PRICE
PER COPY
₹25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/TECH/WPP-337/WEST/2021-23
RNI REGN. NO. 18921/1970
REGN NO . MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 03 (PAGES: 40) | 15 TO 21 JANUARY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

REGISTER NOW

IDMA - SAP WEBINAR

on

Generating global opportunities for a future-ready India
on Friday, 4th February, 2022 - | 3:00 PM - 4:00 PM IST
(Details on Page No. 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 03** **15 to 21 January 2022**

IDMA ACTIVITIES:

FSSAI MATTERS:

GOVERNMENT NOTIFICATIONS:

CUSTOMS MATTERS:

PARLIAMENT NEWS:

INTERVIEW:

IPR MATTERS:

NATIONAL NEWS:

Generating global opportunities for a future-ready India

Join us for an exclusive webinar

4th February, 2022 | 3:00 PM - 4:00 PM IST | Register now

Dear IDMA Member,

IIDMA & SAP are joining hands once again after the successful Global Bharat Webinar in 2021 for the IDMA - SAP WEBINAR on “Generating Global Opportunities for a Future-ready India on Friday, 4th February, 2022 from 3:00 PM to 4:00 PM IST. The information on the webinar and the Register link is **(https://growthmattersforum.com/webinar/generating-global-opportunities-for-a-future-ready-india?source=IDMA).**

The Registration is complimentary but necessary. Request members to REGISTER NOW and take benefit from the same.

As you aware, India's MSME segment is one of our economy's most potent growth engines. Now with the clarion call to Make in India and build an Atmanirbhar Bharat, today, the national expectations are pinned on the sector more than ever. So it is time for Leaders like you to embrace technology for sustainable growth and greater resilience.

We're proud to kickstart the 2022 edition of the Global Bharat Webinars with the 1st virtual session to help expand your business to global markets and scale new heights.

IDMA & SAP invite you to join us and discover how your business can access the right technology platforms and solutions to explore new global market opportunities and enable a digital-first company.

Request members to join this webinar to know more about the Global Bharat initiative & how technology will enable you to grow faster and help your companies and the Indian Pharma Industry!

Thanks & regards,

Daara Patel
Secretary - General

IDMA representation to Joint Secretary, Ministry of Commerce on IDMA's views with respect to India @ 2047- reg.

IDMA have submitted representation on 11th January 2022 to Ms Nidhi Mani Tripathi, Joint Secretary, Ministry of Commerce, Government of India with the copies to Ms. S Aparna, IAS, Secretary, Department of Pharmaceuticals, Government of India, New Delhi and Mr. Udaya Bhaskar, Director General, Pharmexcil, Hyderabad on the above subject:

Further to the Web meeting conducted by Pharmexcil and Ministry of Commerce on 8th January 2022, we, at IDMA, are pleased to place forth our views and suggestions in regards to India@2047 as below:-

IDMA's views with respect to India @ 2047

- **Background**
  - The Indian Pharma industry is third largest manufacturer volume wise. It is composed of small, midsized and large companies focused on development, manufacturing and marketing/ exports.
  - This sector has demonstrated that it is a resilient sector. Have successfully sailed through macroeconomic volatilities.
  - The sector has gained and played the role of a strategic industry for India.
- **Target**
  - We expect the industry to reach USD 130Bn size by 2030, and assuming a similar CAGR it can touch USD 600Bn size by 2047.
  - This would require the industry to adopt new capabilities and to adapt to the changing environment and to the patients' needs. The ecosystem partners such as academia also need to upgrade, the Government may need to handhold and the regulations may be needed to be reformed.
- **Some key factors to be considered, for achieving this target, are as follows**
  - Developing India's capabilities for manufacturing of APIs, KSMs, Basic Chemicals, critical excipients, etc.
  - Developing Indian Formulation industry's capabilities to handle biosimilars and large molecules.
  - Promoting India's exports (more than 50% of our exports go to the RoW countries) - Signing MRA with RoW countries (those not a part of PICs) (almost 140 countries) to accept GMP issued by Indian regulators as an evidence of GMP in order to waive inspections. This would enable quick and seamless access of these markets by WHO GMP certified Indian manufacturers.
  - Innovation- Developing Innovation and R&D centers of excellence for Pharma and Biologics, in order to prepare the industry for going up the value chain.
  - Healthtech / IT- Developing expertise in digital and data driven technologies for development, manufacturing and supply chain in pharmaceuticals and healthcare.
- **Policy areas of intervention and shared Industry-Government commitment is required in**
  - Developing people and skills – filling gap between industry and academia, skilling industry.
  - Strengthening the SME sector by special incentives.
  - Developing policies and incentives for upstream capacity building in APIs and specialty chemicals.
  - Pro-research environment – Investment based or outcome based incentives in research (R&D centers), development (BABE, F&D), fast tracking approvals, promoting NDDS and incremental innovations through Price controls relaxations and simplified regulatory approvals, etc. Strengthening intellectual property development and management framework.
  - Regulatory reforms- Reforms in laws and regulations aimed at promoting the growth of the industry through ease of doing initiatives, reducing compliance burden, decriminalization of minor offenses, modifying the pricing framework

to take into account the uncertainties and volatilities. Changes in the pharma regulations should be done phase-wise keeping in mind that we have to address the national needs, that of affordability and quality, and the role of SMEs in nation building. At the same time aligning with global standards – WHO GMP, ICH and PICs should also be a long term goal with suitable handholding.

- Digitalization- Helping and guiding industry in adopting industry 4.0 models, promoting digital intervention through cross collaboration with STEM graduates in pharma and healthcare.
- Promoting partnerships – industry – industry, industry- Government, industry academia and so on, using shared resources, collaborative approach. If we want to create excellence in Pharma industry, we shall also need to create excellence in academia, support industries, infrastructure, etc.

Trust the above views of IDMA along with the suggestions would be accepted by the Ministry and Government with regards to India@2047. We would be too happy to meet you in person and explain IDMA's views with respect to India@2047 in greater detail.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

● ● ●

Request to postpone the implementation of monograph for Ferrous Ascorbate – IP 2018 addendum 2021: IDMA representation to Secretary-cum-Scientific Director, IPC

IDMA have submitted representation on 14th January 2021 to The Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India, Ghaziabad on the above subject:

Respected Sir,

Greetings from Indian Drug Manufacturers' Association (IDMA).

IDMA is India's largest and a responsible association, representing the interests of over 1100+ manufacturers of pharmaceutical formulations and APIs. We appreciate the IPC for the wonderful work done in last several decades in setting the apt standards for drugs and formulations. It has helped the industry in a great way.

The recent disruption in our operations due to the pandemic has slowed down a lot of activities and we are trying to focus on manufacturing and maintaining supply chain for essential medicines for India and the World.

We would request your attention to the monograph of Ferrous Ascorbate IP 2018 addendum 2021. We have received request from some API manufacturers, that they have yet not been able to successfully upgrade and validate their manufacturing to produce API that could comply to the newly published monograph of Ferrous Ascorbate listed in IP 2018 addendum 2021, with respect to the requirements for content of Iron and Ascorbic acid. In this context, it might cause a temporary disruption in the availability of this API in the market, and this might disrupt availability of its formulations too. We therefore request you to please postpone the implementation of monograph of Ferrous Ascorbate IP 2018 addendum 2021 for a period of 6 months i.e. upto 30th June 2022. This will give a little more time to the API manufacturers to compete their development and validation part and also enable the formulation manufacturers to upgrade their formulation based on the revised API specifications.

We hope you will consider our request favorably and issue suitable directions for the industry.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

● ● ●

SECOND EDITION

#ETIPWS

ET Healthworld.com

INDIA PHARMA WORLD SUMMIT

Technological Disruption in Pharma 2.0

MARCH 25, 2022 | VIRTUAL EVENT

We Proudly Present

IDMA

Our Supporting Partner

Be a part of the thought leadership that will decode the technological and logistical disruptions in the pharmaceutical sector, ushered in by the entrepreneurial spirits of the veterans and fresh minds of the industry.

REGISTER NOW

Partnership & Marketing Alliance

ASHISH KUMAR | ashish.kumar3@timesinternet.in | +91 974 076 1921

SAURAV PRAKASH | c-saurav.prakash@timesinternet.in | +91 828 555 0210

For Speaking Opportunities & Nomination

MANVI SAXENA | manvi.saxena@timesinternet.in | +91 886 051 0296

ANCHAL DWIVEDI | anchal.dwivedi@timesinternet.in | +91 912 027 4773

Request for Inputs - Discontinuation of Export Promotion Capital Goods (EPCG Scheme in the Foreign Trade Policy) - reg.

Dear Member,

We have received a communication from PHARMEXCIL (as reproduced below) on the above mentioned subject requesting us to provide our suggestions / Inputs on the same. Request members to kindly peruse through the trailing email and respond accordingly.

In view of the above, we request member companies to share their views/inputs on the following aspects:

- Need for continuation of EPCG scheme(in one para)
- Product wise, HS code wise details of Capital goods for retaining in the EPCG Scheme
- The list of capital goods India is strong in manufacturing and available in the Domestic market, for inclusion in Negative list
- Need for including Second hand machines under the Scheme

Members are requested to submit their suggestions/inputs on **https://forms.gle/3b7Vkrp5RiL7b9Co6** before 24th January 2022 to enable the Council to represent the matter with DGFT.

Thanks & regards,

Daara B Patel
Secretary - General

Pharmaceuticals Export Promotion Council of India

(Set Up by Ministry of Commerce & Industry, Governemnt of India)

PXL/HO/Cir-127/2021-22 Date: 20.01.2022

Hyderabad

IDMA (Indian Drug Manufacturers' Association)

Dear Sir/Madam,

Subject: Request for Inputs - Discontinuation of Export Promotion Capital Goods (EPCG Scheme in the Foreign Trade Policy)

We would like to bring to the notice of member companies that there is a proposal to discontinue the Export Promotion Capital Goods Scheme (EPCG) and DGFT has sought the comments from the industry on the need for continuation of the said Scheme.

The EPCG Scheme allows import of capital goods for pre-production, production and post-production at Zero customs duty and subject to fulfilment of specific export obligation equivalent to 6 times of duties, taxes and cess saved on capital goods, to be fulfilled in 6 years from date of issue of authorization. However, the Department of Revenue is of the view that EPCG Scheme is hampering growth of the domestic capital goods industry and it is in favour of gradually phasing it out.

In view of the above, we request member companies to share their views/inputs on the following aspects:

- Need for continuation of EPCG scheme(in one para)
- Product wise, HS code wise details of Capital goods for retaining in the EPCG Scheme
- The list of capital goods India is strong in manufacturing and available in the Domestic market, for inclusion in Negative list
- Need for including Second hand machines under the Scheme

Members are requested to submit their suggestions/inputs on **https://forms.gle/3b7Vkrp5RiL7b9Co6** before 24th January 2022 to enable the Council to represent the matter with DGFT.

Thanking you,

Uday Bhaskar
Director General

AUSHADH SANDESH

Dear Members,

Aushadh Sandesh is a Bi-monthly e-Newsletter. This is an initiative by NPPA to report current affairs and events related to Pharmaceutical industry and the NPPA. This newsletter has been curated purely for informative purposes and do not reflect the official policy or position of NPPA.

e-Newsletter is available on NPPA website: **https://www.nppaindia.nic.in.** Interested members are requested to visit their website for complete information.

Regards,

Daara B. Patel
Secretary-General, IDMA

● ● ●

FSSAI MATTERS

Food Safety and standards Authority First Amendment Regulations, 2021 : Extending the timeline for compliance to provisions related to labelling requirements - reg.

STD/ADV(S&S)/SP-05/G(E1156), dated 13th January, 2022

To

1. *ED (CS) - with a request to communicate to Food Safety Commissioners of all States/UTs*
2. *Advisor (QA)*
3. *Head (RCD) / Head (Regulations) / Head (Legal)*
4. *Director (Imports) — with a request to communicate to all Authorized Officers*
5. *All Regional Directors, FSSAI*
6. *All Central Licensing Authorities, FSSAI*
7. *CITO, FSSAI: For uploading this direction on FSSAI website.*

1. Reference is drawn to the Food Safety and standards Authority (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) first Amendment Regulations, 2021 notified on 6th September, 2021 and subsequent direction dated 22nd October, 2021 for extending the timeline for compliance to provisions related to labelling requirements up to 1st July 2022.

2. Representation were received from various stakeholders requesting to permit the use of either old or new names of pro-biotic strains for the product packaging as the taxonomy of several pro-biotic microorganisms specified under Schedule VII of above mentioned regulations have been revised in line with global updating in their name.

3. After due consideration of the representations **it has been decided to allow the use of either old or new names of pro-biotic strains for the product packaging till further order,** as it does not compromise with the safety of food products and also allowed by other regulator across the globe.

4. This issues with approval of the competent authority.

Bhaskar N, Advisor (Science & Standards Division), Food Safety and Standards Authority of India, A Statutory authority under the Ministry of Health and Family Welfare) Science and Standards Division, FDA Bhawan, Kotla Road, New Delhi-110002

● ● ●

Draft Rules to amend the Medical Devices Rules, 2017 published - reg.

Drugs & Cosmetics Notification G.S.R.19(E), dated 18th January 2022

Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.729(E), dated the 12th October, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on 12th October, 2021;

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

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), with consideration that consultation with Drugs Technical Advisory Board shall be held as per the provisions, the Central Government hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:-

1. (1) These rules may be called the **Medical Devices (….. Amendment) Rules, 2022.**

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

2. In the Medical Devices Rules, 2017 (hereinafter to be referred as said rules), in rule 19B, in sub-rule (2), in item (iii), at the end, the following Proviso and Explanation thereto shall be inserted, namely:-

"Provided that in case the applicant submits, on or before the 28th February, 2022, an undertaking that applicant shall obtain the ISO 13485 certificate on or before the 31st May, 2022 in lieu of certificate of compliance as referred in clause (iii) of sub-rule (2) of rule 19B, a provisional registration number shall be generated which will remain valid up to the 31st May, 2022 or the date on which the applicant obtained such ISO certificate whichever is earlier. The said generated provisional registration number shall be valid for all purposes.

Explanation: For the removal of doubt, it is hereby declared that in case of such ISO 13485 certificate not obtained before the 31st May, 2022 as per undertaking referred in the Proviso by the applicant the provisional registration shall be deemed to have been cancelled for all purposes without any notice."

3. In the said rules, in rule 19C, for the words "shall mention the registration number" the following words, letters and figures shall be substituted, namely:-

"may, if so desired, mention the registration number or provisional registration number, as the case may be, for a period up to the 31st May, 2022, thereafter it shall be mandatory for all registration holders".

4. In the said rules, in rule 19D, in sub-rule (2), in item (iii), at the end, the following Proviso and Explanation thereto shall be inserted, namely:-

"Provided that in case the applicant submits, on or before the 28th February, 2022, an undertaking that applicant shall obtain the ISO 13485 certificate on or before the 31st May, 2022 in lieu of certificate of compliance as referred in clause (iii) of sub-rule (2) of rule 19D, a provisional registration number shall be generated which will remain valid up to the 31st May, 2022 or the date on which the applicant obtained such ISO certificate whichever is earlier. The said generated provisional registration number shall be valid for all purposes.

Explanation: For the removal of doubt, it is hereby declared that in case of such ISO 13485 certificate not obtained before the 31st May, 2022 as per undertaking referred in the Proviso by the applicant

the provisional registration shall be deemed to have been cancelled for all purposes without any notice."

5. In the said rules, in rule 19E, for the words "shall mention the registration number" the following words, letters and figures shall be substituted, namely:-

"may, if so desired, mention the registration number or provisional registration number, as the case may be, for a period up to the 31st May, 2022, thereafter it shall be mandatory for all registration holders".

Dr Mandeep K Bhandari, Joint. Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi

***Note:-** The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R.78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R.918(E), dated the 31st December, 2021.*

● ● ●

Drugs Rules, 1945 amended (1st Amendment of 2022) - reg.

Drugs & Cosmetics Notification G.S.R.20(E), dated 18th January 2022

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section(1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.567(E), dated the 8th August, 2019, in the Gazette of India, Extraordinary, Part II, section 3, sub- section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 10th August, 2019;

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

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

1. (1) These rules may be called the Drugs (Amendment) **Rules, 2022.**

(2) They shall come into force on the **first day of January, 2023.**

2. In the Drugs Rules, 1945, in rule 96, after sub-rule (4), following sub-rule shall be inserted, namely:-

"(5) Every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear Quick Response code on its label at each level packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the following minimum particulars, namely:-

(i) Unique product identification code,

(ii) Name of the API,

(iii) Brand name (if any),

(iv) Name and address of the manufacturer,

(v) Batch no.,

(vi) Batch size,

(vii) Date of manufacturing,

(viii) Date of expiry or retesting,

(ix) Serial shipping container code,

(x) Manufacturing licence no. or import licence no.

(xi) Special storage conditions required (if any).".

F.No.X.11014/17/2019-DR

Dr Mandeep K Bhandari, Joint. Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi

***Note:-** The principal rules were published in the Official Gazette vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R.848(E), dated the 9th December, 2021.*

● ● ●

New Drugs and Clinical Trials Rules, 2019 amended (2nd Amendment of 2022) - reg

Drugs & Cosmetics Notification G.S.R.21(E), dated 18th January 2022

Whereas a draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019, was published as required by sub-section(1) of section 12 read with sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.524(E), dated the 2nd August, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 2nd August, 2021;

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

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the New Drugs and Clinical Trials Rules, 2019, namely:-

1. (1) These rules may be called the **New Drugs and Clinical Trials (2nd Amendment) Rules, 2022.**

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

2. In the New Drugs and Clinical Trials Rules, 2019 (hereafter referred to as the principal rules), in rule 2, in sub-rule (1), after clause (l), the following clause shall be inserted, namely:-

"(la) "Designated Registration Authority" means the authority designated under sub-rule (1) of rule 17;"

3. In the principal rules, in Eighth Schedule, in Form CT-03,-

(a) In para1,-

(i) for the words, "The designated authority", the words "The Designated Registration Authority" shall be substituted;

(ii) the words, "Regulation of", shall be omitted;

(b) For the words, "Central Licensing Authority", the words "Designated Registration Authority" shall be substituted.

F.No.X.11014/13/2021-DR

Dr Mandeep K Bhandari, Joint. Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi.

***Note:-** The principal rules were published in the Gazette of India vide notification number G.S.R.227(E), dated the 19th March, 2019 and last amended vide notification No. G.S.R.14(E), dated the 13th January, 2022.*

● ● ●

Draft Rules to further amend the Medical Devices Rules, 2017 - reg.

Drugs & Cosmetics Notification G.S.R.23(E) dated 18th January 2022

The following draft of certain rules further to amend the Medical Device Rules, 2017, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation after publication with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration or after the expiry of a period

of forty-five days from the date on which the copies of the Gazette of India these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No.434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the **Medical Devices (.....Amendment) Rules, 2021**.

(2) These rules shall, unless specified otherwise, come into force on the date of its final publication in the Official Gazette.

2. In the Medical Devices Rules, 2017, after rule 43, the following rule shall be inserted, namely:-

"43A. Suspension and cancellation of license- (1) If the manufacturer or licensee fails to comply with any of the conditions of an import license, or any provisions of the Act and these rules, the Central Licensing Authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under rules, or suspend it for such period as it thinks fit either wholly or in respect of any of the part of medical device to which it relates or direct the licensee to stop import, sale or distribution of the said medical device and, thereupon, order the destruction of medical device and the stock thereof in presence of officer authorized by Central Licensing Authority, if in its opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or rules made thereunder:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority under this rule may, within thirty days of the serving of the order, may file appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity for hearing, pass such order as it thinks fit.".

Dr Mandeep K Bhandari, Joint. Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi.

***Note:-** The Medical Devices Rules, 2017 was published in the Official Gazette vide notification No. G.S.R. 78(E), dated 31st January, 2017 and last amended vide notification number G.S.R. ..... (E), dated.....*

● ● ●

Drugs Rules, 1945 amended (2nd Amendment of 2022) - reg.

Drugs & Cosmetics Notification G.S.R.30(E), dated 20th January 2022

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.628(E), dated the 13th September, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 13th September, 2021;

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

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

1. (1) These rules may be called the Drugs **(2nd Amendment) Rules, 2022.**

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

2. In the Drugs Rules, 1945, in Schedule K, in the table, after serial number 38 and the entries relating thereto, the following serial number and entries shall be inserted, namely:-

Class of Drugs	Extent and Conditions of Exemption
"39. Liquid Antiseptics for household use	The provisions of Chapter IV of the Act and rules made thereunder, which require them to be covered with a sale license in Form 20 or Form 20A, subject to the following conditions, namely:- (a) The drugs are manufactured by licensed manufacturers; (b) the drugs do not contain any substance specified in Schedule G, H, H1 or X; (c) the drugs are sold in the original unopened containers of the licensed manufacturer; (d) the drugs are purchased from a licensed wholesaler or a licensed manufacturer."

F.No. X.11014/10/2021-DR

Dr Mandeep K Bhandari, Joint Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R.20(E), dated the 18th January, 2022.

● ● ●

Retention of ISO Containers to meet future requirements - reg.

Customs Circular No.01/2022 dated 18th January 2022

To

All Principal Chief Commissioners/ Chief Commissioners of Customs/ Customs (Preventive),

All Principal Chief Commissioners/ Chief Commissioners of Customs & Central tax,

All Principal Commissioners/ Commissioners of Customs/ Customs (Preventive),

All Principal Commissioners/ Commissioners of Customs & Central tax,

All Principal Director Generals/Director Generals under CBIC.

1. Kind attention is invited to Board's Instructions Nos.07/2021-Customs dated 24.04.2021, 08/2021-Customs dated 27.04.2021 and 12/2021-Customs dated 25.05.2021 relating to relaxation of various procedures relating to facilitation of COVID related consignments.

2. Board has received representations through the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, for providing relaxations in the re-export of ISO Containers imported temporarily for combating the COVID Pandemic. Such containers have been used for efficient transportation of Liquid Medical Oxygen due to the inherent advantage related to multi-modal transportation (by Road/Rail/Waterways/Airways).

3. The issue has been examined. Board hereby guides all the field formations to allow extension of time period for re-exports of ISO containers meant for transportation of Liquid Medical Oxygen grade, if imported under Notification No.104/1994-Customs dated 16.03.1994, till 30.09.2022, upon receipt of requests from the importers, in this regard.

4. Further, in respect of ISO Containers imported on lease by availing IGST exemption under serial number 557B of Notification No.50/2017-Customs dated 30.06.2017, it is hereby clarified that as long as ISO containers are in India under a valid lease and the IGST amount is paid on such lease amount under CGST law, the IGST is not required to be paid on the value of the ISO containers, and in such a situation the need for re-export would not arise.

5. Any difficulty in the implementation of this Circular may be brought to the notice of the Board.

F. No.450/179/2017-Cus- IV

Ananth Rathakrishnan, Deputy Secretary (Customs), Central Board of Indirect Taxes & Customs, Ministry of Finance, Department of Revenue, New Delhi

● ● ●

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Support to Pharma Technology Institutes

Lok Sabha Unstarred Question No.3376

Shrimati Veena Devi:

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

(a) whether any special initiative have been taken/ proposed to be taken by the Government for advancement of pharma technology institutes in order to reduce dependency on imports for active pharmaceutical materials in the country;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answered on 17th December 2021

A. (a) & (b): Department of Pharmaceuticals has set up seven National Institutes of Pharmaceuticals Education and Research (NIPERs) at Mohali (Punjab), Ahmedabad (Gujarat), Hajipur (Bihar), Hyderabad (Telangana), Guwahati (Assam), Kolkata (West Bengal) and Raebareli (Uttar Pradesh) to nurture and promote quality and excellence in pharmaceutical education and research in India. These are institute of national importance, which besides imparting master's and doctorate education, conduct high end research in various specializations in the field of pharmaceuticals and medical devices.

An amount of about Rs. 937 cr. has been released to these NIPERs during last five years. Since inception, about 7,347 Masters and 467 PhD fellows have passed out from these institutions, 5,277 research papers published in various reputed journals, 301 patents filed and 161 MOUs signed with industry and other academic institutions.

Parliament has recently passed NIPER (Amendment) Bill, 2021 which aim to improve administrative functioning of these institutes and enhance the number and scope of courses being offered by them.

Further, the Government has recently launched Production Linked Investment (PLI) Scheme for enhancing domestic production of Active Pharmaceutical Ingredients (APIs)/ Key Starting Materials (KSMs)/ Drug Intermediaries (DIs). NIPERs have been associated with the scheme for providing technical assistance, testing facilities, etc.

(c) Does not arise.

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Exorbitant Price of Patented Medicines

Lok Sabha Unstarred Question No. 3377

Shri Shanmuga Sundaram K.:

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

(a) the details of steps taken by the Government to control the prices of abnormally high priced patented medicines of MNCs in the country;

(b) whether the Government proposes to opt for Negotiated Pricing Model instead of adopting Reference Pricing System; and

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

Answered on 17th December 2021

A. (a) National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled medicines specified in the National List of Essential Medicines (NLEM) as included in the Schedule- I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Any medicine (patented or non-patented) included in Schedule-I of DPCO, 2013 comes under purview of price control. In case of non-scheduled medicines (including non-scheduled patented drugs), increase in Maximum Retail Price (MRP) is limited to 10% of the previous year's price.

However, a manufacturer producing a new drug patented under the Indian Patent Act, 1970 is exempted from provisions of DPCO, 2013 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.

(b) and (c): The prices of drugs are regulated as per provisions of DPCO, 2013, which is based upon the National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012), which follows the principles of essentiality and market-based pricing. Changes, if any, in the method of price regulation of drugs will require a change in the extant pricing policy.

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Banning of Diclofenac for Vets

Lok Sabha Unstarred Question No. 3382

Dr. Arvind Kumar Sharma:

Shri Shankar Lalwani:

Dr. Bharatiben Dhirubhai Shiyal:

Shri Vishnu Datt Sharma:

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

(a) whether the Government has banned or is taking steps to ban Diclofenac for vets as it has been cited as the cause for depletion of vulture population;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answered on 17th December 2021

A. (a) to (c): Central Government has already prohibited the manufacture, sale and distribution of diclofenac and its formulations for animal use as per the Gazette notification vide GSR No.499(E) dated 4th July, 2008.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Drugs for Treatment of Cancer

Lok Sabha Unstarred Question No. 3399

Shri Sukhbir Singh Jaunapuria:

Shrimati Ranjanben Dhananjay Bhatt:

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

(a) whether the Government has taken any concrete steps to enable the Central Public Sector Undertakings to manufacture drugs for the treatment of cancer and if so, the details thereof;

(b) the details of the prices of drugs manufactured by the CPSUs vis-à-vis the drugs manufactured by private pharmaceutical companies;

(c) whether the Government proposes to reduce the price of drugs required for the treatment of cancer;

(d) if so, the details thereof and the steps taken in this direction so far; and

(e) if not, the reasons therefor?

Answered on 17th December 2021

A. (a) to (e) : There are five pharma Public Sector Undertakings (PSUs) under the aegis of the Department of Pharmaceuticals, namely (i) Bengal Chemicals & Pharmaceuticals Limited (BCPL), (ii) Hindustan Antibiotics Limited (HAL), (iii) Indian Drugs & Pharmaceuticals Limited (IDPL), (iv) Karnataka Antibiotics & Pharmaceutical Limited (KAPL) and (v) Rajasthan Drugs & Pharmaceuticals Limited (RDPL). But, none of the pharma PSUs are manufacturing any drugs for the treatment of cancer.

However, National Pharmaceutical Pricing Authority (NPPA), an attached office of Department of Pharmaceuticals, which is mandated for price regulation of scheduled drugs, has fixed the ceiling prices of 86 anti-cancer scheduled formulations under the National List of Essential Medicines (NLEM), 2015. Further, NPPA has also put a cap of 30% Trade Margin on 42 selected non-scheduled anti-cancer medicines on pilot basis under 'Trade Margin Rationalization' approach. Under this approach, the Maximum Retail Price (MRP) of 526 brands of anti-cancer medicines have been reduced by upto 90%.

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Bulk Drug Park in Telangana

Lok Sabha Unstarred Question No. 3404

Shri Venkatesh Netha Borlakunta:

Shrimati Kavitha Malothu:

Shri Pasunoori Dayakar:

Dr. G. Ranjith Reddy:

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

(a) the status of implementation of the scheme 'Promotion of Bulk Drug Parks' in the country, State/UT-wise;

(b) the details of criteria set for selection of a particular place for setting up Bulk Drug Park;

(c) whether Telangana is known as pharmacy of the country and if so, the details thereof;

(d) whether the Government proposes to set up Bulk Drug Park under the Bulk Drug Parks Scheme in Telangana; and

(e) if so, the details thereof?

Answered on 17th December 2021

A. (a) to (e): The scheme "Promotion of Bulk Drug Parks" provides for grant-in-aid support for creation of Common Infrastructure Facilities to 3 bulk drug parks. The selection criteria is laid down in the detailed guidelines of the scheme, which are available on the website of the Department of Pharmaceuticals i.e. http://pharmaceuticals.gov.in. Under this scheme, Department of Pharmaceuticals has received proposals from 13 states, including Telangana. The proposals are under evaluation.

Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)

Proposal for Setting up of Pharma Park in Haryana

Lok Sabha Unstarred Question No. 3407

Shri Dharambir Singh:

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

(a) whether world class Bulk Drugs and Medical Devices Parks (Pharma Park) have been established in States including Haryana and if so, the details thereof;

(b) whether the Government has received any proposal from the State Government of Haryana for setting up Pharma Park in several district of the State;

(c) if so, the details thereof, district-wise; and

(d) the name of the places where Pharma Parks have been established recently along with the cost incurred in this regard?

Answered on 17th December 2021

A. (a) to (d): Under the scheme for "Promotion of Bulk Drug Parks", Department of Pharmaceuticals has received proposals seeking financial assistance from 13 States including Haryana wherein the proposed site for bulk drug park is located in Hisar District. The scheme provides for grant-in-aid support to 3 Bulk drug Parks.

Under the scheme "Promotion of Medical Devices Parks", Department of Pharmaceuticals has received proposals seeking financial assistance from 16 States/Union Territories including Haryana. After evaluation of the proposals, the Government vide letter dated 24.09.2021 has granted in-principle approval financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh.

Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)

Awareness Compaign for Generic Medicines

Lok Sabha Unstarred Question No. 3412

Shri Achyutananda Samanta

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

(a) the number of Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) Centres functioning in the country, State-wise;

(b) the details of steps being taken by the Government to ensure that medicines are consistently available at these Centres at reasonable prices, so that patients are not compelled to buy medicines at higher prices; and

(c) the details of the steps being taken by the Government to enhance awareness regarding the efficacy of generic medicines and build confidence in the same?

Answered on 17th December 2021

A. (a): As on 12.12.2021, about 8,578 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are functional under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) covering all districts of the country. State/Union Territory-wise list of PMBJKs is enclosed as Annexure.

(b): In order to make Janaushadhi medicines more accessible, Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (PoS) application for value added services has been implemented under the scheme. The medicines to individual Kendras are supplied through three warehouses at Gurugram, Chennai and Guwahati and 39 distributors appointed across the country.

(c): Pharmaceutical & Medical Devices Bureau of India (PMBI), the implementing agency for the scheme spreads awareness about generic medicines through various types of advertisements such as TV, FM Radio, Auto wrapping, Cinema, Bus Brandings, State Transport Bus Stands, Digital Screen Advertisement at Railway Stations, etc. In addition, PMBI also educates the public regularly about usages of Jan Aushadhi generic medicines through various social media platforms like Facebook, Twitter, Instagram, Youtube, etc. The Bureau also organizes seminars and workshops to spread awareness about the scheme. Further, to propagate achievements of the scheme and create awareness about its benefits Jan Aushadhi Diwas is celebrated every year on 7th March.

Annexure

Statement referred to in part (a) of Lok Sabha Unstarred Question No. 3412 for 17.12.2021 raised by Shri Achyutananda Samanta regarding Awareness Compaign for Generic Medicines

State/UT- wise list of PMBJK's functional across the country as on 12.12.2021		
Sr. No.	**Name of the State/UT**	**Number of PMBJK**
1	Andaman & Nicobar	3
2	Andhra Pradesh	183
3	Arunachal Pradesh	28
4	Assam	87
5	Bihar	272
6	Chandigarh	7
7	Chhattisgarh	241
8	Delhi	375
9	Goa	10
10	Gujarat	551
11	Haryana	234
12	Himachal Pradesh	63
13	Jammu And Kashmir	119
14	Jharkhand	75
15	Karnataka	956
16	Kerala	961
17	Ladakh	2
18	Lakshadeep *	0
19	Madhya Pradesh	240
20	Maharashtra	623
21	Manipur	33
22	Meghalaya	15
23	Mizoram	22
24	Nagaland	16
25	Odisha	345
26	Puducherry	18
27	Punjab	304
28	Rajasthan	137
29	Sikkim	3
30	Tamil Nadu	862
31	Telangana	158
32	DNH & D&D	36
33	Tripura	24
34	Uttar Pradesh	1178
35	Uttarakhand	215
36	West Bengal	182
Grand Total		**8,578**

Minister in the Ministry of Chemicals and Fertilizers (Dr. Mansukh Mandaviya)

Import of Surgical Devices

Lok Sabha Unstarred Question No. 3414

Shrimati Rajashree Mallick:

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

(a) whether it is a fact that 70 percent of the demand of medical devices, surgical supplies and equipments are imported from abroad;

(b) if so, the details of items imported during last three years;

(c) whether the Government is planning to set up medical device park in the State especially in Odisha;

(d) if so, the details thereof; and

(e) if not, the reasons therefor?

Answered on 17th December 2021

A. (a): Yes Sir.

(b): The status of medical devices forming the top 5 categories of the total import is as below:

Category wise imports (Values in mn USD)				
S. No.	Segment	Imports F.Y. 2018-19	Imports F.Y. 2019-20	Imports F.Y. 2020-21
1	Electronics Equipment	3676.64	3646.53	3568.64
2	Surgical Instruments	190.18	180.10	103.62
3	Conusumables & Disposables	966.10	1076.23	1470.77
4	IVD Reagent	482.73	527.20	871.89
5	Implants	384.79	415.35	225.63
	TOTAL	**5700.44**	**5845.41**	**6240.55**

(c) to (e): The Department of Pharmaceuticals has notified the scheme "Promotion of Medical Devices Parks" on 21.07.2020. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. Under the scheme "Promotion of Medical Devices Parks", Department of Pharmaceuticals received proposals seeking financial assistance from 16 States/Union Territories. After evaluation of the proposals, the Government vide letter dated 24.09.2021 has in-principally approved financial assistance for common infrastructure facilities for 4 medical device parks i.e. Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh.

Minister in the Ministry of Chemicals & Fertilizers (Dr. Mansukh Mandaviya)

Covaxin Clinical Trial

Lok Sabha Unstarred Question No. 3426

Shri Thomas Chazhikadan:

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

(a) whether the Government is aware that several participants in the Covaxin clinical trial in Bhopal reported that the possible side-effects of the trial were not explained to them;

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

(c) whether the Government has ordered any inquiry to see if such trial was in compliance with New Drugs and Clinical Trials Rules, 2019; and

(d) if so, the details thereof?

Answered on 17th December 2021

A. (a) to (d): As per the provision under New Drugs and Clinical Trials Rules, 2019, in all trials, a freely given, informed, written consent is required to be obtained from subjects of each study before their inclusion in clinical trial. CDSCO has informed that as per available information, none of the participants in the Covaxin clinical trial have been enrolled without taking an informed consent.

The Central Drugs Standard Control Organization (CDSCO) had received complaint regarding violations in the conduct of clinical trial of COVAXIN leading to death of trial participant in one of the clinical trial site at People's Hospital, Bhopal.

CDSCO has evaluated the case in consultation with expert committee & the committee after detailed deliberation opined that Serious Adverse Events (SAE) death is not related to the study vaccine and is not trial related.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

High Cost of Drugs For the Treatment of Spinal Muscular Atrophy

Lok Sabha Unstarred Question No.3447

Shri Feroze Varun Gandhi:

Shri Hanuman Beniwal:

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

(a) the total number of reported cases of spinal muscular atrophy in the country, State/UT-wise;

(b) whether the Government is aware of the high cost of drugs for the treatment of spinal muscular atrophy particularly the injections used in its treatment and if so, the details thereof;

(c) the customs duty, GST and other taxes levied on such drugs;

(d) whether the Government has taken any steps to control the prices of SMA drugs, and if so, the details thereof; and

(e) if not, whether the Government proposes to undertake such steps to make the medicine/injection more affordable or proposes to bear the high expenditure on medicine/injection for treatment of patients including children?

Answered on 17th December 2021

A. (a) ICMR has initiated a National Registry wherein epidemiological data is collected for Rare diseases and other inherited disorders. Data of a total of 4001 rare disease cases (storage disorders, small molecular inborn errors of metabolism, primary immune deficiency disorders, skeletal dysplasia, neuromuscular disorders, haemoglobinopathies and bleeding disorders) have been collected till 31st October, 2021. The number of patients of Spinal Muscular Atrophy enrolled in the registry portal is 295. Information specific to each State/UT is not maintained centrally.

(b) & (c) As informed by the Department of Revenue, Ministry of Finance, for general imports, medicines used in the treatment of Spinal Muscular Atrophy attract Basic Custom Duty of 10% and IGST of 12%. However, individuals are allowed to import medicine for Spinal Muscular Atrophy without payment of Customs Duty and IGST (Nil Custom Duty and Nil IGST) if the following conditions are satisfied:

(i) the goods are imported by an individual for personal use;

(ii) it is certified in the Form as applicable, by the Director General or Deputy Director General or Assistant Director General, Health Services, New Delhi, Director of Health Services of the State Government or the District Medical Officer/Civil Surgeon of the district, in each individual case

(iii) the importer produces the said certificate to the Deputy Commissioner of Customs or the Assistant Commissioner of Customs, as the case may be, at the time of clearance or gives an undertaking to furnish the said certificate.

(d) &(e) In order to help the patients in terms of affordable medicines, Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufactures selected under the Scheme for domestic manufacturing of various product categories, which also include Orphan drugs. The Guidelines for the Scheme are available on the website of the Department of Pharmaceuticals under the tab 'Schemes'.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

In Rajya Sabha

New drug policy

Rajya Sabha Unstarred Question No. 1778

Shri P. Bhattacharya

Shri Harnath Singh Yadav

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

(a) whether Government has formulated a new drug policy, if so, the salient features thereof;

(b) by when it is likely to be announced and from which date it is being implemented;

(c) the steps taken in that regard;

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

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

Answered on 14th December 2021

A. (a) to (e): The National Pharmaceutical Pricing Policy (NPPP) in place was formulated by Government and notifled on 07th December, 2012. This policy was formulated with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines — "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-bring for all. In pursuance of National Pharmaceutical Pricing Policy, 2012 (NPPP-2012), the Government notified the Drugs (Prices Control Order, 2013 (DPCO-2013). As per the provisions of DPCO, 2013, the ceiling price of all scheduled formulations appearing in National List of Essential Medicines (NLEM), are fixed by National Pharmaceutical Pricing Authority (NPPA) and are uniform throughout the country. All the manufacturers of these drugs are required to sell their product equal to or lower than the ceiling price. Further NPPA monitors the prices of non-scheduled drugs to see that the animal price rise remains below 10% on the Maximum retail price.

Minister of State for Chemicals & Fertilzers and New & Renewable Energy (Shri Bhagwanth Khuba)

"The next decade will be the golden age of India's vaccine industry"

Adar Poonawalla, CEO of the Serum Institute of India, Pune, spoke to Group Editorial Director Raj Chengappa on the Covid vaccine journey and his plans ahead. Excerpts:

Q. What is the USP of the Serum Institute of India?

Since I took over in 2011, I have been building capacity ahead of time for all vaccines, and even the new ones that we were going to launch. That really has come in handy during the Covid crisis because we were able to use those facilities quickly, rejig them and buy new specific equipment where needed. I won't call it risk but just future planning that enabled us to produce so much so quickly.

Q. What lessons has the pandemic taught us about battling the virus?

Some of the lessons learnt are to do things in advance. Whether it was capacity planning or distribution to the entire country, a huge coordination and logistics effort was needed. I think we worked very well. We didn't cut corners, we did everything so fast, and that is what I want to see in the years to come. I hope this momentum continues after the pandemic. We can't go back to the way of doing things where we take a long time to get clarity on permission for licences. India has so many opportunities, the world wants to invest in us as an alternative to China. We must take advantage of that. The government can look at how to simplify policies, improve further permissions and licences.

Q. How can we make India a vaccine superpower?

We have already achieved that in some way as 60-70 per cent of the vaccine supply globally comes from India. We need funding to go up the value chain so that we have our own research and innovation. For that, you need to be able to make a decent profit. In India, unlike the US or Europe, it is frowned upon if companies grow beyond a certain size and make profit. But these profits will ultimately be used for reinvestment in capacity and innovation in the country. The pricing policies, the environment in which you get your permissions and licences faster to build new factories, innovate, plough back into research and incentivise exports—these are

the sort of things that will cement our place as a vaccine superpower. The next 10 years are going to be the golden age of India's vaccine industry. We must take advantage of it.

Q. Does Covishield protect against Omicron?

There is no reason to believe that the vaccines that are licensed today—not just Covishield but others as well—will not protect you against Omicron. The data is still coming in. If these vaccines come down to 40-50 per cent in their efficiency, that is when you go for a booster dose. This is until you get new vaccines which many companies, including SII, are working on.

Q. What kind of pressures did you face in the past year?

We knew we had to get things done in record time because each month gone by would result in more lives being lost to Covid. That was the only thing at the back of my mind. My team of 8,000 people worked tirelessly. Without the team implementing my objectives, targets and strategies, we would be nowhere.

Q. What are Serum Institute's next big plans?

We have Covovax, which could be used as a vaccine of choice for children all the way down to the age of 3. We are going to produce Sputnik Light if we get a

licence soon. Our fourth vaccine—the nasal one being developed in partnership with Codagenix—may take a year to come. It will be an excellent option to cover all Covid variants.

Efforts to manufacture Sputnik, the Russian vaccine, have so far borne no fruit. The result is that between them, SII and BBIL have supplied over 1.4 billion doses to the Indian government since January 2021, with SII accounting for around 85 per cent of it. As of December 27, over 830 million people had received their first dose and 580 million had been given double doses. It was a herculean effort and credit goes to the outstanding work done by both central and state governments and their agencies to ensure that inoculation centres were set up with quality storage and safety practices across the country—all done with speed and battling great odds.

The central government has paid the two companies a whopping Rs 23,000 crore altogether. This has given them the incentive to not only augment their existing supply but also work on newer vaccines. BBIL is on the verge of getting clearance for its nasal vaccine. Ella calls it the 'kiss vaccine' because it protects the nasal passage, mouth and the upper respiratory tract—the key areas vulnerable to the virus. Bhushan believes that if it is cleared, it will be a game changer because the ease of administering it could help overcome vaccine hesitancy. Meanwhile, SII has got clearance for Covovax, a protein sub-unit vaccine that it has manufactured in collaboration with Novavax, the US biotech company, and the Coalition for Epidemic Preparedness and Innovation (CEPI).

Bhushan sees the success of Adar Poonawalla (who took a huge risk by stockpiling vaccines even before they were cleared) and Krishna Ella in using the oldest and safest platform to make a vaccine indigenously as signs of India's vaccine capability truly coming of age. India was already the vaccine capital of the world before Covid struck, supplying over 60 per cent of the world's needs. As Bhushan says, "Now that we can move from the R&D stage to approval and supply all in one year for vaccines—when earlier it could take years to do so—it will be a huge fillip for the future." For him, the lessons are that "we must be proactive and encourage R&D, that we must trust our manufacturers to deliver and support them financially and in other ways. This would result in us having strong multinational companies headquartered in India, and not in Europe or the US".

Yet, even as we celebrate the success of the country's adult vaccination programme, as 2022 dawned, the threat of Covid-19 remained as high not just in India but across the world. The virus has shown that it was wilier than humans by mutating to an even more virulent variant called Omicron that has already forced countries to impose lockdowns and India to re-introduce night curfews in many cities. Yet, if the vaccines haven't been able to defeat the virus, despite its many avatars, Covid-19 too has been corralled to an extent. Both Covaxin and Covishield are shown to provide good immunity from the variant, though it may decline as months go by, necessitating a booster dose for recipients.

The resurgence of the virus doesn't detract from the enormous good that has resulted from the efforts of Ella and Poonawalla. There were other worthy newsmakers in 2021 whom we have profiled in the following pages, including Mamata Banerjee, for winning a third term as chief minister of West Bengal by thrashing the BJP; Prime Minister Narendra Modi, for making a major privatisation push to overcome the hesitancy of the past; a clutch of business start-ups gaining unicorn status despite the economic downturn; Neeraj Chopra, for winning India's first Olympic gold in athletics and our hearts with his sporting feat; and Akshay Kumar and Bhuvan Bam for hogging the entertainment limelight with their masterly performances.

But none of them could overshadow the singular achievement of Krishna Ella and Adar Poonawalla for saving thousands of lives and making us feel safer with their vaccines against the worst catastrophe that has befallen humankind in recent years. For this reason, india today has declared them Newsmakers of the Year 2021.

Source: India Today, 10.01.2022

India to push for TRIPS waiver on Covid drugs at WTO

India will push for a waiver of certain provisions of the global intellectual property rights agreement for Covid-19 medicines and products at a mini ministerial meeting called by the World Trade Organization to firm up its pandemic response.

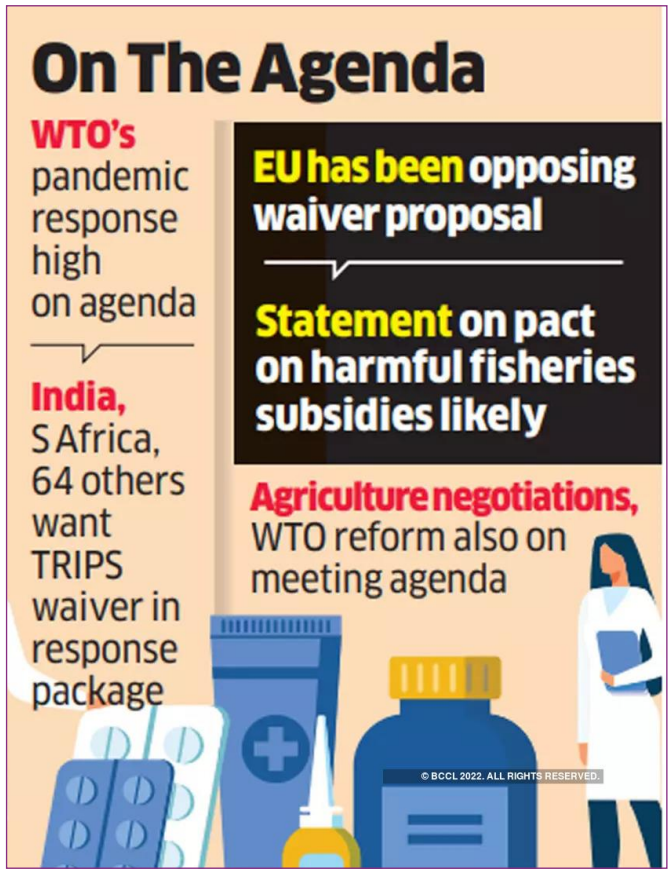
"The meeting is being held to discuss the WTO response both to the current pandemic and future ones to ensure that multilateral trade rules, including the intellectual property system, support international efforts to combat health crises," said an official.

India and South Africa, supported by 64 WTO members, want the TRIPS waiver proposal to be part of the pandemic response but the European Union has been blocking the proposal.

New Delhi has asserted that any WTO response to pandemic without the waiver will not be "credible".

India has pitched for a global pandemic response system that would map manufacturing capacities and demand of medicines and medical equipment and allow special visas or permits for healthcare professionals.

India has also suggested that the WTO consider an 'escape clause' for countries, relying on flexibilities in trade agreements, to avoid disputes while tackling the pandemic and any other in future. It has also suggested that during the current Covid-19 pandemic, a pool of goods such as oxygen concentrators, essential medicines and oximeters,



and services through temporary measures involving special permits for short duration supply of healthcare professionals for four to eight weeks, both physically or remotely, to address acute shortages could be created.

WTO Director-General Ngozi Okonjo-I weala has called for urgent action towards a comprehensive WTO outcome on pandemic response.

"Members will also make their statements on an agreement on harmful fisheries subsidies," the official said.

In the second round of interventions, members have been invited to talk on mapping out future WTO work and objectives in respect of multilateral agriculture negotiations and reform of the WTO's negotiating function, dispute settlement, and monitoring and deliberative functions.

Source: Economic Times, 20.01.2022

Bombay HC sets aside rejection of refund claims by GST authorities

Claim had been rejected as it was filed after 2 yrs; Court sets rejection aside as authorities had not considered earlier SC relaxation on time limit due to Covid

The Bombay High Court has quashed an order by the GST authorities that had rejected the refund claim of an assessee because it was filed after two years, a time limit set by the rules. This was done since the authorities have not taken into cognizance the earlier Supreme Court verdict that excluded the period from March 15, 2020 and October 02, 2021 from the time limit due to Covid.

However, the high court did not go into the validity of the circular and the question of striking it down.

The petitioner concerned filed the first refund application for the period July 2018 to September 2018 on August 21, 2020 online on the GST portal. The said application, however, was rejected by the assistant commissioner of CentralGST (CGST) in Mumbai on September 05, 2020 on the ground that there were certain deficiencies in the said application.

As such, the petitioner filed the second refund application on September 08, 2020, but this was also rejected by the assistant commissioner, pointing out deficiency.

Thereafter, the petitioner filed a third refund application on September 30, 2020, but that was rejected by the official mentioned above on the ground that the application had surpassed the time of two years, set by GST rules given in a circular issued by the Central Board of Indirect Taxes and Customs.

Aggrieved petitioner went to the Bombay high court, seeking to declare a said rule of limiting the refund within two years as ultra vires the Constitution.

The petitioner also sought quashing and setting aside the rejection order and direction to restore the third refund application of the petitioner.

HC observed that it is not in dispute that the first and second refund applications were rejected on the ground of certain deficiencies in those applications.

The third refund application was required to be filed within two years in accordance with the GST rules.

However, in this petitioner's case, such limitation period fell between March 15, 2020 and October 02, 2021, a period which was excluded by the Supreme Court in all proceedings irrespective of the limitation prescribed under the general law or special law.

Earlier, the apex court in a suo motu writ petition had issued directions that in computing the period of limitation in any suit, appeal, application and or proceedings, the period from March 15, 2020 till October 2, 2021 will stand excluded due to Covid waves.

As such, the high court ruled that the assistant commissioner, CGST, is required to exclude the period of limitation falling during the said period.

It ruled that the third refund application filed by the petitioner was within the period of limitation prescribed.

Owing to this, the high court found the order by the CGST official to be contrary to the order passed by the Supreme Court.

However, the high court did not go into the validity of the circular which prescribes the time limit for refund claims, saying the same can be considered in the appropriate case.

Sandeep Sehgal, partner tax at AKM Global, said,"The GST department, without taking cognizance of the relaxations available therein for the limitations, rejected the refund application. Hence, the high court has rightly ruled in favour of the taxpayer."

Source: Indivjal Dhasmana, Business Standard, 17.01.2022

● ● ●

Booster dose can contain spread of virus, experts

By the end of February 22 or early week of March, pandemic could be over but majority of the people though will require booster dose, informed expert

New Delhi : A surge in coronavirus cases caused by the Omicron variant increasing day by day. Healthcare experts

indicate that majority of the people will require booster dose in containing the spread of virus.

Speaking at a webinar on Omicron and booster dose, organised by Hospital & Diagnostics Committee, PHDCCI leading healthcare thought leaders spoke about booster doses are important along with other key COVID appropriate behaviour.

Initiating the discussion Dr Harsh Mahajan, Chair, Hospital & Diagnostics Committee, PHDCCI, mentioned that the Omicron variant of the virus, even though clinically ascertained to be not as lethal, has the potential to cause another wave of the pandemic. He further said that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms.

Informing that by the end of February 22 or early week of March, pandemic could be over but majority of the people though will require booster dose, Dr.ChandrakantLahariya, epidemiologist and health specialist spoke about the choice of booster dose and urged Government to allow people for choice of booster dose vaccination. On the choice of the booster dose he mentioned mRNA based booster dose will be the first choice, protein based booster dose will be second and same vaccine taken earlier will be the third choice.

Talking about the Omicron variant, Dr. Lahariya said,"Decoupling of disease which means the cases are increasing because of high transmissibility of the variant but the hospitalization cases are very less and also decreasing. With 90 percent of population of India has received one or two shots of the vaccine, we are at a good state and vaccine are really working to provide us a protection of getting severe disease. He further said that people with prior infection recovery and vaccination than they have 14 fold higher immunity for various COVID variants even for Delta.

" Sharing the clinical and diagnostic perspective of the COVID infection with different variants. Mentioning about the initial days, Dr. Anant Mohan, Professor and Head, Pulmonary Medicine and Sleep Disorders, AIIMS, New Delhi, said, "Earlier there was a fear and we do not have infrastructure or the experience of dealing with the virus where lockdown had played a major role in containing the spread of virus and simultaneously for building infrastructure and preparing for disease. Positive side of the Omicron pandemic, he mentioned that 90-95% of people recover with the home isolation and do not require hospitalization while the high transmissibility of Omicron is a negative side. Hopefully the Omicron pandemic will come down as speedily as it has gone high in infection rate."

Briefing in detail about the coronavirus time to time mutations and its different variants of concern, Dr Anusha Rohit, Head, Department of Microbiology, The Madras Medical Mission, said, "The potential transmission mechanism of SARS CoV-2 variants of concern which are increased transmission window, increased viral shedding, increased environmental stability and increased binding to host receptor. Alpha, Beta, Gamma and Delta as the variants of concern and Eta, Lota, Kappa, Lambda and Mu as variants of interest which are named after the letters of Greek alphabet. It has 32 mutations on spike protein while Delta variant has nine. If the virus only causes mild infection than natural vaccination of the population might occur and result in end of the pandemic. Get vaccinated, wear mask, maintain physical distancing, ventilate indoor spaces, keep good hygiene and selfisolate if you develop symptoms is the key to survive."

Dr. Deep Goel,Co-Chairs of the Hospital & Diagnostics Committee, PHDCCI, said, "Not all the mutations are bad but this variant (Omicron) will get us immune against other variants. The paranoia of COVID is still there and people are not able to cope up with that yet. This virus will be there for long and we need to learn to live and co-exist with this".

Source: ET Healthworld.com, 17.01.2022

● ● ●

At-home test kits are on the rise due to Omicron, but how accurately can nasal swabs detect Covid?

Over the past two years, diagnosing a coronavirus infection has often required probing the nose. Health

care workers have inserted slender swabs deep into the recesses of Americans' nasal passages, while at-home test kits have asked us to master the shallow double-nostril twirl.

"The traditional approach to diagnosing respiratory infections has been to go after the nose," said Dr. Donald Milton, an expert on respiratory viruses at the University of Maryland.

But the rapid spread of the omicron variant, and questions about the sensitivity of at-home tests, have rekindled a debate over whether the best way to detect the virus is to sample a different site: the mouth.

"The virus shows up first in your mouth and throat," Milton said. "That means that the approach we're taking to testing has problems."

Collecting samples of saliva, or swabbing the inside of the mouth, could help identify people who are infected with the virus days earlier than nasal swabs do, some research suggests.

The science is still evolving, and the data paint a complex picture, suggesting that saliva-based tests have limitations of their own. Many labs are not currently set up to process saliva, nor are the at-home antigen tests available in the United States authorized for it.

But even the saliva skeptics acknowledge that oral specimens have some unique advantages. And with omicron on the march, some experts say that testing companies, labs and federal officials should be working more urgently to determine the best sample sites and types for the virus.

"We need to be adaptable," said Anne Wyllie, a microbiologist at the Yale School of Public Health, who is one of the developers of SalivaDirect, a noncommercial polymerase chain reaction (or PCR) testing protocol. "I see so many either labs or governments who are so fixated on a certain sample type or a certain test that even with changing data or test preferences, they don't make the necessary adaptations to their testing programs."

The Case for Saliva

Scientists began investigating saliva testing in the early months of the pandemic. They were eager to find a testing method that would be more comfortable than the deep nasopharyngeal swabs that were the standard at the time and that would not require trained health care workers or nasal swabs, both of which were in short supply. With saliva, people could simply spit into a tube and hand it over for processing.

Some laboratory professionals were skeptical that saliva testing would be a reliable way to detect infection.

"There were concerns initially that saliva was not the gold standard sample, that it wasn't the most sensitive sample," said Glen Hansen of the clinical microbiology and molecular diagnostics laboratory at Hennepin County Medical Center in Minnesota.

But by fall 2020, dozens of studies had suggested that saliva was a suitable sample for testing.

"There's been a growing body of evidence that at the very least, saliva performs well — it's as good as, if not better, when it's collected properly, when it's processed properly," Wyllie said.

Evidence also emerged that the virus tended to appear in saliva before it built up in the nose, suggesting that saliva samples might be the best way to detect infections early.

Milton and his colleagues recently found that in the three days before symptoms appear and the two days after, saliva samples contained about three times as much virus as nasal samples and were 12 times as likely to produce a positive PCR result. After that, however, more virus began accumulating in the nose, according to the study, which has not yet been published in a scientific journal.

The Food and Drug Administration has now authorized numerous saliva-based PCR tests, which have proved popular for screening students in schools.

"Saliva really has turned out to be a valuable specimen type and one that has increasingly been advocated as a primary testing sample," Hansen said.

Saliva's advantages may be more pronounced with omicron, which appears to replicate more quickly in the upper respiratory tract and have a shorter incubation period than earlier variants. Any testing method that can reliably detect the virus earlier is particularly valuable, experts said.

The Complications

Saliva also has trade-offs. While the virus appears to build up in saliva early, the nose may be a better place to detect it later in the course of infection.

Researchers at the California Institute of Technology found that while the virus often spiked first in saliva, it ultimately rose to higher levels in the nose. Their results suggest that highly sensitive tests, like PCR tests, may be able to pick up infections in saliva days earlier than they do in nasal swabs, but that less-sensitive tests, like antigen tests, might not.

The data on saliva are still mixed, some experts noted.

"There are these few studies that I have found really very interesting," said Dr. Mary K. Hayden, an infectious disease doctor and clinical microbiologist at Rush University Medical Center in Chicago.

But Hayden said she was interpreting the new studies cautiously because "for years and years and years," research has suggested that nasopharyngeal specimens are best for detecting respiratory viruses.

Some scientists also have practical concerns. The mouth is "a little more of an uncontrolled environment compared to the nasal passages," said Joseph DeRisi, a biochemist at the University of California, San Francisco, who is a president of the Chan Zuckerberg Biohub and an author of the cheek swab paper. "Did you drink a Coke right before you took the test? The pH will be different. And those things matter."

Saliva can be "viscous and difficult to work with," especially when patients are sick and dehydrated, Dr. Marie-Louise Landry, Director of the clinical virology laboratory at Yale New Haven Hospital, said in an email.

Ultimately, different approaches may be required in different circumstances. For people who have had symptoms for several days, nasal swabs might be a good choice, while saliva might be best suited for the large-scale surveillance screening of asymptomatic people, Hansen suggested. "We need to get the right test into the right places," he said.

In Britain, some at-home tests require swabbing both the throat and the nose, an approach that may be worth pursuing, experts said.

"Sampling multiple sites is always going to give you an edge," Hayden said.

But if test manufacturers want to add saliva samples or throat swabs, they will need to validate their tests with those samples and submit the data to regulators. At a Senate hearing Tuesday, Dr. Janet Woodcock, acting commissioner of the FDA, noted that manufacturers might also have to reconfigure their tests to accommodate the larger swabs that are designed for the throat.

It is not yet clear whether any of the major at-home testing companies have plans to do so. "We continue to monitor and evaluate," said John M. Koval, a spokesperson for Abbott Laboratories, which makes rapid antigen tests. "Our test is currently indicated for nasal use only."

Source: ET, 18.01.2022

● ● ●

Fourth Covid vaccine partially effective against Omicron, Israeli study shows

JERUSALEM: A fourth dose of Covid-19 vaccine boosts antibodies to higher levels than the third jab but provides only partial protection against the Omicron variant of coronavirus, according to a preliminary study conducted in Israel.

The yet-to-be peer-reviewed study tested the efficacy and safety of vaccines and analysed whether the combination of vaccines from different manufacturers would affect the rate of increase of antibodies.

The researchers from Sheba Medical Center in Israel gave second booster shots in a trial to its staff, and studied the effect of the Pfizer booster in 154 people after two weeks and the Moderna booster in 120 people after one week.

Preliminary results indicate that one week after the administration of a fourth dose of Moderna vaccine, the rate of antibodies increased similarly to that found one week after the administration of a fourth dose of Pfizer.

The study also found that two weeks after the administration of a fourth dose of Pfizer, there was a further

increase in antibodies, slightly more than that measured after the first week. Additional results show that the safety level of the vaccine is similar in both in the Pfizer and Moderna vaccines.

"The increase observed in the level of antibodies is slightly higher than the peak level observed after the booster dose was given -- the third dose," said Professor Gilli Regev-Yochai from Sheba Medical Center.

"We understand that despite the significant increase in antibodies after the fourth vaccine, this protection is only partially effective against the Omicron strain, which is relatively resistant to the vaccine," Regev-Yochai said.

The researchers noted that the vaccines, which were very effective against the previous strains, is less effective against the Omicron variant.

The fourth dose restores and even slightly exceeds the protection provided by the third dose, they said.

"Although the vaccines we have today do not provide optimal protection against infection with the Omicron strain, it is correct to continue the vaccination campaign for at-risk populations," Regev-Yochai added

Source: ET Healthworld.com, 18.01.2022

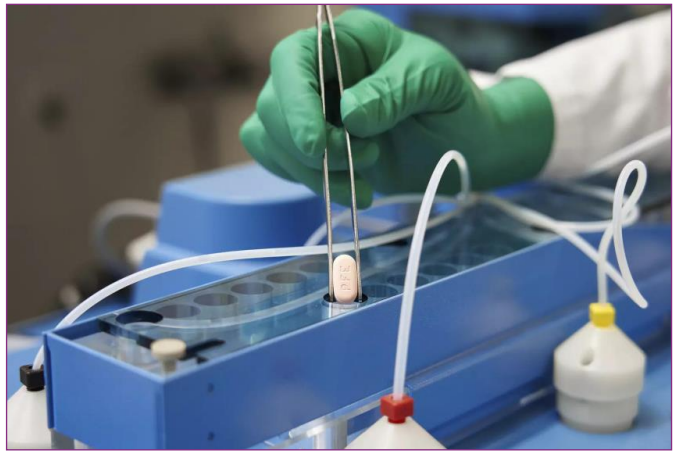
● ● ●

Covid treatment: Govt issues revised guidelines on use of drugs, therapies

The revised guidelines continue to recommend emergency use authorization (EUA) or off-label use of remdesivir in patients with "moderate to severe" disease and those with no renal or hepatic dysfunction within 10 days of the onset of any symptom

There is no evidence of injectable steroids benefitting Covid patients not requiring oxygen supplementation or in continuation after discharge, according to the revised 'Clinical Guidance for Management of Adult COVID-19 Patients'. The revised guidelines issued by AIIMS, ICMR-COVID-19 National Task Force and Joint Monitoring Group (DGHS) under the Union health ministry also stated that anti-inflammatory or immunomodulatory therapy, such as steroids, can have the risk of secondary infection like invasive mucormycosis, when used too early, at higher dose or for longer than required.

Injection methylprednisolone 0.5 to one mg/kg in two divided doses, or an equivalent dose of dexamethasone, can be given usually for a duration of five to 10 days in moderate cases, the guidelines stated. The same drug in two divided doses of one to two mg/kg can be given for same duration in severe cases.



"Inhalational budesonide (given via metered dose inhaler/dry powder inhaler) at a dose of 800 mcg BD for five days can be given in mild cases if symptoms (fever and/or cough) are persistent beyond five days of disease onset," it was stated in the guidelines.

If cough persists for more than two-three weeks, one should opt for investigation for tuberculosis and other conditions, they stated.

The revised guidelines continue to recommend emergency use authorization (EUA) or off-label use of remdesivir in patients with "moderate to severe" disease and those with no renal or hepatic dysfunction within 10 days of the onset of any symptom.

It warned against use of the drug for patients who are not on oxygen support or in home settings.

According to the guidelines, EUA or off-label use of the tocilizumab drug may be considered for use in the presence of severe disease, preferably within 24 to 48 hours of onset of severe disease or intensive care unit (ICU) admission.

Tocilizumab may be considered for patients with significantly raised inflammatory markers, and not improving despite use of steroids with there being no active bacterial, fungal or tubercular infection, they stated. Coronavirus patients have been classified into those affected by mild, moderate and severe disease, the guidelines stated.

According to the guidance note, upper respiratory tract symptoms without shortness of breath or hypoxia has been

categorised as mild disease and have been advised home isolation and care." Those suffering from mild Covid should seek medical attention if they have difficulty in breathing, high grade fever, or severe cough lasting for more than five days.

Those having breathlessness with SpO2 fluctuating between 90-93 per cent, can get admitted to a ward, and they will be considered moderate cases. Such patients should be given oxygen support and awake proning should be encouraged in all patients requiring supplemental oxygen therapy, in sequential position changes every two hours, the guidelines stated.

Respiratory rate over 30 per minute, breathlessness or SpO2 lower than 90 per cent on room air should be considered as severe disease and such patients have to admitted to an ICU as they will need respiratory support, they stated. Such patients should be put on respiratory support. Non-invasive ventilation (NIV) -- helmet or face mask interface depending on availability -- may be considered in those with increasing oxygen requirements if work of breathing is low.

High flow nasal cannula should be considered in patients with increasing oxygen requirements. Intubation should be prioritised in patients with high work of breathing if NIV is not tolerated and institutional protocol for ventilatory management should be used when required, the new guidelines stated.

Those aged above 60 years, or those having cardiovascular disease, hypertension and coronary artery disease diabetes mellitus and other immunocompromised states, such as HIV, active tuberculosis, chronic lung, kidney or liver disease, cerebrovascular disease or obesity are at high risk for severe disease and mortality, the guidelines stated.

Source: ET Healthworld.com, 18.01.2022

● ● ●

Mankind Pharma forays into critical care segment

Mankind Pharma stated that it has forayed into the critical care segment in the country with the launch of a dedicated division. The new division Saviour Mankind has commenced operation, with a product range that includes anti-infectives and medications for stroke and trauma management. Mankind Pharma stated that it has forayed into the critical care segment in the country with the launch of a dedicated division.

The new division Saviour Mankind has commenced operation, with a product range that includes anti-infectives and medications for stroke and trauma management.

''Through this division, we hope to partner with doctors in saving the lives of critically ill patients," stated Mankind Pharma CEO Sheetal Arora.

With the launch, Mankind Pharma added that it aspires to aid the community in leading a healthy life by formulating, developing, commercializing, and delivering affordable and accessible medicines that satisfy the urgent medical needs.

Source: Free Press Journal, 20.01.2022

● ● ●

About Good Governance

While governance is often equated with government, it, in fact, involves much more. Governance occurs at all levels and encompasses the ways that formal government, non-governmental groups, community organisations and the private sector manage resources and affairs.

Three factors that largely determine the efficacy of any system of governance are the quality of leadership, the characteristics of the governed, and the nature of the structures and processes employed to exercise authority and meet human needs.

The capacity of any institution to effect and manage change, and to respond creatively to challenges that lie before it, entails the development of a number of critical skills. These include the ability to maintain a clear perception of social reality and of the forces operating in it; to properly assess the resources of the community; and to implement decisions with an openness and flexibility that avoid all traces of dictatorial behaviour, among others. This constellation of skills must obviously draw on both intellectual and moral resources.

Good governance, in essence, is a moral and spiritual practice whose compass is found within the human heart. Only as the inner lives of citizens are transformed will the vision of an aatmanirbhar Bharat and the integrity of governmental and public institutions be safeguarded.

Source: A K Merchant, ET, 20.01.2022

● ● ●

Govt to allow sale of some drugs sans prescription

India will soon allow the sale of certain drugs without the requirement of a prescription, as part of a new over-the-counter (OTC) policy for drugs. The Drugs Technical Advisory Board (DTAB), the government's top advisory body on drugs, has approved the new policy and a draft notification will soon be issued by the health ministry, a senior government official said.

The DTAB has approved a list of OTC drugs which includes medicines like antifungal infections, analgesics (pain killers), cough syrups, decongestants, laxatives, antiseptics and medicines for gum infections.

"The aim is to reduce treatment cost and also promote self-care without compromising safety," added the official. Unlike other countries like the US, UK or China, India does not have a policy framework to support and regulate distribution, marketing and consumption of OTC drug.

This is despite the fact that commonly used medicines for cough and cold as well as contraceptives are sold over the counter. Neither the Drugs and Cosmetics Act, 1940 nor the Drugs & Cosmetics Rules, 1945 (D&C) defines OTC medicines.

Officials told ET that the list of over-the-counter drugs has been shortlisted, based on evidence of their safety, availability, and non-habit forming nature.

Source: Teena Thacker, ET Bureau, 20.01.2022

● ● ●

A cognitive dissonance in drug regulation?

The letter raised several issues, including the fact that India was promoting expensive diagnostics and drugs with limited evidence.

"Despite the weight of this evidence and the crushing death of the delta wave, we find the mistakes of the 2021 response repeating itself in 2022. We urge you to intervene to stop the use of drugs and diagnoses that are clinically relevant." Unsuitable for managing COVID-19," the signatories wrote. In particular, experts urged the government to discourage the use of "alternative therapies, drugs, antibodies, 'cocktails', and drugs such as mollupiravir, which are expected to be widely misused".

The letter comes days after Balram Bhargava, Director General of the Indian Council of Medical Research (ICMR), India's apex medical research body, also raised the alarm once again over the use of Molnupiravir. "The known and unknown risks of the drug outweigh its benefits," he remarked.

The drug received emergency use approval from India's drug regulator, the Central Drugs Standard Control Organization (CDSCO), in early January as a treatment for mild and moderate Kovid-19 patients, prompting eight Indian generic companies to launch the drug. The way was paved. first line of treatment. The CDSCO is headed by the Drug Controller General of India (DCGI).

While Molnupiravir is the latest flashpoint, as evidenced by protests from experts, this is not the first time the DCGI's office has sparked controversy. Over the past two years, it has issued emergency approvals to a number of drugs with limited evidence to improve the condition of COVID-19 patients. On the other hand, ICMR's National Task Force on COVID Management has been conservative in supporting several drugs that were given emergency approval.

In the context of India's fight against the pandemic, the ICMR's opinion matters. Its task force issues COVID-19 clinical guidelines which are considered to be the guiding document on treatment protocols for hospitals across the country. The team reviewing the evidence on new COVID drugs includes some of the country's leading doctors, including Randeep Guleria, director of the All India Institute of Medical Sciences (AIIMS) and Raman Gangakhedkar, former head of epidemiology at ICMR.

However, differing views between the drug controller and the ICMR's clinical guidelines are now hurting India's COVID-19 response, putting public health at risk, several experts spoke to Mint. The lack of coordination between the ICMR's national task force and the drug controller's office is leading to irrational use of the drug, confusion among the medical community and increasing additional treatment costs for patients.

Certain drugs that are not approved by DCGI's office and not supported by ICMR's clinical guidelines have found their way into many private hospitals in the country. The average cost of hospitalization due to COVID-19 in a private hospital can be anywhere 50,000 more 2 lakhs. Experts estimate that expensive COVID-19 treatment accounts for 40% of this cost.

"India needs rational use of medicines in the private and public sectors especially during the pandemic. Lina Menghani, an activist working on access to drugs, said, "There cannot be two different clinical guidelines. Once a drug is approved by the regulator, it is actually monitoring. There's no way to know how it's going to be administered," Menghani said.

The lack of coordination is especially unacceptable because the pandemic is two years old. A synchronized playbook—where the ICMR and drug controllers work together—should have been in place.

"Covid in 2022 is different than in 2020. Two years ago, physicians didn't know what treatments worked and so there was some logic in prescribing some of these drugs—just because we didn't have the evidence," Doctor. Rajeev Jayadevan, a Kerala-based physician and one of the signatories of the open letter, said. "But now, we have clear evidence of what works and what doesn't. Prescribing some of these drugs is no longer acceptable, especially in asymptomatic or mild cases." Emails to the drug regulator and ICMR seeking comments on its approval procedures remained unanswered.

approval with warnings

Let us take a closer look at some of the drugs that have raised eyebrows. Molnupiravir, first.

Molnupiravir is a repurchased anti-viral drug by American drugmakers Merck and Ridgeback Biotherapeutics that works by introducing an "error" in the SARS Cov2 virus. It prevents its replication in the immune system. Ever since the drug has been tested, it has been in vogue. The companies touted interim results — results in the middle of the trial — saying the drug showed more than 70% efficacy in reducing hospitalizations. After initial enthusiasm, the drug failed to show significant improvement in moderate to severe Covid-19 patients. final test. The relative risk reduction of death after hospitalization or using the drug was 30%. The United States Food and Drug Administration (USFDA) advisory committee was divided when it approved the drug and reduced it to 13/10 votes.

The USFDA said in a public statement that molanupiravir is not authorized for use in patients younger than 18 years old because it can affect bone and cartilage growth. It also said that this drug is not authorized for pre-exposure or post-exposure prevention of COVID-19 or for initiation of treatment in patients hospitalized due to Covid-19. Additionally, the use of the drug among pregnant women is also not recommended because in laboratory studies, the drug was shown to cause fetal harm.

Unlike the USFDA, the Indian drug regulator has not come out with any such advisory—instead, it has asked pharma companies to educate doctors about the drug's risks and side effects.

SP Kalantri, a professor of medicine at the Mahatma Gandhi Institute of Medical Sciences in Sevagram, told Mint that there is a need for careful monitoring given the drug's small benefits in a highly selected population. "ICMR has been careful in interpreting the findings and withholding the drug from the COVID management protocol is entirely justified. It seems that the drug regulator has been a bit hasty in approving the drug.

MSD (Merck in the United States and Canada), in response to an email to Mint, defended the approval.

"Restrictive emergency use was granted to eight generic manufacturers in India that have entered into a voluntary licensing agreement with MSD. We provided relevant information as requested to help DCGI determine the most appropriate use of molnupiravir in India ," the company said.

"We are confident in the clinical profile of molnupiravir, which has demonstrated a significant reduction in our risk of hospitalization or death. Phase 3 clinical trial with no safety concerns compared to the placebo group Not seen," said MSD.

work fast

What are the other drugs that have been approved by DCGI's office that have sparked controversy?

One was itolizumab, a monoclonal antibody that was launched at the cost of 32,000 for four vials. It was approved in July 2020 based on clinical trials conducted on 30 patients. Favipiravir, another commonly used Covid-19 drug, was approved in the same month. It is also plagued with inconclusive evidence.

Glenmark, a Mumbai-based pharma company that conducted the trial, said the drug was "safe and effective". However, according to a study published in the medical journal Elsevier in November 2020, there was not a statistically significant difference in favipiravir. patient recovery.

In November 2021, Epily Therapeutics, the Canadian clinical trial partner of Fujifilm (the Japanese company that discovered the molecule), reported that a study of the drug provided "a primary endpoint of time to sustained clinical improvement". did not achieve statistical significance for" of mild to moderate patients. The trial enrolled 1,231 patients in the US, Mexico and Brazil. In Japan, the drug is not recommended for use with COVID-19 and is prescribed as a flu medicine.

Then, an antibody cocktail drug by US drugmaker Regeneron Pharmaceuticals, which was approved in India in May 2021 (famous because Donald Trump got it), has also been approved by the drug controller. According to Regeneron, it is not effective against the Omicron variant.

"While Regeneron's currently authorized Regene-CoV antibodies have reduced potency against Omicron, they are active against Delta, which is currently the most prevalent variant in the US," the company said in a statement on December 16, 2021. The USFDA, too, revised its guidelines and advised against the use of the drug because it is ineffective in the omicron wave.

"Circulating SARS-CoV-2 viral variants, including Omicron, may be associated with resistance to monoclonal antibodies," said a statement from the US Department of Health and Human Services. Based on the information, the department decided to stop its allotment. Despite such emerging evidence of drug use in healthcare facilities in the country, DCGI's office has not issued any clarification on the use of the drug.

As we mentioned earlier, some of the above drugs are not recommended by the National Task Force of ICMR due to lack of evidence on clinical benefit.

The existing guidelines of the task force have a provision for limited drugs for the treatment of Kovid-19. These include the anti-asthma drug budesonide for mild patients, remdesivir for moderately ill patients, and tocilizumab in extreme cases. Nevertheless, during the early days of the pandemic, the task force also recommended the use of hydroxychloroquine, despite mounting evidence against the drug's ineffectiveness.

shrouded in secrecy

Meanwhile, the functioning of the Drugs Controller's Office of India remains opaque.

For example, little is known about drug and vaccine approval processes for COVID-19 – the evidence that was considered. The Drug Controller is guided by a group known as the 'Subject Expert Committee'. In the last two years, there has been little or no disclosure on the members who approved the COVID-19 drugs and vaccines. According to the government's previous statements, these members are "domain knowledge experts in the fields of pulmonology, immunology, microbiology, pharmacology, pediatrics, internal medicine, etc".

Such secrecy runs in contrast to the practices of many other countries, including the USFDA, which is considered one of the world's most stringent regulators. For example, before a drug can be taken for approval, companies in the US are required to make a public presentation to an independent panel of experts on the product. This presentation is open to the public.

During the pandemic months, presentations were made in video conferences and anyone could attend online. Once a drug is approved for emergency use, the USFDA issues a detailed account of the drug's uses, side effects, and its effects on different population groups. This is backed up with a number of scientific papers that support the rationale behind the approval.

The time has come for the Indian drug regulator to make such lengthy disclosures. And naming the members of the subject committee can be a good start.

"It is no secret that the drug controller's office was under tremendous pressure from pharma companies to approve certain drugs. But, during the pandemic, it may not be business as usual," said activist Leena Menghani.

He said making opaque decisions hurts public health, especially since most Indians pay from their own pockets.

Source: Bharat Times, 17.01.2022

● ● ●

UK hopes FTA with India will address peak tariffs on Scotch, vehicles, pharma

Reducing tariffs on intermediates like Indian textiles, vehicle parts could help British industry, according to report on UK's strategic approach to FTA

The UK is hopeful that its FTA with India will help bring down tariff peaks applied on items such as Scotch whisky, vehicles and chemicals & pharmaceuticals. These goods together accounted for almost a third of overall import duties imposed by India on British goods in 2019.

"A new FTA with India could reduce these tariff barriers and increase the competitiveness of UK exports in the Indian market, further enhancing trade," according to a report on 'UK's Strategic Approach to the India-UK FTA' compiled by the UK Department for International Trade.

In an observation favouring Indian exporters, the study also pointed out that it could be beneficial for the UK industry if it removes tariffs on Indian imports of items such as textiles and textiles articles and vehicles as most of these imports were used as intermediate products in the UK.

Bilateral FTA

India and the UK launched negotiations for a bilateral free trade agreement (FTA) last week covering a multitude of areas including goods, services, and investments, and have set a year-end deadline for concluding the pact. The two sides seek to double bilateral trade in goods and services from existing $50 billion to $100 billion by 2030.

Annual duties on UK exports to India were estimated be around £810 million based on 2019 trade data of which £164 million was on account of whisky attracting tariffs of 150 per cent, £49 million on account of vehicles and parts (not railway-related) attracting tariffs averaged at 59 per cent and £43 million on account of chemicals and pharmaceuticals attracting peak tariff of 100 per cent. Annual duties of £184 million were also imposed on precious stones and metals in 2019.

"Removing tariffs through an FTA would benefit UK businesses by increasing competitiveness, especially when compared to competitors exporting to India from countries without an FTA," the report stated.

India is projected to become the world's fourth largest economy by 2030 and is one of the UK's most economically and strategically important trade and investment partners, the report said stressing on the importance of an FTA with India.

"India is one of the dynamic, fast-growing economies at the heart of the Indo-Pacific and while our bilateral trading relationship is already significant, amounting to £23.3 billion in 2019, an FTA could strengthen it further as UK exports could increase by up to £16.7 billion by 2035," it pointed out.

Middle-class market

The Indian middle-class market is growing fast –estimated to encompass 60 million consumers by 2030 – and is expected to increase the country's demand for healthcare, education, and premium products. India's overall demand for imports is projected to reach £1.38 trillion per year by 2035, it added. "An FTA with India could support jobs across the UK. Experimental analysis shows that exports to India were estimated to support (directly and indirectly) around 63,000 UK jobs in 2016," it said.

Source: Amiti Sen, Business Line, 19.01.2022

● ● ●

India set to achieve $650 billion exports target in 2021-22: Piyush Goyal

India is set to achieve $650 billion exports target in the current financial year, Commerce and Industry Minister PiyushGoyal said on Monday.

Out of the targeted $650 billion, $400 billion will be merchandise exports while the rest $250 billion will be services exports. Chairing a review meeting of all major Export Promotion Councils (EPCs), Goyal said the $650 billion exports target for the current financial year is achievable.

He noted that merchandise exports reached $300 billion mark in the first nine months of the current financial year. "In December alone we touched $37 billion goods exports despite the Omicron fear factor weighing high. This month, in 15 days till January 15, we have reached $16 billion," he said.

Goyal assured Export Promotion Councils that his Ministry would do whatever it takes in handholding the EPCs and resolving their issues to attain even higher export targets in the next financial year. The minister urged the EPCs and entrepreneurs to avail of the Government's initiatives towards Ease of Doing Business such as obtaining clearances through the National Single Window System. He assured the Industry representatives to pursue their demands during the various FTA negotiations. Speaking of the government's efforts to improve the ease of living and the ease of doing business, Goyal said that more than 25,000 compliances have been reduced.

Source: Economic Times, 21.01.2022

• • •

Have you renewed your **Membership** for the years

2020-2021 & 2021-2022

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 /Fax: 022 - 2495 0723

• • •

IDMA BULLETIN SUBSCRIPTION FORM

Date : _____

To
The Subscription Department
Indian Drug Manufacturers' Association ,
102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai – 400 018, India.
Email: admin@idmaindia.com /accounts@idmaindia.com / Web: www.idma-assn.org

Kindly enter my subscription to **"IDMA Bulletin".**

The details are as follows:

Name of the subscriber ……

Current institutional attachment ……

Designation ……

Delivery Address ……

City …… Pin code ……State ……..

Country ……..…….....…Phone no. (with STD/ISD code) ……

E-mail address ……..…..

Subscription details

Subscription Period: One year

Subscription Type: India / Foreign

Subscription starts from: Month …… Year……

Payment details

Cheque No ……..…… Dated ……. Drawn on ..…..…….....…

Amount ……Date: ……

Signature of the subscriber

Annual subscription rates:

India (INR)

Members	Government Research/Educational Institutions	Non-Members
1000	2000	4000

Overseas (US$) :-

Individual
USD 400

Kindly note: *IDMA Bulletin* is Published on 7th, 14th, 21st and 30th of every Month.
(IDMA GSTIN:27AAATI3594D1ZO)

- Subscriptions are for calendar year only
- Please return the filled form to the above mentioned address.
- Cheque should be issued in favour of **"Indian Drug Manufacturers' Association",** payable at Mumbai.
- Please allow at least two weeks for commencement of new subscription.
- Claims for missing issues can be made only within fifteen days of publication

IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  The RTGS details are as follows:- BANK: BANK OF BARODA
  Account Name : ***Indian Drug Manufacturers' Association,*** *Bank A/c No. : Current A/c* ***76080200000242***
  Bank : ***BANK OF BARODA,*** *Branch Address : Worli Branch, Mumbai-18,* ***IFSC : BARB0VJWORL***
  MICR CODE : 400012339
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Melvin Rodrigues — Cell: +9821868758 (Email: actadm@idmaindia.com)/
Geeta Suvarna — — Cell: +9820161419 (Email: publications@idmaindia.com)

PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org www.indiandrugsonline.org**

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in `
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

***KINDLY NOTE**:*

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association"*****.**
- For **RTGS / NEFT**: Account Name***: Indian Drug Manufacturers' Association*****, Bank****: CITIBANK N.A,* ***Bank Account Number:****0036274115,* ***IFSC Code****: CITI0100000,* ***Branch****: Fort Branch, Mumbai – 400 001.*
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, "A"-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018.Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723
E-mail: **admin@idmaindia.com/mail_idma@idmaindia.com,** *Website:* **www.idma-assn.org / www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 21.01.2022

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**