas during the pandemic. Through greater interaction with the industry associations, manufacturers as well as state authorities, the Department of Pharmaceuticals took steps to ensure that supply chains were not compromised during lockdown and unlock phases.

Further, NPPA constituted an inter-ministerial Committee to monitor trends of export and import of APIs/Formulations and Medical Devices to ensure timely availability of key drugs, assess bottlenecks and impediments in imports of APIs and suggest possible alternative sources & export trend analysis to ensure domestic availability of key drugs and Medical Devices during the pandemic. Control Rooms were also set up by the Department of Pharmaceuticals and NPPA to ensure seamless availability of drugs.

(c) & (d): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, as an ongoing process, regularly monitors the production and availability of drugs under para 21 of the DPCO, 2013.

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