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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 13 (PAGES: 72) | 01 TO 07 APRIL 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

Clarivate along with IDMA and BDMAI are jointly organising the webinar

Webinar: Trends in global API manufacturing and strategic success in regulatory affairs

Friday, 16th April 2021 3:30PM – 5:00PM IST

(More details on Page No. 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 13** **01 to 07 April 2021**

IDMA ACTIVITIES:

RELEASE OF ADDENDUM 2021 TO INDIAN PHARMACOPOEIA 2018:

TRIBUNAL ORDINANCE

DGFT MATTERS:

GOVERNMENT COMMUNICATIONS:

PARLIAMENT NEWS:

NEW DEVELOPMENTS:

NATIONAL NEWS:

FEATURE:

Clarivate™

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Clarivate along with Indian Drug Manufacturers' Association (IDMA) and Bulk Drug Manufacturers Association (India) are jointly organising a webinar

"Trends in global API manufacturing and success in regulatory affairs" on 16th April 2021 at 3:30 pm IST

This webinar will cover two major topics:

Trends in global API manufacturing

In the first topic we will focus on an overview of the global API industry taking a deep dive into where top API manufacturers are located, their capabilities, and proficiency in specific product classes.

We will also look at the impact COVID-19 has had on supply chains and the API manufacturing industry, and provide tips to identify and evaluate potential portfolio candidates based on industry needs and trends.

What is the key to strategic success in regulatory affairs?

In the second topic we will talk about how to unlock a well-defined, multinational regulatory strategy. The pandemic has created many unforeseen challenges in adapting regulatory strategies to meet the needs of the day. Without a sound strategy, you'll struggle to get your life saving treatment approved and to patients. This limits both patient access to medicines your company creates as well as limiting commercial success.

Educating your regulatory affairs (RA) team and aligning your regulatory strategy across critical functions is key to driving success. By breaking down the process into manageable chunks, your RA team can take the lead in crafting a robust strategy interlinked with competitive analysis.

Topics that will be covered:

- An overview of the global API industry
- A deep dive into where top API manufacturers are located, their capabilities, and proficiency in specific product classes
- A look at the impact COVID-19 has had on supply chains and the API manufacturing industry
- Tips to identify and evaluate potential portfolio candidates based on industry needs and trends
- What is the definition of a regulatory strategy?
- What are the common challenges and how can we overcome them?
- How can we provide a pathway for continual improvement across our organization?
- How can we begin to implement these changes within our organization?

Join this webinar to gather a deeper understanding of the global API industry and uncover how you can design your regulatory strategy efficiently and confidently.

Register now.

The direct link to the webinar registration page is: **https://discover.clarivate.com/API_and_Regulatory_SAsia**

Looking forward to your usual active participation by way of registrations and in making this webinar a grand success.

Thanks & regards,

Daara Patel
Secretary General

Webinar: Trends in global API manufacturing andstrategic success in regulatory affairs

Friday, 16th April 2021 3:30PM – 5:00PM IST

In collaboration with Indian Drug Manufacturers' Association (IDMA) and BulkDrug Manufacturers' Association India (BDMA)

3:30 – 3:35 pm	Opening Address	**Mr. Yogin Majmudar** Past President Indian Drug Manufacturers'Association (IDMA) 5 min.
3:35 – 3:40 pm	Welcome Address	**Ms. Jo Butlin** VP Sales, Life Sciences R&D Clarivate, United Kingdom 5 min.
3.40 – 3.45 pm	Introduction	**Ms. Madhurima Datta** Manager – Pharma, South Asia Clarivate, India 5 min.
3.45 – 4.10 pm	**Trends in global API manufacturing** - An overview of the global API industry, - A deep dive into top API manufacturers - A look at the impact COVID-19 - Tips to identify potential portfolio candidates	**Dr. Leticia Fereira Terra** Solution Consultant Clarivate, Brazil 25 min.

4.10 – 4:35 pm	**What is the key to strategic success in regulatory affairs?** - Definition of a regulatory strategy - Common challenges and to overcome them - Pathway for continual improvement across the organization - Implementing the changes within organization	**Mr. Sam Kay** Solution Consultant Clarivate, United Kingdom25 min.
4.35 – 4:55 pm	**Q&A Session** - Trends in global API manufacturing - What is the key to strategic success in regulatory affairs?	**Panelists** • **Dr. Leticia Fereira Terra** Solution Consultant Clarivate, Brazil • **Mr. Sam Kay** Solution Consultant Clarivate, United Kingdom **Moderators** • **Ms. Parita Patel** Director Product Management, Generics Clarivate • **Ms. Madhurima Datta** Manager – Pharma, South Asia Clarivate, India 20 min.
4:55 – 5:00 pm	Vote of thanks	**Mr. V.V. Krishna Reddy**National President BDMA 5 min.

IDMA Representation to NPPA Chairperson on Unprecedented increase in the Prices of Paracetamol Active Pharmaceutical Ingredients (API) – reg.

The Association has submitted the following representation on 5th April 2021 to Smt Shubhra Singh, IAS, Chairperson, National Pharmaceutical Pricing Authority, New Delhi with copy to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association!

"When the National Pharmaceutical Pricing Policy (NPP), which forms the basis of the DPCO 2013, was presented in 2012, two broad objectives were outlined. Firstly, a regulatory framework to ensure availability of essential medicines at reasonable prices, and secondly, to provide sufficient opportunity for innovation and competition to support the growth of industry.

In the nine years since the NPP 2012, the pharmaceutical industry in India has ensured that the first objective has already been met as quality medicines are widely available and accessible across the country, at prices that are amongst the lowest in the world. However, the second objective has been severely impacted due to the surge in input costs over the past year. The egregious increase in input costs has not only affected activities across the pharmaceutical value chain but pharmaceutical companies are under intense pressure to maintain operating margins. The table below outlines the increase in costs shared by some of our members, broadly segregated across three components - raw materials, packing materials and freight costs.

Costs	Item	% Price Increase over last year
Raw material	Paracetamol	100%
Propylene Glycol		300%
Packing material	PET bottles	40%
PVC/PVDC		40%
Paper board		20%
Corrugated boxes		20%
Freight	Transportation costs	20%

The gyrating prices of many raw materials are a cause for serious concern. The recent spurt in the prices of the Active Pharmaceutical Ingredient (API) of Paracetamol, an essential antipyretic, is attributed to an escalation in the price of para amino phenol (PAP), a key starting material to manufacture Paracetamol, which is imported from China. Paracetamol has been under price control for the past eight years and its ceiling price has increased by 3% in the last eight years for the 125mg syrup while decreased by 3% in the last eight years for the 500mg tablet strengths. But in the same eight year period the price of the API of Paracetamol has almost tripled, and doubled within the last one year. but there is a huge disparity between increase in the API price of Paracetamol and the corresponding increase allowed in its ceiling price, for the same period. Additionally the price per kg of DCDA intermediates used in Metformin have increased from $1.90 to $3 and are soon expected to touch $4 per kg. Gliclazide prices have increased from $80 to $120 per kg.

The price of a derivative of artemisinin, an anti-malarial drug, which is cultivated in China and Central Asia, has gone up over 3 times in a year. Propylene Glycol, is used as a drug solubilizer in topical, oral, and injectable medications, and as a stabilizer for vitamins, and as a water-miscible cosolvent in liquid formulations. The price of Propylene Glycol which is used in almost every dosage form has increased four times in the last one year, impacting the cost of manufacturing across every type of formulation.

There has been an unprecedented rise in the cost of packing material like PVC/PVDC blister foils and PET bottles to the tune of 40% in the last twelve months. The cost of corrugated boxes and paper board, used for packing the formulations have gone up by 30 to 40 percent, due to a ban on the import of waste paper, leading to a shortage of pulp. Spiraling diesel prices have led to an increase of 20% in transportation costs.

The huge escalation in input and transportation costs as illustrated above, and their cascading effect on the pharmaceutical value chain, throws up severe challenges

to maintain the viability of the pharmaceutical business for many of our members.

You will appreciate, that despite the COVID-19 pandemic severely affecting the pharmaceutical industry in terms of input costs, operations and viability, the industry has ensured manufacturing and availability of all medicines at affordable prices throughout the pandemic.

Based on the above facts we have four recommendations that we request to be implemented within the framework of the existing price control mechanism to help us partially tide over these extremely exigent circumstances.

1) We request for an increase of 20% for all non-scheduled formulations for the current year over last year, under para 19 of DPCO 2013 as the circumstances are indeed extraordinary.

2) Please allow the prices of those scheduled formulations whose retail prices are below the ceiling price, to be raised up to the ceiling price. Many manufacturers of scheduled formulations are suffering on this count and para 13(2) of DPCO 2013 needs to be relaxed under the current circumstances.

3) Instead of the current method of revising the ceiling prices as per the Wholesale Price Index (WPI) which are announced annually in April every year, please hence forward revise the ceiling prices based on the Consumer Price Index (CPI) as it is a more realistic indicator of inflation. For instance the CPI was 6.7% in the calendar year 2020 as against only 0.54% WPI.

4) Under Para 18(i) of DPCO 2013, re-fixation of ceiling prices for common formulations between NLEM 2015 & NLEM 2021 would be undertaken. As a result of Para 18(i) the current ceiling price is much lower than the first ceiling price fixed under DPCO 2013 for many scheduled formulations. We fear, if the re-fixation of ceiling prices exercise is undertaken this year, it may lead to a further reduction in ceiling prices to the tune of 15 to 20%. In light of the current situation, we request that Para 18(i) of DPCO 2013 should be deleted or amended."

● ● ●

Narcotics Commissioner of India visit to IDMA Office on Thursday, March 25th, 2021

Shri Rajesh Dhabre, IRS - Narcotics Commissioner of India being welcomed by Mr Mahesh Doshi, National President, IDMA along with Mr Devesh Malladi, Chairman, NDPS Committee, Dr George Patani, Hon General Secretary, IDMA and Mr Daara B Patel, Secretary – General. Shri Onkar Mishra, Superintendent was also present.

Shri Rajesh Dhabre, IRS - Narcotics Commissioner of India along with Shri Onkar Mishra, Superintendent visited IDMA office on March 25th, 2021. Mr Mahesh Doshi, National President, IDMA, Mr Devesh Malladi, Chairman, NDPS Committee, Dr George Patani, Hon General Secretary, IDMA, Mr Daara B Patel, Secretary- General

along with Sr Members from the pharma industry were present at the said meeting.

The following issues were discussed:

1) Issuance of Import/Export NOCs:

   Delays in issuance of import/Export NOCs and digitalisation of the process of issuance of the same.

2) Route change for export consignments:

   Permit route change 48 hours prior to export of a consignment of Narcotic, Psychotropic or Controlled substances, by intimating CBN from the registered email IDs of the Companies.

3) Letter regarding substances not under the purview of NDPS:

   Issuance of letters by CBN, as requested by Trade, for certain substances which are controlled in other countries and not in India.

4) Online payment of fee through Bharatkosh for Import/ Export of Psychotropic substances:

   Delays in generation of challan leading to further delays in the submission of an application form through Bharatkosh.

5) Provision of deletion of product name on CBN portal:

   Provision for deletion of a product name on the CBN portal, for a Psychotropic substances which are discontinued by trade/industry.

6) Timely issuance of licenses or renewal of licenses of Manufactured or Essential Narcotic Drugs (ENDs), as per Rule 38), which stipulates 30 working days.

7) Permission for Destruction of Manufactured Drugs and Essential Narcotic Drugs, as per Rule 45-A, within 30 days from the date of receipt of such an application and the destruction carried out within a further period of 30 days, from the date of appointment of such a committee.

8) A quarterly VC meeting with CBN to resolve pending issues was also requested.

   A representation on the above points was also submitted to the Narcotics Commissioner's office.

● ● ●

Contribution of Multivitamins, Vitamin C, Zinc & Vitamin D3 Tablets to our Maharashtra Police Force

ATTENTION MEMBERS

We have received a letter from Shri Brijesh Singh, Special Inspector General of Police (Admin), Maharashtra State, Mumbai to provide Multivitamins, Vitamin C, Zinc & Vitamin D3 Tablets for our Maharashtra Police. Copy of their request letter is attached for your kind consideration and necessary action:

As you are aware, our Police Forces are striving very hard and protecting us 24/7 from this Covid-19 Pandemic, which has badly affected the entire Country for over a year. They have been serving the society selflessly despite the risk of themselves and their families being affected by this pandemic. This is an excellent opportunity for us to take care of the health of our Police Force and also a great CSR opportunity.

Last year on the behest of the letter received from Shri Krishna Prakash, IPS, Special Inspector General of Police (Admin), Maharashtra State, our Members had contributed Vitamin C, Vitamin D3 & Multivitamin tablets to our Maharashtra Police. Some of our members had contributed directly to the Maharashtra Police and hence, we don't have their list but the list of members who had contributed through IDMA office are as follows:-

(1)	**Abbott Healthcare**	**(2)**	**Amoli Organics/Umedica Labs.**
(3)	**Apex Laboratories**	**(4)**	**Bharat Parenterals**
(5)	**Blue Cross Laboratories Pvt. Ltd.**	**(6)**	**Fermenta Biotech Ltd.**
(7)	**Intas Pharmaceuticals Ltd.**	**(8)**	**Sun Pharmaceuticals Inds. Ltd.**
(9)	**USV Pvt Ltd.**		

The Maharashtra Police require 2 Lakh strips of Vitamin D3 (each strip consisting of 8 tablets), 4 Lakh Strips of Vitamin C & Zinc Tablets and also, 4 Lakh Strips of Zincovit Tablets for their Police Personnel. Request you to kindly supply the above mentioned tablets or any other equivalent tablets manufactured by your esteemed organization to them. Whatever generous contribution you make would be highly appreciated. The tablets may kindly be delivered to their Head office in Colaba, opposite Regal Theatre, Mumbai. The tablets may kindly be delivered to :-

PI Santosh Tore
Maharashtra Police Headquarters, Shahid Bhagat Singh Marg,
Opposite Regal Theatre, Coloba, Mumbai 400 001. Mobile # 9082126674

Mr Melvin Rodrigues (9821868758/actadm@idmaindia.com) will coordinate this activity on behalf of IDMA. Looking forward to your usual prompt and positive response. Thanks and regards, Please stay safe and stay well. Daara B Patel, Secretary-General, IDMA

D & I (ADMIN)/Vitamin/28/2021
महाराष्ट्र राज्य पोलीस मुख्यालय
Maharashtra Rajya Police Mukhyalaya
Shahid Bhagat Singh Marg, Colaba,
06 APR 2021

To,

The Secretary-General
Indian Drug Manufactures' Association
A/102, Poonam Chambers,
Dr. Annie Beasant Road,
Worli, Mumbai- 400 018.

Dear Shri Daara B. Patel

With reference to our discussions, we are thankful to your earlier support to the Maharashtra Police in this moment of pandemic crisis. As you all know that the Police Force is working at the front lines, protecting all in this moment. The health of police personnel is a prime concern today, as 34678 police have been tested positive, and we have lost 359 police personnel due to COVID-19 in Maharashtra State till date.

We require **2 lacs strips** of Vitamin D3 (each consisting of 8 tablets), **4 lacs strips** of Vitamin C Tablets and **4 lacs strips** of Zincovit Tablets for the police personnel of Maharashtra Police.

Thanking you in anticipation.

Yours truly,

(Brijesh Singh)
Spl. Inspector General of Police (Admin)
Maharashtra State, Mumbai.

Contact person : Santosh Tore, Asst. Police Inspector, Mob- 9082126674

Health and Wellness Conclave 2021: A Report

Health and Wellness Conclave presented by Social talks, was held at Hotel Madhuban, Rajpura Road, Dehradun, on 20th March 2021. The One-day wellness conclave focused on promoting Pharma in the field of health and wellness.

The conclave brought together the finest wellness visionaries from across the globe and industry leaders from India. Doctors, Professionals and other patrons of the wellness industry made Health and Wellness Conclave 2021 a mega success.

The conclave was inaugurated by Shri Ganesh Joshiji, Hon'ble Cabinet minister (MSME), Government of India, and Sadhvi Bhagawati Saraswati ji. The other dignitaries who graced the conclave with their presence were :

Dr Rajeev Singh Raghuvanshi, Secretary - cum - Scientific Director, Indian Pharmacopoeia Commission (IPC).

Dr Diwakar Sukul - Chairman - World Book of Records - London, UK.

Shri Atul Nasa - Deputy Drugs Controller - Delhi. Shri Daara B Patel - Secretary General – IDMA.

Dr Mrunal Jayant - United States Pharmacopoeia (USP),

Health and wellness conclave 2021 was supported by:

Indian Pharmacopoeia - Ministry of Health & Family Welfare - Government of India, United States Pharmacopeia, Indian Drug Manufacturers' Association & National Chamber of Pharmaceutical Manufacturers of Sri Lanka.

WBR - World Book of Records from London was the Prestigious Partner and Media Partner was Sahara News Network.

The health and wellness conclave began with lightening of the lamp.

Shri Atul Nasa, Deputy Drugs Controller, made presentation on Antimicrobial Resistance (AMR) (Presentation is reproduced in the following pages)

Dr Rajeev Singh Raghuvanshi, Secretary - cum - Scientific Director, Indian Pharmacopoeia Commission (IPC), made presentation on IPC's Role in Ensuring Quality and Promoting Rational Use of Antimicrobials in India (Presentation is reproduced in the following pages):


2021 HEALTH & WELLNESS CONCLAVE
IPC's Role in Ensuring Quality and Promo
Rational Use of Antimicrobials in
Indian Pharmacopoeia Commission
IPC
IDMA
SAHARA
KAMKU


NESS CONCLAVE
PRESTEGIOUS PARTNER
LLNESS
ONCLAVE
Social Talks
Health & Wellness


MEDIA PARTNER
SAHAR
NEWS NETW
HEALTH P
KAMKU


Antimicrobial Resis ce
Atul Nasa
Head of Office
Dy. Drugs Contr
Controlling and Licensin
(Email ID: atulnasa@gm


IPC
IDMA
2021
WE SS
C AVE

Presentation by Shri Atul Nasa, Deputy Drugs Controller, Delhi

Antimicrobial Resistance

Atul Nasa
Head of Office
Dy. Drugs Controller
Controlling and Licensing Authority
(Email ID: atulnasa@gmail.com)

20-03-2021

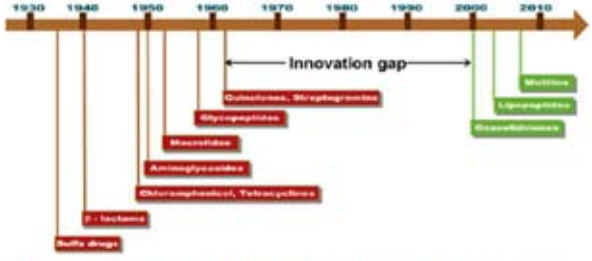
Antibiotics are Life Saving Medicines

- Discovery of Penicillin changed the practice of medicine
- Antibiotics are life saving in serious infections
- Most achievements in medicine – organ transplants, cancer treatment, major surgery – attributed to use of antibiotics

Alexander Fleming

20-03-2021

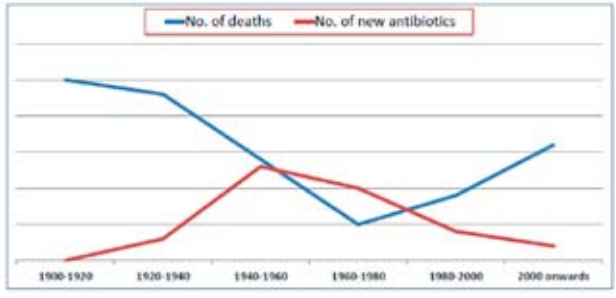
The Golden Age of Antimicrobials



Between 1962 & 2000, No New Class of Antibiotics Were Introduced!

20-03-2021

The Rise & Fall of Antibiotics



A Failing Market – Between 1960-2000, No Major Classes Were Introduced

20-03-2021

Statutory Functions

- Drugs & Cosmetics Act, 1940 and Rules made there under
- Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954
- Drugs (Prices Control) Order, 2013
- Medical Devices Rules, 2017

20-03-2021

Availability of Quality Drugs

- Availability of quality drugs is utmost important from the perspective of consumers health
- Spurious and Not of Standard Quality (NSQ) Drugs are a patient safety issue as :
  - It can challenge quality of treatment
  - lead to sub-therapeutic dosage
  - lead to emergence of drug resistance
  - Spread of diseases and cause economic burden on the society.

20-03-2021

Antimicrobial Resistance (AMR)

Antimicrobial resistance (AMR) is the development by a disease-causing microbe, through mutation or gene transfer, of the ability to survive exposure to an antimicrobial agent that was previously an effective treatment.

✓AMR is rapidly becoming a major public health risk and is threatening to undo decades of advances in treating disease.

✓**Antibiotic Resistance threatens to return us to the pre-antibiotic era**

20-03-2021

Causes of AMR .....

- **Misuse, Overuse, Inadequate use of antibiotics**
- **Sold without medical supervision/ without Prescription of R.M.P.**

Can be regulated under D & C Act, 1940 & Rules, 1945

- Prophylactic use before surgery
- Antibiotics used for viral infection
- Spread of resistant microbes in hospitals due to lack of hygiene
- Incomplete course of treatment taken by patient
- Antibiotics in Animal feeds

20-03-2021

Schedule H1 Drugs

- Restrict the over the counter sale of antibiotics
- State Drug Inspectors conduct surprise raids at the Chemist shops/Pharmacies to ensure that the Provisions of the Drugs and Cosmetics Rules especially in respect of **Schedule H1** are strictly complied by the licensees

Covers Three Major Categories of Drugs:

THIRD GENERATION & NEWER ANTIBIOTICS	ANTITB DRUGS	HABIT FORMING DRUGS
• Cephalosporin Group e.g. Cefixime • Levofloxacin • Others	• Isoniazid • Ethambutol • Refampicin • Pyrazinamide • Others	• Alprazolam • Codeine • Tramadol • Others

20-03-2021

Schedule H 1 Drugs (Rule 65 & 97)

In Schedule H1, following drug substances and their salts **(Total 46 drugs) excluding those intended for topical or external use (Except ophthalmic and ear or nose preparations):**

Alprazolam, Balofloxacin, Buprenorphine, Capreomycin, Cefdinir, Cefditoren, Cefepime, Cefetamet, Cefexime, Cefoperazone, Cefotaxime, Cefpirome, Cefpodoxime, Ceftazidime, Ceftibuten, Ceftizoxime, Ceftriaxone, Chlordiazepoxide, Clofazimine, Codeine, Cycloserine, Diazepam, Diphenoxylate, Doripenem, Ertapenem, Ethionamide, Feropenem, Gemifloxacin, Imipenem, Levofloxacin, Meropenem, Midazolam, Moxifloxacin, Nitrazepam, Pentazocine, Prulifloxacin, Sodium Para-aminosalicylate, Sparfloxacin, Thiacetazone, Tramadol and Zolpidem, Ethambutol HCl, Isoniazid, Pyrazinamide, Rifabutin, Rifampicin

20-03-2021

Schedule H Drugs

Rx

A Schedule H Drug

Composition

SCHEDULE H PRESCRIPTION DRUG – CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Manufactured By:

No requirement for maintaining the separate record in register of the sale of Schedule H drugs

20-03-2021

Schedule H1 Drugs

Rx

A Schedule H1 Drug

Composition

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION: - It is dangerous to take this preparation except under medical supervision. - Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Manufactured By:

Mandatory requirement for maintaining the separate record in register of the sale of Schedule H1 drugs

20-03-2021

Schedule H1 drugs

Conditions:

✓ The Supply of a drug specified in Schedule H1 shall be recorded in a **separate register** at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and,

✓ Such record shall be maintained for **Three Years** and be open for inspection.

Suggested Format for the record of Sale of Schedule H1 drugs

Sr. No.	Name of Product	Quantity Supplied	Quantity Prescribed	Bill. No. & Date	Patient Name	Patient Contact No.	Prescriber Name	Prescription Date

20-03-2021

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th March, 2018

F.No. Z-28015/2/2012-TR.—Whereas, the Central Government is satisfied, that tuberculosis is a dangerous epidemic disease, threat to life and is a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of tuberculosis is the cornerstone of tuberculosis prevention and control strategy. Further, inappropriate diagnosis and use poor or incomplete treatment with anti-tubercular drugs may contribute to complications, disease spread and emergence of drug resistant tuberculosis;

2. Whereas, to ensure proper tuberculosis diagnosis and its management in patients and their contacts and to reduce tuberculosis transmission and further to address the problems of emergence and spread of Drug Resistant-Tuberculosis, it is essential to collect complete information of all tuberculosis patients;

3. Now, therefore, in the interest of public health to control and prevent the tuberculosis disease, the Central Government, specify the following vis-a-vis, namely:-

(1) The Healthcare Providers, termed as Clinical Establishment hereforth, shall notify every tuberculosis patient to local Public Health Authority, namely, District Health Officer or Chief Medical Officer of a District and Municipal Health Officer of urban local bodies in whatever way they are known, or their designated District Tuberculosis Officers in a format as specified in, -

(i) Annexure-I by the Medical Laboratories;

(ii) Annexure-II by the Medical Practitioners.

(2) All Pharmacy, Chemists and Druggist dispensing anti-tubercular medicines, shall notify respective tuberculosis patients along with details of medicines as per Annexure-III and maintain a copy of prescription - Annexure-IV, the treating Medical Practitioner as per Schedule H1 of the Drugs and Cosmetics Rules, 1945, and shall forward the same either electronically or in hard copy, to the Nodal Officer of the District or any Officer authorized by Nodal Officer.

(3) Considering the importance of patient support needed for complete and appropriate treatment of all tuberculosis patients are encouraged to self-notify themselves with their own details and that of treating medical practitioners.

4. Definitions: For the purpose of this notification, unless the context otherwise requires, the expressions -

(i) 'Tuberculosis patient' means a patient diagnosed with at least one clinical specimen positive for acid fast bacilli, or culture positive for Mycobacterium tuberculosis or rapid diagnostic molecular test positive for tuberculosis, or any other tests recommended by Ministry of Health and Family Welfare, Government of India or a patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and initiated on anti-tubercular drugs.

(ii) "clinical establishment" shall have the meaning assigned to it, clause (c) of Section 2 of the Clinical Establishment Registration and Regulation Act, 2010, (23 of 2010).

5. List and contact details of the concerned State Tuberculosis Officers and District Tuberculosis Officers, shall be regularly updated by the Central Tuberculosis Division, in the Ministry of Health and Family Welfare, Government of India and made available on www.tbcindia.gov.in and http://tbcindia.gov.in/ who are responsible for implementation of tuberculosis notification in their respective areas of jurisdiction and shall ensure that following action is taken by local public health staff of general health system of rural or urban local bodies, on receipt of information on tuberculosis patient notification through hard copy or through online application named Nikshay.

(1) patient home visit as per convenience of patient;

(2) counselling of tuberculosis patient and family members.

20-03-2021

(3) treatment adherence and follow up support ensure treatment completion;

(4) contact tracing, symptoms screening, evaluation of tuberculosis symptomatics and offering isoniazid chemoprophylaxis to eligible contacts;

(5) offering HIV counselling and testing, drug susceptibility testing;

(6) linking with available social welfare and support schemes.

6. Secured web portal like http://Nikshay.gov.in/shall be made available by the Central Tuberculosis Division to all practitioners, clinical establishments, pharmacies, chemists, druggists and patients for end to end notification of the diseases.

7. The information on tuberculosis notification received by Public Health Staff, shall be used only for extending the care and support, take appropriate public health action as mentioned in paragraph 5 above, including financial and non-financial incentives to patients, like free drugs and diagnostics, screening for co-morbidities, drug susceptibility testing, information technology based treatment adherence support system for improving quality care, etc., and providing feedback to the respective treating medical practitioner; provided that the confidentiality of the individual identity of the tuberculosis patients shall be maintained.

8. Tuberculosis patients notified from Pharmacies, Chemists and Druggists and those patients self-notified, shall be contacted and verified by Public Health Authority or their authorized representative.

9. For tuberculosis patients notified from Medical Laboratory, Chemist and self-notification by tuberculosis patient, staff of public health system will gather information to complete notification which include basis of diagnosis, site of disease, history of anti-tubercular treatment and classify type of tuberculosis patient.

10. These measures shall prevail over the earlier measures issued vide order F.No. Z-28015/5/2012-TR, dated the 7th May 2012 and its amendment dated the 25th July 2015.

11. The Clinical Establishment, Pharmacy, Chemist and Druggist, failing to notify a tuberculosis patient to the nodal officer, as mentioned in paragraph 5 above and local public health staff of general health system of rural or urban local bodies, not taking appropriate public health action on receiving tuberculosis patient notification as per paragraph 5 above, may attract the provisions of sections 269 and 270 of the Indian Penal Code (45 of 1860), as the case may be, which are reproduced below:

"269. Negligent act likely to spread infection of disease dangerous to life. - Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine, or with both.

270. Malignant act likely to spread infection of disease dangerous to life. - Whoever malignantly does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to two years, or with fine, or with both."

ARUN KUMAR IDA, Economic Advisor

20-03-2021

Reporting Format for the Sale of Anti – TB Drugs

Annexure III **TB Notification reporting format for Pharmacy, Chemist & Druggist**

Period of reporting: From ...../...../..... To ...../...../.....

Name of the Reporting (pharmacy): ..... Telephone (with STD): .....

Mobile number: ..... Complete Address: .....

Sr. No.	Name of TB Patient (reference Rule *)	Father/ Husband's name	Age (in) *	Sex (Male/Female /Transgender) **	Full mail identification number *	Complete residential address	PIN no*	Patient Phone number	Date of TB Diagnosis**	Date of TB treatment initiation **	Date of prescription*	Date of Dispensing Medicine*	Number of Days for which Medicines dispensed*	Name of treating medical practitioner (Prescriber) *	Address & Registration no. of treating medical practitioner

* Mandatory ** Not mandatory

Signature: ..... Date: ...../...../.....

Submit the requisite information on online portal https://nikshay.gov.in or to report the same to the TB-Officer

20-03-2021

Management of AMR

(Role of Drugs Control Department)

- By ensuring the Quality of drug samples including Antimicrobials
- By ensuring the compliance of relevant provisions of Drugs & Cosmetics Rules 1945:
  - ✓ Presence of Registered Pharmacist – Patient Counselling,
  - ✓ Dispensing of drugs as per prescription
  - ✓ Ensuring the sale of drugs only as per Prescription of R.M.P.
  - ✓ To avoid multi-dispensing of drugs on a single prescription.
  - ✓ To avoid substitution of drugs prescribed by R.M.P.
  - ✓ Maintenance of Schedule H1 Register

20-03-2021

Management of AMR

(Role of Drugs Control Department)

- ✓ Maintenance of records of Anti-TB drugs in the prescribed proforma given by Govt. of India
- ✓ Ensuring proper storage conditions

- By restricting the sale of irrational FDCs recently banned by Govt. of India
- **By Education and training of chemists/pharmacies** through Chemist Associations for compliance of relevant provisions of Drugs & Cosmetics Rules 1945, including rational and appropriate dispensing of antimicrobials.
- The Department regularly participates in "Perfect Health Mela" in which officers of this Department **sensitize the general public/consumers** about Misuse/overuse, Inadequate use of antibiotics, Prescriptions to be taken correctly, Potency upto Expiry date and Do's & Don't for the consumers.

20-03-2021

Presentation by Dr Rajeev Singh Raghuvanshi, Secretary - cum - Scientific Director, Indian Pharmacopoeia Commission (IPC)

IPC's Role in Ensuring Quality and Promoting Rational Use of Antimicrobials in India

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002

Antimicrobials

- Includes antibiotics, antivirals, antifungals, and antiparasitics
- Medicines used to prevent and treat infections in humans and animals

Antimicrobial Resistance (AMR)

- AMR occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to antimicrobials
- Makes infections harder to treat and increasing the risk of disease spread, severe illness, and death
- Antibiotics and other antimicrobial medicines become ineffective and infections become increasingly difficult or impossible to treat

2

Emergence and Spread of AMR

- AMR occurs naturally over time, usually through genetic changes
- The main drivers of antimicrobial resistance include:
  - Misuse and overuse of antimicrobials
  - Poor infection and disease prevention and control in health-care facilities
  - Poor access to quality medicines
- AMR organisms are found in humans, animals, food, plants and the environment (in water, soil and air)
- They can spread from person to person or between people and animals, including from food of animal origin.

3

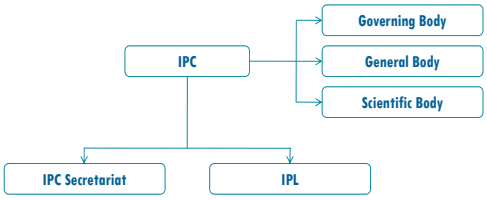
Quality of Antimicrobials

- Many ways in which antimicrobials can be of poor quality:
  - Low antimicrobial content
  - Poor formulation
  - Containing impurities, intermediary compounds or isomers
- Consequences of poor quality antimicrobials are treatment failure, prolonged illness, adverse drug reactions, and increased rates of morbidity and mortality
- Poor quality antimicrobials may lead to lower, sub-inhibitory concentrations of the API leading to treatment failure probably due to development of AMR
- Pharmacopoeia addresses this issue through setting drug standards for ensuring the quality, safety and efficacy of antimicrobials

4

Indian Pharmacopoeia Commission (IPC)

- An autonomous Institute established on 1st January 2009 under the Ministry of Health & Family Welfare, Govt. of India
- Three tier structure comprising of Governing Body, General Body and Scientific Body
- Various Expert Working Groups to guide on setting drug standards



5

IPC Mission

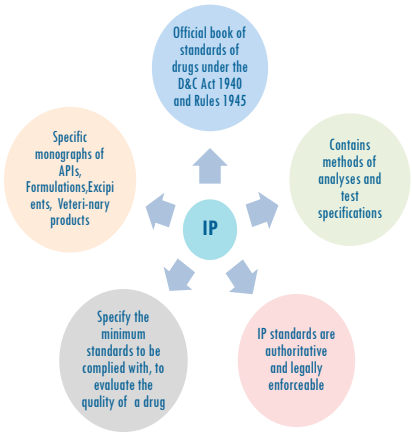
- To promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including APIs, excipients and dosage forms, used by healthcare professionals, patients and consumers

IPC Vision

- To promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacture and analysis

6

Indian Pharmacopoeia (IP)

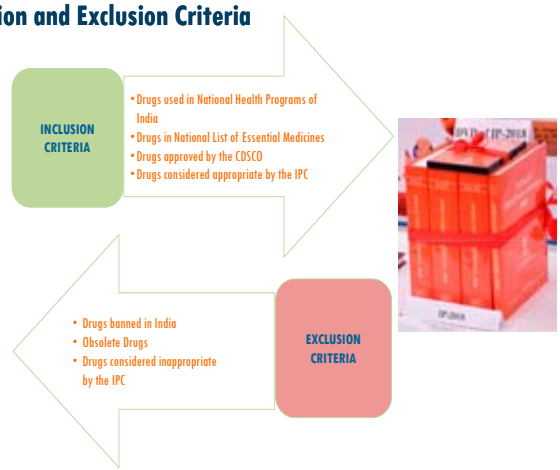


7

IP Monograph Development

8

Inclusion and Exclusion Criteria



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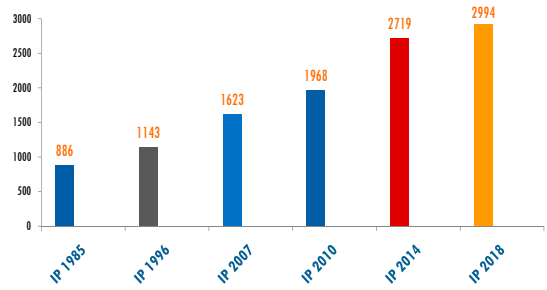
Journey of IP Editions

10

Release of IP Editions

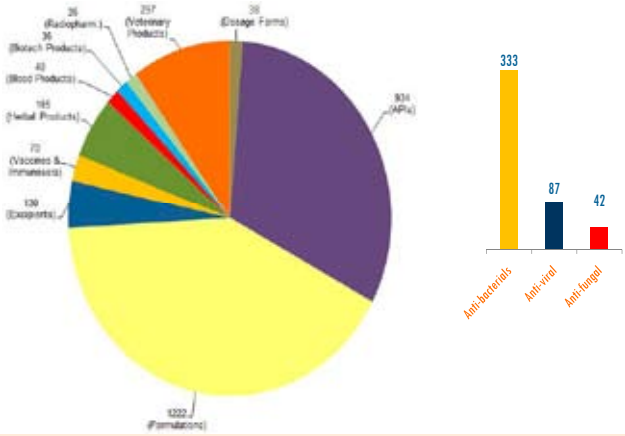
11

IP Monograph Development



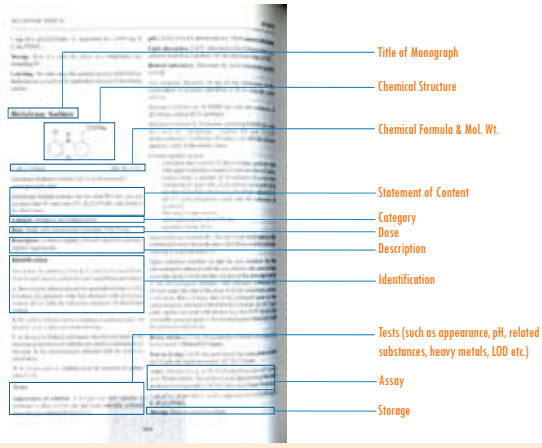
12

IP 2018: Monograph Status



13

IP Monograph Structure



14

Up-gradation of Antimicrobial Standards: Albendazole

- Albendazole is an effective treatment for a range of parasitic diseases
- Disintegration test addresses concerns about the efficacy of chewable tablets that are swallowed whole, either intentionally or unintentionally
- For Albendazole chewable tablets, disintegration testing cannot replace dissolution testing as the solubility of Albendazole at 37°C throughout the physiological pH range (pH value 1-7.5) is reported to be low
- Failure to comply with a dissolution test indicates that the bioavailability of the product is too low, leading to ineffective products in use for mass administration
- Surveys have shown that the dissolution properties of Albendazole chewable tablets on the market are poor
- Dissolution test included in the IP monograph of Albendazole in January 2019 to ensure the quality of the marketed products in India

15

Setting Standards of COVID-19 Related Drugs

- New Monograph Additions
  - Remdesivir API & Injection
  - Favipiravir API & Tablets
  - Ivermectin Tablets
- Monograph Revisions
  - Hydroxychloroquine Sulphate
  - Isopropyl Alcohol
  - Isopropyl Rubbing Alcohol
- Reference Standard Development
  - Favipiravir
  - Hydroxychloroquine Sulphate
  - Ivermectin
  - Azithromycin
  - Dexamethasone

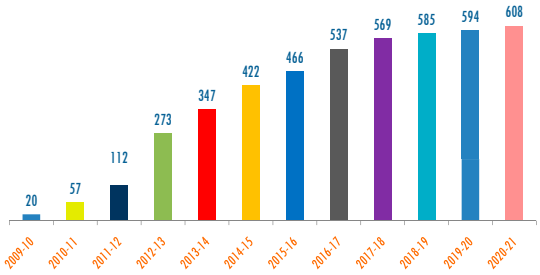
16

Antimicrobial Standards Under Development

- New Monographs being Developed
  - Itraconazole
  - Itaconazole Tablets — Fungal infections
  - Valacyclovir
  - Valacyclovir Tablets — Herpes zoster
  - Sofosbuvir — Chronic hepatitis C
  - Zanamivir — Common flu

17

Development of IP Reference Substances



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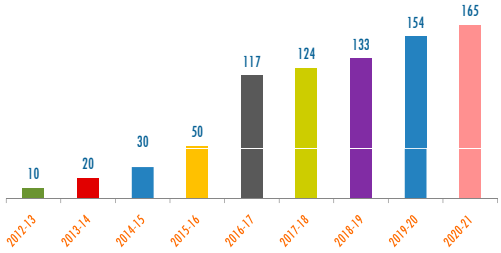
Development of Impurities



19

NFI: Reference Book for Rational Use of Medicines

- Published by IPC at regular interval to promote the rational use of medicines in India
- An advisory/reference document for healthcare professionals
- Contains monographs for therapeutics that are rational, economical and based on disease profile
- NFI monographs provide details on appropriate dose to be used
- Also monographs on rational combinations of drugs are included
- Development of AMR may be minimized during treatment of infections by:
  - use of appropriate dose, and
  - rational combinations of the antimicrobials

20

NFI 2021: Monograph Status of Anti-infectives

- NFI 2021 (6th edition) with total 591monographs
- Dedicated chapter on anti-infectives with 126 drug monographs:
  - Antiamoebic, Antigiardial and Antitrichomonial Drugs : 06
  - Antibacterial Drugs : 41
  - Antifilarial Drugs : 02
  - Antifungal Drugs : 08
  - Anthelminthics : 05
  - Anti-Leishmaniasis Drugs : 03
  - Antimalarial Drugs : 13
  - Antimycobacterial Drugs : 20
  - Antiretrovirals : 22
  - Drugs for Schistosomiasis : 01
  - Antiviral Drugs : 05
- Separate appendix on AMR to understand the development of AMR and to overcome the same

21

Acknowledgement

….. and others

Thank You

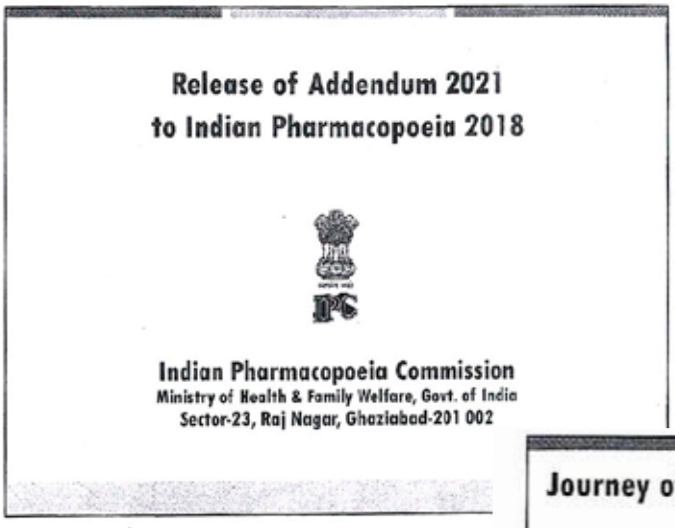
22

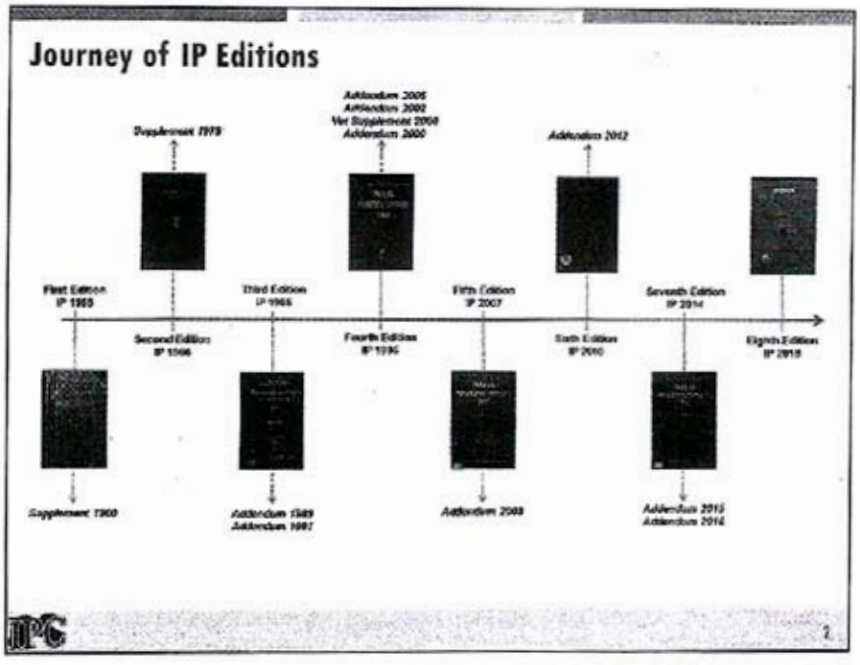
Release of IP Addendum 2021 on 31st March 2021.

In order to further strengthen the standards of the drugs being manufactured and/or marketed in India, IPC has come out with the publication of the Addendum 2021 to Indian Pharmacopoeia (IP) 2018. Shri Rajesh Bhushan, Secretary-Health & Family Welfare, Government of India and Chairperson-Indian Pharmacopoeia Commission (IPC) released the IP Addendum 2021 on 31st March 2021 at Nirman Bhawan, New Delhi in presence of the officials of Ministry of Health & Family Welfare, Government of India, representatives of various Pharma Associations, and IPC officials.

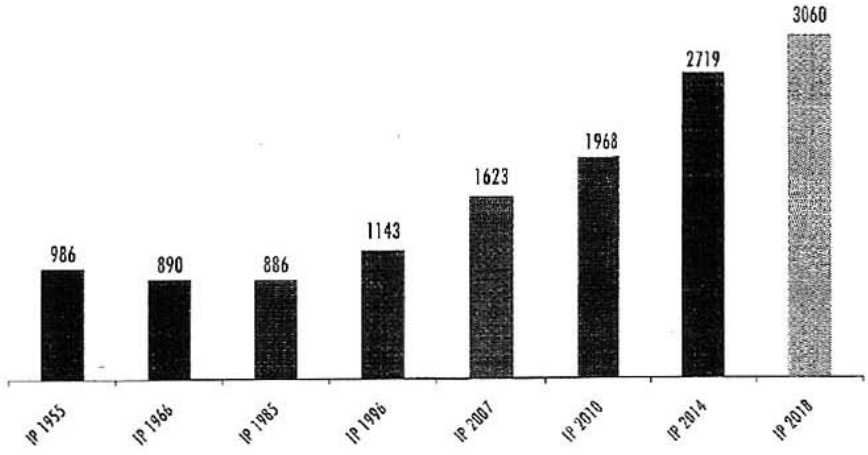
Addendum 2021 to IP 2018 contains a total of 66 new drug monographs [including 59 Chemical, 05 Herbs & Herbal Products, and 02 Blood & Blood-Related Products] and 04 new General Chapters. In addition, a total of 260 monograph amendments have also been included in the content of the IP Addendum 2021 that would further upgrade the quality of drug standards included in the IP. The effective date of this Addendum has been kept as 1st October 2021 and a total period of six months is being given to the stakeholders to implement the new standards included therein.

On this occasion, Sh. Rajesh Bhushan appreciated the contributions of members of the Scientific Body of IPC, various Expert Working Groups of IP, and IPC scientists in bringing out this Addendum 2021. He further expressed that with the publication of IP Addendum 2021, IP will make a big contribution for overall strengthening of the drugs regulation in India.





IP Monograph Development



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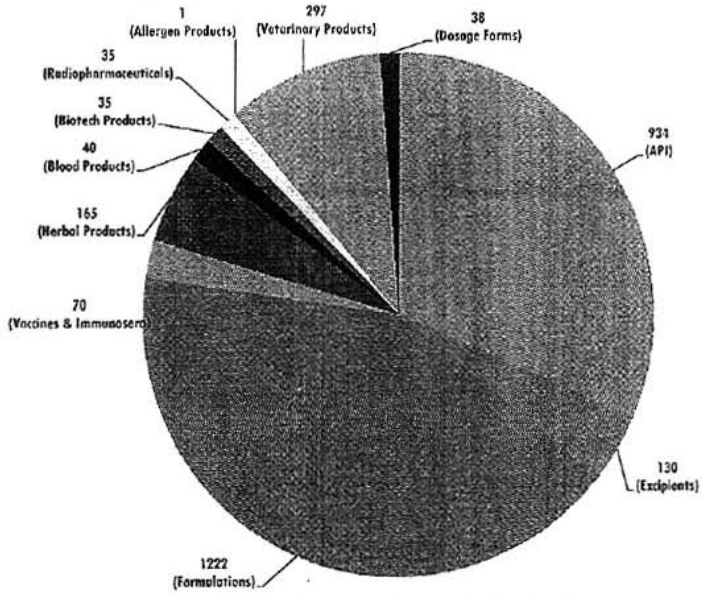
IP 2018: Monograph Status



4

IP Addendum 2021: Salient Features

- Effective Date: 1st October 2021
- New Monograph Additions: 66
  - Chemical : 59
  - Herbs & Herbal Products: 05
  - Blood & Blood Related Products: 02
- New General Chapters: 04
- FDC Monographs: 13
- Monograph Revisions/Amendments: 260
- Monographs on COVID-19 Related Drugs
  - Favipiravir API & Tablets
  - Remdesivir API & Injection
  - Ivermectin Tablets
- IP is first Pharmacopoeia to have standards of these drugs

IPC 5

IP Addendum 2021: New Monograph Additions

- Category wise Additions
  - Antidiabetic: 02 (Vildagliptin API & Tab)
  - Antimalarial: 02 (Lumefantrine API & its combination)
  - Antihypertension: 05 (e.g. Amlodipine combinations)
  - Antiviral: 06 (e.g. Favipiravir, Remdesivir)
  - Antiretroviral: 06 (e.g. Dolutagravir API & its combination)
  - Antianaemic: 03 (Ferrous aascorbate & its combinations)
  - Antibacterial: 03 (Tigecycline & its formulation)
  - Antifungal: 03 (Luliconazole & its formulations)
- Monograph Revisions
  - Glycerin (Capillary GC method for RS)
  - Hydroxychloroquine sulphate (Assay by HPLC, Test for RS)
  - Isopropyl alcohol (Capillary GC method for RS)
  - Isopropyl rubbing alcohol (Assay by GC method)

IPC 6

IP Addendum 2021: New Monograph Additions

- Blood & Blood Related Products
  - Blood grouping reagents used by blood transfusion services & diagnostic laboratories
  - New monographs will strengthen the quality assurance systems in blood transfusion services
  - Also help manufacturers of these blood grouping reagents to ensure standard quality of blood grouping reagents
- Herbs & Herbal Products
  - Bael: Fruits used in Sharbat/Murabba (antidiabetic)
  - Chaulai: Superfood containing high content of proteins, vitamins, mineral (improve digestion)
  - Patha: Historically used to treat ulcers, wound, snakebite, malaria (antipyretic)
  - Upakunchika: To treat asthma, bronchitis, inflammation (antidiarrheal)

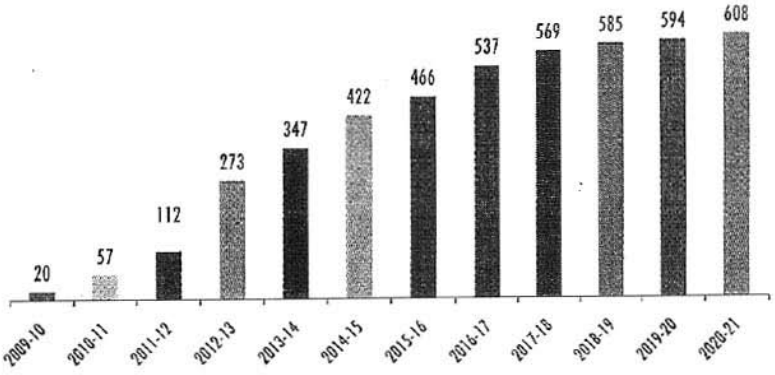
IPC 7

IP Addendum 2021: Monograph Up-gradations

- Chemical Monographs Revisions
  - Addition of Test for Related Substances: 04 (e.g. Thyroxine Tab)
  - Revision of Test for Related Substances: 18 (e.g. Piperacillin & Tazobactam Inj, Lamivudine & Zidovudine Tab)
  - Identification (TLC to HPLC): 02 (e.g. Ormeloxifene HCl)
  - Test for Related Substances (TLC to HPLC): 01 (e.g. Hyoscine butylbromide)
  - Dissolution (UV to HPLC): 02 (e.g. Sodium valproate GR Tab)
  - Addition of Dissolution: 01 (e.g. Thyroxine Tab, Sulfasalazine GR Tab)
  - Revision of Assay: 02 (e.g. Hydroclorathiazide Tab)

IPC 8

Development of IP Reference Substances



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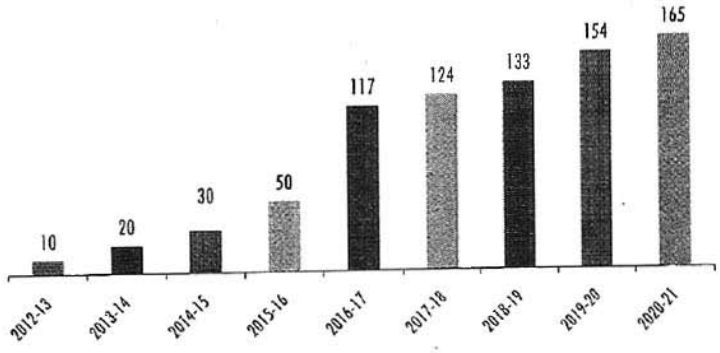
Development of Impurities



12

Sale of IP & IPRS: Revenue Generation

Sale of IP

2015-16	Rs. 96.76 Lacs
2016-17	Rs. 100.89 Lacs
2017-18	Rs. 642.87 Lacs
2018-19	Rs. 495.44 Lacs
2019-20	Rs. 287.95 Lacs
2020-21	Rs. 92.50 Lacs
Total	Rs. 1716.41 Lacs

Sale of IPRS

2015-16	Rs. 192.04 Lacs
2016-17	Rs. 261.38 Lacs
2017-18	Rs. 455.38 Lacs
2018-19	Rs. 517.80 Lacs
2019-20	Rs. 474.88 Lacs
2020-21	Rs. 525.39 Lacs
Total	Rs. 2426.87 Lacs

TOTAL: 4143.28 Lacs

IPC 13

Government decides to shutdown IPAB: A Victory for IDMA and the Indian Pharmaceutical Industry

ATTENTION MEMBERS

We, at IDMA, tried to block undue exploitation by MNCs and their International Associations and Associates through their influence in IPAB. Moreover, the Commercial Courts in India have come of age and maturity to impartially hear IP/Patent matters. Overall, a very welcome development. This could not have been possible without the blessings of the National President and the active support of Daara ji ! A Team work.

With this IPAB comes to an end, a great victory for IDMA.

Dr Gopakumar G Nair

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 4*th April,* 2021/*Chaitra* 14, 1943 (*Saka*)

THE TRIBUNALS REFORMS (RATIONALISATION AND CONDITIONS OF SERVICE) ORDINANCE, 2021

NO. 2 OF 2021

Promulgated by the President in the Seventy-Second Year of the Republic of India.

An Ordinance further to amend the Cinematograph Act, 1952, the Customs Act, 1962, the Airports Authority of India Act, 1994, the Trade Marks Act, 1999 and the Protection of Plant Varieties and Farmers' Rights Act, 2001 and certain other Acts.

WHEREAS The Tribunal Reforms (Rationalisation and Conditions of Service) Bill, 2021 has been introduced in the House of the People on the 13th day of February, 2021;

AND WHEREAS the aforesaid Bill could not be taken up for consideration and passing in the House of the People;

AND WHEREAS Parliament is not in session and the President is satisfied that circumstances exist which render it necessary for him to take immediate action;

NOW, THEREFORE, in exercise of the powers conferred by clause (1) of article 123 of the Constitution, the President is pleased to promulgate the following Ordinance:—

CHAPTER I

PRELIMINARY

Short title and commencement.

1.(*1*) This Ordinance may be called the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021.

(*2*) It shall come into force at once.

Definitions.

2.In this Ordinance, unless the context otherwise requires,–

(a) "notified date" means the date of commencement of this Ordinance;

(b) "Schedule" means the Schedule appended to this Ordinance;

CHAPTER II

AMENDMENTS TO THE CINEMATOGRAPH ACT, 1952

Amendment of Act 37 of 1952.

3. In the Cinematograph Act, 1952, —

(a) in section 2, clause (h) shall be omitted;

(b) in section 5C,–

(i) for the word "Tribunal", at both the places where it occurs, the words "High Court" shall be substituted;

(ii) sub-section (2) shall be omitted;

(c) sections 5D and 5DD shall be omitted;

(d) in section 6, the words "or, as the case may be, decided by the Tribunal (but not including any proceeding in respect of any matter which is pending before the Tribunal)" shall be omitted;

(e) in sections 7A and 7C, for the word "Tribunal", wherever it occurs, the words "High Court" shall be substituted;

(f) in sections 7D, 7E and 7F, the words "the Tribunal,", wherever they occur, shall be omitted;

(g) in section 8, in sub-section (2), clauses (h), (i), (j), and (k) shall be omitted.

CHAPTER III

AMENDMENTS TO THE COPYRIGHT ACT, 1957

Amendment of Act 14 of 1957.

3. In the Copyright Act, 1957,—

(a) in section 2,—

(i) clause (aa) shall be omitted;

(ii) clause (fa) shall be re-lettered as clause (faa) and before the clause (faa) as so re-lettered, the following clause shall be inserted, namely:—

'(fa) "Commercial Court", for the purposes of any State, means a Commercial Court constituted under section 3, or the Commercial Division of a High Court constituted under section 4, of the Commercial Courts Act, 2015;'; 4 of 2016.

(iii) for clause (u), the following clause shall be substituted, namely:—

'(u) "prescribed" means,—

(A) in relation to proceedings before a High Court, prescribed by rules made by the High Court; and

(B) in other cases, prescribed by rules made under this Act;';

(b) in section 6,—

(i) for the words "Appellate Board", wherever they occur, the words "Commercial Court" shall be substituted;

(ii) the words "constituted under section 11 whose decision thereon shall be final" shall be omitted;

(c) in Chapter II, in the Chapter heading, the words "AND APPELLATE BOARD" shall be omitted;

(d) sections 11 and 12 shall be omitted;

(e) in sections 19A, 23, 31, 31A, 31B, 31C, 31D, 32, 32A and 33A, for the words "Appellate Board", wherever they occur, the words "Commercial Court" shall be substituted;

(f) in section 50, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(g) in section 53A,—

(i) for the words "Appellate Board", wherever they occur, the words "Commercial Court" shall be substituted;

(ii) in sub-section (2), the words "and the decision of the Appellate Board in this behalf shall be final" shall be omitted;

(h) in section 54, for the words "Appellate Board", the words "Commercial Court" shall be substituted;

(i) for section 72, the following section shall be substituted, namely:—

Appeals against orders of Registrar of Copyrights.

"72. (1) Any person aggrieved by any final decision or order of the Registrar of Copyrights may, within three months from the date of the order or decision, appeal to the High Court.

(2) Every such appeal shall be heard by a single Judge of the High Court:

Provided that any such Judge may, if he so thinks fit, refer the appeal at any stage of the proceeding to a Bench of the High Court.

(3) Where an appeal is heard by a single Judge, a further appeal shall lie to a Bench of the High Court within three months from the date of decision or order of the single Judge.

(4) In calculating the period of three months provided for an appeal under this section, the time taken in granting a certified copy of the order or record of the decision appealed against shall be excluded.";

(j) in sections 74 and 75, the words "and the Appellate Board", wherever they occur, shall be omitted;

(k) in section 77, the words "and every member of the Appellate Board" shall be omitted;

(l) in section 78, in sub-section (2),—

(i) clauses (cA) and (ccB) shall be omitted;

(ii) in clause (f), the words "and the Appellate Board" shall be omitted.

CHAPTER IV

AMENDMENTS TO THE CUSTOMS ACT, 1962

Amendment of Act 52 of 1962.

5. In the Customs Act, 1962,–

(a) in section 28E, clauses (ba), (f) and (g) shall be omitted;

(b) in section 28EA, the proviso shall be omitted;

(c) in section 28F, sub-section (1) shall be omitted;

(d) in section 28KA,—

(i) in sub-section (1), for the word "Appellate Authority", at both the places where they occur, the words "High Court" shall be substituted;

(ii) sub-section (2) shall be omitted;

(e) in section 28L, the words "or Appellate Authority", wherever they occur, shall be omitted;

(f) in section 28M,—

(i) in the marginal heading, the words "and

Appellate Authority" shall be omitted;

(ii) sub-section (2) shall be omitted.

CHAPTER V

AMENDMENTS TO THE PATENTS ACT, 1970

Amendment of Act 39 of 1970.

6. In the Patents Act, 1970,—

(a) in section 2, in sub-section (1),—

(i) clause (a) shall be omitted;

(ii) in clause (u), sub-clause (B) shall be omitted;

(b) in section 52, the words "Appellate Board or", wherever they occur, shall be omitted;

(c) in section 58,—

(i) the words "the Appellate Board or", wherever they occur, shall be omitted;

(ii) the words "as the case may be" shall be omitted;

(d) in section 59, the words "the Appellate Board or" shall be omitted;

(e) in section 64, in sub-section (1), the words "by the Appellate Board" shall be omitted;

(f) in section 71, for the words "Appellate Board" and "Board", wherever they occur, the words "High Court" shall be substituted;

(g) in section 76, the words "or Appellate Board" shall be omitted;

(h) in section 113,—

(i) in sub-section (1),—

(A) the words "the Appellate Board or", wherever they occur, shall be omitted;

(B) the words "as the case may be" shall be omitted;

(ii) in sub-section (3), the words "or the Appellate Board" shall be omitted;

(i) in Chapter XIX, for the Chapter heading, the Chapter heading "APPEALS" shall be substituted;

(j) sections 116 and 117 shall be omitted;

(k) in section 117A, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(l) sections 117B, 117C and 117D shall be omitted;

(m) in section 117E, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(n) sections 117F, 117G and 117H shall be omitted;

(o) in section 151,—

(A) in sub-section (1), the words "or the Appellate Board", at both the places where they occur, shall be omitted;

(B) in sub-section (3), for the words "the Appellate Board or the courts, as the case may be", the words "the courts" shall be substituted;

(p) in section 159, in sub-section (2), clauses (xiia), (xiib) and (xiic) shall be omitted.

CHAPTER VI

AMENDMENTS TO THE AIRPORT AUTHORITY OF INDIA ACT, 1994

Amendment of Act 55 of 1994.

7. In the Airports Authority of India Act, 1994,—

(a) in section 28A, clause (e) shall be omitted;

(b) in section 28E, for the word "Tribunal", at both the places where it occurs, the words "Central Government" shall be substituted;

(c) sections 28I, 28J and 28JA shall be omitted;

(d) in section 28K,——

(i) in sub-section (1),—

(A) for the words "Tribunal in such form as may be prescribed", the words "High Court" shall be substituted;

(B) in the proviso, for the word "Tribunal", the words "High Court" shall be substituted;

(ii) sub-sections (2), (3), (4) and (5) shall be omitted;

(e) section 28L shall be omitted;

(f) in section 28M, the words "or the Tribunal" shall be omitted;

(g) in section 28N, in sub-section (2), for the word "Tribunal", the words "High Court" shall be substituted;

(h) in section 33, the words "or the Chairperson of the Tribunal" shall be omitted;

(i) in section 41, in sub-section (2), clauses (gvi), (gvii), (gviii) and (gix) shall be omitted.

CHAPTER VII

AMENDMENTS TO THE TRADE MARKS ACT, 1999

Amendment of Act 47 of 1999.

8. In the Trade Marks Act, 1999,—

(a) in section 2, in sub-section (1), —

(i) clauses (a), (d), (f), (k), (n), (ze) and (zf) shall be omitted;

(ii) for clause (s), the following clause shall be substituted, namely:—

'(s) "prescribed" means,—

(i) in relation to proceedings before a High Court, prescribed by rules made by the High Court; and

(ii) in other cases, prescribed by rules made under this Act;';

(b) in section 10, for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(c) in section 26, for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(d) in section 46, in sub-section (3), for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(e) in section47, —

(i) for the words "Appellate Board", at both the places where it occurs, the words "High Court" shall be substituted;

(ii) for the word "tribunal", wherever it occurs, the words "Registrar or the High Court, as the case may be," shall be substituted;

(f) in section 55, in sub-section (1), for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(g) in section 57, —

(i) for the words "Appellate Board", wherever it occurs, the words "High Court" shall be substituted;

(ii) for the word "tribunal", wherever it occurs, the words "Registrar or the High Court, as the case may be," shall be substituted;

(h) in section 71, in sub-section (3), for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(i) in Chapter XI, for the Chapter heading, the

Chapter heading "APPEALS" shall be substituted;

(j) sections 83, 84, 85, 86, 87, 88, 89, 89A and 90 shall be omitted;

(k) in section 91,for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(l) sections 92 and 93 shall be omitted;

(m) for section 94, the following section shall be substituted, namely:—

Bar to appear before Registrar.

"94. On ceasing to hold the office, the erstwhile Chairperson, Vice-Chairperson or other Members, shall not appear before the Registrar.";

(l) sections 95 and 96 shall be omitted;

(m) in section 97, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(n) in section 98, for the words "Appellate Board" and "Board", wherever they occur, the words "High Court" shall be substituted;

(o) sections 99 and 100 shall be omitted;

(p) in section 113, —

(i) for the words "Appellate Board", at both the places where they occur, the words "High Court" shall be substituted;

(ii) for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(q) in section 123, the words "and every Member of the Appellate Board" shall be omitted;

(r) in sections 124 and 125, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(s) in section 130, the words "the Appellate Board or" shall be omitted;

(t) in section 141, for the words "Appellate Board", at both the places where they occur, the words "High Court" shall be substituted;

(u) in section 144, for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(v) in section 157, in sub-section (2),—

(i) clauses (xxxi) and (xxxii) shall be omitted;

(ii) in clause (xxxiii), for the words "Appellate Board", the words "High Court" shall be substituted.

CHAPTER VIII

AMENDMENTS TO THE GEOGRAPHICAL INDICATIONS OF GOODS (REGISTRATION AND PROTECTION) ACT, 1999

Amendment of Act 48 of 1999.

9. In the Geographical Indications of Goods (Registration and Protection) Act, 1999,—

(a) in section 2, in sub-section (1), clauses (a) and (p) shall be omitted;

(b) in section 19, for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(c) in section 23, for the words "and before the Appellate Board before which", the words "before whom" shall be substituted;

(d) in section 27, —

(i) for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(ii) for the word "tribunal", wherever it occurs,

the words "Registrar or the High Court, as the case may be," shall be substituted;

(e) in Chapter VII, for the Chapter heading, the Chapter heading "APPEALS" shall be substituted;

(f) in section 31,—

(i) for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(ii) sub-section (3) shall be omitted;

(g) sections 32 and 33 shall be omitted;

(h) in sections 34 and 35, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(i) section 36 shall be omitted;

(j) in sections 48,—

(i) for the words "Appellate Board", at both the places where it occurs, the words "High Court" shall be substituted;

(ii) for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(k) in sections 57 and 58, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(l) in section 63, the words "the Appellate Board or" shall be omitted;

(m) in section 72, for the words "Appellate Board", wherever they occur, the words "High Court" shall be substituted;

(n) in section 75, for the word "tribunal", the words "Registrar or the High Court, as the case may be," shall be substituted;

(o) in section 87, in sub-section (2), clause (n) shall be omitted.

CHAPTER IX

AMENDMENTS TO THE PROTECTION OF PLANT VARIETIES AND FARMERS' RIGHTS ACT, 2001

Amendment of Act 53 of 2001.

10. In the Protection of Plant Varieties and Farmers' Rights Act, 2001,–

(a) in section 2, —

(i) clauses (d), (n) and (o) shall be omitted;

(ii) for clause (q), the following clause shall be substituted, namely:—

'(q) "prescribed" means,—

(A) in relation to proceedings before a High Court, prescribed by rules made by the High Court; and

(B) in other cases, prescribed by rules made under this Act;':

(iii) clauses (y) and (z) shall be omitted;

(b) in section 44, the words "or the Tribunal" shall be omitted;

(c) in Chapter VIII, for the Chapter heading, the Chapter heading "APPEALS" shall be substituted;

(d) sections 54 and 55 shall be omitted;

(e) in section 56,—

(i) for the word "Tribunal", wherever they occur, the words "High Court" shall be substituted;

(ii) sub-section (3) shall be omitted;

(f) in section 57,–

(i) for the word "Tribunal", wherever it occurs, the words "High Court" shall be substituted;

(ii) sub-section (5) shall be omitted;

(g) sections 58 and 59 shall be omitted;

(h) in section 89, the words "or the Tribunal" shall be omitted.

CHAPTER X

AMENDMENTS TO THE CONTROL OF NATIONAL HIGHWAYS (LAND AND TRAFFIC) ACT, 2002

Amendment of Act 13 of 2003.

11. In the Control of National Highways (Land and Traffic) Act, 2002,—

(a) in section 2,–

(i) clause (a) shall be omitted;

(ii) after clause (d), the following clause shall be inserted, namely:—

'(da) "Court" means the principal Civil Court of original jurisdiction in a district, and includes the High Court in exercise of its ordinary original civil jurisdiction;';

(iii) clause (l) shall be omitted;

(b) in Chapter II, in the Chapter heading, the words "AND TRIBUNALS, ETC." shall be omitted;

(c) section 5 shall be omitted;

(d) for section 14, the following section shall be substituted, namely:–

Appeals.

"14. An appeal from any order passed, or any action taken, excluding issuance or serving of notices, under sections 26, 27, 28, 36, 37 and 38 by the Highway Administration or an officer authorised on its behalf, as the case may be, shall lie to the

Court.";

(e) sections 15 and 16 shall be omitted;

(f) in section 17, for the word "Tribunal", at both the places where it occurs, the word "Court" shall be substituted;

(g) section 18 shall be omitted;

(h) in section 19, for the word "Tribunal", at both the places where it occurs, the word "Court" shall be substituted;

(i) section 40 shall be omitted;

(j) in section 41,—

(i) the words "or every order passed or decision made on appeal under this Act by the Tribunal" shall be omitted;

(ii) the words "or Tribunal" shall be omitted;

(k) in section 50, in sub-section (2), clause (f) shall be omitted.

CHAPTER XI

AMENDMENTS TO THE FINANCE ACT, 2017

Amendment of Act 7 of 2017.

12. In the Finance Act, 2017 (hereinafter referred to as the Finance Act),—

(i) for section 184, the following section shall be substituted, namely:—

Qualifications, appointment, etc., of Chairperson and Members of Tribunal.

"184. (*1*) The Central Government may, by notification, make rules to provide for the qualifications, appointment, salaries and allowances, resignation, removal and the other conditions of service of the Chairperson and Members of the Tribunal as specified in the Eighth Schedule:

Provided that a person who has not completed the age of fifty years shall not be eligible for appointment as a Chairperson or Member:

Provided further that the allowances and benefits so payable shall be to the extent as are admissible to a Central Government officer holding the post carrying the same pay:

Provided also that where the Chairperson or Member takes a house on rent, he may be reimbursed a house rent subject to such limits and conditions as may be provided by rules.

(2) The Chairperson and Members of a Tribunal shall be appointed by the Central Government on the recommendation of a Search-cum-Selection Committee (hereinafter referred to as the Committee) constituted under sub-section (3), in such manner as the Central Government may, by rules, provide.

(3) The Search-cum-Selection Committee shall consist of—

(a) the Chief Justice of India or a Judge of Supreme Court nominated by him— Chairperson of the Committee;

(b) two Secretaries nominated by the Government of India — Members;

(c) one Member, who—

(i) in case of appointment of a Chairperson of a Tribunal, shall be the outgoing Chairperson of the Tribunal; or

(ii) in case of appointment of a Member of a Tribunal, shall be the sitting Chairperson of the Tribunal; or

(iii) in case of the Chairperson of the Tribunal seeking re-appointment, shall be a retired Judge of the Supreme Court or a retired Chief Justice of a High Court nominated by the Chief Justice of India:

Provided that, in the following cases, such Member shall always be a retired Judge of the Supreme Court or a retired Chief Justice of a

High Court nominated by the Chief Justice of India, namely:—

(i) Industrial Tribunal constituted by the Central Government under the Industrial Disputes Act, 1947; 14 of 1947.

(ii) Tribunals and Appellate Tribunals constituted under the Recovery of Debts Due to Banks and Financial Institutions Act, 1993; 51 of 1993.

(iii) Tribunals where the Chairperson or the outgoing Chairperson, as the case may be, of the Tribunal is not a retired Judge of the Supreme Court or a retired Chief Justice or Judge of a High Court; and

(iv) such other Tribunals as may be notified by the Central Government in consultation with the Chairperson of the Search-cum-Selection Committee of that Tribunal; and

(d) the Secretary to the Government of India in the Ministry or Department under which the Tribunal is constituted or established — Member-Secretary.

(4) The Chairperson of the Committee shall have the casting vote.

(5) The Member-Secretary of the Committee shall not have any vote.

(6) The Committee shall determine its procedure for making its recommendations.

(7) Notwithstanding anything contained in any judgment, order or decree of any court or in any law for the time being in force, the Committee shall recommend a panel of two names for appointment to the post of Chairperson or Member, as the case may be, and the Central Government shall take a decision on the recommendations of the Committee preferably within three months from the date on which the Committee makes its recommendations to the Government.

(8) No appointment shall be invalid merely by reason of any vacancy or absence in the Committee.

(9) The Chairperson and Member of a Tribunal shall be eligible for re-appointment in accordance with the provisions of this section:

Provided that in making such re-appointment, preference shall be given to the service rendered by such person.

(10) The Central Government shall, on the recommendation of the Committee, remove from office, in such manner as may be provided by rules, any Member, who—

(a) has been adjudged as an insolvent; or

(b) has been convicted of an offence which involves moral turpitude; or

(c) has become physically or mentally incapable of acting as such a Member; or

(d) has acquired such financial or other interest as is likely to affect prejudicially his functions as a Member; or

(e) has so abused his position as to render his continuance in office prejudicial to the public interest:

Provided that where a Member is proposed to be removed on any ground specified in clauses (b) to (e), he shall be informed of the charges against him and given an opportunity of being heard in respect of those charges.

Explanation.— For the purposes of this section, the expressions —

(i) "Tribunal" means a Tribunal, Appellate Tribunal or Authority as specified in column (2) of the Eighth Schedule;

(ii) "Chairperson" includes Chairperson, Chairman, President and Presiding Officer of a Tribunal;

(iii) "Member" includes Vice-Chairman, Vice-Chairperson, Vice-President, Account Member, Administrative Member, Judicial Member, Expert Member, Law Member, Revenue Member and Technical Member, as the case may be, of a Tribunal.";

(ii) in section 184 as so substituted, after sub-section (10) and before the *Explanation*, the following sub-section shall be inserted and shall be deemed to have been inserted with effect from the 26th May, 2017, namely:—

"(11) Notwithstanding anything contained in any judgment, order, or decree of any court or any law for the time being in force, —

(i) the Chairperson of a Tribunal shall hold office for a term of four years or till he attains the age of seventy years, whichever is earlier;

(ii) the Member of a Tribunal shall hold office for a term of four years or till he attains the age of sixty-seven years, whichever is earlier:

Provided that where a Chairperson or Member is appointed between the 26th day of May, 2017 and the notified date and the term of his office or the age of retirement specified in the order of appointment issued by the Central Government is greater than that which is specified in this section, then, notwithstanding anything contained in this section, the term of office or age of retirement or both, as the case may be, of the Chairperson or Member shall be as specified in his order of appointment subject to a maximum term of office of five years.".

Amendment of section 186.

13. Section 186 of the Finance Act shall be renumbered as sub-section (1) thereof, and after sub-section (1) as so renumbered, the following sub-section shall be inserted, namely:—

"(2) Subject to the provisions of sections 184 and 185, neither the salary and allowances nor the other terms and conditions of service of Chairperson, Vice-

Chairperson, Chairman, Vice-Chairman, President, Vice-President, Presiding Officer or Member of the Tribunal, Appellate Tribunal or, as the case may be, other Authority may be varied to his disadvantage after his appointment.".

Amendment of Eighth Schedule.

14. In the Finance Act, in the Eighth Schedule, —

(i)items 10, 12, 14, and 15 shall be omitted;

(ii) for item 16, the following item shall be substituted, namely:—

(1)	(2)	(3)
16.	National Consumer Disputes Redressal Commission	The Consumer Protection Act, 2019 (35 of 2019)

Transitional provisions.

15. (*1*) Notwithstanding anything contained in any law for the time being in force, any person appointed as the Chairperson or Chairman or President or Presiding Officer or Vice-Chairperson or Vice-Chairman or Vice-President or Member of the Tribunal, Appellate Tribunal, or, as the case may be, other Authorities specified in the Schedule and holding office as such immediately before the notified date, shall, on and from the notified date, cease to hold such office, and he shall be entitled to claim compensation not exceeding three months' pay and allowances for the premature termination of term of his office or of any contract of service.

(*2*) The officers and other employees of the Tribunals, Appellate Tribunals and other Authorities specified in the Schedule appointed on deputation, before the notified date, shall, on and from the notified date, stand reverted to their parent cadre, Ministry or Department.

(*3*) Any appeal, application or proceeding pending before the Tribunal, Appellate Tribunal or other Authorities specified in the Schedule, other than those pending before the Authority for Advance Rulings under the Income-tax Act, 1961, before the notified date, shall stand transferred to the Court before which it would have been filed had this Ordinance been in force on the date of filing of such appeal or application or initiation of the

43 of 1961.

proceeding, and the Court may proceed to deal with such cases from the stage at which it stood before such transfer, or from any earlier stage, or de novo, as the Court may deem fit.

(*4*) The balance of all monies received by, or advanced to, the Tribunal, Appellate Tribunal or other Authorities specified in the Schedule and not spent by it before the notified date, shall, on and from the notified date, stand transferred to the Central Government.

(*5)* All property of whatever kind owned by, or vested in, the Tribunal, Appellate Tribunal or other Authorities specified in the Schedule before the notified date, shall stand transferred to, on and from the notified date, and shall vest in the Central Government.

Power to remove difficulties.

16. (1) If any difficulty arises in giving effect to the provisions of this Ordinance, the Central Government may, by general or special order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Ordinance, as appear to it to be necessary or expedient for removing the difficulty.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before each Houses of Parliament.

THE SCHEDULE
(*See* section 15)

1. Appellate Tribunal under Cinematograph Act, 1952 (37 of 1952).
2. Authority for Advance Rulings under Income-tax Act, 1961 (43 of 1961).
3. Airport Appellate Tribunal under Airports Authority of India Act, 1994 (Act 55 of 1994).
4. Intellectual Property Appellate Board under Trade Marks Act, 1999 (47 of 1999).
5. Plant Varieties Protection Appellate Tribunal under Protection of Plant Varieties and Farmers' Rights Act, 2001 (53 of 2001).

RAM NATH KOVIND,
President.

———

DR. G. NARAYANA RAJU,
Secretary to the Govt. of India.

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DGFT amends Para 1.03, 3.20(a) & 4.12(vi) of HBP 2015-2020: Validity extended upto 30th September 2021 - reg

DGFT Public Notice No. 48/2015-2020, dated 31st March, 2021.

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade hereby makes, with immediate effect, the following amendments:

In the Handbook of Procedures (HBP), 2015-20:

1. In para 1.01, the phrase “shall remain in force until 31st March, 2021' is substituted by the phrase "shall remain in force until 30th September, 2021.'.
2. In para 3.20 (a), the phrase ‘or 31.03.2021, whichever is later' is substituted by the phrase 'or 30.09.2021, whichever is later'.
3. In para 4.12(vi), the date 31.03.2021', as appearing in the first sentence is substituted by “30.09.2021.'

Effect of this Public Notice: Validity of the existing Hand Book of Procedures, 2015-20 is extended upto **30th September, 2021.**

File no. 01/75/171/00001/AM20/FTP Cell (Pt.IV))

Amit Yadav, Director General of Foreign Trade, Ex-officio Addl. Secretary, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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DGFT amends Para 1.01, 4.14, 5.01(a) & 6.01(d) (ii) of FTP 2015-2020: Validity extended upto 30th September 2021- reg.

DGFT Notification No. 60/2015-2020, dated 31st March, 2021

S.O. (E) In exercise of powers conferred by Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 read with paragraph 1.02 of the Foreign Trade Policy (FTP) 2015-2020, as amended, the Central Government hereby makes, with immediate effect, the following amendments in the FTP 2015-2020:

1. In para 1.01, the phrase “shall remain in force upto 31st March, 2021 unless otherwise specified' is substituted by the phrase “shall remain in force upto 30th September, 2021 unless otherwise specified.'

2. In para 4.14, the date “31.03.2021' as appearing in the last line is substituted by “30.09.2021.

3. In para 5.01(a), the date ‘31.03.2021' as appearing in the second sentence is substituted by “30.09.2021'.

4. In para 6.01(d) (ii), the date ‘31.03.2021' as appearing in the last line is substituted by “30.09.2021.

Effect of this Notification: The existing Foreign Trade Policy 2015-2020 which is valid upto 31.03.2021 is extended upto **30.09.2021**

File no. 01/75/171/00001/AM20/FTPCell(Pt.IV)

Amit Yadav, Director General of Foreign Trade, Ex-officio Addl. Secretary, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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National Policy for Rare Diseases 2021

1. Background:

Ministry of Health and family Welfare, Government of India formulated a National Policy for Treatment of Rare Diseases (NPTRD) in July, 2017. Implementation of the policy, however, faced certain challenges. A limiting factor in its implementation was bringing States on board and lack of clarity on how much Government could support in terms of tertiary care. Public Health and Hospitals is primarily a State subject. Stakeholder consultation with the State Governments at the draft stage of formulation of the policy could not be done in an elaborate manner. When the policy was shared with State Governments, issues such as cost effectiveness of interventions for rare disease vis- à-vis other health priorities, the sharing of expenditure between Central and State Governments, flexibility to State Governments to accept the policy or change it according to their situation, were raised by some of the State Governments.

In the circumstances, though framed with best intent, the policy had implementation challenges and gaps, including the issue of cost effectiveness of supporting such health interventions for limited resource situation, which made it not feasible to implement. Given the challenges in implementing the policy, the need for wider consultation and recommendations, a decision was taken to reframe the National Policy for Treatment of Rare Diseases. An Expert Committee was constituted by Ministry of Health and Family Welfare in November, 2018 to review the NPTRD, 2017. The Terms and References of the Expert Committee are given below:

a. To review the national Policy for Treatment of rare Diseases, 2017 and to suggest amendments/ changes as may be required.

b. To define Rare diseases for India.

c. To draft National Policy for Rare Diseases.

d. To suggest vision and strategy in country's context.

Pending reframing the policy, the earlier policy has been kept in abeyance vide a non-statutory Gazette Notification dated 18-12-2018, till the revised policy is issued or till further orders, whichever is earlier.

Based on the report of the Expert Committee and with the approval of the competent authority, the draft National Policy for Rare Diseases, was finalized and placed in the public domain on 13.1.2020 inviting comments/views from all the stakeholders, general public, organisations and States/UTs.

Comments/suggestions received from general public/organisations/stake holders/States/UTs were referred to DGHS for examination and to submit recommendations. DGHS constituted an Expert Committee to examine the comments/suggestions received. Based on the examination of the comments/ suggestions received and recommendations of the same Expert Committee and after further deliberation, the National Policy for Rare Diseases has been finalised.

2. Rare Diseases: Issues & Challenges:

The field of rare diseases is complex and heterogeneous. The landscape of rare diseases is constantly changing, as there are new rare diseases and conditions being identified and reported regularly in medical literature. Apart from a few rare diseases, where significant progress has been made, the field is still at a nascent stage. For a long time, doctors, researchers and policy makers were unaware of rare diseases and until very recently there was no real research or public health policy concerning issues related to the field. This poses formidable challenges in development of a comprehensive policy on rare diseases. Nevertheless, it is important to take steps, in the short as well as long term, with the objective of tackling rare diseases in a holistic and comprehensive manner.

2.1 The varying definitions of rare diseases:

WHO defines rare disease as often debilitating lifelong disease or disorder with a prevalence of 1 or less, per 1000 population. However, different countries have their own definitions to suit their specific requirements and in context of their own population, health care system and resources. In the US, rare diseases are defined as a disease or

condition that affects fewer than 200,000 patients in the country (6.4 in 10,000 people). EU defines rare diseases as a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people. Japan identifies rare diseases as diseases with fewer than 50,000 prevalent cases (0.04%) in the country. A summary of the prevalence based definitions of rare diseases used in various countries is tabulated below:

Table 1: Definitions of Rare Disease in different countries

Sr No.	Country	Prevalence less than per 10,000population
1	USA	6.4
2	Europe	5.0
3	Canada	5.0
4	Japan	4.0
5	South Korea	4.0
6	Australia	1.0
7	Taiwan	1.0

Source: The I.C. Verma Sub-Committee Report 'Guidelines for Therapy and Management'

The use of varying definitions and diverse terminology can result in confusion and inconsistencies and has implications for access to treatment and for research and development. According to a study[1], that reviewed and analysed definitions across jurisdictions, most definitions, as discussed above, appear to consider disease prevalence, but other criteria also apply sometimes, such as - disease severity, whether the disease is life-threatening, whether there are alternative treatment options available, and whether it is heritable. The study found that relatively few definitions included qualifiers relating to disease severity and/or a lack of existing treatments, whereas most definitions included a prevalence threshold. The average prevalence thresholds used to define rare diseases ranges among different jurisdictions from 1 to 6 cases/10,000 people, with WHO recommending a prevalence less than 10/10,000 population for defining rare diseases. The study concluded that attempts at harmonising the differing definitions, should focus on standardizing objective criteria such as prevalence thresholds and avoid qualitative descriptors like severity of the disease.

However, it has been contested that disease prevalence alone may also not be an accurate basis for defining rare diseases, as it does not take into account changes in population over time. Hence, some have suggested that a more reliable approach to arriving at a definition could be based on the factors of – a) location - a disease which is uncommon in one country may be quite common in other parts of the world; b) levels of rarity - some diseases may be much more rare than other diseases which are also uncommon; and c) study-ability - whether the prevalence of a disease lends itself to clinical trials and studies.

This underscores the need for further research to better understand the extent of the existing diversity of definitions for rare diseases and to examine the scope of arriving at a definition, which is best suited to the conditions in India. It shall be done on a priority basis as soon as sufficient data is available. Steps have already been taken for creation of a hospital based National Registry for rare diseases in India by ICMR.

2.2 Diagnosis of rare diseases:

Early diagnosis of rare diseases is a challenge owing to multiple factors that include lack of awareness among primary care physicians, lack of adequate screening and diagnostic facilities.

Traditional genetic testing includes tests that can only address a few diseases. As a result, physicians most often provide their best guess on which tests are to be done. If the test is negative, further testing will be required using next generation sequencing based tests, or chromosomal microarray which are applicable, but expensive and time- consuming processes with interpretation and counselling issues at times.

There is a lack of awareness about rare diseases in general public as well as in the medical fraternity. Many doctors lack appropriate training and awareness to be able to correctly and timely diagnose and treat

1 *Richter, T., Nestler-Parr, S., Babela, R., Khan, Z. M., Tesoro, T., Molsen, E., & Hughes, D. A. (2015). Rare Disease Terminology and Definitions – A Systematic Global Review: Report of the ISPOR Rare Disease Special Interest Group [Electronic version]. Value in Health, 18, 906-914. Available at: https://www.ispor.org/raredisease-terms-definitions.pdf*

these conditions. According to a recent report[2], it takes patients in United States (US) an average of 7.6 years and patients in United Kingdom (UK) an average of 5.6 years to receive an accurate diagnosis, typically involving as many as eight physicians (four primary care and four specialists). In addition, two to three misdiagnoses are typical before arriving at a final diagnosis. Delay in diagnosis or a wrong diagnosis increases the suffering of the patients exponentially. There is an immediate need to create awareness amongst general public, patients & their families and doctors, training of doctors for early and accurate diagnosis, standardization of diagnostic modalities and development of newer diagnostic and therapeutic tools.

2.3 Challenges in research and development:

A fundamental challenge in research and development for the majority of rare diseases is that there is relatively little known about the pathophysiology or the natural history of these diseases. Rare diseases are difficult to research upon as the patient pool is very small and it often results in inadequate clinical experience. Therefore, the clinical explanation of rare diseases may be skewed or partial. The challenge becomes even greater as rare diseases are chronic in nature, where long term follow-up is particularly important. As a result, rare diseases lack published data on long-term treatment outcomes and are often incompletely characterised.

This makes it necessary to explore international and regional collaborations for research, collaborations with the physicians who work on any rare disease and with patient groups and families dealing with the consequences of these disorders. This will help gain a better understanding of the pathophysiology of these diseases, and the therapeutic effects that would have a meaningful impact on the lives of patients. There is also a need to review and where possible modify, clinical trial norms keeping in mind the particular challenges in rare diseases, without compromising on the safety and quality of the drugs or diagnostic tools.

2.4 Challenges in treatment:

2.4.1 Unavailability of treatment:

Availability and access to medicines are important to reduce morbidity and mortality associated with rare diseases. Despite progress in recent years, effective or safe treatment is not available for most of the rare diseases. Hence, even when a correct diagnosis is made, there may not be an available therapy to treat the rare disease. There are between 7000 - 8000 rare diseases, but less than 5% have therapies available to treat them. About 95% rare diseases have no approved treatment[3] and less than 1 in 10 patients receive disease specific treatment. Where drugs are available, they are prohibitively expensive, placing immense strain on resources.

2.4.2 Prohibitive cost of treatment:

As the number of persons suffering from individual rare diseases is small, they do not constitute a significant market for drug manufacturers to develop and bring to market drugs for them. For this reason, rare diseases are also called 'orphan diseases' and drugs to treat them are called "orphan drugs". Where, they do make drugs to treat rare diseases, the prices are extremely high apparently to recoup the cost of research and development. At present very few pharmaceutical companies are manufacturing drugs for rare diseases globally and there are no domestic manufacturers in India except for Food for Special Medical Purposes(FSMP) for small molecule inborn errors of metabolism. Due to the high cost of most therapies, the government has not been able to provide these for free. It is estimated that for a child weighing 10 kg, the annual cost of treatment for some rare diseases, may vary from Rupees 10 Lakhs to more than 1 crore per year with treatment being lifelong and drug dose and cost increasing with age and weight.

Countries have dealt with this unique problem of high cost through various means that were suited to their local needs. Instruments like the Orphan Drug Act (ODA) in US & Canada, provide incentives to drug manufacturers to encourage them to manufacture drugs for rare diseases. The economic incentives & safeguards offered under the Act ensure benefits to the local patients. However, the exorbitant prices of drugs for rare diseases has led to concerns even in the developed countries

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[2] *Rare Disease Impact Report: Insights from patients and the medical community available at: https://globalgenes.org/wp-content/uploads/2013/04/ShireReport-1.pdf*

[3] *https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30006-3/fulltext*

about maintaining sustainability of the rare diseases funding/reimbursement programmes. The exorbitant prices have led to calls for transparency in setting prices of drugs and for price control and have even prompted scrutiny and congressional inquiries.

3. The Indian Scenario:

Data on how many people suffer from different diseases that are considered rare globally, is lacking in India. The cases identified so far have been diagnosed at tertiary hospitals. The lack of epidemiological data on incidence and prevalence of rare diseases impedes understanding of the extent of the burden of rare diseases and development of a definition. It also hampers efforts to arrive at correct estimation of the number of persons suffering from these diseases and describe their associated morbidity and mortality. In such a scenario, the economic burden of most rare diseases is unknown and cannot be adequately estimated from the existing data sets.

Although extremely challenging, considering the complexity of various diseases and the difficulty in diagnosis, there is a clear need to undertake systematic epidemiological studies to ascertain the number of people suffering from rare diseases in India.

So far only limited number of diseases has been recorded in India from tertiary care hospitals that are globally considered as rare diseases though ambit may encompass from 7000 to 8000 disorders. The commonly reported diseases include Primary immunodeficiency disorders, Lysosomal storage disorders (Gaucher's disease, Mucopolysaccharidoses, Pompe disease, fabry disease etc.) small molecule inborn errors of metabolism (Maple Syrup urine disease, organic acidemias, etc.), Cystic Fibrosis, osteogenesis imperfecta, certain forms of muscular dystrophies and spinal muscular atrophy, etc.

4. Experiences from other countries:

While preparing the policy for rare diseases in India, policies of other countries have been reviewed. In United States of America, development of drugs for rare disease is sought to be encouraged through the Orphan Drugs Act, which incentivises industry by way of market exclusivity, grants to researchers and tax incentives on expenditure incurred during evaluation of drugs for their therapeutic potential. However, critics have pointed out that pharmaceutical companies have taken advantage of this arrangement and 'gamed the system' to maximise profits. The European Joint Programme on Rare Disease mostly focuses on research. National Health Service (NHS) England, for example, provides that the treatment for Spinal Muscular Atrophy (SMA) will be made available to the youngest and most severely-affected (SMA Type 1) patients immediately by Biogen (The pharmaceutical company that manufactures treatment for SMA), with NHS England offering funding on National Institute for Health and Care Excellence (NICE) publication of final guidance. In Singapore, a fund - Rare Disease Fund – has been created to fund five medicines to treat three rare disease conditions. In Malaysia and Australia subsidised access for eligible patients is provided for expensive and lifesaving drugs.

5. Need to balance competing priorities of public health in resource constrained settings:

Rare diseases place a major economic burden on any Country and especially in resource-constrained settings. The financial capacity to support exorbitant cost of treatment, is an important consideration in public health policy development with reference to treatment for rare diseases. In resource-constrained settings, it is pertinent to balance competing interests of public health for achieving optimal outcome for the resources allocated. As resources are limited and have multiple uses, the policy makers have to make choice of prioritizing certain set of interventions over others- the appropriate choice is then to support those interventions that would provide more number of healthy life years for given sum of money while simultaneously looking at the equity i.e., interventions that benefit poor who cannot afford healthcare are prioritized. Thus, interventions that address health problems of a much larger number of persons by allocating a relatively smaller amount are prioritized over others such as funding treatment of rare diseases where much greater resources will be required for addressing health problems of a far smaller number of persons.

Hence, any policy on rare diseases needs to be considered in the context of the available scarce resources and the need for their utmost judicious utilization for maximizing the overall health outcomes for the whole of society measured in terms of increase of healthy life years.

6. Definition of Rare Diseases:

6.1 There is no universal or standard definition of rare disease. A disease that occurs infrequently is generally considered a rare disease, and it has been defined by different countries in terms of prevalence – either in absolute terms or in terms of prevalence per 10,000 population. A country defines a rare disease most appropriate in the context of its own population, health care system and resources.

6.2 As mentioned above, India faces the limitation of lack of epidemiological data to be able to define rare diseases in terms of prevalence or prevalence rate, which has been used by other countries. To overcome this, a hospital based National Registry for Rare Diseases has been initiated by ICMR by involving centers across the Country that are involved in diagnosis and management of Rare Diseases. This will yield much needed epidemiological data for rare diseases. In the absence of epidemiological data on diseases considered as rare in other countries, it is not possible to prescribe threshold prevalence rates to define a disease condition as rare.

Till the time such data is available and the Country arrives at a definition of a rare disease based on prevalence data, the term rare diseases, for the purpose of this policy, shall construe the following groups of disorders identified and categorized by experts based on their clinical experience:

Group 1: Disorders amenable to one-time curative treatment:

a) Disorders amenable to treatment with Hematopoietic Stem Cell Transplantation (HSCT) –

i. Such Lysosomal Storage Disorders (LSDs) for which Enzyme Replacement Therapy (ERT) is presently not available and severe form of Mucopolysaccharoidosis (MPS) type I within first 2 years of age.

ii. Adrenoleukodystrophy (early stages), before the onset of hard neurological signs.

iii. Immune deficiency disorders like Severe Combined Immunodeficiency (SCID), Chronic Granulomatous disease, Wiskot Aldrich Syndrome, etc.

iv. Osteopetrosis

v. Fanconi Anemia

b) Disorders amenable to organ transplantation

i. Liver Transplantation-Metabolic Liver diseases:

a. Tyrosinemia,

b. Glycogen storage disorders (GSD) I, III and IV due to poor metabolic control, multiple liver adenomas, or high risk for Hepatocellualr carcinoma or evidence of substantial cirrhosis or liver dysfunction or progressive liver failure,

c. MSUD (Maple Syrup Urine Disease),

d. Urea cycle disorders,

e. Organic acidemias.

ii. Renal Transplantation-

a. Fabry disease

b. Autosomal recessive Polycystic Kidney Disease (ARPKD),

c. Autosomal dominant Polycystic Kidney Disease (ADPKD) etc.

iii. Patients requiring combined liver and kidney transplants can also be considered if the same ceiling of funds is maintained. (Rarely Methyl Malonic aciduria may require combined liver & Kidney transplant) etc.

Group 2: Diseases requiring long term / lifelong treatment having relatively lower cost of treatment and benefit has been documented in literature and annual or more frequent surveillance is required:

a) Disorders managed with special dietary formulae or Food for special medical purposes (FSMP)

i) Phenylketonuria (PKU)

ii) Non-PKU hyperphenylalaninemia conditions

iiii) Maple Syrup Urine Disease (MSUD)

iv) Tyrosinemia type 1 and 2

v) Homocystinuria

vi) Urea Cycle Enzyme defects

vii) Glutaric Aciduria type 1 and 2

viii) Methyl Malonic Acidemia

ix) Propionic Acidemia

x) Isovaleric Acidemia

xi) Leucine sensitive hypoglycemia

xii) Galactosemia

xiii) Glucose galactose malabsorbtion

xiv) Severe Food protein allergy

b) Disorders that are amenable to other forms of therapy (hormone/ specific drugs)

i) NTBC for Tyrosinemia Type 1

ii) Osteogenesis Imperfecta – Bisphosphonates therapy

iii) Growth Hormone therapy for proven GH deficiency, Prader Willi Syndrome and Turner syndrome, Noonan syndrome.

iv) Cystic Fibrosis- Pancreatic enzyme supplement

v) Primary Immune deficiency disorders -Intravenous immunoglobulin and sub cutaneous therapy (IVIG) replacement eg. X-linked agammablobulinemia etc.

vi) Sodium Benzoate, arginine, citrulline, phenylacetate (Urea Cycle disorders), carbaglu, Megavitamin therapy (Organic acidemias, mitochondrial disorders)

vii) Others - Hemin (Panhematin) for Acute Intermittent Porphyria, High dose Hydroxocobalamin injections (30mg/ml formulation – not available in India and hence expensive if imported)

viii) Large neutral aminoacids, mitochondrial cocktail therapy, Sapropterin and other such molecules of proven clinical management in a subset of disorders

Group 3: Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy.

3a) Based on the literature sufficient evidence for good long-term outcomes exists for the following disorders

1. *Gaucher Disease (Type I & III {without significant neurological impairment})*
2. *Hurler Syndrome [Mucopolysaccharisosis (MPS) Type I] (attenuated forms)*
3. *Hunter syndrome (MPS II) (attenuated form)*
4. *Pompe Disease (Both infantile & late onset diagnosed early before development of complications)*
5. *Fabry Disease diagnosed before significant end organ damage.*
6. *MPS IVA before development of disease complications.*
7. *MPS VI before development of disease complications.*
8. *DNAase for Cystic Fibrosis.*

3b) For the following disorders for which the cost of treatment is very high and either long term follow up literature is awaited or has been done on small number of patients

1. *Cystic Fibrosis (Potentiators)*
2. *Duchenne Muscular Dystrophy (Antesensce oligoneucletides, PTC)*
3. *Spinal Muscular Atrophy (Antisense oligonucleotides both intravenous & oral & gene therapy)*
4. *Wolman Disease*
5. *Hypophosphatasia*
6. *Neuronal ceroid lipofuschinosis*

6.3. The list of diseases under Group 1, Group 2 and Group 3 are not exhaustive and will be reviewed periodically based on updated scientific data by the Technical Committee.

7. Policy Direction:

The policy aims at lowering the incidence and prevalence of rare diseases based on an integrated and comprehensive preventive strategy encompassing awareness generation, premarital, post-marital, pre-conception and post-conception screening and counselling programmes to prevent births of children with rare diseases, and, within the constraints on resources and competing health care priorities, enable access to affordable health care to patients of rare diseases which are amenable to one-time treatment or relatively low cost therapy.

Considering the limited data available on rare diseases, and in the light of competing health priorities, the focus would be on prevention of rare diseases as a priority for all the three groups of rare diseases identified by Experts. Public Health and hospitals being a State subject, the Central Government would encourage & support the States

in their endeavour towards screening and prevention of rare diseases through Centres of Excellence under Rare Disease Policy and Nidan Kendras under Department of Biotechnology.

8. Prevention & Control of Rare Diseases:

8.1 Capacity building of health professionals:

The Central Government will work with the State governments to build capacity of health professionals at various levels. The content of such capacity building would be based on the roles of various health professionals. The Centres of Excellence would develop Standard Operating Protocols to be used at various levels of care for patients with rare diseases to improve early diagnosis, better care coordination and quality of life.

8.2 Prevention at different levels:

Though in the last two decades, due to advancement in technologies, understanding of the pathophysiological mechanisms of rare genetic disorders has somewhat improved, yet the treatment modalities are few and the available therapies may not lead to "cure'. More importantly these are exorbitantly costly and not universally available &accessible. Accordingly, prevention needs to be the focus for all genetic disorders. The prevention of genetic disorders can be done at multiple levels. For application of these strategies, the first step is to build the capacity of health professionals and increase awareness in the population at large about the prevalence of such diseases and prevention measures. Frontline workers will be adequately capacitated for screening of rare diseases. Adequate IEC material will be designed and made available across multiple levels of the health care pyramid as this forms a basic pillar of tackling the issue of limited awareness.

8.2.1 Primary Prevention: This aims at preventing the occurrence of the disease, i.e., preventing birth of an affected child. Though not always feasible, this strategy yields the highest returns in terms of decreasing the incidence & prevalence of rare disorders in the population in the long run. Some of the strategies can be as follows:

Examples include avoidance of pregnancy in advanced age, or any other rare monogenic disorder by not marrying a carrier, carrier couples not reproducing etc., but these are not feasible options in the real world scenario. So in most situations the feasible preventive strategy is secondary prevention. However, a simple checklist will be made available to primary health care providers in the health and wellness clinics to identify a couple at risk based on disease in a previous sib or family history of that disorder.

8.2.2: Secondary prevention: This strategy focuses on avoiding the birth of affected fetus (prenatal screening and prenatal diagnosis), early detection of the disorders, appropriate medical intervention to ameliorate or minimize the manifestations (newborn screening).

a) Prenatal screening: The common screening methods presently recommended for all pregnancies include biochemical screening and ultrasonography for chromosomal disorders like Down syndrome etc. and ultrasonography for other structural defects. In the context of rare diseases objective of the prenatal screening and diagnosis is to identify the high risk mothers for having an affected fetus with a rare disease. These mothers can be identified based on the family history (previous affected child or affected relative with a known or suspected genetic disorder). Based on the suspected disease a targeted screening of the affected child or couple for a specific disorder or a carrier testing for monogenic disorders using next generation sequencing technique can be offered, the later being presently expensive.

b) Prenatal diagnosis by invasive testing (e.g., by Chorionic villus sampling and amniocentesis): is possible for any single-gene disorder if the disease causing variant in the gene / enzyme defect is known and for any chromosomal abnormality. Most common indications are known single gene disorders or chromosomal abnormality in a previous affected child in the family. These tests can also be offered if the married couple is found to be carrier for any single gene disorder and mutations have been identified in the couple. Now a day, prenatal diagnosis for above mentioned disorders are widely available in India at many institutions. The invasive procedures are performed by obstetricians and fetal medicine experts. These procedures however carry a small risk of fetal loss which is very low if done by experienced specialists. This has to be explained to the family before the procedure.

Cost would primarily depend on the type of the test to be performed on the sample. If the fetus is found to be affected, the couple has the option for termination of pregnancy, the legal age of which in India has been increased to 24 weeks of pregnancy.

c) ***Newborn screening (NBS):*** is the best example of secondary prevention in which the babies are screened with in few days of birth before symptoms of the disease manifest and treatment is initiated which prevents morbidity and mortality. In the developed world NBS is being offered for many rare disorders particularly the treatable ones (e.g., LSDs, SCID) apart from the common disorders.

d) ***Early postnatal diagnosis and treatment:*** before development of severe manifestations /complications which are irreversible is also included in secondary prevention for disorders amenable to therapy which would require increasing awareness and better availability of diagnostics. Timely referral of the suspected patients & their families to appropriate facilities that are equipped to make a correct diagnosis and where indicated, initiate treatment is the key. Genetic testing will also be augmented by laboratories under the National Genomics Core funded by the Department of Biotechnology and Institute of Genomics and Integrative Biology (IGIB) & Centre for Cellular and Molecular Biology (CCMB) under CSIR.

8.2.3: Tertiary prevention refers to provision of better care and medical rehabilitation to those rare disease patients who present at an advanced stage of the disease. It encompasses providing best supportive care to the affected patients with various rare disorders including the ones for which no specific treatment is available. This would improve quality of life of affected individuals and families. Supportive care includes developmental assessment and intervention including early stimulation and behavioural intervention, physical therapy and rehabilitation, provision of visual and hearing aids and above all emotional and psychological support to affected individuals and families.

8.2.4: Optimal screening and diagnosis strategy: Considering the competing priorities within available resources, universal screening of all pregnancies and/ or all newborns in the country for all rare disorders is not feasible. The policy recommends a screening and diagnostic strategy wherein those pregnant women in whom there is a history of a child born with a rare disease and that rare disease diagnosis has been confirmed, would be offered prenatal screening test(s) through amniocentesis and / or chorionic villi sampling. This strategy is in sync with the policy direction of reducing the incidence of rare diseases in the population. In cases where, the diagnosis could not be established during the prenatal period, it would be imperative to offer to the newborn or the infant as the case may be and would include newborn screening for (a) small molecule Inborn Errors of Metabolism by liquid chromatography – tandem mass spectrometry (LC-MS/MS), (b) diagnosis of SCID by T cell receptor excision circles (TREC) and (c) diagnosis of lysosomal storage disorders (LSDs) by microfluids / LC-MS/ MS. (d) diagnosis of disorders by newer but economical molecular diagnostic platforms.

9. Centres of Excellence (COE) and Nidan Kendras

9.1 The Government will notify selected Centres of Excellence, which will be premier Government tertiary hospitals with facilities for diagnosis, prevention and treatment of rare diseases. To begin with the following institutes would be notified as Centers of Excellence for Rare Diseases:

a) All India Institute of Medical Sciences, New Delhi

b) Maulana Azad Medical College, New Delhi

c) Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

d) Post Graduate Institute of Medical Education and Research, Chandigarh

e) Centre for DNA Fingerprinting & Diagnostics, Hyderabad

f) King Edward Medical Hospital, Mumbai

g) Institute of Post-Graduate Medical Education and Research, Kolkata

h) Center for Human Genetics (CHG) with Indira Gandhi Hospital, Bengaluru

However, more Centres of Excellence can be added for regional outreach if they are found to be suitable in

terms of infrastructure and human resources based on recommendations of technical committee.

9.2 The responsibilities and activities of the COEs would be as follows:

- Education & Training at all levels
- Screening – Antenatal, neonatal (specified disorders), High risk screening (both antenatal & in newborns and children)
- Diagnostics- Cytogenetic, molecular, Metabolic
- Prevention by prenatal screening & diagnosis
- Research in the area of low cost diagnostics & therapeutics.
- Treatment of rare diseases.

9.3 The proposed COEs shall be given one-time financial support upto a ceiling of Rs 5 crore for procurement of equipment as per individual centers need for strengthening patient care services for screening, diagnosis and prevention (prenatal diagnosis) of rare diseases based on a gap analysis. The list of equipments which are likely to be useful for these activities is annexed.

9.4 These Centre of Excellence will take the required decision for treatment and fund allocation on rare diseases cases within 02 weeks of receiving the fresh application.

9.5 **Nidan Kendras**: Nidan Kendras have been set up by Department of Biotechnology (DBT) under Unique Methods of Management and treatment of Inherited Disorders (UMMID) project for genetic testing and counseling services. These Nidan Kendras will be performing screening, genetic testing and counseling for rare diseases. Nidan Kendras possessing the facility for treatment may do so under the guidance and supervision of a CoE.

List of Nidan Kendras is given below:

- Lady Hardinge Medical College (LHMC), Delhi
- Nizam's Institute of Medical Sciences (NIMS), Hyderabad, Telangana
- All India Institute of Medical Sciences (AIIMS), Jodhpur
- Army Hospital Research & Referral, Delhi
- Nil Ratan Sircar (NRS) Medical College and Hospital, Kolkata

Currently Nidan Kendras / Mentor Institutes are supporting aspirational districts for screening of rare diseases. List of aspirational districts covered under the programme is given below:

Name of the Mentor Institute	Aspirational District	State
LHMC, New Delhi	Mewat	Haryana
CDFD, Hyderabad	Yadgir	Karanataka
AIIMS, New Delhi	Haridwar	Uttarakhand
CMC, Vellore	Washim	Maharashtra
MAMC, New Delhi	Ranchi / Bokaro	Jharkhand
SGPGIMS, Lucknow	Shrawasti	Uttar Pradesh
NIIH (KEM hospital campus), Mumbai	Nandurbar	Maharashtra

More aspirational districts will be covered in future either by setting up of more Nidan Kendras or by adopting more than one aspirational districts by existing Nidan Kendras.

10. Government of India support in treatment:

The following initiatives shall be taken for patients of Rare Diseases:

i. Financial support upto Rs. 20 lakh under the Umbrella Scheme of Rashtriya Arogaya Nidhi shall be provided by the Central Government for treatment, of those rare diseases that require a one-time treatment (diseases listed under Group 1). Beneficiaries for such financial assistance would not be limited to BPL families, but extended to about 40% of the population, who are eligible as per norms of Pradhan Mantri Jan Arogya Yojana, for their treatment in Government tertiary hospitals only.

ii. State Governments can consider supporting patients of such rare diseases that can be managed with special diets or hormonal supplements or other relatively low cost interventions (Diseases listed under Group 2).

iii. Keeping in view the resource constraints, and a compelling need to prioritize the available resources to get maximum health gains for the community/ population, the Government will endeavour to create alternate funding mechanism through setting up a

digital platform for voluntary individual and corporate donors to contribute to the treatment cost of patients of rare diseases.

iv. Voluntary crowd-funding for treatment

Keeping in view the resource constraint and competing health priorities, it will be difficult for the Government to fully finance treatment of high cost rare diseases. The gap can however be filled by creating a digital platform for bringing together notified hospitals where such patients are receiving treatment or come for treatment, on the one hand, and prospective individual or corporate donors willing to support treatment of such patients. The notified hospitals will share information relating to the patients, diseases from which they are suffering, estimated cost of treatment and details of bank accounts for donation/ contribution through online system. Donors will be able to view the details of patients and donate funds to a particular hospital. This will enable donors from various sections of the society to donate funds, which will be utilized for treatment of patients suffering from rare diseases, especially those under Group 3. Conferences will be organised with corporate sector companies to motivate them to donate generously through digital platform. Ministry of Corporate Affairs will be requested to encourage PSUs and corporate houses to contribute as per the Companies Act as well as the provisions of the Companies (Corporate Social Responsibility Policy) Rules, 2014 (CSR Rules). Promoting health care including preventive health care is included in the list in the Schedule for CSR activities.

Treatment cost of the patient will be first charge on this fund. Any leftover fund after meeting treatment cost can be utilized for research purpose also.

11. Development of manpower:

Following initiatives will be taken for strengthening of manpower:

- State Governments will be requested to create Department of Medical Genetics at least in one medical colleges in the State for imparting education and increasing awareness amongst health care professionals.
- Services of Nidan Kendras set up under Department of Biotechnology will also be utilised for training of medical practitioners and staff for screening for rare diseases.

12. Constitution of Consortium:

(a) Consortium of Centres of Excellence so created will synchronize prevention and treatment efforts. AIIMS, Delhi will be the nodal hospital to coordinate with other Centres of Excellence for various activities relating to prevention and treatment of rare disease.

(b) National Consortium for Research and Development on therapeutics for Rare Diseases: National Consortium can be provided with an expanded mandate to include research & development, technology transfer and indigenization of therapeutics for rare diseases. It will be convened by Department of Health Research (DHR) with ICMR as a member.

13. Increasing affordability of drug related to rare diseases:

(a) Research & Development activities on rare diseases

Indian Council of Medical Research (ICMR), Department of Biotechnology, Department of Pharmaceuticals, Department of science and Technology and Council for Scientific Education & Research will be requested to promote research and development in the field of rare diseases for diagnosis and treatment of rare diseases.

Creation of an integrated research pipeline to start the development of new drugs, for which pharmaceutical companies would be encouraged and research organizations as well as funding agencies would be involved in this important endeavour. Research for repurposing the drugs and use of biosimilar would be encouraged. Approval for new drugs and decision related to trials will continue to be provided by Drugs Controller General of India under the New Drugs and Clinical Trial Rules, 2019.

(b) Ministry of Finance will be requested for reduction in custom duties on import of medicines related to rare diseases.

(c) Ministry of Chemicals and Fertilizers, Department of Pharmaceutical (DoP), National Pharmaceutical Pricing Authority (NPPA) shall take measures to document and make publicly available the prices of drugs for rare diseases and work towards affordability of drugs for rare diseases, in consultation with the Ministry of Health and Family Welfare.

(d) Measures for creating conducive environment for indigenous manufacturing of drugs for rare diseases would be taken**.** Department of Pharmaceuticals, Department for Promotion of Industry and Internal Trade (DPIIT) will be requested to promote local development and manufacture of drugs for rare diseases at affordable prices and take legal/legislative measures for creating conducive environment for indigenous manufacturing of drugs for rare diseases at affordable prices. PSUs would be encouraged for local manufacturing of drugs for rare diseases.

14. Implementation strategy:

Keeping in view lack of availability of epidemiological data on rare diseases, constraints on resources and competing health priorities, the focus of the Government will be on the following:

i. The Government will have a hospital based National Registry for Rare Diseases at ICMR with the objective of creating a database of various rare diseases. Steps have already been taken in this direction by ICMR. Over a period of time, the registry is expected to yield information on hospital based data and disease burden.

ii. The Government shall take steps to create awareness amongst all the levels of health care personnel as well as general public towards the rare diseases. This will encourage people to seek pre-marital genetic counselling, identification of high- risk couples & families and also result in prevention of births as well as early detection of cases of rare diseases. Simple standard protocols/algorithms would be developed for screening and diagnosis in order to avoid missing cases and provide best possible management

iii. Public Health and hospitals being a State subject, the Central Government shall encourage and support the State Governments in implementation of a targeted preventive strategy.

iv. The Government shall provide financial assistance upto Rs. 20.00 lakh (under the Umbrella Scheme of Rashtriya Arogya Nidhi) to the entitled population, as per PMJAY norms, for their treatment in Government tertiary hospital, for rare diseases amenable to one-time treatment (identified under Group 1).

v. The State Governments may undertake treatment of disorders managed with special dietary formulae or food for special medical purposes (FSMP) and Disorders that are amenable to other forms of therapy (hormone/ specific drugs)- diseases covered under Group 2.

vi. The Government shall notify selected Centres of Excellence at premier government hospitals for comprehensive management of rare diseases. The Centres of Excellence will be provided one time grant subject to maximum of Rs. 5 crore each for infrastructure development for screening, tests, treatment, if such infrastructure is not available.

vii. The Government shall create a digital platform for bringing together notified Centres of Excellence where patients of rare diseases can receive treatment or come for treatment, on the one hand and prospective voluntary individual or corporate donors willing to support treatment of such patients. Funds received through this mechanism will be utilized for treatment of patients suffering from rare diseases.

viii. In order to maintain transparency of transactions in provision of funding under RAN/ crowd funding etc., the Centres of Excellence receiving the funds should have linkages with the ICMR registry.

ix. The Government shall facilitate the creation of an enabling environment that promotes research & development of diagnostic and therapeutic modalities within the Country**.** Consortium of Centres of Excellence shall be created so that research efforts are synchronized. AIIMS, Delhi will be nodal hospital to coordinate with other Centres of Excellence for various activities.

x. State Governments will be requested to create Department of Medical Genetics at least in one medical college in the State for imparting education and increasing awareness amongst health care professionals. This will strengthen manpower base in the country for managing Rare Diseases.

xi. Department of Pharmaceuticals, Department for Promotion of Industry and Internal Trade (DPIIT) will be requested to promote local development and manufacture of drugs for rare diseases by public and private sector pharmaceutical companies at affordable prices and take legal/

legislative measures for creating conducive environment for indigenous manufacturing of drugs for rare diseases at affordable prices. PSUs could also be encouraged for local manufacturing of drugs for rare diseases.

xii. Ministry of Finance will be requested for reduction in custom duties on import of medicines related to rare diseases.

Annexure

- ***Suggestive List of Equipment, which may be required for strengthening of patient services at Centres of Excellence for screening, diagnosis and preventive (prenatal diagnosis) of rare disease.***
- ***Cytogenetic workstation with software with Fluorescent in situ hybridization***
- ***Multimode readers for both ELISA and fluorescent enzyme assays***
- ***DNA Sequencer with 8 capillary sequencer***
- ***Mi Seq next generation sequencer***
- ***Next Seq next generation sequencer***
- ***Liquid chromatography Mass Spectroscopy (Tandem Mass Spectrometry)***
- ***HPLC (quarternery pump high Performance Liquid Chromatography)***
- ***GCMS (gas chromatography Mass Spectrometry)***
- ***Microfluidics platform***
- ***Real Time PCR (96 well format) for real time polymerase chain reaction***
- ***High throughput rNA and DNA extraction systems***
- ***Quality Check stations and microtips station***
- ***Chromosomal Micro array platform***
- ***Newborn Screening platfrom for fluroimmunoassay***
- ***Antenatal screening equipment (one stop screening for pre-ecclampsia and chromosomal aneuploidies)***
- ***Bio-informatics set up for Nest generation data analysis using High End desktop***
- ***Eonis tm system for DNA based newborn screening for rare disorders***
- ***Capillary Electrophoresis system for newborn screening of hemoglobinopathies***
- ***Upgradation of existing equipment's may also be considered to save costs benefiting a larger section***
- ***Any other with permission of the MOHFW with proper justification and as decided by a technical committee of experts set up by MoHFW.***

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In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Compliance of Biomedical Waste Management Rules

Rajya Sabha Unstarred Question No: 2905

Shri Sushil Kumar Gupta:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state;

(a) whether the Ministry has advised the Central Pollution Control Board to ensure strict compliance of Biomedical Waste Management Rules; and

(b) if so, the details thereof?

Answered on 22nd March 2021

A. (a) & (b) The Government had notified the Bio-medical Waste Management (BMWM) Rules, 2016 on 28th March, 2016 in supersession of the Bio-medical Waste (Management and Handling) Rules, 1998 with the objective to regulate and improve segregation, collection, processing, treatment and disposal of bio-medical waste in an environmentally sound manner. The Rules prescribe standards for treatment and disposal of biomedical waste generated in Health Care Facilities (HCFs) and treated by Common Biomedical Waste Treatment Facilities (CBWTFs). The Central Pollution Control Board (CPCB) is entrusted with the following responsibilities under the BMWM Rules, 2016:

- Prepare Guidelines on bio-medical waste management;
- Co-ordination of activities of State Pollution Control Boards or Pollution Control Committees (SPCBs/ PCCs);
- Conduct training courses for authorities dealing with BMW management;
- Lay down standards for new technologies and prescribe specifications for treatment and disposal of BMW;
- Lay down criteria for establishing CBWTFs;
- Undertake random inspection or monitoring of HCFs and CBWTFs
- Review and analyse the data submitted by the SPCBs/ PCCs on BMW management;
- Undertake inspection and monitoring of HCFs operated by the Director General, Armed Forces; and
- Undertake or support research/ operational research regarding BMW

Further, to ensure safe disposal of biomedical waste during COVID-19 pandemic, CPCB has brought out dedicated 'Guidelines for Handling, treatment and disposal of waste generated during treatment, diagnostics and quarantine of COVID-19 patients'. CPCB is also monitoring the COVID-19 waste management through a High Level Task Team with representation from Ministry of Environment Forest & Climate Change, Ministry of Health & Family Welfare, Ministry of Housing & Urban Affairs, Ministry of Defence, Ministry of Jal Shakti, SPCBs/PCCs, State Environment Departments and State Departments of Health.

Minister of State in the Ministry of Environment, Forest and Climate Change (Shri Babul Supriyo)

Public Procurement Policy for MSEs

Rajya Sabha Unstarred Question No: 2983

Shri G.V.L Narasimha Rao:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) whether Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2018 setting 25 per cent target for MSEs in Government/ CPSUs has been properly implemented;

(b) the share of procurement from MSEs by different Government/ Ministries/ Departments and Central PSUs;

(c) the share of procurement from SC/ST and women-owned enterprises vis-à-vis sub-target norm;

(d) the reasons for shortfall in achieving sub-targets for SC/ST, women-owned enterprises;

(e) whether Government is aware that some large corporates are setting up wholly owned MSEs

subsidiaries to grab public procurement tenders; and

(f) if so, whether Government will allow such large corporate' promoted subsidiaries from bidding?

Answered on 22nd March 2021

A. (a): Yes, Sir.

(b) & (c): Public Procurement Policy for MSEs Order, 2012 mandates 25% annual procurement from MSEs including 4% from MSEs owned by SC/ST and 3% from MSEs owned by women by Central Ministries/ Departments and Central Public Sector Enterprises (CPSEs). As per information on MSME SAMBANDH Portal, the share of procurement from MSEs during the last two and current financial year (as on date 17.03.2021) alongwith the share of procurement from SC/ST & Women owned MSEs is as under:

Financial Year	Buyers	Total Procurement (Rs in Crores)	Procurement from MSEs (including SC/ST owned MSEs) (Rs in Crores)	Procurement from MSEs owned by SC/ST (Rs in Crores)	Procurement from MSEs owned by Women (Rs in Crores)
2018-19	165 CPSEs	153477.05	40399.54 (26.32%) (No. of MSEs benefited 128124)	824.71 (0.54%) (No. of MSEs benefited 4587)	232.56 (0.15%) (No. of MSEs benefited 1410)
2019-20	141 CPSEs	131360.69	39631.76 (30.17%) (No. of MSEs benefited 157671)	692.77 (0.53%) (No. of MSEs benefited 6332)	393.43 (0.30%) (No. of MSEs benefited 3657)
2020-21 (As on 17.03.2021)	137 CPSEs	103037.14	31477.65 (30.52%) (No. of MSEs benefited 136411)	579.70 (0.56%) (No. of MSEs benefited 5115)	569.44 (0.55%) (No. of MSEs benefited 3690)

(d): The CPSEs sometimes encounter challenges in procurement from SC-ST & Women MSEs.

However, due to collective efforts by the CPSEs/ Ministries concerned, the participation of SC/ST & Women MSEs in public procurement has shown an increasing trend since 2017-18.

(e): No, Sir.

(f): In view of above, it does not arise.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Revenue Generated from Foreign Companies Operating in the Country

Rajya Sabha Unstarred Question No: 3053

Dr. Fauzia Khan

Q. Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

(a) the number of foreign companies operating in India at present, State-wise;

(b) the number of foreign companies registered during last five years;

(c) whether Government received revenue from the foreign companies by way of fees/charges for filling/ registering various documents; and

(d) if so, the details of the amount received from these companies during each of the last five years?

Answered on 23rd March 2021

A. (a) to (d): Foreign Company is defined under section 2(42) of the Companies Act, 2013 as any company or body corporate incorporated outside India which (a) has a place of business in India whether by itself or through an agent, physically or through electronic mode and (b) conducts any business activity in India in any other manner.

The number of foreign companies operating in India at present State-wise are as per Annexure-1. The number of foreign companies registered during last five years, and details of fees/ charges for filling/ registering various documents during last five years are as under:

Year	Number of foreign companies registered.	Details of fees/ charges for filling/ registering various documents (in Rs).
2015-16	161	11,77,38,000
2016-17	160	10,06,02,000
2017-18	134	14,29,92,000
2018-19	118	13,58,22,000
2019-20	122	13,19,94,000

Annexure- 1

Annexure referred to in reply to parts (a) to (d) of Rajya Sabha Unstarred Question No. 3053 for 22.03.2021:

Name of the State/ UT	Number of Foreign Companies Operating in the Country at present
Andhra Pradesh	49
Assam	1
Bihar	3
Chandigarh	2
Chhattisgarh	1
Delhi	1444
Goa	5
Gujarat	49
Haryana	251
Karnataka	261
Kerala	28
Madhya Pradesh	7
Maharashtra	825
Manipur	1
Orissa	10
Puducherry	1
Punjab	6
Rajasthan	14
Tamil Nadu	213
Telangana	37
Uttar Pradesh	76
Uttarakhand	5
West Bengal	61
Total	**3350**

The Minister of State for Finance and Corporate Affairs (Shri Anurag Singh Thakur)

COVID-19 Vaccine Fatalities and Liability

Rajya Sabha Unstarred Question No: 3121

Shri Derek O' Brien:

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

(a) the number of fatalities that have been resulted due to administration of COVID-19 vaccine; in the country;

(b) the authority responsible in case of an adverse effect arising out of administering the COVID-19 vaccine among the patient, the vaccine manufacturer, the Government, the doctor or any other party; and

(c) the grievance redressal mechanism for issues arising out of administering COVID-19 vaccine including fatalities?

Answered on 23rd March 2021

A. (a): As on 16th March 2021, a total of 89 deaths of vaccinated persons have been reported following COVID-19 vaccine vaccination. None of the deaths so far have been causally attributed to COVID-19 vaccination as per the current evidence.

(b) & (c): Adverse Event Following Immunization (AEFI) are monitored through a well-structured & robust AEFI surveillance system. Causality Assessment of all serious and severe AEFIs are done by the designated AEFI committee to determine if AEFI is related to vaccine or vaccination process or otherwise.

Adequate measures have been put in place to manage AEFIs like availability of anaphylaxis kits at each vaccination site, immediate referral to AEFI management center and observation of vaccine recipients for 30 minutes at session site for any adverse events so as to take timely corrective measure. Also the AEFI management of such cases are provided free of cost treatment in Public Health Facilities.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

Export of Vaccine to Other Nations

Rajya Sabha Unstarred Question No: 3129

Shri Sambhaji Chhatrapati:

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

(a) whether Government has received proposals for exports of vaccine to combat COVID-19 in some other countries;

(b) if so, the details of the countries from which such requests have been received;

(c) the extent to which it would be viable to export the vaccine to other countries, in a scenario where the

country itself needs a huge number of vaccine doses for inoculation of its own people; and

(d) the policy of preference in case Government decides to export the vaccine to other countries?

Answered on 23rd March 2021

A. (a) to (d): A sub-Group of the National Expert Group on Vaccine Administration for COVID-19 was constituted to consider all matters related to vaccine export of COVID-19 vaccines and take necessary decisions with due regard to domestic production and ensuring adequate availability for the national vaccine programme for COVID-19. This Sub-Group closely monitors the supplies.

External supplies of Made-in-India COVID19 vaccines started w.e.f. 20.01.2021. Supplies have been undertaken in the form of "Grants-in-aid", commercial sales by the manufacturers and through GAVI's COVAX facility. GAVI's COVAX facility has more than 190 members including India. Country-wise details for supply of vaccines till 17 March 2021 are enclosed. More than 7.47 crore vaccine doses have been supplied to Stats/UTs within the country so far.

Once an epidemic takes form of a pandemic, its management has to be done keeping the entire globe as unit and in most circumstances it is not possible to take either States-specific or country-specific approach. Hence, export of COVID-19 vaccine which facilitates global action to vaccination is important to simultaneously protect the high-risk population in all the countries of the world, thereby breaking the chain of transmission and minimizing chances of import of COVID-19 cases from foreign countries as well as neighbouring countries to India.

Low/middle income Countries as well as nations with limited access to pharmaceutical technologies are at debilitating disadvantages in dealing with the pandemic. To this end, Govt. of India has allowed only limited export of vaccines while according highest priority to domestic needs.

Sr. No.	Country	Grant	Commer-cial	COVAX	Total Supplies
		Quantity	Quantity	Quantity	
1	Bangladesh	20	70		90
2	Myanmar	17	20		37
3	Nepal	10	10	3.48	23.48
4	Bhutan	1.5		0.24	1.74
5	Maldives	2		0.12	2.12
6	Mauritius	1	1		2
7	Seychelles	0.5			0.5
8	Sri Lanka	5	5	2.64	12.64
9	Bahrain	1			1
10	Brazil		40		40
11	Morocoo		70		70
12	Oman	1			1
13	Egypt		0.5		0.5
14	Algeria		0.5		0.5
15	South Africa		10		10
16	Kuwait		2		2
17	UAE		2		2
18	Afghanistan	5		4.68	9.68
19	Barbados	1			1
20	Dominica	0.7			0.7
21	Mexico		8.7		8.7
22	Dominican Republic	0.3	0.2		0.5
23	Saudi Arabia		30		30
24	El Salvador		0.2		0.2
25	Argentina		5.8		5.8
26	Serbia		1.5		1.5
27	UN Health workers		1		1
28	Mongolia	1.5			1.5
29	Ukraine		5		5
30	Ghana	0.5	0.02	6	6.52
31	Ivory Coast	0.5		5.04	5.54
32	St. Lucia	0.25			0.25
33	St. Kitts & Nevis	0.2			0.2
34	St. Vincent & Gren-adines	0.4			0.4
35	Suriname	0.5			0.5
36	Antigua & Barbuda	0.4			0.4

37	DR Congo	0.5		17.16	17.66
38	Angola			6.24	6.24
39	Gambia			0.36	0.36
40	Nigeria			39.24	39.24
41	Cambodia			3.24	3.24
42	Kenya	1		10.20	11.2
43	Lesotho			0.36	0.36
44	Rwanda	0.5		2.40	2.9
45	Sao Tome & Principe			0.24	0.24
46	Senegal	0.25		3.24	3.49
47	Guatemala	2			2
48	Canada		5.00		5
49	Mali			3.96	3.96
50	Sudan			8.28	8.28
51	Liberia			0.96	0.96
52	Malawi	0.5		3.60	4.1
53	Uganda	1.00		8.64	9.64
54	Nicaragua	2.00		1.35	3.35
55	Guyana	0.8			0.8
56	Jamaica	0.50			0.50
57	UK		50		50.00
58	Togo			1.56	1.56
59	Djibouti			0.24	0.24
60	Somalia			3.00	3.00
61	Seirra Leone			0.96	0.96
62	Belize	0.25			0.25
63	Botswana	0.30			0.30
64	Mozam-bique	1.00		3.84	4.84
65	Ethiopia			21.84	21.84
66	Tajikistan			1.92	1.92
67	Benin			1.44	1.44
68	Eswatini	0.20		0.12	0.32
69	Bahamas	0.20			0.20
70	Cape Verde			0.24	0.24
71	Iran		1.25		1.25
72	Uzbekistan			6.60	6.60
73	Solomon Islands			0.24	0.24
74	Laos			1.32	1.32
Total		**81.25**	**339.67**	**174.99**	**595.91**

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

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NEW DEVELOPMENTS

Will COVID-19 vaccines need to be adapted regularly?

Influenza vaccines need to be evaluated every year to ensure they remain effective against new influenza viruses. Will the same apply to COVID-19 vaccines? In order to gauge whether and to what extent this may be necessary, a team of researchers from Charité - Universitätsmedizin Berlin compared the evolution of endemic 'common cold' Coronaviruses with that of influenza viruses. The researchers predict that, while the pandemic is ongoing, vaccines will need to undergo regular updates. A few years into the post-pandemic period, however, vaccines are likely to remain effective for longer. This study has been published in *Virus Evolution.*

Influenza viruses are masters at evading the human immune system. They undergo such rapid changes that antibodies produced by the immune system in response to a previous infection or vaccination become unable to neutralize them. This is why the complex task of evaluating and updating the seasonal influenza vaccine has to be repeated every year. Mutations within SARS-CoV-2 have already produced a number of variants, some of which (such as the South African variant) partially evade the body's immune response. As a result, some vaccine manufacturers have already started to develop new versions of their vaccines. What does this mean for the future? Will COVID-19 vaccines mirror influenza vaccines in requiring regular updates?

In order to gauge whether, over the long term, SARS-CoV-2 is likely to demonstrate an immune evasion capability on par with that of influenza viruses, Charité virologists have studied the genetic evolution of the four currently known 'common cold' Coronaviruses. These relatively harmless Coronaviruses are known to be responsible for approximately 10 percent of common colds in the world and have been in circulation in humans significantly longer than SARS-CoV-2. Just like SARS-CoV-2, they enter human cells using the 'spike protein', a surface protein which gives the virus its characteristic crown-like appearance (and name). The spike protein also forms the target of all current COVID-19 vaccines.

For their study, the researchers focused on the two longest-known Coronaviruses (termed 229E and OC43), tracing changes in the spike gene approximately 40 years into the past. The researchers started by comparing sequences from a range of old samples which had been deposited in a genetic sequence data bank. Based on the mutations which had emerged over time, they then produced phylogenetic trees for both Coronaviruses. The researchers compared their findings with the phylogenetic tree of H3N2, an influenza subtype which is particularly effective at evading the human immune response.

The researchers' calculations revealed one feature which was common to the phylogenetic reconstructions of both the Coronaviruses and the influenza virus: all three had a pronounced ladder-like shape. "An asymmetrical tree of this kind likely results from the repeated replacement of one circulating virus variant by another which carried a fitness advantage," explains the study's first author, Dr Wendy K Jó from Charité's Institute of Virology. "This is evidence of 'antigenic drift', a continuous process involving changes to surface structures which enable viruses to evade the human immune response. It means that these endemic Coronaviruses also evade the immune system, just like the influenza virus. However, one also has to look at the speed with which this evolutionary adaptation happens."

For this step, the researchers determined the three viruses' evolutionary rates. While the influenza virus accumulated 25 mutations per 10,000 nucleotides (genetic building blocks) per year, the Coronaviruses accumulated approximately 6 such mutations in the same timeframe. The rate of change of the endemic Coronaviruses was therefore four times slower than that of the influenza virus. "As far as SARS-CoV-2 is concerned, this is good news," summarizes Prof Dr Christian Drosten, Director of the Institute of Virology and a researcher at the German Center for Infection Research (DZIF).

SARS-CoV-2 is currently estimated to change at a rate of approximately 10 mutations per 10,000 nucleotides per year, meaning the speed at which it evolves is substantially higher than that of the endemic Coronaviruses. "This rapid genetic change in SARS-CoV-2 is reflected in the emergence of numerous virus variants across the globe," explains study lead Prof Dr Jan Felix Drexler, a researcher at both the Institute of Virology and the DZIF. "This, however, is likely due to the high rates of infection seen during the pandemic. When infection numbers are so high, a virus is able to evolve more rapidly. Based on the rates of evolution seen in the endemic common cold Coronaviruses, we expect that SARS-CoV-2 will start to change more slowly once infections start to die down - meaning once a large proportion of the global population has developed immunity either as a result of infection or through vaccination. We expect therefore that COVID-19 vaccines will need to be monitored regularly throughout the pandemic and updated where necessary. Once the situation has stabilized, vaccines are likely to remain effective for longer."

(Materials provided by Charité - Universitätsmedizin Berlin. Note: Content may be edited for style and length).

Source: Science Daily, 25.03.2021 (Excerpts)

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Cadila Healthcare Working on Needle-free, 2-Dose Vaccine

Cadila Healthcare will test whether its DNA plasmid platform Covid-19 vaccine can be given in two doses instead of three through a needle-free injection as the company looks to catch up with rivals.

The drug company is conducting phase-3 trials with over 20,000 participants to test whether its three-dose vaccine ZyCoV-D prevents virologically confirmed symptomatic Covid-19 cases compared to the placebo. The vaccine candidate is administered on day 1, day 28 and day 54.

"The phase-3 Clinical Trials currently on are for a three-dose vaccine. There is no change in this. Further, we are also conducting a study looking at the possibility of administering two doses so that it can help immunise people faster," a Cadila spokesperson told ET in an email.

Ahmedabad-based Cadila started its clinical trials in November. The company is working on third-generation vaccines that use lab-made DNA of the antigen that induces an immune response against a pathogen.

In an interview to brokerage Jefferies in February, the company's management indicated that the first dose will be provided to all 28,000 participants by the first week of March. Cadila is also working on using a reusable needle-free injector device that would make the vaccine administration easier.

Source: Divya Rajagopal, ET-HelathWorld, The Economic Times, 02.04.2021

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DCGI to consider Russian vaccine Sputnik V for emergency use today

The Centre on Wednesday, 31.03.2021 assured the States that there would not be any shortage of Covid-19 shots as it opens up vaccinations to all above the age of 45, but cautioned that wastage has to be kept below one per cent, it said.

Till late on Tuesday, 30.03.2021 6.31 crore vaccinations have been done. The numbers are expected to go up significantly from Thursday with a wider section of the population eligible to be covered.

Meanwhile, a subject expert committee advising the Drugs Controller General of India (DCGI) on Covid-19 vaccines is expected to meet on Thursday, 01.04.2021 to review additional data on Russian vaccine Sputnik V, submitted by Dr Reddy's Laboratories, which has tied up with the Russian Direct Investment Fund, for conducting trials as well as marketing it in India. DCGi is considering authorising Sputnik V for emergency use.

During a video conference meeting with State Health Secretaries, State Health Mission directors and State immunisation officers, Union Health Secretary Rajesh Bhushan urged the officials to identify pockets of low vaccination coverage, particularly in districts that are witnessing a surge in cases, and correct the situation, an official statement said.

As many as 47 districts across several States are seeing a spike in Covid-19 cases of late.

The Centre particularly wanted all eligible healthcare workers and frontline workers in these areas identified and registered for the vaccination. It also wanted the States to archive all incorrect and duplicate entries on the Co-WIN (Covid Vaccine Intelligence Work) portal.

Source: The Hindu, 02.04.2021

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Trade policy extended by six months to September 30

The Government on Wednesday, 31.03.2021 further extended the validity of the current Foreign Trade Policy (FTP), which provides a road map for boosting external commerce in goods and services, by six months through September 30.

The latest move will enable exporters to continue to get incentives under a clutch of extant programmes — including the Remission of Duties and Taxes on Exported Products (which replaced the flagship Merchandise Exports From India Scheme, or MEIS, from January 1), interest equalisation scheme and transport subsidy scheme (for farm exports) — without any hiccups.

The validity of the FTP for 2015-20 was already extended by a year through March 31, 2021 in the wake of the Covid-19 pandemic, mainly to maintain policy stability and soften the blow to exporters.

Exemption from the payment of IGST and compensation cess on the imports made under the advance/EPCG authorisations and by the export-oriented units has also been extended by six months through September 30. Similarly, the validity of "status holder" certificates for exporters will also be extended up to end-September. Such a certificate suggests an entity is recognised by the government as export house/trading house or star trading House. A statement by the commerce ministry suggested that the extension is aimed at providing "continuity in the policy regime" in view of the unprecedented situation arising out of the pandemic.

The government has budgeted Rs. 13,000 crore for the RoDTEP scheme for FY22. But the actual outgo will likely far exceed the budgetary allocation, exporters have said. Similarly, under the interest equalisation scheme, the government has budgeted Rs.1,900 crore for FY22, against Rs. 1,600 crore (RE) for FY21. This scheme usually allows manufacturing and merchant exporters an interest subsidy of 3% on pre-and-post-shipment rupee credit for exports of 416 products (tariff lines).

The incentives are crucial to keep exports from sliding further in the aftermath of the pandemic, as supply chains have been hit and demand from key markets, too, has faltered. Goods exports in February grew by 0.7% on-year, although the contraction in the first 11 months of this fiscal was still to the tune of 12%.

FE had first reported on March 21 that the announcement of a new FTP could be delayed, thanks to not just Covid-induced disruptions but also a policy dilemma over the continuation of certain key export programmes that have been challenged successfully by the US at the World Trade Organisation (WTO).

Washington had claimed that these schemes were inconsistent with global trade rules and that "thousands of Indian companies are receiving benefits totalling over $7 billion annually from these programmes".

India had appealed against the ruling of the WTO's dispute body in response to the US plea in November 2019. But with the WTO's appellate body remaining dysfunctional for over a year now, ironically due to the US' blocking of the appointment of judges, the fate of India's appeal remains uncertain.

The programmes that have been challenged include the MEIS and those relating to special economic zones, export-oriented units, electronics hardware technology parks, capital goods and duty-free imports for re-exports.

While India has already replaced the MEIS, the biggest scheme, with a WTO-compliant tax refund programme from January 1, others still continue. New Delhi believes that it has a strong case and the verdict of the appellate body, when it comes, should go in its favour. Unless a decision is made by the appellate tribunal on the appeal, the findings of the WTO's dispute panel can't be binding on India.

The pandemic has also forced the government to undertake a comprehensive review of its FTP architecture for the next five years, given the country now needs fresh policy responses to counter the massive damage caused by the pandemic.

Source: Financial Express, 01.04.2021

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Government asks pharma companies to expand Clinical Trials

The department of biotechnology is supporting pharmaceutical companies in clinical trials on covid-19 vaccines under various schemes

Scientists and vaccine developers should apply for complementary clinical trials on infants, children, pregnant women and immunocompromised people, the department of biotechnology (DBT) said, with the aim of expanding the country's Covid-19 vaccination strategy to more population groups.

The trials will be funded by the Coalition for Epidemic Preparedness Innovations (CEPI), a global alliance financing and coordinating the development of vaccines against infectious diseases. The DBT is supporting the implementation of the Ind-CEPI Mission, India

Centric Epidemic Preparedness through Rapid Vaccine Development.

CEPI will offer up to $140 million in funding to vaccine developers and other research institutions globally for rapid complementary clinical data on Covid-19 vaccines. The clinical trials are sought to advance current Covid-19 immunization efforts by providing data on demographics and age groups such as pregnant and lactating women, infants and children, and those who have low immunity levels, who may at present not be eligible to receive vaccines.

If the trials show that these vaccines are safe, tolerable and produce an immune response in such populations, the trial data could inform and influence current vaccination strategies globally to expand access to these key groups, CEPI said. Clinical studies in some age groups such as infants and children could also provide important information on the size of vaccine doses needed to have an impact, it said.

Indian vaccine makers and scientists should also take part in the trials to generate data on whether booster doses are required, the duration a vaccine remains effective and the potential impact of novel coronavirus variants on vaccine performance, the government has said.

India has already revised the intervals between two doses of Covishield from the existing 4-6 weeks to 4-8 weeks following scientific evidence showing enhanced protection against covid by increasing the interval of the second dose. Other nations are considering doing the same or using a mix of vaccines to increase the use of available stock and speed up mass vaccination. The government has said that clinical trials may provide additional data on dose timing and 'mix and match' strategies.

DBT is supporting pharmaceutical companies in clinical trials on Covid-19 vaccines under various schemes. Some of the companies receiving DBT support are Cadila Healthcare Ltd (Zydus Cadila), Biological E, Gennova, Bharat Biotech International Ltd for two trials, Seagull BioSolutions Pvt Ltd and Aurobindo Pharma Ltd.

India rolled out its nationwide vaccination drive on 16 January with the vaccination of healthcare workers, followed by frontline workers from 2 February. The next phase of vaccination began on 1 March for those more than 60 years and for those aged 45 and above with specified comorbidities. Starting 1 April, the Centre has extended vaccination for all persons above 45 years irrespective of whether or not they have comorbidities.

Source: Neetu Chandra Sharma, LiveMint, 31.03.2021

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Bharat Biotech mulls booster dose six months after second shot of Covid vaccine

Bharat Biotech, the maker of Covaxin vaccine, is evaluating the option of adding a booster dose to its two-shot jab, amid concerns that emerging variants may weaken the effectiveness of vaccines designed to fight against older strains of coronavirus, a government official said.

The company is studying administration of a booster dose in a separate Phase-2 trial. It has approached the Subject Expert Committee (SEC) under India's drug regulator with a proposal to administer the booster dose after six months of the second dose. "The company has presented amendments in the approved protocol, proposing administration of a booster dose. It is examining what would be a potential of a booster dose," added the official. In a meeting held last week, the SEC recommended that the company should conduct the booster dose study only with 6 mcg (microgram) strength and also follow up with the participants for six months after the booster dose.

"The firm should present the details of the primary and secondary objectives and various assessments to be carried out in the subjects," state the minutes of the meeting. The committee has asked the company to submit the revised clinical trial protocol for evaluation. The SEC is the body that recommends the use of new vaccines and drugs to the drug controller. Bharat Biotech will have to take its approval for adding a booster dose. Separately, the SEC has permitted the company to 'unblind' participants above the age of 45. This means people who participated in the clinicals trials will be told whether they were given the vaccine or a placebo.

Source: Teena Thacker, Economic Times, 02.04.2021

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DCGI directs SLAs, labs & associations to implement e-governance from April 15

To bring uniformity, traceability and accountability in evaluation and disposal of licenses, the Drugs Controller

General of India (DCGI) has directed State Licensing Authorities (SLAs), drug testing labs and pharmaceutical associations to implement e-governance through online national drug licensing system which can be accessed through https://statedrugs.gov.in from April 15, 2021 onwards.

The same has been made functional for testing with effect from March 31, 2021 for validation of the system. Online national drug licensing system will be shifted from validation mode to operational mode for all purposes with effect from April 15, 2021 onwards.

"The applicants and regulators involved in processes have been urged to avail this facility of testing followed by operationalization," the DCGI in a notice stated.

As per the DCGI notice, this is to inform that the issue of developing an online portal for issuance of sales and marketing license has been discussed in various Drugs Consultative Committee (DCC) meetings and Central Drugs Standard Control Organisation (CDSCO) has taken this task for development of such online portal to bring uniformity, traceability and accountability in evaluation and disposal procedure of such applications for issuance of licenses or certificates across the country for the benefit of all the stakeholders."

CDSCO in pursuance to implement e-governance had launched various online services through Sugam portal on November 14, 2015.

The DCGI had also directed all SLAs and manufacturers for online submission of applications for issuance of Form 41 (Registration Certificate) and Form 10 (Import License) for veterinary vaccines through Sugam portal.

The applicants seeking for such certificates/licenses may now apply through online Sugam portal as per the checklist in the developed modules. The facility of offline submission of applications in hard copy may not be available after March 25, 2021 for processing, according to a CDSCO notice.

Sugam is an e-Governance system to discharge various functions performed by CDSCO under Drugs and Cosmetics (D&C) Act, 1940. The software system developed is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions and approvals.

It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online and generate the permissions online and generate MIS reports. It contains step-by-step guidance to the applicants of the Sugam portal with screenshots of the workflow for various application submissions.

Following sections which are detailed in Sugam are user registration and login, applicant dashboard, managing sub login accounts, form submission for various processes and post approval changes.

Applications were made in hard copy dossier format to various divisions in CDSCO before the Sugam portal was introduced. The timelines for granting permissions or approvals for applications were almost three times more than what is there in the current scenario.

Source: Shardul Nautiyal, Pharmabiz, 05.04.2021

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FEATURE

Patient-centricity must drive the pharma sector

Nilesh Gupta

"You treat a disease: you win, you lose. You treat a person, I guarantee you you'll win, no matter what the outcome." These words by Hunter Doherty "Patch" Adams, the doctor-comedian-author, truly underline the patient-centric approach that is bringing in a paradigm shift in healthcare.

However, just as the Indian pharma industry needs to revise and revamp its operating model and offerings, of equal importance is the flexibility and evolution of the regulatory system.

Covid-19 has shown that a comprehensive patient-centric approach is the future of healthcare and the pharma

industry. It must infuse and define the industry's purpose and vision. With technology and digitisation pervading the industry at a far rapid pace than ever imagined, this shift will be much more immediate than imagined.

Today, physicians need better tele-medicine and training standards to ensure that a virtual touch translates to healing; equally, pharma companies have to look beyond drug innovation to a digital revolution in how we do research, how we manufacture, and how we test products.

India enjoys an eminent position in the global pharmaceutical market — a position that was created through hard work and grit. The $41-billion Indian pharma industry exports to 200 countries.

The industry is the largest provider of generic drugs globally and supplies over 50 per cent of the global demand for vaccines, 40 per cent of generic medication in the US and 25 per cent of all medicines in the UK.

For decades we have lived up to the proud claim of being the pharmacy of the world. Covid only served to reinforce it. From ensuring supply of essential drugs, re-purposing existing drugs, expediting the supply of PPEs and testing kits, to supplying vaccines to other nations while balancing a huge domestic demand, India has once again proven its leadership in supporting the world in tackling widespread health crises. It is humbling to see that we were once again given the opportunity to serve, and do what we have done during previous crises such as those associated with tuberculosis, HIV, and malaria.

Covid also showed us that despite the size and spread of the industry, being agile and adaptive are not management mantras, but are essential to our survival. From ensuring stable supply chains to being at the frontier of the latest developments in the pharma sector, the industry has made rapid progress.

A recent example is when a number of firms had to recall their batches of diabetes drug Metformin due to NDMA impurity levels. The industry took immediate action, addressed the issue and relaunched the drug, ensuring supply to much-needy patients. As a responsible global healthcare partner, the industry has always ensured compliance with global quality practices. However, as leaders we should set the bar. A lot more remains to be done for India to be the global benchmark in quality manufacturing. Pharmaceutical manufacture and testing is complex, with a lot of human touch.

Tap the data:

In many ways, we are still manufacturing and testing the way we did 20 years ago. This cannot be the story for the next 20 years. Even if you keep aside areas like continuous manufacturing, there is a huge amount of data being generated by our machines and instruments that must be used.

Whether it is to optimise manufacturing yields, avoid batches that fail, or build in testing into the process, there is so much that can be done. Being patient-centric for the pharma industry means ensuring that patients are front and centre in all that we do — that today means boldly ushering in a new age of automation and digitisation to ensure controls like we never had before on our products, processes, and quality systems.

Part of being the global benchmark is a constant understanding of the benchmark. A frank exchange with bodies like the USFDA is a must. While mission critical inspections of Indian facilities by the USFDA have resumed, the pace of these inspections has been limited by Covid. Other regulatory bodies such as those of Europe, the UK and Australia have shown openness to alternative modes of inspection such as virtual/remote audits.

In a Covid-19 world, hold up in approvals for new products and plants creates gaps in drug supplies and vulnerabilities in supply chains. Part of being patient-centric for regulators is to ensure that they get the innovation, approval and inspection cycle going, whatever it takes.

Patient-centricity in all we do is the much-needed shot in the arm for this industry to now rise to its true level.

The writer is MD, Lupin Ltd

Source: www.thehindubusinessline.com, 28.03.2021


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Dear Partner,
The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
Because our biggest success lies in your infinite trust in us. And we will always ensure that we treat that trust with the utmost care.
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