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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022, Hotel Sahara Star, Mumbai

(Details on Page: 4)

IDMA & APTAR PHARMA - WEBINAR

on "Accelerating & De-risking your Injectable Product Development with PremiumCoat®"

Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

(Details on Page: 6)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 Issue No. 36 22 to 30 September 2021

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
1961 – 2021 (60 Glorious Years)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,
Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022
Hotel Sahara Star, Mumbai

We are happy to inform you that our Association will be completing 60 glorious years in 2022. The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry. The main objectives of the celebrations are:

- Showcasing Pharmaceutical and Allied Industries across the Globe
- Disseminating knowledge on various subjects
- Highlighting the achievements of IDMA

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. IDMA Margi Memorial Best Patent Awards
2. IDMA ACG-SCITECH Research Paper Awards
3. IDMA Corporate Citizen Awards

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been met in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government and Regulators. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

We are sure you will be an integral part of the Grand Celebrations.

IDMA 60th ANNUAL PUBLICATION 2022

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc and leave an enduring impression on everyone connected with the Industry.

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OPPORTUNITIES FOR SPONSORSHIPS:

We invite sponsors for our 60th Year Celebrations as below:

PLATINUM SPONSOR : Rs.25 Lakh

DIAMOND SPONSOR : Rs.15 Lakh

GOLD SPONSOR : Rs.10 Lakh

SILVER SPONSOR : Rs.5 Lakh

Sponsors will be provided special benefits & privileges: For details please contact IDMA Secretariat.

REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
Delegate	Rs.6,000/- plus GST @ 18%
(For more than 4 registrations from one Company, the 5th registration will be complimentary)	

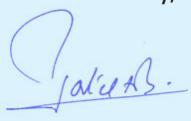
Mr. Melvin Rodrigues	**Ms. Geeta Survana**	**Ms. Batul Bismillah**
9821868758	9820161419	9920045226
actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com

Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

Yours faithfully,



Daara B Patel
Secretary–General

INVITATION ~ IDMA & APTAR PHARMA - Webinar on "Accelerating & De-risking your Injectable Product Development with PremiumCoat®" for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

Dear Member,

~ REGISTER NOW ~

IDMA & APTAR PHARMA - Webinar on "Accelerating & De-risking your Injectable Product Development with PremiumCoat®" for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

Aptar Pharma and Indian Drug Manufacturers' Association (IDMA) is organizing a Webinar on "Accelerating & De-risking your Injectable Product Development with PremiumCoat®" for Tuesday, 12th October 2021 from 3.00 pm to 4.00 pm

The abstract of the webinar is given below :

Aptar Pharma is a global leader in the design and manufacturing of a broad range of pharmaceutical delivery, consumer product dispensing and active material science solutions. Our portfolio of Vial Stoppers, Pre-Filled Syringe components and Services support our customer's drug development process to ensure their successful launch and life-cycle management. Our PremiumCoat® platform combines a market-proven ETFE film-coating with a pure rubber formulation and best-in-class process to accelerate and derisk your drug development. Aptar Pharma's expert demonstrated PremiumCoat® stoppers' ability to reduce Extractables and Leachables, their performance in multipiercing situation and compatibility with different vial sizes and designs.

Moderator : **Mr. S R Vaidya,** *Chairman, MSME Committee*

International Speakers for this webinar are

1.	**Mr. Jean-Edouard Rabier** Mr. Rabier has over 20 years of Sales experience in the pharmaceutical industry, including 11 years in injectable primary packaging. After a decade spent working at West Pharmaceutical Services, Jean-Edouard joined the Aptar Pharma Injectables division in September 2020, where he is Business Director responsible for the Vial Containment Stoppers product portfolio.	
2.	**Mr. Sébastien Cordier** Mr. Sébastien is the Technical Product Manager for PremiumCoat® projects at Aptar Pharma's Injectables division. A graduate of MINES ParisTech and EDHEC Business School in France, Mr. Sébastien spent over 15 years in the automotive industry, where he developed a strong expertise in plastics and elastomers, before joining Aptar Pharma in 2020. In his current role as Technical Product Manager at Aptar Pharma, Sébastien is responsible for the PremiumCoat® platform of vial stoppers and syringe plungers, and is dedicated to supporting customer development projects involving coated elastomeric solutions.	

Jo**in us in our webinar on October 12th at 3pm to discover more about the Premium Coat platform and our Injectables solutions.**

Please find the registration link to the webinar below:

https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,VjPgRYWeX0GWg7qPokPKGw,vhU8TNwV5kqyzLgXOBFrTg,JOrcacfx-kyEnekq9cfLGA,VcR1XY6SXEi8sIB8KPNqCA,iuHPd4H6QU2Y4x3Bwfd-mA?mode=read&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

Members are requested to participate in this webinar in large numbers and avail benefits from the same.

Thanks & regards,

Daara B Patel Secretary – General	**Prachi Singhai** Manager-Marketing & Communication, India & SE Asia
Indian Drug Manufacturers' Association 102, A Wing, Poonam Chamber, A Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai-400018. Maharashtra. India. Tel No. 022 24974308 / 24944624 **Cell:** +91 9821868758 **Email :** idma2@idmaindia.com/ actadm@idmaindia.com **Website:** www.idma-assn.org	**Aptar Mumbai** part of Aptargroup, Inc., Crystal, Lake, Illinois, USA, and having, Registered Office at R - 854, TTC Industrial Estate Thane, Belapur Road, MIDC RABALE, Navi Mumbai, 400701 Mumbai, India. **Tel. :** 61951900 / Cell # 9892026098 **Email:** prachi.singhai@aptar.com **Website :** www.aptar.com

Preamble

Through the latest Patents (Amendment) Rules, 2021, the Government of India has extended the 80% reduction in Patent filing and prosecution to all Educational Institutions.

The Draft Patents (Amendment) Rules, 2021 published in Gazette of India on 9th February, 2021 defined 'eligible educational institution' *as "an institution established by a Central, Provincial or State Act, which is owned or controlled by the Government, and is wholly or substantially financed by the Government",*

Subsequently in August, 2021, the Commerce and Industry Minister Hon'ble Mr. Piyush Goyal in August, 2021, announced that 80% fee reduction will apply to all recognized educational institutions whether it is government (owned), government-aided, or private institutions. Accordingly, on 21st September, 2021, Minister of Commerce and Industry notified Patents (Amendment) Rules, 2021, wherein 'eligible educational institution' is now defined as *a university established or incorporated by or under Central Act, a Provincial Act, or a State Act, and includes any other educational institution as recognised by an authority designated by the Central Government or the State Government or the Union territories in this regard;"*

The relevant Notification is reproduced below.

MINISTRY OF COMMERCE AND INDUSTRY

(Department for Promotion of Industry and Internal Trade)

NOTIFICATION

New Delhi, the 21st September, 2021

G.S.R. 646(E).—Whereas the draft of certain rules, further to amend the Patents Rules, 2003 was published as required under sub-section (3) of section 159 of the Patents Act, 1970 (39 of 1970), *vide* notification of the Government of India in the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade) number G.S.R. 106 (E), dated the 09th February, 2021 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of thirty days from the date on which copies of the Official Gazette containing the said notification were made available to public;

And, whereas, copies of the Official Gazette in which the said notification was published were made available to the public on the 09th February, 2021;

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

Now, therefore, in exercise of the powers conferred by section 159 of the Patents Act, 1970 (39 of 1970), the Central Government hereby makes the following rules further to amend the Patents Rules, 2003, namely: -

1. (1) These rules may be called the Patents (Amendment) Rules, 2021.

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

2. In the Patents Rules, 2003 (hereinafter referred to as the principal rules), in rule 2, after sub-rule (c), the following shall be inserted, namely:-

   "(ca) "educational institution" means a university established or incorporated by or under Central Act, a Provincial Act, or a State Act, and includes any other educational institution as recognised

by an authority designated by the Central Government or the State Government or the Union territories in this regard;".

3. In the principal rules, in rule 7,-

(i) in sub-rule (1), for the second proviso, the following proviso shall be substituted, namely:-

"Provided further that in the case of a small entity, or startup, or educational institution, every document for which a fee has been specified shall be accompanied by Form-28.";

(ii) for sub-rule (3), the following sub-rule shall be substituted, namely:-

"(3) In case an application processed by a natural person, startup, small entity or educational institution is fully or partly transferred to a person other than a natural person, startup, small entity or educational institution, the difference, if any, in the scale of fees between the fees charged from the natural person, startup, small entity or educational institution and the fees chargeable from the person other than a natural person, startup, small entity or educational institution, shall be paid by the new applicant along with the request for transfer.".

4. In the principal rules, in the FIRST SCHEDULE, in Table 1, for the headings and sub-headings,

"

Number of Entry	On what payable	Number of the relevant Form	For e-filing		For physical filing	
			Natural person(s) or Startup(s) or Small entit(y)/(ies)	Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies)	Natural person(s) or Startup(s) or Small entit(y)/(ies)	Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies)

",

the following headings and sub-headings shall be substituted, namely:—

"

Number of Entry	On what payable	Number of the relevant Form	For e-filing		For physical filing	
			Natural person(s) or Startup(s) or Small entit(y)/(ies) or educational institution(s)	Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies) or educational institution(s)	Natural person(s) or Startup(s) or Small entit(y)/(ies) or educational institution(s)	Other(s), alone or with natural person(s) or Startup(s) or Small entit(y)/(ies) or educational institution(s)

".

5. In the principal rules, in the SECOND SCHEDULE, for Form 28 the following form shall be substituted, namely:-

"

FORM 28

THE PATENTS ACT, 1970

(39 of 1970)

AND

THE PATENTS RULES, 2003

TO BE SUBMITTED BY A SMALL ENTITY /STARTUP/EDUCATIONAL INSTITUTION

[See rules 2 (fa), 2(fb), 2(ca) and 7]

1	Insert name, address and nationality.	I/We……. applicant/patentee in respect of the patent application no..... or patent no.....hereby declare that I/we am/are a small entity in accordance with rule 2(fa) or a startup in accordance with rule 2(fb) or an educational institution in accordance with rule 2(ca) and submit the following document(s) as proof:
2	Documents to be submitted	
	i. For claiming the status of a small entity:	
	A. For an Indian applicant: Evidence of registration under the Micro, Small and Medium Enterprises Development Act, 2006(27 of 2006).	
	B. In case of a foreign entity: Any other document.	
	ii. For claiming the status of a startup	
	A. For an Indian applicant: Any document as evidence of eligibility, as defined in rule 2(fb).	
	B. In case of a foreign entity: Any other document.	
	iii For claiming the status of an educational institution	
	A. For an Indian applicant: Any document as evidence of eligibility, as defined in rule 2(ca).	
	B. In case of a foreign educational institution: Any other document.	
3	To be signed by the applicant(s) /patentee(s)/authorized registered patent agent.	The information provided herein is correct to the best of my/our knowledge and belief. Dated this ... day of..... ..20 …..
4	Name of the natural person who has signed.	Signature…….

F. No. P-24027/4/2020-IPR-III]

Shruti Singh, Joint Secretary

Note : The principal rules were published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-Section (ii) vide number S.O. 493 (E) dated the 2nd May, 2003 and last amended vide notification number G.S.R. 689 (E) dated the 4th November, 2020.

Clarification in respect of refund of tax specified in Section 77(1) of the CGST Act and Section 19(1) of the IGST Act-Reg.

Trade Notice No.12/CGST&CXIMUMBAI Zone/2021, dated 27th September 2021

To:
All Trade Associations (through respective E-mails)

Copy to:

1. *All the Principal Commissioners/Commissioners of CGST and Central Excise, Mumbai Zone.*
2. *Superintendent of Computer Cell for uploading website (http://gstmumbai.gov.in).*
3. *PRO, GST and Central Excise, Mumbai Central for displaying on Notice Board at GST Bhavan, 15, M.K.Road, Churchgate, Mumbai - 400 020.*
4. *The Principal Commissioner GST Policy Wing, CBIC, New Delhi.*
5. *Master file.*

1. Please find enclosed herewith a copy of Circular No. 162/18/2021-GST dated 25th September, 2021, issued vide F. No. CBIC-20001/8/2021-GST by the GST Policy Wing of Centrai Board of Indirect Taxes and Customs, New Delhi, on the above subject, which is self-explanatory. The aforesaid circular is available on CBIC websites https:/www.cbic.gov.in and https://cbic-gst.gov.in.

2. Trade Associations are requested to bring the contents of this Circular to the notice of their members and the trade in general.

F.No.1/1-116/GST-Cell/PCCO/2018/Pt.I/2624

Rajiv Garg, Additional Commissioner (PCCO), CGST & & CX, Mumbai Zone, New Delhi.

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Registration and Labelling requirements of Medical Devices - Reg.

F. No. 29/Misc/03/2021-DC (28), dated 28th September, 2021

To
All the States/UTs Drugs Controllers.

As you are aware that, Ministry of Health & Family Welfare (MoHFW) has issued notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, as under, which is effective from 01.04 2020. The Ministry has also issued notification G.S.R 102(E) dated 11.02.2020, regarding registration requirements for such medical devices which is effective from 01.04 2020.

As per the notification, from 01.04.2020 till September 2021, such Medical Devices will be under voluntary registration scheme. Thereafter, from October, 2021- Class A & B Medical Devices will be under compulsory registration scheme up to September- 2022 and Class C & D Medical Devices will be under compulsory registration scheme up to September-2023.

Various representations have been received recently from stakeholders informing that complete preparedness of Industry in this regard remains to be achieved, in light of disruption due to COVID-19 pandemic situation.

The representations are under consideration of Ministry of Health and Family welfare, Govt. of India. You are requested to take note of the same with a view to ensure uninterrupted supply of such medical devices and access to the patients till a decision is taken on the representations.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare, New Delhi

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DoPT MATTERS

Appointment of Mr Abhishek Kumar Singh as Deputy Secretary in DoP - reg.

Office Memorandum F.No. 2/5/2021-EO (MM-I), dated 29th September, 2021

1. Shri Abhishek Kumar Singh, IFoS(CG:2009), who was recommended for Central deputation by the Ministry of Environment, Forest and Climate Change, has been selected for appointment as Deputy Secretary in the Department of Pharmaceuticals, Delhi under the Central Staffing Scheme for a period of four years from the date of taking over charge of the post or until further orders, whichever event takes place earlier. He may kindly be relieved of his duties immediately with instructions to take up his new assignment in the Department of Pharmaceuticals.

2. It may be noted that as per ACC's directions conveyed in DoP&T's Circular No. 3/4/2004-E0(MM-I) dated 17th August, 2005, an officer should join the post within three weeks from the date of issue of DoP&T's appointment order, failing which the process of debarment from the Central Staffing Scheme shall be initiated.

Hrisheekesh Arvind Modak, Deputy Secretary, Dept. of Personnel & Training, Ministry of Environment, Forest and Climate Change,

Shri Rameshwar P. Gupta, Secretary, Dept. of Personnel & Training, Ministry of Environment, Forest and Climate Change, New Delhi

● ● ●

CORPORATE AFFAIRS MATTERS

Extension of time for holding of Annual General Meeting (AGM) for the Financial year ended on 31.03.2021 - reg.

Office Memorandum, CL-II-03/252/2021-0/o DGCoA-MCA, dated 23rd September 2021

To

1. All RDs

2. MI ROCS

1. The Central Government has received representations seeking extension of time for holding Annual General Meeting (AGM) for the financial year 2020-21 ending on 31st March 2021 citing many difficulties faced due to second wave of Covid-19 and consequent lockdowns etc,

2. Accordingly, it has been decided to advise the Registrar of Companies (RoCs) to accord approval for extension of time for a period of two Months beyond the due date by which companies are required to conduct their AGMs for the financial year 2020-21 ended on 31st March 2021,

3. Kindly find enclosed a copy of the standard template for the order to be issued by RoCs under third proviso to sub-section (1) of section 96 of the Companies Act, 2013 (the Act) for granting extension of time for conducting of AGM for the Financial Year 2020-21 ended on 31.03.2021 .

4. Please take this action with utnlost urgency and issue order before the close of the office today and forward the copy of the order to this office before for consolidation and uploading it on the MCA21 website. Also display this order on the Notice Board of your respective offices,

5. This issues with approval of the Competent Authority.

Gaurav, Deputy Director, Office of the Director General of Corporate Affairs, Ministry of Corporate Affairs, New Deihi.

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Amendment in Para 2.04 of Handbook of Procedures of FTP (2015-2020) - Extension of timelines -reg.

Public Notice No.25/(2015-2020), dated 28th September, 2021

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

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

1. In para 1.01, the phrase 'shall remain in force until 30th September, 2021' is substituted by the phrase 'shall remain in force until 31.03.2022.'
2. In para 3.20 (a), the phrase 'or 30.09.2021, whichever is later' is substituted by the phrase 'or 31.03.2022, whichever is later'.
3. In para 4.12(vi), the date '30.09.2021', as appearing in the first sentence is substituted by '31.03.2022.'

Effect of this Public Notice:

Validity of the existing Hand Book of Procedures, 2015-20 is extended upto 31st March, 2022.

F.No. 01/75/171/00002/AM22/FTP CELL

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

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Amendment in Para 2.54 of Handbook of Procedures of FTP (2015-2020) - Extension of timelines - reg.

Public Notice No.26/(2015-2020), dated 29th September, 2021

In exercise of powers conferred under Para 1.03 and 2.04 of the Foreign Trade Policy, 2015-2020, the Director General of Foreign Trade hereby amends Para No.2.54 (d)(v)(ii) of the Handbook of Procedures of FTP (2015-2020) and extends the deadline to install and operationalise Radiation Portal Monitors and Container Scanners in the designated sea ports up to 31.03.2022.

Effect of this Public Notice:

The timelines for installation and operationalisation of Radiation Portal Monitors and Container Scanners in the designated sea ports is extended from existing 30.09.2021 to 31.03.2022.

F.No.01/89/180/53/AM-01/PC-II(B)/E-2382)

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

● ● ●

Extension in the Export Obligation period of specified Advance & EPCG Authorisations till 31.12.2021 - reg.

Notification No. 28/2015-2020-DGFT, dated 23rd September 2021

1. In exercise of powers conferred by Section 5 of FT(D&R) Act, 1992, read with Paragraph 1.02 of the Foreign Trade Policy 2015-20, as amended from time to time, the Central Government hereby makes following amendments in the Hand Book of the procedure 2015-20.

2. The following sub-para is added after Subpara 4.42(i) of HBP :

"4.42 (j):

a. For Advance Authorisations, where original or extended Export Obligation (EO) period is expiring during the period between 01.08.2020 and 31.07.2021, the Export Obligation period would be extended till 31.12.2021 without any composition fees. However this extension is subject to 5% additional export obligation in value terms (in free Foreign Exchange) on the balance Export Obligation on the date of expiry of the original/extended export obligation period.

b. The option to avail EO extensions with payment of composition fees under this para (4.42 (d),(e),(f)) would remain available for these authorizations as per eligibility.

c. In cases where Advance Authorisation Holder has already obtained EO extension upon the payment of composition fee, the refund of the composition fee will not be permitted.

3. The following Sub para is added after Subpara para 5.17 (e) of HBP :

"5.17 (f):

a. For EPCG Authorisations, where original or extended Export Obligation (EO) period is expiring during the period between 01.08.2020 and 31.07.2021, the Export Obligation period would be extended till 31.12.2021 without any composition Fees. However this extension is subject to 5% additional export obligation in value terms (in free Foreign Exchange) on the balance Export Obligation on the date of expiry of the original/extended export obligation period.

b. The option to avail EO extensions with payment of composition fees under this para (5.17(c)) would remain available for these authorisations as per eligibility.

c. In cases where EPCG Authorisation Holder has already obtained EO extension upon the payment of composition fee, the refund of the composition fee will not be permitted.

4. Customs authorities shall allow export accordingly and EO fulfillment details as per above provisions will be checked/verified by the RA at the time of EODC/ Closure/Regularisation. Authorisation Holders need not approach RA or make any application to avail this benefit.

Effect of the Notification: Another option to avail extension in Export Obligation period till 31.12.2021 in case of specified Advance Authorisations and EPCG Authorisations is provided without any composition fees subject to 5% additional export obligation on balance exports to be fulfilled..This is in addition to EO extensions facility (upon payment of the composition fees) already provided in FTP/ HBP.

File no. 01/94/180/501/AM20/PC-4

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

● ● ●

Extending Validity of Foreign Trade Policy 2015-2020 upto 31.03.2022-reg.

Notification No. 33/2015-2020, dated: 28th September, 2021

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

1. In para 1.01, the phrase 'shall remain in force upto 30th September, 2021 unless otherwise specified' is substituted by the phrase 'shall remain in force upto 31.03.2022 unless otherwise specified.'
2. In para 4.14, the date '30,09.2021' as appearing in the last line is substituted by '31.03.2022".
3. In para 5.01(a), the date '30.09.2021' as appearing in the second sentence is substituted by '31.03.2022'.
4. In para 6.01(d) (ii), the date '30.09.2021" as appearing in the last line is substituted by '31.03.2022'.

Effect of this Notification: The existing Foreign Trade Policy 2015-2020 which is valid upto 30th September, 2021 is extended upto 31'st March, 2022.

File No. 0I/75/171/00002/AM22/FTP CELL

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

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CUSTOM MATTERS

Covid-19 Vaccine exempted from whole of the duty of Custom wef 1st Oct 2021 Valid till 31st Dec 2021- reg.

Notification No. 45/2021—Customs, dated 29th September, 2021

1. In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby exempts the goods of the description specified in column (3) of the Table below, falling within the Chapter, heading, sub—heading or tariff item of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) specified in column (2) of the said Table, when imported into India, from the whole of the duty of customs leviable thereon under the said First Schedule, namely:-

TABLE

S.No.	Chapter, heading, sub-heading or tariff item	Description
(1)	(2)	(3)
I.	30	COVID-19 vaccine

2. This notification shall come into force on 1st October, 2021 and remain in force upto and inclusive of the 31st December, 2021.

F. No. CBIC-190354/66/2021-TO(TRU-I)-CBEC

Rajeev Ranjan, Under Secretary. Ministry of Finance, Department of Revenue, New Delhi

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Directions under Section 5 of the Environment (Protection) Act, 1986 to not grant or renew CTO unless Environment Clearance, as applicable, has been obtained - reg.

20th September, 2021

To
Chairmen of all State/UT Pollution Control Boards and Pollution Control Committees

1. Whereas, prior Environmental Clearance is a statutory requirement for project/activities covered in the schedule of the EIA Notification 2006, issued under section 3 of the Environment (Protection) Act, 1986.

2. And whereas, obtaining the consents under Water (Prevention & Control of Pollution) Act, 1974 & Air (Prevention & Control of Pollution) Act, 1981 is mandatory for all industrial units in Red, Orange and Green categories.

3. And whereas, the grant of EC and Consents are requirements under different statutes and are not inter-dependent and can be carried out as a parallel process.

4. And whereas, many a times it has been observed that while industrial units are in possession of valid 'Consent to Establish' (CTE)/ 'Consent to Operate' (CTO) issued by State Pollution Control Boards (SPCBs)/ UT Pollution Control Committees (UTPCC), however, they have not obtained the Environmental Clearance (EC), even though it was required as per provisions of EIA Notification 2006.

5. And whereas, it has been observed that this situation is arising because majority of the SPCBs/ UTPCCs are issuing CTE/CTO to projects without ascertaining the applicability of prior EC to projects/ activities, resulting in an avoidable situation of closure for even those industries also who seek to carry out their activities following due procedure.

6. Now therefore, in exercise of powers conferred by section 5 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government, hereby directs that all SPCB/UTPCC shall :

i. Ascertain the applicability of EIA Notification at the time of grant/renewal of CTE and stipulate appropriate condition for obtaining Environmental Clearance (EC), if applicable, before construction/ commencement of project/activity.

ii. Ensure that the project proponent possesses a valid Prior EC in terms of the extant EIA Notification, if applicable, at the time of grant/ renewal of CTO and no CTO shall be granted or renewed unless EC, if applicable, has been obtained.

7. This is issued with the approval of the Competent Authority.

F. No. 1A3-22/19/2021-1A.III [E 164361]

A K Agrawal, Director, Ministry of Environment, Forest and Climate Change, Impact Assessment Division, New Delhi.

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MoEF notification on Plastic Waste Management (Second Amendment) Rules, 2021 - Reg.

G.S.R. 647(E), dated 17th September, 2021

Whereas, the Plastic Waste Management Rules, 2016 were notified by the Ministry of Environment, Forest and Climate Change vide notification number G.S.R. 320 (E), dated the 18th March, 2016;

Whereas clause (b) of sub-rule (1) of rule 4 of the said rules provides that carry bags made of recycled plastic or products made of recycled plastic shall not be used for

storing, carrying, dispensing or packaging ready to eat or drink food stuff;

Whereas, Food Safety and Standards Act, 2006 (34 of 2006) is an Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto;

Now therefore, in exercise of powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the said rule in public interest, hereby makes the following rules to further amend the Plastic Waste Management Rules, 2016, namely:-

1. (1) These rules may be called the Plastic Waste Management (Second Amendment) Rules, 2021.

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

2. In the Plastic Waste Management Rules, 2016, in rule 4, in sub-rule (1), for clause (b), the following clause shall be substituted, namely: -

"(b) carry bags made of recycled plastic or products made of recycled plastic can be used for storing, carrying, dispensing, or packaging ready to eat or drink food stuff subject to the notification of appropriate standards and regulation under the Food Safety and Standards Act, 2006 (34 of 2006) by the Food Safety and Standards Authority of India;".

F. No. 17/17/2021-HSMD

Naresh Pal Gangawar, Joint Secretary, MInistry of Environment, Forest and Climate Change, New Delhi.

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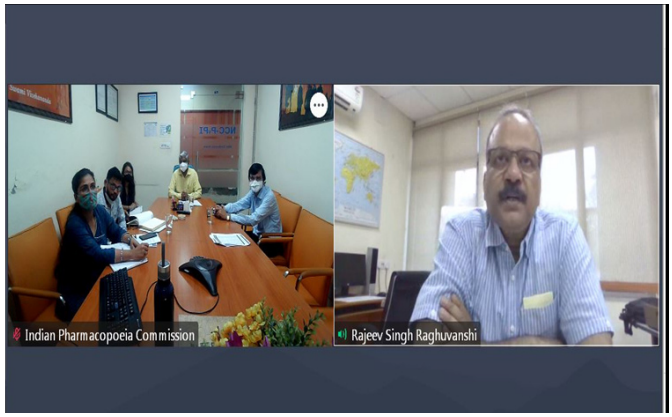
Press Release

18th Skill Development Programme on Pharmacovigilance for Medical Products



The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) located at Indian Pharmacopoeia Commission Ghaziabad, organized 18th "Skill Development Programme on Pharmacovigilance for Medical Products" from 13th to 17th September, 2021 through virtual mode. The Webinar started with **welcome address by Dr. Jai Prakash**, Officer-in-Charge, PvPI, followed by **Keynote address by Dr. Rajeev Singh Raghuvanshi**, Secretary-cum-Scientific Director IPC. Dr. Raghuvanshi extended his warm greetings and best wishes to all the participants on behalf of IPC. He also shared his expectation to further expand PvPI.

Total 199 registered participants from **Maharashtra, Uttar Pradesh**,**Tamil Nadu,West Bengal, Telangana, Karnataka, Kerala, Gujarat, Madhya Pradesh, Andhra Pradesh, Rajasthan, Uttarakhand, Himachal Pradesh, Bihar, Jharkhand, Chhattisgarh, Odisha, Punjab, Haryana, Delhi and Pondicherry,** participated in this training programme. The participants including Industry Professionals, Physicians, Academicians, Coordinators & Pharmacovigilance Associates of ADR monitoring Centres, Research Scholars, Students (Pharmacy and Medical) across the country. Dr.Shashi Bhushan, Dr. R.S Ray, Ms Shrishti Saroha, Mr. Akash Deep Rawat, Mr. Girjesh Vishwakarma, Mr. Omkar Mishrafrom NCC PvPI supported during the workshop.

During the 5 days Skill Development Programme, **16 technical sessions** were conducted on various topics of Pharmacovigilance including Basics of Pharmacovigilance to in-depth Signal detection method and Regulatory intervention/outcomes etc in an understandable language to the participants. All participants appreciated the Skill Development Programme.

*Note: Please visit IPC website (*www.ipc.gov.in*) for regular updates.*

In Lok Sabha & In Rajya Sabha

Rajya Sabha

Increase in Export of Medical Equipments and Medicines

Rajya Sabha Unstarred Question No. 2127(H)

Ms. Saroj Pandey:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether it is a fact that an increase in the export of medical equipments and medicines from the country has been registered during COVID period; and

(b) if so, the increase noted in export as compared to that in pre-COVID period and the amount of foreign exchange earned through this export by the country?

Answered on 06th August 2021

A. (a) & (b): The value of India's export of medical equipments and medicines during COVID period i.e. 2020-21 and pre- COVID period i.e. 2019-20 is as under:

(Value in US$ million)

Sr. No.	Item	2019-20	2020-21 (P)
1.	Ayush and herbal products	428.1	539.9
2.	Bulk drugs, drug intermediates	3885.9	4429.7
3.	Drug formulations, Biologicals	15940.6	19042.0
India's Total Export of Medicines		20254.6	24011.6
1.	Medical and scientific instrument	1487.6	1381.4
2.	Surgicals	448.9	432.2
India's Total Export of Medical Equipments		1936.5	1813.6

Source: DGCI&S, Kolkata

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Trade with China

Rajya Sabha Unstarred Question No. 2131

Shri G.C. Chandrashekhar:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the details of imports and exports between India and China during the last three years and the current year, product/ quantity/value and year-wise;

(b) whether India's trade deficit with China has increased during the said period and if so, the details thereof and the reasons therefor; and

(c) whether India is considering to maintain a separate negative list of items on which it will give limited or no tariff concessions to Chinese imports under the Regional Comprehensive Economic Partnership (RCEP) trade agreements and if so, the details thereof along with the response of the Chinese Government thereto?

Answered on 06th August 2021

A. (a) : The details of India's exports to and imports from China, principal commodity wise and value wise during the last three years and the current year is given at **Annexure**.

(b): India's trade deficit with China has declined from USD 53.57 billion in 2018-19 to USD 44.02 billion in 2020-21. The details are as below:

(Values in USD Billion)

Trade with China				
	2018-19	2019-20	2020- 21	2021-22 (till April 2021)
Import	70.32	65.26	65.21	6.51
Export	16.75	16.61	21.19	2.29
Trade deficit	53.57	48.65	44.02	4.22

(Source: DGCIS)

(c): India has not joined the Regional Comprehensive Economic Partnership (RCEP) trade agreement, signed by 15 countries on 15 November, 2020.

Annexure

Annexure referred to in reply to Rajya Sabha Unstarred Question No.2131 for answer on 6th August, 2021. India's exports and imports to/from China during FY 2018 -19, 2019-20, 2020-21 and 2021-22 (till April 2021).

(Values in USD Million)

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
AC, REFRIGERATION MACHNRY ETC	1663.17	34.60	1620.58	25.63	1252.29	23.54	155.50	1.94
ACCUMULATORS AND BATTERIES	1019.31	2.57	926.30	1.53	887.15	1.00	83.99	0.13
AGRO CHEMICALS	705.62	82.23	633.70	83.10	837.60	101.70	121.94	7.72
AIRCRAFT, SPACECRAFT AND PARTS	7.49	15.74	12.04	15.59	3.58	7.75	0.10	0.14
ALCOHOLIC BEVERAGES	0.24	0.50	0.20	0.90	0.61	3.82	0.02	0.06
ALUMINIUM, PRODUCTS OF ALUMINM	1212.17	13.02	995.70	60.51	770.08	404.24	72.16	68.41
ATM, INJCTNG MLDING MCHNRY ETC	328.22	88.97	294.33	118.96	286.20	125.89	23.54	16.09
AUTO COMPONENTS/ PARTS	1238.29	73.64	1124.11	65.44	1257.50	82.92	121.57	10.03
AUTO TYRES AND TUBES	93.22	2.52	93.44	1.57	29.79	1.39	3.48	0.29
AYUSH AND HERBAL PRODUCTS	1.07	13.09	1.61	11.82	1.82	24.40	0.11	2.43
BICYCLE AND PARTS	194.85	2.08	100.70	3.30	118.29	4.72	11.69	1.14
BOOKS, PUBLICATIONS ANDPRNTNG	20.69	0.82	23.40	0.71	13.54	0.17	1.18	0.04
BUFFALO MEAT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BULK DRUGS, DRUG INTERMEDIATES	2405.42	173.45	2323.95	219.42	2615.71	300.11	219.67	19.87
BULK MINERALS AND ORES	8.43	348.15	10.33	277.34	10.63	154.58	1.77	1.90
CARPET(EXCL. SILK) HANDMADE	28.27	15.92	27.33	11.49	12.15	10.45	1.11	0.71
CASHEW	0.09	0.14	0.00	0.13	0.00	0.00	0.00	0.00

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
CASHEW NUT SHELL LIQUID	0.00	0.20	0.00	0.00	0.00	0.00	0.00	0.00
CASTOR OIL	0.00	374.60	0.00	340.76	0.03	424.04	0.00	61.44
CERAMICS AND ALLIED PRODUCTS	459.70	19.28	459.55	26.65	421.50	23.53	30.66	0.95
CEREAL PREPARATIONS	17.08	0.82	12.29	0.75	11.58	0.68	0.70	0.16
CMNT, CLINKR AND ASBSTOS CMNT	8.54	0.08	10.54	0.07	7.82	0.03	1.61	0.01
COAL,COKE AND BRIQUITTES ETC	698.89	0.00	160.32	0.00	20.71	2.86	3.86	0.00
COCOA PRODUCTS	1.20	0.79	1.16	0.98	0.73	0.89	0.04	0.10
COFFEE	0.70	1.54	0.17	1.82	0.00	1.65	0.00	0.21
COIR AND COIR MANUFACTURES	2.42	101.36	2.64	89.73	1.38	108.80	0.47	43.85
COMPUTER HARDWARE, PERIPHERALS	4002.21	27.10	4192.87	24.18	5305.97	22.78	539.11	1.23
CONSUMER ELECTRONICS	2093.58	11.67	2235.13	12.12	2384.90	18.17	266.17	1.03
COPPER AND PRDCTS MADE OF COPR	251.55	244.38	189.86	266.97	180.14	779.76	20.79	93.40
COSMETICS AND TOILETRIES	166.43	33.12	166.34	40.35	155.34	27.21	18.56	1.84
COTTON FABRICS, MADEUPS ETC.	252.53	30.15	242.01	25.01	149.46	26.26	11.18	2.42
COTTON RAW INCLD. WASTE	0.37	504.70	8.07	186.73	0.02	604.38	0.00	131.39
COTTON YARN	7.44	1272.52	4.00	586.36	3.92	667.92	0.29	58.70
CRANES, LIFTS AND WINCHES	689.69	7.16	630.52	3.85	522.29	5.77	46.97	0.19
DAIRY PRODUCTS	0.00	0.01	0.00	0.03	0.00	0.08	0.00	0.01
DRUG FORMULATIONS, BIOLOGICALS	149.50	33.16	164.97	40.24	198.50	39.36	20.01	4.93
DYE INTERMEDIATES	218.41	95.34	195.62	56.37	185.28	52.78	18.39	4.47
DYES	152.67	201.46	154.70	286.68	133.46	277.72	17.08	28.10
ELECTRIC MACHINERY AND EQUIPME	2639.81	297.61	2506.30	211.23	2269.80	138.26	206.88	8.88
ELECTRODES	24.31	0.62	20.88	0.54	20.91	0.44	2.66	0.02
ELECTRONICS COMPONENTS	5810.64	116.65	6071.08	112.52	6191.32	148.88	701.11	14.82

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
ELECTRONICS INSTRUMENTS	2370.65	303.55	2279.54	559.43	2669.91	281.81	244.16	23.57
ESSENTIAL OILS	18.76	3.34	16.31	3.15	12.38	4.59	1.05	0.35
FERTILEZERS CRUDE	8.55	0.35	9.84	0.53	13.48	0.93	1.47	0.05
FERTILEZERS MANUFACTURED	2044.74	0.75	1811.09	2.14	1537.75	1.37	27.91	0.28
FINISHED LEATHER	26.00	87.27	38.43	56.21	21.01	49.09	1.64	6.96
FLOOR CVRNG OF JUTE	0.04	2.04	0.02	1.68	0.00	2.63	0.00	0.10
FLORICLTR PRODUCTS	3.77	0.46	3.75	0.32	3.54	0.28	0.78	0.06
FOOTWEAR OF LEATHER	194.73	39.15	162.35	54.63	71.83	36.93	5.62	5.24
FOOTWEAR OF RUBBER/CANVAS ETC.	203.67	0.37	197.15	0.39	97.63	0.45	6.65	0.04
FRESH FRUITS	6.28	5.58	11.98	4.54	10.29	3.23	0.34	1.25
FRESH VEGETABLES	0.00	1.28	0.16	0.14	0.01	0.19	0.00	0.00
FRUITS / VEGETABLE SEEDS	2.18	0.52	1.43	1.19	2.92	0.81	0.14	0.00
GLASS AND GLASSWARE	704.94	20.52	698.61	28.13	562.08	29.40	52.29	2.45
GOLD	12.59	85.73	0.00	0.00	0.00	0.00	0.00	0.00
GOLD AND OTH PRECS METL JWLERY	4.46	0.18	5.06	0.33	2.83	0.55	0.28	0.01
GRANIT, NATRL STONE AND PRODCT	38.06	442.85	26.61	441.47	17.20	466.70	1.01	72.03
GRAPHITE, EXPLSIVS AND ACCESOR	71.26	0.53	60.63	0.05	37.67	0.32	4.36	0.01
GROUNDNUT	0.00	1.01	0.00	34.64	0.00	77.34	0.00	0.18
GUERGAM MEAL	0.00	92.31	0.25	30.62	0.62	21.93	0.06	2.88
HANDCRFS (EXCL. HANDMADE CRPTS)	425.59	17.15	432.62	36.11	341.42	10.31	13.61	0.74
HANDLOOM PRODUCTS	2.29	1.14	0.54	0.70	0.34	0.27	0.02	0.02
HND TOOL, CTTNG TOOL OF METALS	310.27	14.91	302.36	11.44	367.61	11.57	35.42	0.99
HUMAN HAIR, PRODUCTS THEREO	2.94	147.73	2.94	183.01	0.83	298.12	0.03	51.98
IC ENGINES AND PARTS	313.84	167.26	242.68	173.05	238.37	170.34	38.10	20.24
INDL. MACHNRY FOR DAIRY ETC	3831.39	162.60	4012.03	186.95	3940.03	206.11	342.84	21.04

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
INORGANIC CHEMICALS	725.87	60.44	601.82	45.28	519.20	62.63	59.44	4.40
IRON AND STEEL	1422.38	318.91	1121.34	513.92	895.40	2512.55	82.56	125.23
IRON ORE	0.00	952.82	0.00	2134.16	0.00	4245.45	0.00	526.73
JUTE HESSIAN	0.01	0.01	0.00	0.01	0.00	0.00	0.00	0.02
JUTE YARN	0.00	0.00	0.03	0.00	0.00	0.00	0.00	0.00
LEAD AND PRODUCTS MADE OF LED	1.52	13.81	6.24	5.59	1.40	0.30	0.08	0.00
LEATHER FOOTWEAR COMPONENT	11.84	0.83	11.62	1.37	9.35	0.54	0.87	0.13
LEATHER GARMENTS	0.13	8.79	0.33	8.86	0.12	1.78	0.00	0.00
LEATHER GOODS	24.21	11.67	23.76	10.73	11.99	6.11	1.00	0.51
MACHINE TOOLS	832.54	27.08	724.38	14.43	742.27	21.56	66.50	2.00
MANMADE STAPLE FIBRE	91.29	57.09	119.54	45.62	70.00	18.41	6.47	2.12
MANMADE YARN, FABRICS, MADEUPS	1026.08	58.56	1107.92	42.66	1163.92	39.96	153.25	2.93
MARINE PRODUCTS	8.61	723.86	15.47	1345.41	11.58	869.93	0.34	112.15
MEDICAL AND SCIENTIFIC INSTRUM	517.66	61.28	588.04	57.28	742.84	58.31	70.96	5.06
MICA	0.55	51.73	0.67	33.49	0.64	46.38	0.12	5.83
MILLED PRODUCTS	0.00	0.98	0.01	0.71	0.01	0.01	0.00	0.01
MISC PROCESSED ITEMS	20.38	4.71	29.35	2.19	22.83	2.32	2.97	0.17
MOLLASES	0.00	0.13	0.00	0.05	0.00	0.00	0.00	0.00
MOTOR VEHICLE/CARS	32.34	10.26	40.02	9.50	10.35	20.50	7.83	4.50
MOULDED AND EXTRUDED GOODS	535.94	17.67	564.58	17.22	527.28	15.92	55.79	2.23
NATRL SILK YARN, FABRICS, MADEUP	29.94	0.94	28.62	0.77	10.97	0.47	1.32	0.11
NATURAL RUBBER	0.08	0.08	0.16	0.01	0.08	4.49	0.00	0.00
NEWSPRINT	0.00	0.00	0.00	0.00	0.01	0.00	0.00	0.00
NICKEL, PRODUCT MADE OF NICKEL	41.17	4.24	78.71	39.06	51.85	9.90	5.13	0.12
NUCLER REACTR, INDL BOILR, PRT	149.89	13.48	170.62	26.68	176.51	21.13	9.43	1.63
OFFICE EQUIPMENTS	20.98	0.08	28.17	0.15	46.36	0.24	2.94	0.00
OIL MEALS	0.10	1.23	0.09	0.63	0.25	20.03	0.03	3.07

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
OPTICAL ITEMS (INCL.LENS ETC)	298.27	5.04	170.11	3.71	187.62	3.22	13.57	0.22
ORGANIC CHEMICALS	3589.98	2519.35	3223.86	1899.67	3483.37	1494.44	483.01	92.77
OTH NON FEROUS METAL AND PRODC	604.03	2.24	574.39	3.65	449.54	3.22	44.08	0.43
OTH TXTL YRN, FBRIC MDUP ARTCL	572.25	6.55	529.48	4.70	477.22	4.85	38.37	0.18
OTHER CEREALS	0.20	0.01	0.05	0.01	0.00	0.01	0.00	0.00
OTHER COMMODITIES	1104.16	51.70	933.27	56.85	820.01	85.72	76.56	8.45
OTHER CONSTRUCTION MACHINERY	723.12	26.66	572.31	28.95	630.14	18.97	58.07	2.34
OTHER CRUDE MINERALS	47.58	2.15	40.87	0.81	11.69	0.59	0.95	0.25
OTHER JUTE MANUFACTURES	1.16	0.22	0.56	0.26	1.48	0.29	0.20	0.04
OTHER MEAT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
OTHER MISC. ENGINEERING ITEMS	1036.28	59.16	1013.44	54.12	940.68	67.00	94.54	5.35
OTHER MISCELLAENIOUS CHEMICALS	574.53	36.00	555.63	54.17	685.82	76.85	55.55	6.43
OTHER OIL SEEDS	0.54	0.01	0.51	0.00	0.96	0.00	0.02	0.00
OTHER PLASTIC ITEMS	609.92	6.99	559.47	7.74	303.17	7.60	22.18	0.72
OTHER PRECIOUS AND BASE METALS	0.34	0.00	0.04	0.00	0.03	0.00	0.00	0.00
OTHER WOOD AND WOOD PRODUCTS	1.14	55.35	1.44	19.81	0.66	2.61	0.09	0.05
OTHR RUBBER PRODCT EXCPT FOOTW	201.23	64.01	189.70	61.98	164.38	77.43	18.85	6.77
PACKAGING MATERIALS	86.52	7.22	79.14	10.18	66.29	8.91	6.81	0.69
PAINT, VARNISH AND ALLID PRODC	388.81	46.05	429.23	26.14	456.27	47.04	50.69	7.42
PAPER, PAPER BOARD AND PRODUCT	522.83	117.90	532.17	127.42	373.23	314.38	46.69	47.19
PEARL, PRECS, SEMIPRECS STONES	64.11	230.41	61.24	60.67	45.20	88.03	5.03	14.52
PETROLEUM PRODUCTS	302.27	2854.42	340.44	2128.05	183.63	1043.39	22.57	133.20

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
PETROLEUM: CRUDE	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PLASTC SHT, FILM, PLTS ETC	735.71	34.70	796.73	36.21	751.26	40.38	85.94	3.99
PLASTIC RAW MATERIALS	1345.48	1043.35	1245.01	777.92	1160.07	882.11	285.65	11.01
PLYWOOD AND ALLIED PRODUCTS	280.02	6.75	250.82	6.61	151.86	8.66	12.02	0.51
POULTRY PRODUCTS	0.27	0.03	0.02	0.06	0.02	0.00	0.00	0.00
PRIME MICA AND MICA PRODUCTS	183.13	4.04	199.04	4.00	199.39	4.62	19.33	0.48
PROCESSED FRUITS AND JUICES	21.48	15.53	20.48	15.83	18.63	15.90	1.82	0.33
PROCESSED MEAT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PROCESSED MINERALS	382.08	23.10	183.73	81.19	198.91	46.41	16.20	2.26
PROCESSED VEGETABLES	5.50	2.34	15.79	0.83	7.76	6.51	0.66	0.12
PRODUCTS OF IRON AND STEEL	1731.07	74.08	1585.00	81.89	1313.44	61.38	95.70	9.27
PROJECT GOODS	553.28	0.69	438.28	0.69	347.92	0.23	18.35	0.17
PULP AND WASTE PAPER	21.00	0.15	24.34	6.26	20.84	9.45	2.41	0.00
PULSES	47.86	4.33	51.58	35.77	46.36	20.27	3.96	3.99
PUMPS OF ALL TYPES	245.85	24.18	205.95	31.89	240.73	24.17	24.67	1.95
RAILWY TRNSPRT EQUIPMNTS, PRTS	180.64	3.36	204.90	3.08	180.48	2.86	27.15	0.58
RAW HIDES AND SKINS	0.56	0.00	1.09	0.01	1.01	0.00	0.04	0.00
RESIDUL CHEMICL AND ALLED PROD	2520.78	268.60	2406.86	286.95	2683.67	354.68	272.96	36.69
RICE -BASMOTI	0.00	0.13	0.00	0.23	0.00	0.37	0.00	0.08
RICE(OTHER THAN BASMOTI)	0.00	0.97	0.00	0.78	0.00	103.70	0.00	31.11
RMG COTTON INCL ACCESSORIES	88.27	74.00	89.11	65.56	67.49	41.18	4.56	4.24
RMG MANMADE FIBRES	112.78	14.32	124.61	10.06	70.42	4.85	3.72	0.27
RMG OF OTHR TEXTLE MATRL	96.69	8.74	110.13	12.68	157.62	4.51	2.62	0.41
RMG SILK	1.51	0.24	1.99	0.19	0.33	0.31	0.01	0.10
RMG WOOL	2.34	2.44	3.66	2.45	1.84	1.80	0.01	0.07
SADDLERY AND HARNESS	0.37	0.27	0.49	0.38	0.73	0.33	0.03	0.08

Principle Commodity Groups	2018-19		2019-20		2020-21		2021-22 (Till April, 2021)	
	Import	Export	Import	Export	Import	Export	Import	Export
SESAME SEEDS	0.00	6.28	0.60	3.31	0.00	14.00	0.00	0.18
SHEEP/GOAT MEAT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SHELLAC	0.01	4.26	0.26	3.10	0.66	7.88	0.00	0.99
SHIP, BOAT AND FLOATING STRUCT	78.81	0.00	69.96	3.21	83.27	0.00	0.12	0.00
SILK CARPET	0.00	0.02	0.00	0.02	0.00	0.87	0.00	0.05
SILK WASTE	5.20	13.32	2.25	11.49	0.39	18.48	0.00	1.93
SILK,RAW	99.13	0.00	95.06	0.00	31.99	0.02	0.93	0.00
SILVER	321.53	0.00	46.26	0.00	51.76	0.00	1.16	0.00
SPICES	66.28	447.49	87.44	765.60	106.86	970.44	14.33	145.94
SPORTS GOODS	187.14	0.99	165.10	2.48	175.76	2.57	13.33	0.17
STATIONRY/OFFCE, SCHOOL SUPPLY	42.97	2.59	40.64	1.36	18.09	1.94	2.01	0.06
SUGAR	0.35	16.08	0.69	14.85	0.96	52.25	0.32	3.62
SULPHER, UNROASTED IRON PYRITE	0.27	54.91	0.21	47.96	0.13	55.57	0.00	12.93
SURGICALS	74.57	10.50	72.31	16.48	87.38	7.44	6.48	0.38
TEA	2.82	26.52	1.76	27.43	8.69	31.15	0.30	0.51
TELECOM INSTRUMENTS	7416.77	137.39	5648.30	181.21	6476.10	304.28	524.34	74.90
TIN AND PRODUCTS MADE OF TIN	4.75	0.00	2.15	0.00	1.41	0.00	0.22	0.00
TOBACCO MANUFACTURED	0.95	0.76	1.81	0.53	0.04	0.19	0.00	0.04
TOBACCO UNMANUFACTURED	0.41	0.60	3.89	0.01	5.75	0.00	0.37	0.00
TWO AND THREE WHEELERS	5.09	5.77	5.19	6.37	4.50	2.25	2.42	0.01
VEGETABLE OILS	0.46	17.74	0.56	52.70	0.22	451.00	0.10	11.24
WHEAT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
WOLLEN YARN, FABRICS, MADEUPS ETC	39.60	12.90	40.26	4.44	15.38	0.85	1.62	0.22
WOOL, RAW	5.90	0.58	6.26	0.02	8.13	0.07	0.96	0.04
ZINC AND PRODUCTS MADE OF ZINC	15.90	55.30	8.21	83.31	5.66	15.11	0.43	4.50
Total	70319.64	16752.80	65260.75	16614.32	65212.25	21188.72	6514.27	2290.81

(Source: DGCIS)

The Minister of State in The Ministry of Commerce and Industry
(Smt. Anupriya Patel)

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Lok Sabha

Increase in Death Due to Non-Communicable Diseases

Lok Sabha Unstarred Question No. 3128

Shri. Syed Imitiaz Jaleel:

Shri Asaduddin Owaisi:

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

(a) whether Government is aware that the Lancet Global Health in collaboration with a number of other organisations has come out with a paper showing seven lakh death caused by strokes in India in 2019 and if so, the details thereof;

(b) whether in the wake of COVID-19 deaths, death from Non-Communicable diseases have been left out, if so, the details thereof;

(c) whether Non-Communicable disease deaths have increased manifold due to non-operation of Out Patient Departments and postponment of surgeries; and

(d) if so, the details thereof and the steps being taken by the Government to restrict the deaths from Non-Communicable diseases in the country in the wake of COVID-19?

Answered on 06th August 2021

A. (a): A study 'The burden of neurological disorders across the states of India: The Global Burden of Disease Study 1990-2019" was published in Lancet 2021 by ICMR. As per the study, the number of deaths due to stroke was 6.99 lakhs in the country in 2019.

(b) to (d) Patients with non-communicable diseases are getting treatment at various health facilities in the health care delivery system including Districts Hospitals, Medical Colleges, Central Institutes like AIIMS and private sector hospitals. Relevant data related to patients registered for treatment, including surgeries, is maintained by the Institutions and Hospitals concerned at their own level.

Data of deaths is maintained by the Office of the Registrar General & Census Commissioner, India (ORGI).

Health is a state subject. The Department of Health & Family Welfare, however, provides technical and financial support to the States/UTs under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), as part of National Health Mission (NHM), based on the proposals received in Program Implementation Plans (PIPs) from the States/ UTs and subject to the resource envelope. The programme focusses on strengthening infrastructure, human resource development, health promotion & awareness generation for prevention, early diagnosis, management and referral to an appropriate level of healthcare facility for treatment of the given Non-Communicable Diseases.

A population-based initiative for prevention, control and screening for common Non-Communicable Diseases (NCDs) i.e. Diabetes, Hypertension and common Cancers viz. Oral, Breast and Cervical Cancers, has been rolled out in the country under NHM and also as a part of Comprehensive Primary Health Care under Ayushman Bharat – Health and Wellness Centres. Under the initiative persons more than 30 years of age are targeted for their screening for common NCDs.

Under NPCDCS, 640 NCD Clinics at District level and 5148 NCD Clinics at Community Health Centre level have been set up to ensure the treatment of common NCDs.

Patients with Non-Communicable Diseases are diagnosed and treated at various tertiary health care facilities such as Medical Colleges, Central Institutes like AIIMS, etc. The treatment in Government health facilities is either free, or highly subsidized for the poor and needy. The treatment for in-patient care is also available under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PMJAY) for 10.74 crore families eligible under AB-PMJAY as per Socio Economic Caste Census (SECC) database.

Under Free Drugs Service Initiative of NHM, financial support is provided to States/UTs for provision of free essential medicines. Furthermore, quality generic medicines are being made available at affordable prices to all, under Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in collaboration with the State Governments.

Guidelines and advisories were sent by Ministry of Health and Family Welfare to State/UT Governments from time to time emphasizing the need for continuation of non-COVID essential health services for management of NCDs during COVID pandemic.

States/UTs were also advised to utilize the Population Based Screening (PBS) data during containment activities in order to identify those with NCDs and to place them under health surveillance.

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

Development o Vaccines against Delta Variant

Lok Sabha Unstarred Question No.3134

Shri Rodmal Nagar:

Shri Kanakmal Katara:

Shrimati Keshari Devi Patel:

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

(a) whether the Government is providing assistance to various institutes for developing vaccine for the Delta Variant of COVID-19;

(b) if so, the details thereof; and

(c) the funds allocated/financial assistance given for the aforesaid research carried out by these institutes as on date, institute-wise?

Answered on 06th August 2021

A. (a) to (c) Department of Biotechnology, Government of India, has provided support to industry and academia for COVID-19 vaccine development, whereby different platforms of vaccine candidates are being developed. All vaccines under development and manufacturing are also being studied for effectiveness against emerging Variants of Concern (VOCs). The Department of Biotechnology has allocated approximately Rs.490 Crore to support Covid-19 vaccines development efforts by Indian academia and industry.

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

Term Loan to Companies for R&D

Lok Sabha Unstarred Question No. 3135

Dr. A. Challakumar:

Shri M. Selvaraj:

Q. Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) whether CSIR has sanctioned soft term loan to various companies for R&D during the last three years;

(b) if so, the details thereof and the criteria adopted for sanctioning the loans;

(c) the number of companies provided loan, the term of loan and the name of projects for which loan was extended along with the present status of loan recovery; and

(d) whether any company has turned sick after getting loan and if so, the details thereof?

Answered on 06th August 2021

A. (a) Yes. Council of Scientific & Industrial Research (CSIR) has sanctioned soft loan to eight companies for R&D during the last 3 years.

(b) Council of Scientific & Industrial Research (CSIR) provides soft loan for R&D activities to companies under the New Millennium Indian Technology Leadership Initiative (NMITLI) Scheme. The financial support to industry is in the form of soft loan with 3% interest. The loan is repaid in annual installments over a period of 10 years. Criteria adopted for granting loan is based on selection of project through CCEA approved procedure involving rigorous screening and project review. The criteria for selection of the project are based on novelty of the proposal, potential technological benefits and the ability of industry to capture those benefits.

(c) Name of companies, name of projects, amount of loan given, period of loan given during last 3 years are given in Annexure-I. *(Not reproduced here)*

(d) None of the companies which received loan from CSIR during last 3 years has reported sick after taking the loan.

Minister of State (Independent Charge) of Science and Technology and Earth Sciences (Dr. Jitendra Singh)

Guidelines for the Possible Third Wave of Covid-19

Lok Sabha Unstarred Q. No 3137

Shri Uday Pratap Singh:

Kunwar Danish Ali:

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

(a) whether the Government has made adequate arrangements for Remdesivir injections and other essential medicines along with guidelines for the treatment of children in State/UTs keeping in view of the possible third wave of the COVID-19 pandemic;

(b) the steps taken by the Government to curb the laxity on the part of people for not adhering to COVID-19 appropriate behavior across the country;

(c) the number of cases of Delta and Delta plus variant reported across the country, State/UT-wise; and

(d) whether the virus is dominant even after vaccination and if so, the details thereof; and

(e) the steps being taken to check the spread of Delta variant?

Answered on 06th August 2021

A. (a): Health is a state subject. Ministry of Health and Family Welfare (MoHFW) is supporting States/ UTs with requisite technical support besides providing financial and logistic support to upgrade health infrastructure for managing COVID cases in children and also for addressing any surge in Paediatric COVID cases in future.

Ministry of Health and Family Welfare (MoHFW) has issued "Guidelines on Operationalization of COVID Care Services for Children & Adolescents" on 14th June 2021 and"Guidelines for Management of COVID19 in Children (below 18 years)" on 18th June 2021. These guidelines were disseminated to States/ UTs followed by orientation meetings.The Operational guidelines have detailed list of drugs required for Paediatric COVID care at various levels of facilities.

A Drugs Coordination Committee (DCC) has been constituted as an institutional mechanism under Department of Pharmaceuticals for efficient decision making on all the issues with respect to COVID-19 related drugs including their availability through inter-departmental consultations.

All States/UTs and State Drugs Controllers have been requested to verify stock of drugs and check other malpractices and take effective steps to curb hoarding and black marketing of emergency drugs.

A COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID-19 management.

During the FY 2020-21, funds to the tune of Rs.8257.88 crore has been released to the States/ UTs towards the India COVID-19 Emergency Response and Health System Preparedness Package.

In addition, 'India COVID-19 Emergency Response & Health System Preparedness Package: Phase-II' has also been approved by the Cabinet with Rs 23,123 crores (with Rs. 15,000 Cr as Central Component & Rs 8,123 Cr as State component) and is to be implemented from 1st July 2021 to 31st March 2022. So far Rs. 1827.78 crore has been released to States/ UTs in 2021-22 under ECRP Phase-II in FY 2021-22.

It includes support to State/UT level for ramping up Health Infrastructure including those in rural, tribal and peri-urban areas closer to the community, providing support for procurement of drugs and diagnostics to enhance service delivery at district and sub district levels for management of COVID-19 cases (including pediatric care) and for maintaining a buffer of drugs, support for IT Interventions such as implementation of Hospital Management Information System and expanding access to tele-consultations in all districts, and support for capacity building and training for all aspects of management of COVID-19.

Under the National COVID Vaccination Program, Government of India is procuring vaccines and providing them free of cost to States and UTs. As on 5th August 2021, a total of about 48.93 crore doses have been supplied to States/UTs from all sources i.e. Government of India's COVID vaccine supply free of cost to all States/UTs, State/UTs and Private Hospitals procured COVID vaccine.

(b): Ministry of Health and Welfare has also issued "An Illustrated Guide on COVID Appropriate Behaviour" and several other materials are placed on Ministry website for wide circulation.

Ministry of Home affairs has issued orders from time to time under Disaster Management Act, 2005 directing States/UTs governments to ensure adherence to COVID appropriate behavior as part of National directives for COVID-19 management.

Ministry of Health and Family Welfare has also shared various IEC materials including Paediatric COVID Care with States/ UTs to generate awareness on COVID-19 appropriate behavior.

(c) and (d): As on 04th August 2021, total of 83 cases of delta plus variant have been reported in India, State/ UT wise detail is placed at Annexure.

(e):To monitor the variants of SARS-CoV-2 virus, initially genomic sequencing was conducted through National Institute of Virology, Pune. Subsequently, Government of India established Indian SARS-CoV-2 Genomic Consortium (INSACOG) in December 2020 as a consortium of 10 laboratories of Ministry of Health & Family Welfare, Dept. of Biotechnology, Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR). The network of INSACOG laboratories has since been increased to 28.

While monitoring the prevalence of variants through the network of labs, as per advice from experts it is noted that the public health measures to manage the Pandemic in the field and the treatment protocol remain the same and the five-fold strategy of test-track-treat-vaccinate and COVID appropriate behavior is to be followed at the field level.

Annexure

Delta Plus (includes AY.1, AY.2 and AY.3) as on 04/08/2021	
State / UT	**No. of reported cases**
Andaman Nicobar	0
Andhra Pradesh	2
Assam	1
Arunachal Pradesh	0
Bihar	0
Chandigarh	4
Chhattisgarh	0
Dadra Nagar Haveli	0
Delhi	0
Goa	0
Gujarat	2
Haryana	1
Himachal Pradesh	1
Jammu & Kashmir	1
Jharkhand	0
Karnataka	3
Kerala	3
Ladakh	0
Lakshadweep	0
Madhya Pradesh	11
Maharashtra	33
Manipur	1
Meghalaya	0
Mizoram	0
Nagaland	1
Odisha	1
Puducherry	0
Punjab	2
Rajasthan	1
Sikkim	0
Tamil Nadu	10
Telangana	2
Tripura	0
Uttar Pradesh	2
Uttarakhand	1
West Bengal	0
Total	**83**

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

Illegal Manufacturing of Opioid Tablets

Lok Sabha Unstarred Question No.3150

Shri Rajiv Ranjan Singh Alias Lalan Singh:

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

(a) whether the Government is aware that Opioid tablets are being produced by many Pharma companies illegally in the country and if so, the details thereof;

(b) the number of cases that have been reported in last three years for illegal manufacturing and marketing of Opioid Tramadol tablets across the country;

(c) whether North India is one of the hubs for manufacturing Opioid and many raids have been conducted and recovery made there; and

(d) if so, the action taken along with the details of all the seizures made in this regard during the last three years?

Answered on 06th August 2021

A. (a): a) to (d): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

As informed by Narcotics Control Bureau under the Ministry of Home Affairs, the details of the Opioid Tramadol seizure cases during the last three years by the Central and State Drug Law enforcement agencies attached as annexure.

Annexure

Details of seizure of Drug 'Tramadol'

S. No.	Year	Total number of cases	Total quantity seized		
			In Kgs	Tablets in No.	Inj. in No.
1	2018	54	32,774.464	12,84,32,120	245
2	2019	54	14.411	25,75,873	3,48,508
3	2020	63	242.45	81,01,192	450

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

Policies to Prepare for Future Pandemics

Lok Sabha Unstarred Q. No 3168

Shri Lalubhai Babubhai Patel:
Shri B.B. Patil:
Shri Khagen Murmu:

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

a) whether the Government has taken cognizance that apart from strengthening the vaccination drive, there is an urgent need to develop health policies to improve preparedness for third wave or future pandemics;

b) if so, the initiative(s) taken/being taken by the Government in this regard; and

c) the measures taken/being taken by the Government to strengthen coordination between natural and social scientists to enable translation of scientific findings into public health policies and practices?

Answered on 06th August 2021

A. (a) to (c)

Health is a state subject. Government of India has provided the required technical support and has also supported the states through logistic and financial support to further strengthen the existing health infrastructure to tackle COVID-19 pandemic.

Some of the ongoing initiatives to further strengthen healthcare infrastructure include:

- With the intent to reduce the risk of cross infection to non-COVID patients as well as to maintain continuity of non-COVID essential health services in the country, a three-tier arrangement of dedicated COVID-19 health facilities [(i) COVID Care Center (CCC); (ii) Dedicated COVID Health Centre (DCHC) and (iii) Dedicated COVID Hospital (DCH)] has been implemented in the country.
- Government of India, to supplement the hospital facilities has roped in tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry etc. Further, many large temporary treatment facilities were established by DRDO to manage surge in COVID-19 cases in the country.
- The isolation bed capacity and ICU bed capacity which was only 10,180 and 2,168 before the first lockdown (as on 23rd March 2020) in being enhanced continuously and is currently at 18,03,266 isolation beds and 1,24,598 ICU beds (as on 3rd August 2021).
- The daily liquid medical oxygen (LMO) supply, which was about 1292 MTs per day in February 2021 increased to 8593 MTs in April 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Restrictions were imposed on industrial use of oxygen.
- A dynamic and transparent framework for allocation of medical oxygen in consultation with States/UTs and all the stakeholders such as relevant Ministries, manufacturers/suppliers of liquid oxygen etc. was prepared.
- Online digital solutions viz. Oxygen Demand Aggregation system (ODAS) and Oxygen Digital Tracking System (ODTS) have been developed

to ascertain the demand for medical oxygen from all medical facilities and to track their transportation.

- To avoid wastage of medical oxygen, guidelines on rational use of oxygen were issued on 25th September 2020, and further revised and disseminated to States on 25th April 2021.
- 1,02,400 oxygen cylinders were procured in April and May of 2020 and distributed to States. Further orders for additional 1,27,000 cylinders have been placed on 21.04.2021 (54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type). Deliveries of the same have started and 73,352 (56,108 B-type and 14,244 D-type) cylinders have been delivered as on 3rd August 2021.
- To generate oxygen at the health facility level, PSA plants are being established in each district hospitals, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country.
- Further, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, more than 39,000 oxygen concentrators have been allocated to various States.
- A COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID-19 management.
- A Drugs Coordination Committee (DCC) has been constituted as an institutional mechanism under Department of Pharmaceuticals for efficient decision making on all the issues with respect to COVID-19 related drugs including availability through inter-departmental consultations.
- Remdesivir is a patented drug, manufactured in India under voluntary licenses granted by Gilead Life Sciences USA (the patent holder) to 7 Indian pharmaceutical companies. Manufacturing capacity was augmented from 38 lakh vials per month in March 2021 to nearly 122 lakh vials per month in June 2021. In addition, 40 additional manufacturing sites were approved by the CDSCO, thus increasing the manufacturing sites from 22 (in March 2021) to 62 (June 2021).
- All States/UT and State Drugs Controllers have been requested to verify stock of drugs and check other malpractices and take effective steps to curb hoarding and black marketing of some drugs like Remdesivir.
- Department of Pharmaceuticals and the Drug Controller General of India (DCGI) have actively coordinated with the industry to enhance availability of Amphotericin B through identification of manufacturers, alternate drugs and expeditious approvals of new manufacturing facilities.
- Besides, the existing five manufacturers, DCGI had issued permissions to manufacturing / marketing of Amphotericin B Liposomal Injection to six additional firms.
- The guiding principle to avert/ minimize the risk of future resurgence of COVID-19 cases in the country remains the five-fold strategy of test-track-treat-vaccinate and COVID appropriate behavior.
- Ministry of Health & Family Welfare continues to provide technical guidance for managing various aspects of COVID-19. So far more than 150 guidelines/advisories/SoPs/plans have been provided to States/UTs. Taking note of ingress of COVID-19 pandemic in peri-urban and rural areas, Ministry of Health & Family Welfare on 16th May 2021 issued an SOP on COVID-19 Containment & Management in Peri-urban, Rural & Tribal areas.
- Further COVID-19 treatment protocols and advisories both for adults as well as pediatric age groups were issued and widely disseminated to promote rational use of drugs and oxygen.
- During the F.Y. 2019-20. funds to the tune of Rs.1113.21 crore was released to the States/ UTs under NHM towards management and containment of COVID-19 pandemic.

In September 2020, the Union Government further allowed use of SDRF by the States for oxygen generation and storage plants in hospitals; strengthening ambulance services for transport of patients; and setting up containment zones, COVID-19 care centres. States were allowed to spend maximum 35% of annual allocation of funds under SDRF for the financial year 2019-20. The ceiling was further enhanced to 50% during the financial years 2020-21 and 2021-22 for containment measures of COVID-19.

- During the FY 2020-21, funds to the tune of Rs.8257.88 crore has been released to the States/UTs towards the India COVID-19 Emergency Response and Health System Preparedness Package.
- In addition, 'India COVID-19 Emergency Response & Health System Preparedness Package: Phase-II' has also been approved by the Cabinet with Rs 23,123 crores (with Rs. 15,000 Cr as Central Component & Rs 8,123 Cr as State component) and is to be implemented from 1st July 2021 to 31st March 2022. So far Rs. 1827.78 crore has been released to States/UTs in 2021-22 under ECRP Phase-II in FY 2021-22.

  It includes support to State/UT level for ramping up Health Infrastructure including those in rural, tribal and peri-urban areas closer to the community, providing support for procurement of drugs and diagnostics to enhance service delivery at district and sub district levels for management of COVID-19 cases (including pediatric care) and for maintaining a buffer of drugs, support for IT Interventions such as implementation of Hospital Management Information System and expanding access to tele-consultations in all districts, and support for capacity building and training for all aspects of management of COVID-19.
- Further, under the National COVID Vaccination Program, Government of India is procuring vaccines and providing them free of cost to States and UTs. As on 3rd August 2021, a total of about 50.21 crore doses have been supplied to States/UTs from all sources i.e. Government of India's Covid vaccine supply free of cost to all States/UTs, State/UTs and Private Hospitals procured Covid vaccine.

  The COVID-19 response strategy since inception is supported by expert groups comprise of epidemiologists, scientists, microbiologists, clinicians etc. drawn from eminent institutions including World Health Organization. Further, the research community and pharmaceutical industry including vaccine manufacturers have supported COVID-19 response in terms of research and development of vaccines, as well as their production.

  Union Ministry of Health through Department of Health Research has also been commissioning studies to find answers to pressing research questions related to COVID-19. These projects have been awarded and funds provided to ICMR and non-ICMR scientists in various important areas.

  In addition, recently Indian Council of Medical Research had put out a call for proposals, inviting concept proposals in various areas related to COVID-19. These include clinical research, epidemiology, operational & socio-behavioral research and diagnostics & biomarkers. Selected proposals with public health translational value will be funded after scientific review by ICMR.

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

Nasal Vaccine to Protect Against Covid-19

Lok Sabha Unstarred Question No.3179

Shri B. B. Patil:

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

(a) whether the Government proposes to manufacture a nasal vaccine to protect against COVID-19;

(b) if so, the details thereof along with the tests done and the outcome in this regard; and

(c) whether the Government has adequate mechanism to carry out the vaccination across the country in a timely manner, if so, the details thereof?

Answered on 06th August 2021

A. (a) & (b): Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health & Family Welfare in consultation with Subject Expert Committee (SEC), has granted permission on 12.02.2021 to M/s Bharat Biotech International Limited for conduct of Phase-I clinical trial of COVID-19 Vaccine for Intranasal route of administration.

(c): COVID-19 vaccination is an ongoing and dynamic process, which is being guided by National Expert Group on Vaccine Administration for Covid-19 (NEGVAC) on the basis of concurrent scientific evidence.

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

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Govt working to ensure balanced trade deals: Piyush Goyal

The federal government is working to make sure balanced trade deals and is in talks with nations with which India has equitable commerce curiosity, mentioned commerce and trade minister Piyush Goyal. In an interview with ET's Deepshikha Sikarwar, Goyal – who additionally handles the Ministry of Shopper Affairs, Meals and Public Distribution – mentioned the federal government will unveil sturdy e-commerce pointers that may strike a good stability in defending small shopkeepers, inside commerce, retailers, and guarantee an orderly development of the financial system. Edited excerpts:

Have exports made a definitive restoration?

It's a important restoration. As much as September 21, $185 billion (in exports) is remarkable in India's historical past. So, we are going to shut the primary half of the yr with greater than $195 billion, which is a major achievement for the primary half.

By way of logistics, the exporting group remains to be going through a variety of challenges. How far have we been in a position to tackle them?

Challenges are part of doing enterprise. Our exporters have finished some fantastic work within the final six months regardless of all of the challenges of Covid-19, and shortages of delivery containers. In actual fact, delivery charges are extraordinarily excessive proper now. Regardless of all these constraints, I believe they've finished a wonderful job. On our aspect, now we have tried to supply as a lot help as we are able to by a collection of measures over the past yr and a half. Prime Minister Narendra Modi has advised exporters to search for new alternatives for exports… I believe it is a holistic effort of the federal government, personal sector, exporters, diplomats the world over… immediately, the world seems at India as a trusted associate, as a pal, as a rustic with excessive democratic values with a rule of regulation they will fall again upon. All of this stuff have helped India grow to be a most popular buying and selling vacation spot.

The exporting group is going through a problem with regard to delivery containers. Is there a plan on long-term or medium-term options?

It could definitely be good to have extra ships with the Indian flag, however it's a privately pushed and aggressive enterprise, and deep pockets are required to run it. For a number of years, the charges have been under value and lots of of them have been working at big losses. In that sense, it's simpler mentioned than finished when it comes to changing into a maritime nation. By way of the age-old pondering that large superpowers are at all times maritime nations, I believe the equation has modified. Delivery firms are largely now housed in a couple of European nations, perhaps one or two are additionally from a neighbouring nation. However, by and huge, they're all engaged on the worldwide framework primarily based on market circumstances. At present, ships are taking very lengthy in sure nations, containers are caught at completely different locations, and a few nations have irrational guidelines round Covid-19 testing. All of those have brought on a scarcity. I do hope it will likely be short-term. The pace at which vaccination is occurring the world over, notably in India, I believe we should always be capable of overcome this within the close to future. In the long term, it will likely be fascinating to have extra delivery firms and I might encourage businesspersons and corporates in India to think about entering into the delivery enterprise. It is a fantastic enterprise in the long term. So far as containers are involved, Concor has already issued some trial orders to Indian firms to start out manufacturing in India. I am advised 34 firms had expressed curiosity in manufacturing containers. So, I'm very assured, within the years to return, we are going to grow to be atmanirbhar in container manufacturing.

Does the present scenario warrant a overview of the sale of the Delivery Company of India?

That has no important relationship to the present delivery scenario. It's a world scenario that we're all

going through, and whether or not it stays a totally government-owned firm or managed firm or works within the personal sector, will definitely don't have any affect on its effectiveness or its potential to serve our worldwide commerce.

How properly positioned are we to reap the benefits of the scenario creating in China?

India and our worldwide commerce will stand by itself legs. There could also be issues in a single nation or one other. I do not suppose we have to take a look at that side as a lot as we have to concentrate on strengthening our manufacturing capabilities in making ourselves recognised as a top quality producer at aggressive costs of products and companies, productiveness and high quality as the way in which ahead to broaden our worldwide commerce.

India imposed sure restrictions on investments from sure nations final yr. Is there any re-think on the coverage with regard to greenfield investments from them?

Not but.

We've unveiled a number of PLI schemes beneath which we're encouraging funding…

We've not but utilized our thoughts to it.

A number of authorities departments have expressed concern over the draft ecommerce pointers…

That is the aim of the session. In spite of everything, had it been the ultimate phrase, we'd have issued them as the ultimate guidelines. The actual fact that they've been put within the public area is to get suggestions, which incorporates from all ministries, worldwide and Indian gamers. We welcome suggestions and that is how we will do a greater job of arising with pointers that are equitable and help all sections of trade and enterprise.

By when will they be finalised?

We're nonetheless consulting varied stakeholders and within the means of assessing the worldwide guidelines on related issues. We are going to provide you with very sturdy pointers which might be a good stability, defending our small shopkeepers, inside commerce, retailers, and making certain an orderly development of the financial system.

How are the commerce talks with the UK, US progressing? What's our pondering on guidelines of origin which had a really adverse affect on commerce beneath different FTAs finished up to now?

Excellent. I can guarantee you three issues. One, we're coping with nations the place now we have equitable buying and selling curiosity. For instance, the UAE – which is considered one of our largest buying and selling companions – has big potential sooner or later. Keep in mind the big African market that will get companies behind the UAE. Australia, territorially not as a lot expanded as we might have. UK – after Brexit, they're a giant potential marketplace for India. EU – the place due to Bangladesh being an LDC or Vietnam having an FTA there, a sector like textiles, they've an enormous edge over us in Europe.

So, there are a number of areas the place we are able to equitably work out a set of circumstances in a complete settlement or a free commerce settlement by which we are going to each encourage funding and know-how to return into India, broaden our markets in these nations and within the general context, give a giant push to the Indian financial system.

Work with the UAE is in full swing. We hope to complete the early harvest a part of it inside the subsequent 3-4 months. On the Australian aspect, Tony Abbott, the previous prime minister, got here as a particular commerce envoy, had intensive discussions, and met the PM. They're a part of the Quad and really eager to have an FTA. The minister is right here tomorrow to additional our discussions and fast-tracking it.

With the UK, now we have been having a collection of discussions, largely by video conferencing. We're engaged on many areas and make sure that now we have a balanced settlement in session with all our stakeholders and other people affected by the FTA and promote investments in a giant manner.

Source: Prashant singh, News7 Trends, 30.09.2021

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Domestic pharma market expands 18% in August

MUMBAI: The domestic pharmaceutical market delivered a robust growth of nearly 18% in August, buoyed by sales of acute therapies. The acute medication grew around 17% year-on-year (YoY) in August on a low base, while chronic therapies rose about 12.5% YoY, India Ratings and Research (Ind-Ra) said.

After the normalisation of the high growth this year in the months of April (51.5%) and May (47.8%) led by the lockdown-related lower base last year and higher volume growth, the average Indian pharma market (IPM) growth from June to August 2021 stood at 15.2% YoY. In terms of growth drivers, price, new product launches and volume stood at 9%, 5.9% and 2.9% YoY, respectively, which led to an overall IPM size of Rs 1.63 lakh crore in August (July was Rs 1.61 lakh crore). The market had posted a growth of nearly 14% in July.

Acute therapies including anti-infectives reported a growth of nearly 17 YoY (June and July was over 20% each YoY), while chronic and sub-chronic therapy reported stable growth at 10.8% YoY (6.4% YoY; 7.8% YoY) and 15.3% YoY (11.3%; 11.2%), respectively, in August 2021. During FY21, Ind-Ra said the acute therapy segment reported negative growth on account of Covid, while the chronic therapy segment reported average growth of 7% in the same period.

The contribution of top five therapies to the IPM stood at 58%. These include cardiac (chronic; 13.2% of IPM), anti-infectives (acute; 14.3%), gastro-intestinal (acute; 11.5%), anti-diabetic (chronic; 9.5%) and vitamins (acute; 9.2%).

Source: Times of India, 24.09.2021

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ECGC to get Rs 4,400-crore govt capital support; IPO in FY23

ECGC was set up in 1957 to offer credit insurance services to exporters against risks of non-payment by overseas buyers. It also provides insurance cover to banks against risks in export credit lending to exporters.

The company has recorded "continuous surplus and made dividend payments to the government for the last 20 years". Its IPO, therefore, should be received well by the market, Goyal said.

The government will launch the initial public offering (IPO) of ECGC in FY23 to "unlock its true value" and infuse a capital of Rs 4,400 crore into the company, which has an 85% share in the country's export credit insurance market, over the next five years.

The infusion will improve ECGC's underwriting capacity by Rs 88,000 crore and help additional exports of Rs 5.28 lakh crore over five years, commerce and industry minister Piyush Goyal said after the Cabinet approved the proposal on Wednesday. It will also help generate 5.9 million jobs, including 2,60,000 in the formal sector.

The Cabinet also decided to continue the National Export Insurance Account (NEIA) scheme and approved an infusion of Rs 1,650 crore into the NEIA Trust over five years. This will help the Trust support project exports worth up to Rs 33,000 crore and create 2,60,000 new jobs, including 12,000 in the formal sector.

The comfort of wider insurance cover is the latest in a series of steps, including the decision to set aside Rs 56,027 crore to clear all past dues owed to exporters and the roll-out of export tax refund schemes, initiated by the government to better enable exporters to take advantage of a recent resurgence of merchandise demand in advanced economies.

The proposals to infuse capital into ECGC and NEIA Trust were part of the government's Rs 6.29-lakh-crore relief package, announced on June 28, to soften the blow of the second Covid wave. The detailed proposals have now been endorsed by the Cabinet.

Goyal said the government will infuse Rs 500 crore into ECGC this fiscal and another Rs 500 crore in FY23. Subsequently, based on ECGC's requirement, the remaining amount will be released.

The company has recorded "continuous surplus and made dividend payments to the government for the last 20 years". Its IPO, therefore, should be received well by the market, Goyal said.

The listing will also enable ECGC to mobilise fresh capital from the market either through the IPO or through a follow-on public offer and thereby substantially bolster its ability to settle claims, according to the commerce ministry.

ECGC was set up in 1957 to offer credit insurance services to exporters against risks of non-payment by overseas buyers. It also provides insurance cover to banks against risks in export credit lending to exporters.

The various insurance products offered by ECGC supported exports worth Rs 6 lakh crore in FY21, or 28% of total outbound goods shipment. As many as 97% of the exporters supported by ECGC are small and medium enterprises.

ECGC also insures around 50% of total export credit disbursement by banks, covering 22 lenders — 12 public sector banks and 10 private ones. Over the past decade, it has settled claims of more than Rs 7,500 crore. It now intends to raise its maximum liabilities—the highest amount of claims that the insurer is liable to pay during a single policy period—to Rs 2.03 lakh crore from Rs 1 lakh crore by FY26.

A Sakthivel, president of the exporters' body FIEO, said, "It is the most timely move, as the growing uncertainties in global trade are making exporters jittery and defaults are growing."

Source : FE Bureau, 30.09.2021

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U.S. FDA leaning toward approving Moderna half-dose booster - Bloomberg News

The U.S. Food and Drug Administration (FDA) is leaning toward authorizing half-dose booster shots of the Moderna Inc (MRNA.O) COVID-19 vaccine, Bloomberg News reported on Tuesday, citing people familiar with the matter.

The FDA had been seeking information about the effectiveness of a full third dose of the Moderna vaccine, but is now ready to move forward and consider the half-dose booster Moderna has proposed, the report said. Moderna and the FDA did not immediately respond to Reuters request for comment outside regular business hours.

Moderna on Sept. 1 submitted its application to the U.S. Food and Drug Administration seeking authorization for a booster shot.

The original Moderna vaccine contains 100-micrograms of mRNA in each shot. The company's submission to regulators to authorize a half-dose booster would allow Moderna to produce more.

Reporting by Akriti Sharma in Bengaluru; Editing by Muralikumar Anantharaman

Source : Reuters, 29.09.2021

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'WHO stand on Covaxin a serious setback for India'

NEW DELHI: A national network of scientists and people's science movements has expressed concern over the World Health Organisation not granting emergency use listing for ICMR-Bharat Biotech's Covaxin. It warned that India looked set to repeat the blunders it committed in the Covaxin approval process in the way it was approving Zydus Cadilla's ZyCov-D three-dose vaccine for those 12 years and older. As the WHO delayed clearance for Covaxin seeking more technical details, the All India Peoples Science Network said it was a serious setback to India's plans to distribute the vaccine to other countries and to those travelling abroad who took Covaxin.

In a statement on Wednesday, AIPSN referred to its earlier call for disclosure of Covaxin's trial data and said serious damage was done to India's reputation by this flawed application to the WHO regulators "which has also besmirched the standing of Indian science and regulatory systems, which will now come under heightened international scrutiny and suspicion".

"BB applied to DCGI for EUA with grossly inadequate data from clinical trials inviting rejection, followed by behind-the-scenes arm twisting by government which resulted in the grant of EUA. More detailed results of Phase-3 clinical trials were then released by BB in instalments, interim results two months later and complete trial data in June 2021," stated AIPSN.

It said despite criticism from scientists and others, Bharat Biotech was yet to publish results in a peer-reviewed journal after posting just a pre-publication paper.

It urged Centre, ministries and departments to adhere to scientific standards for conduct and analysis of clinical trial results, publication of results as peer-reviewed articles and complete transparency.

Source: Times of India, 30.09.2021

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Extends benefits of Tax Schemes Due to Covid-led Disruption: Exporters to Govt

Several exporters who had availed government schemes for lowering tax outgo against promised exports quantity have reached out to the government, seeking concessions citing continuing Covid-19 disruptions.

Exporters claim they have not been able to meet export obligations due to the pandemic. They say the government should either allow them to continue to avail the scheme by extending their time period or give them tax credit that they can adjust against future tax liabilities.

Some of the exporters are also looking to approach the courts in this regard.

In most cases, the schemes that the exporters availed have been stopped, but many of the old schemes are continuing and will get over only by 2022.

The government had introduced several schemes, including Export Promotion for Capital Goods (EPCG), for exporters, offering several benefits under the indirect tax regime.

The government has issued licences permitting duty free imports to eligible exporters to avail these schemes.

""For a lot of these licences issued prior to implementation of GST, it is not possible in various cases for exporters to meet the export obligation," said Abhishek A Rastogi, partner at law firm Khaitan & Co.

"Under the erstwhile regime, credit was eligible to the extent of the countervailing duty. Under the GST regime, IGST paid subsequent to the assessment or reassessment becomes recoverable as arrears of tax and input tax credit is denied," he said.

Rastogi is defending some such exporters in different courts.

Some of these schemes allow some companies a leeway in certain situations, experts said.

Advance authorisation, for instance, is a scheme whereby a company can import raw materials without paying duties on that if it can demonstrate that these raw materials are to be used in a final product that will eventually be exported.

EPCG is similar to advance authorisation but it has certain different conditions to be fulfilled by the companies.

Source : Economic times, 30.09.2021

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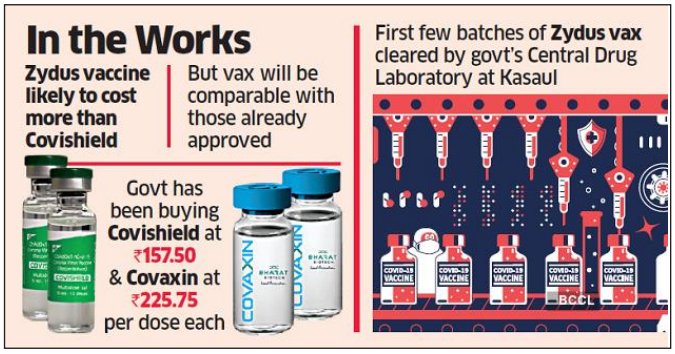
Centre working on pricing of Zydus Cadila COVID-19 vaccine, launch likely on October 2

Its pricing will be decided at a meeting between company representatives and the National Expert Group in Vaccine Administration for Covid (NEGVAC), headed by Niti Aayog member VK Paul, and health ministry officials, likely to be held this week, they said.

The government and Zydus Cadila are expected to decide on the price of ZyCoV-D, the world's first DNA vaccine against Covid-19, this week, people aware of the development said.

"The final meeting to decide on the price of the vaccine is likely to happen this week," one of them told ET. "The company was asked to submit the details regarding the cost. The negotiations are on and a decision will be taken soon."

The Centre is looking to roll out the country's first vaccine approved for children aged 12 years and above on October 2, the birthday of Mahatma Gandhi, the sources said. ZyCoV-D is likely to cost more than Covishield but will be comparable with those already approved, they said.



Its pricing will be decided at a meeting between company representatives and the National Expert Group in Vaccine Administration for Covid (NEGVAC), headed by Niti Aayog member VK Paul, and health ministry officials, likely to be held this week, they said.

The government has been buying Covishield at ₹157.50 per dose and Covaxin at ₹225.75.

Preparations are in full swing to roll out ZyCoV-D as the first few batches of the vaccines have been cleared by the government's Central Drug Laboratory at Kasauli.

Zydus Cadila has also started training vaccinators to administer the vaccine, which is given using a needle-free applicator.

The Indian drug regulator had on August 20 given emergency use authorisation (EUA) to the three-dose ZyCoV-D to be administered to people 12 years and above.

The government is expected to earmark a major chunk of the vaccine for children. The National Technical Advisory Group on Immunisation (NTAGI) is likely to meet on Monday to decide on the guidelines on vaccinating children with underlying medical The Covid-19 working group, which advises the government on vaccines, is of the view that in the first phase only children with underlying medical conditions should be vaccinated first.

Healthy kids are unlikely to get jabs this year as government experts are of the view that there is no need for every child to be vaccinated to attend school.

Zydus developed ZyCoV-D with the support of the department of biotechnology (DBT) and Indian Council of Medical Research (ICMR).

Source: Teena Thacker, The Economic Times, 29.09.2021

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Reimagining healthcare: Making evidence-led decisions to offer value-based care for patients

As countries re-envision healthcare and rebuild economies, there is a unique opportunity for the industry and governments to strengthen healthcare systems by adopting evidence-led interventions.

The COVID-19 pandemic is an unpleasant reminder of how a strong healthcare system matters for the well-being of a nation's people and the economy. It would not be an overstatement to say that systems which are structured on value-based approaches are capable of providing affordable and equitable access to health services for all. Today, as countries re-envision healthcare and rebuild economies, there is a unique opportunity for the industry and governments to strengthen healthcare systems by adopting evidence-led interventions.

The Indian landscape

We, as a country, have made significant progress towards improving health indicators. The average life expectancy has increased from 58 to 69 years. In parallel, the loss of Disability Adjusted Life Years (DALY) has also decreased significantly by over 40%. Having served the healthcare ecosystem across developed and developing markets for nearly three decades, I have witnessed the massive impact that improved healthcare has on the productivity of a nation. In fact, this development in India took place in the same period when the Indian GDP growth had been at peak.

In addition, every health parameter has improved in the last decade – reduction in maternal mortality ratio by 60%, infant mortality ratio by 60%, universal immunization coverage has tripled, drop in diseases like TB, Polio, HIV, malaria.

While these outcomes indicate that we are moving in the right direction, our healthcare system remains an area of concern. However, it is also important to understand that, as a nation, we cannot merely duplicate models that are currently available in other countries. We will need to evolve our own systems and solutions which work for our country. Undoubtedly, our investment in healthcare is inadequate, but merely putting in money is not the solution to the problem. The question then is, what can be done?

Strengthening healthcare systems in India

The development and execution of a well laid out comprehensive strategy is of utmost priority as we endeavor

to improve the performance of our health systems. With technology that exists today, we have a way to promote the right and expected behaviors in the health delivery system, and to monitor and link them back to corrective actions.

Building on a report by BCG on recommendations, there are some critical interventions from a governance point of view which can have immense multiplier effect on the healthcare system initiatives in our country:

Revamping Standard Treatment Guidelines (STGs) for India specific requirements- STGs are defined norms and procedures for the diagnosis and treatment of medical conditions. In India, we have well-defined set of STGs for 200+ conditions in 21 clinical specialties that safeguard adherence to quality and ensure appropriate treatment. However, it would be relevant for some of the guidelines to be established as per India specific requirements for the diagnosis and treatment to be based on "home grown" evidence and situations.

Recently, some of the leading medical institutions in India have taken the lead in creating STGs. For instance, The Tata Memorial Hospital has started creating the National Cancer Grid for the treatment of cancer, in consultation with leading oncologists in India and with the participation of 100+ centers.

Introducing outcome-based measurement in healthcare delivery- With the advent of improved technologies, it has become easier to measure outcomes and track results over a long period of time. Globally, there are many organizations which are now tracking their outcome levels and accordingly undertaking initiatives towards improving the overall success of their interventions. In India, Aravind Eye Hospitals serves as a model example. They have adopted metrics, leveraged cloud-based storage mobile systems, and integrated data collection to improve practice routines. Evidently, this has led to higher productivity and lower treatment costs per surgery.

Linking payouts to outcomes- Globally, a shift towards "value-based reimbursement" is accelerating. There is an increased consensus on the need for a pay model that encourages the delivery of superior value to patients. Novartis in the US, for example, has got into an agreement with a healthcare provider for a heart failure product where the final payment is based on reduction in hospitalization/ readmission rate of patients in a hospital. These innovative ways must be improved regularly to refurbish outcomes and reduce the financial linkage between the outcome and treatment costs.

Over time, such an outcome-based measurement system could inform and affect policy and financing decisions.

Efforts like these can improve access to healthcare for Indian patients as well as drive economic growth by enhancing India's global competitiveness. As we commit to achieving universal health coverage, there is a growing acknowledgement that this cannot be achieved without strengthening our health systems. Clearly, we will need to keep people-centeredness at the core of all decision-making and collectively develop and implement an evidence-based forward-looking strategy to achieve the goal of healthier lives and wellbeing for all.

Sanjay Murdeshwar, Country President & Managing Director, Novartis India

Source: Sanjay Murdeshwar , ETHealthWorld News, 30.09.2021

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Overarching steps in digital health driving India towards paperless, faceless, cash-less governance model: R S Sharma

The four attributes that the government will focus on to build the digital infrastructure are Interoperability, Scalability, Frugality and Openness in order to increase the accessibility and efficiency of the institutions.

New Delhi/Mumbai: India is focusing on to build a robust digital infrastructure and the government is taking overarching steps to significantly improve public health digital infrastructure. These steps, will drive India towards a paperless, faceless and cashless governance model, informed Dr Ram Sewak Sharma, CEO, National Health Authority (NHA).

Addressing the second day of the Global Fintech fest, RS Sharma emphasised that the four attributes that the government will focus on to build the digital infrastructure are Interoperability, Scalability, Frugality and Openness.

Expanding digital healthcare and building infrastructure will not only improve accessibility of medical services but will also lead to greater efficiency and utilization of the available resources.

Stressing on the role of big data in the healthcare delivery model, DR R S Sharma said, "We must leverage

information and technology to deliver the health services. The idea of National Digital Health Mission (NDHM) is to leverage information, communication tech machine learnings and data to make healthcare access delivery universal. Adopting digital systems will reduce cost, bring affordability, reduce traveling cost, and make the data accessible anywhere and anytime."

Further stated that the account aggregator model was a powerful tool for reduction of cost of transaction and will benefit not only the poor but also the financial institutions. He urged everyone to be a part of this transformative financial and digital infrastructure that will improve the functioning and efficiency of various public institutions including the health sector.

The second day of the Global FinTech Fest organised by Fintech Convergence Council (FCC) and Payments Council of India (PCI), of Internet and Mobile Association of India (IAMAI), and the National Payments Corporation of India (NPCI) saw the presence of many eminent leaders along with over 9,000 delegates.

Source: ETHealthWorld News, 29.09.2021

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Serum Institute gets nod for Novavax vaccine trial in 7-11 age group

It is packaged as a ready-to-use liquid formulation in a vial containing ten doses.

Against the backdrop of children returning to school, the Serum Institute of India has received the green signal to conduct trials on the Novavax vaccine in children in the 7 to 11 age group.

The Drug Controller General of India has given its go-ahead for the trial, a source told *BusinessLine*. Serum Institute has an alliance with American company Novavax to make and market its vaccines in low and middle-income countries.

Serum presently is undertaking a trial on the Novavax vaccine in children in the 12 -17 age group, adding to the portfolio of vaccines being developed for children and adolescents, including Bharat Biotech's Covaxin, Johnson and Johnson's single-dose vaccine, and the needle-free DNA vaccine from Zydus Cadila. The Zydus vaccine is, in fact, poised for launch, as decisions are awaited on its pricing and eventual roll-out across the country.

Inoculation target

The Novavax vaccine is part of the government's vaccination plan to get 100 crore people inoculated by the year-end. And recently, Serum' Chief Executive Adar Poonawalla had told media persons that the raw material shortages from the United States had eased, and the company was hoping to outline its production schedule shortly. He was hopeful that the child vaccine could be ready for approval, possibly by early next year.

Last week, Novavax and Serum said they had filed for an emergency use listing on the vaccine with the World Health Organization. The Novavax vaccine is a recombinant nanoparticle protein-based Covid-19 vaccine with Matrix-M™ adjuvant. The submission to WHO was based on the companies' previous regulatory submission to the Drugs Controller General of India (DCGI).

Novavax and SII have cumulative commitments to provide more than 1.1 billion doses to the WHO-supported COVAX facility.

The EUL by the WHO is a prerequisite for exports to numerous countries participating in the COVAX facility, established to allocate and distribute vaccines equitably to participating countries and economies. "In addition to the submission for WHO EUL, SII and Novavax last month completed the submission of modules required by regulatory agencies in India, Indonesia and the Philippines for the initiation of a review of the vaccine, including preclinical, clinical, and chemistry, manufacturing and controls (CMC) data, Novavax said recently.

Novavax' Covid-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination involves two 0.5 ml doses given intramuscularly 21 days apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels, according to the company.

Source: The Hindu Business Line, 29.09.2021

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Big Pharma has the answers?

IFPMA, the biopharma trade body, has made its claim clear: COVID-19 vaccine management should be left to a handful of companies, and all blame lies with governments

The prognosis of the novel coronavirus disease (COVID-19) pandemic is getting gloomier and more worrisome.

The prospects of a return to normalcy any time soon have been dispelled by epidemiologists, immunologists and other kinds of scientists who study influenza, public health and the like.

They predict that there will be fresh outbreaks in several parts of the world, closures of schools and businesses again, more deaths — but probably less than in the second wave which hit India very hard — and hospitals could be inundated.

As experts have warned us time and again, the only way to control the pandemic is through vaccinating most of the population; at least 90 per cent of it. Even then, we may never be able to eradicate the new SARS-CoV-2 since the virus is here to stay in some form or another.

Vaccination provides some kind of immunity, which is why countries have been scrambling for doses to protect their people. At the last count (September 22), more than six billion doses had been administered to people in 184 countries, but in the most jarring and lopsided way:

While rich countries in Europe and elsewhere have immunised more than 70 per cent of their population, 52 of the poorest places, predominantly in Africa, have barely covered 3.5 per cent of their people.

Besides, some countries have stockpiled enough doses to vaccinate their citizens five times over. It is now a "pandemic of the unvaccinated", as United States health officials describe it.

With the highly transmissible Delta variant inflicting fresh havoc, the outlook is worrying even in the US, Canada and much of the European Union. A late-August McKinsey analysis listed lower-income and many middle-income countries as the most vulnerable.

These at-risk countries have not been able to procure enough doses to cover much of their populations. So the projections are that it is likely to take until late 2022 or even early 2023 for them to achieve high vaccine coverage. How long it will take for them to manage the burden of COVID-19 as an endemic disease is anyone's guess.

Mckinsey says its analysis supports the view of others that "the Delta variant has effectively moved overall herd immunity out of reach in most countries for the time being". The biggest risk is the emergence of newer variants that are more transmissible and more liable to cause deaths and, worse, capable of infecting people who have been vaccinated.

It was against such a backdrop that one heard the big boys of the pharma industry tell us recently that they had matters well in hand. The sense of unreality was heightened when, at an online press briefing in early September, leading vaccine manufacturers (Pfizer and Johnson & Johnson) claimed that there would soon be enough vaccines to immunise everyone. By early next year, supply would very likely outstrip demand.

Yes, the world would have more vaccines than needed.

The briefing was organised by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the trade body of the global innovative biopharma industry, and the main point it made was that the management of COVID-19 vaccines should be left to the handful of companies leading the rollout.

The message clearly was that people should stop bleating about the waiver of intellectual property rights (IPR) and let this cohort get on with the job. Global networks of partners to supply raw materials and increase production had already been set up, so bringing in new players would be a waste of time. The need of the time is for people who know how to produce such vaccines to optimise their capacities.

In fact, a simple question on whether the vaccine makers would support a temporary waiver of IPRs to facilitate increased production and ensure equitable distribution provoked a dismissive rejoinder.

"It took us 18 months with our existing plants, knowledge, staff and validated systems to make these vaccines. There will be enough vaccines, so let us focus on that." Besides, tech transfers were being made to selected collaborators in all continents.

But if the World Health Organization (WHO) was insistent on setting up a tech transfer hub in South Africa, it was not the concern of these companies. Both Pfizer and J&J reminded participants at the briefing that they already have such agreements in place with companies of their choice. In short, these are all distractions.

The outright rejection of any need to lift IPRs should tell those championing this measure at the World Trade

Organization (WTO) that they are fighting a hopeless battle. The waiver proposal was moved almost a year ago at WTO and it has made no headway at all, even though the US has, ostensibly, backed it. The Joe Biden administration has not lifted a finger to push the proposal forward.

The IFPMA briefing was revealing in many ways. The self-congratulation was hard to ignore, but it was perhaps justified to some extent because of the record time in which the vaccines were developed, as also the scale-up.

As IFPMA repeatedly points out, production went up from zero to 7.5 billion vaccine doses (expected production at the end of September) in just nine months. By January 2022, it claims, there will be sufficient doses to vaccinate every adult on every continent.

But what of the humongous profits the leading vaccine companies are making? What of equity in reaching the jabs to poor nations?

For this, too, the companies have a ready answer. Pfizer's Albert Bourla says the vaccines are very reasonably priced: They cost the same as a meal in high-income countries, half that in middle-income countries and are supplied at cost to low-income countries. As for vaccine equity, don't doubt it; companies are committed to the idea.

J&J says it has earmarked one billion doses for poor countries, while Pfizer claims that 41 per cent of its doses have been earmarked for middle- and low-income countries.

Both vaccine-makers blame rich countries for the inequity in vaccine access, pointing out that even if governments in G7 countries vaccinate teenagers and adults and decide to give boosters to at-risk populations, there would still be over 1.2 billion doses available for redistribution in 2021 alone.

Source: Latha Jishnu, Millennium Post, 29.09.2021

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Only 1 in 11 gets Covaxin as Bharat Biotech falls short of production targets

MUMBAI: Homegrown Covaxin was to play a major role in vaccination against Covid-19. But eight months after the vaccination drive began, only one in 11 Indians has managed to get the first indigenous vaccine. Bharat Biotech, which manufactures it, has failed to ramp up production at the pace it had envisaged. Stymied by shortages of drug substance and filling capacity, the Hyderabad-based company has repeatedly fallen short of the target it had set for itself. In between, it also saw a batch of its vaccine face quality issues.

Its CMD Krishna Ella recently said the company would supply 5.5 crore doses from October, from the existing 3.5 crore doses-- substantially lower than the initially-expected 10 crore.

In May, in an affidavit before the Supreme Court, the Centre had projected that 55 crore doses of Covaxin -- or an average of 10 crore monthly doses, would be available during August-December. A month later, this was slashed by 20% to eight crore. However, the monthly capacity for August and September is far lower.

This puts a question mark on the company's ability to boost production and supply the numbers as per its commitment. Interestingly, there has been a huge mismatch in the capacity projected both by the company and government, and what has been supplied so far.

Queries sent by TOI to the company on September 24 seeking details of its capacity remained unanswered.

Concerns around the supply of Covaxin have persisted over the last few months, with Serum Institute-manufactured Covishield accounting for over 90% of all vaccines administered. About one crore daily doses are required to vaccinate the entire 94 crore eligible population by December 31.

Over the last few months, there has been no clarity on its output, with different figures being cited by the company and Centre on multiple occasions. For instance, in May the Centre's affidavit in the Supreme Court said, "Bharat Biotech has increased production from 90 lakh a month to 2 crore doses a month and further increase is expected up to 5.5 crore doses a month by July 2021."

In May again, the Department of Biotechnology said the existing capacity of indigenously developed Covaxin will be doubled by May-June and then increased nearly 6-7 fold by August. It was to be increased from one crore doses in April to six to seven crore doses in July and reach nearly 10 crore a month by September this year. Then, in July, the government put out three different sets of numbers in the Rajya Sabha: one crore, 1.75 crore and 2.5 crore as the company's monthly output. And, in August, the government said the monthly production capacity of

Covaxin is projected to be increased to around 5.8 crore by December from 2.5 crore doses.

With the onset of the deadly second wave in March, capacity issues by both Serum Institute and Bharat Biotech led to massive stockouts across the country. The government-initiated efforts to boost Covaxin production-- much later --by roping in Indian Immunologicals, Haffkine Biopharmaceuticals and Bharat Immunologicals and Biologicals, which will take time to ramp up.

The vaccine, developed in collaboration with the Indian Council of Medical Research, was approved by India's drug regulator on January 3. Facing flak over the slow pace of scaling up earlier, the company said the timeline for manufacturing, testing and release for a batch is approximately 120 days. But even nine months later, Bharat Biotech is refusing to address questions over how it has repeatedly failed to fall short of target.

Source: The Times of India, 29.09.2021

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DCGI extends drug imports deadline on shelf-life rule

With the existing deadline till October 31, the latest extension is for six months

The Drugs Controller General of India (DCGI) has extended till April 30 the deadline for allowing import of drugs with residual shelf life less than 60%.

Sharing the DCGI notification with its members, Pharmaceuticals Export Promotion Council of India (Pharmexcil) said import of drugs with less than 60% residual shelf life was being permitted since April 2020. It followed representations from the importers citing delay in clearances at port offices close on the heels of the COVID-19 outbreak. With the existing deadline till October 31, the latest extension is for six months.

Under the Drugs and Cosmetics Act 1945, import of a drug with less than 60% residual shelf life, as on the date of import, should not be permitted by the licensing authority. In exceptional cases, however, the authority can allow import of any drug with a lesser shelf life, but before its expiry date.

Pharmexcil director general Ravi Uday Bhaskar said the decision of the DCGI is bound to come as a relief for importers who are already grappling with a global shortage

of containers, including reefer boxes used to ship pharmaceuticals, and a sharp increase in the freight tariff.

He said India's pharma imports consists primarily of bulk drugs, formulations, vaccines and surgicals.

Imports have increased amid a need for drugmakers to stockpile more raw materials to meet enhanced demand both in the domestic as well as export markets. In particular, demand for anti-virals had risen during the second wave of the pandemic.

On vaccines, he said with the focus of manufacturers in the country shifting to COVID-19 jabs, there was need to import certain other vaccines and their components.

Source: N Ravi Kumar, The Hindu, 28.09.2021

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Government exempts COVID-19 vaccine from customs duty till December 31

The exemption from import duty would help keep low the cost of overseas vaccines.

The government has exempted customs duty on COVID-19 vaccines for three months till December 31, which will boost domestic availability and make them cheaper.

In a notification dated September 29, the Central Board of Indirect Taxes and Customs (CBIC) said the exemption would come into force on October 1, 2021, and remain in force up to December 31, 2021.

Earlier in April, the government had exempted basic customs duty on the import of COVID vaccines for three months. Following the conclusion of the three-month period, COVID-19 vaccines import attracted 10% duty.The exemption from import duty would help keep low the cost of overseas vaccines that are being eyed to supplement domestically made shots of Covishield and Covaxin.

Currently, India imports Russia made Sputnik V vaccine.

India has granted Emergency Use Approval to five vaccines — Serum Institute's Covishield, Bharat Biotech's Covaxin, Russia's Sputnik V, Moderna and Johnson & Johnson.

Source: The Hindu, 30.09.2021

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Floundering private sales of vaccines in India deal blow to Russia's Sputnik V

* Private sales account for 6% of inoculations since May
* Only about 943,000 Sputnik V doses administered in India
* Private sales fall as govt centres give other vaccines for free

NEW DELHI, Sept 29 (Reuters) - Some of India's private hospitals have cancelled orders for Russia's Sputnik V vaccine as they struggle to sell COVID-19 shots amid surging supplies of free doses of other vaccines offered by the government.

Industry officials said low demand and the extremely cold storage temperatures required have spurred at least three big hospitals to cancel orders for Sputnik V, sold only on the private market in the world's biggest vaccine-producing country. "With storage and everything, we have cancelled our order for 2,500 doses," said Jitendra Oswal, a senior medical official at Bharati Vidyapeeth Medical College and Hospital in the western city of Pune.

"Demand is also not great. There is a class of people, barely 1%, that wanted to go for Sputnik. For the rest, anything would do." From May until last week, private hospitals accounted for just about 6% of all vaccines administered in India, although the government had freed them to buy up to a quarter of domestic output, health ministry data show.

India is set to become a major production centre of Sputnik V, with planned capacity of about 850 million shots a year, and low domestic uptake could mean higher exports instead, a step backers are already pushing for Link Indian companies have already started making Sputnik doses.

The health ministry did not immediately respond to a request for comment. Since a June launch event by Indian distributor Dr. Reddy's Laboratories Ltd REDY.NS , only 943,000 doses of Sputnik V have been administered by hospitals, a fraction of the national total of more than 876 million.

Dr. Reddy's, which has imported about 3 million doses of the vaccine from Russia and refunded hospitals for cancelled orders, declined to comment.

Its partner the Russian Direct Investment Fund, which markets Sputnik V internationally, also declined to comment.

CHEAPER, EASIER ALTERNATIVES

The mainstay of India's inoculation drive is the AstraZeneca AZN.L vaccine, which can be stored in regular refrigerators, unlike Sputnik V, which needs temperatures of -18 degrees Celsius (-0.4°F), impossible to guarantee in most of India.

The vaccine is also as much as 47% more expensive than AstraZeneca on the private market.

Avis Hospitals, which runs eight vaccination centres in the southern city of Hyderabad, has also cancelled an order for 10,000 Sputnik V doses, said a source with direct knowledge of the matter who sought anonymity in discussing business matters.

Avis did not respond to an email seeking comment. Another Pune hospital, which declined to be identified, said it had also cancelled its Sputnik V orders. Sputnik V is just one of the vaccines suffering from a sharp fall in private sales.

Pune's Bharati hospital will end its COVID-19 vaccination programme when it runs out of AstraZeneca doses, as daily inoculations have fallen about 90% to 100 from their June levels, Oswal said. Just 9,000 doses remain of stocks of 62,000 it ordered.

Avis's COVID-19 vaccine sales have shrunk 40% with existing stocks expected to last until December, instead of October, said the source.

India's monthly production of vaccine, mainly of the AstraZeneca shot known domestically as Covishield, has quadrupled to 300 million doses from April, when a dramatic surge in infections and deaths prompted a halt in exports. Overseas sales are to resume Link in October. Covishield accounts for 88% of India's inoculations, followed by Bharat Biotech's domestically developed Covaxin. Both are administered for free at government centres since mid-January.

Source: Krishna N. Das and Jatindra Dash, Reuters, 29.09.2021

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FEATURE

Trade Margin Rationalization by the NPPA: Does the End Justify the Means?

Archana Sahadeva

Sahadeva Law Chambers

*(**Note:** These are not IDMA Views, however would make interesting reading for our Members)*

The pharmaceutical industry is witnessing a new trend – Trade Margin Rationalization of drugs / medical devices etc. by the National Pharmaceutical Pricing Authority ('NPPA'). In the present write up, I am attempting to explore whether such an action is legally tenable, in light of the existing provisions of the Drugs (Price Control) Order, 2013 ('DPCO 2013').

The DPCO 2013 envisages price control and price monitoring of drugs categorized as scheduled formulations and non-scheduled formulations. For Scheduled Formulations, i.e. formulations which are included in the 1st Schedule of the DPCO 2013, prices are fixed and notified by the NPPA, in accordance with the formula provided in the DPCO. The formula provides for a trade margin of 16%. On the other hand, for Non-Scheduled Formulations, i.e. formulations which are not included in the 1st Schedule of the DPCO 2013, there is no such price restriction; the only caveat in the DPCO 2013 being that manufacturers can increase the MRP of such formulations upto 10% of the MRP which was prevalent in the preceding twelve months. The manufacturers are however free to fix the base price of such Non-Scheduled Formulations.

Does this imply that the NPPA can never fix the prices of Non-Scheduled Formulations? No. The DPCO 2013 does indeed vest upon the NPPA, powers under Para 19, to be exercised in ***extraordinary circumstances***, if it is necessary to do so in ***public interest***, ***to fix the ceiling price or retail price of any Drug*** for such period as it may deem fit. The NPPA can thus fall back on its power under Para 19 and fix the ceiling price or retail price of any drug; operative words here being 'ceiling price' and 'retail price'. Pertinently, not only are both the terms *viz*. 'retail price' and 'ceiling price' duly defined under the provisions of DPCO 2013, but the manner and formula for calculating the same is also envisaged in the DPCO 2013.

With the aforesaid background, we now focus our attention to the recent notifications issued by the NPPA, by which neither the ceiling price nor the retail price of the drug / medical device is being fixed. Instead, the NPPA is fixing an upper limit of the trade margin, leaving the manufacturers to calculate and fix the MRP basis the capped trade margin.

To understand why the NPPA has undertaken this route of price fixation of drugs, it is imperative to understand how drug pricing in India works. One of the biggest contributors to prices of pharmaceutical products in the country is trade margins or the margins which pharmaceutical companies allow to their distribution chain *viz*. wholesalers/ distributors/retailers. Thus, a trade margin is a powerful tool for a manufacturer to incentivize the trader/retailer to dispense a particular manufacturer's product.

The discussion around Para 19 attains relevance as this very provision is being invoked by the NPPA to issue the trade margin rationalizing notifications. This therefore, begs the question, does Para 19 permit the NPPA to do so? Can the NPPA, on a plain and simple reading of Para 19, fix the trade margin as opposed to calculating and fixing the ceiling price or the retail price, and if so, what formula is being employed by the NPPA to do so?

Para 19 is extracted hereunder:

19. Fixation of ceiling price of a drug under certain circumstances*.- Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.*

Further, the DPCO 2013 defines 'Ceiling Price' as the price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order, *viz*. Para

4 and 'Retail Price' as the price fixed by the Government for a new drug under Para 5. Thus, there is no scope for either calculation of any other price apart from ceiling price and retail price, nor any other method prescribed under the provisions of DPCO 2013 to calculate any other price apart from the ceiling price and / or retail price.

Thus, it can be argued that the very act of invoking Para 19 of the DPCO 2013 to cap the trade margins by the NPPA is illegal, untenable and without authority.

Assuming arguendo that the NPPA is well within its rights to cap the trade margins by invoking its powers under Para 19, DPCO 2013, there still remain the questions of how and how much?

Thus far, the NPPA has issued 3 notifications fixing the trade margins of (a) 42 anti-cancer drugs[1] in the year 2019, (b) oxygen concentrators[2] in June 2021 and most recently of (c) five medical devices[3] *viz*. Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer, in July 2021. The manner in which the trade margins were fixed in the three notifications is as under:

Anti-Cancer Drugs:

The NPPA put a cap on trade margin of 30% and directed manufacturers to fix the retail prices of their respective drugs based on price at first point of sale of product (Price to Stockist), as per the following formula:

Retail price of the product = Price to Stockist (PTS) x $\{\mathbf{1} + (\boldsymbol{TM} / (\mathbf{100} - \boldsymbol{TM})\}$

Where TM = Trade Margin not exceeding 30%

Where PTS = PTS for the month of June, 2018

Oxygen Concentrators:

The NPPA capped the trade margin of Oxygen Concentrator at first point of sale of product (Price to Distributor) and directed manufacturers to fix the Maximum Retail Price of the non- scheduled Drug Oxygen Concentrators, as per the following formula:

Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST

Where TM = Trade Margin not exceeding 70%

Medical Devices:

The NPPA capped the trade margins of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, (v) Glucometer at first point of sale of product (Price to Distributor) and directed the manufacturers to fix the Maximum Retail Price as per the following formula:

Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST

Where TM = Trade Margin not exceeding 70%.

Unfortunately, the manner of fixing the trade margins in the aforesaid notifications provide no clarity on the issue and on the contrary raise multiple questions. Firstly, what is the genesis of the formula used to cap the trade margins? As is evident from the aforesaid, two distinct *formulae* have been used.

Secondly, how and who decides at what rate the trade margin ought to be capped. From the aforesaid notifications, in 3 different cases, in 3 different fact scenarios, the NPPA has capped the trade margins at 30%, 70% and 70% respectively. What is the underlying criteria for taking such a decision? Why only 30% and 70% and not 50% or even 100%, especially since the NPPA maintains that trade margins allowed to retailers goes upto 1800% or more.

What further accentuates the problem with the mechanism adopted by the NPPA, is the fact that the NPPA has inexplicably attached liability to any non-compliance with the trade margin rationalization notifications to the extent of deposit the overcharged amount along with 15% interest p.a. from the date of increase in price, in addition to penalty upto 100% of the overcharged amount; when in fact the DPCO 2013 is silent on the entire trade margin capping issue.

The NPPA is an independent price regulator tasked with the job of pricing drugs and to ensure availability and accessibility of medicines at affordable prices. While it is an accepted case that powers of the Central Government under Para 19 are delegated to the NPPA, it could be argued that the NPPA is overreaching the delegation by

[1] http://www.nppaindia.nic.in/wp-content/uploads/2019/03/Notification-25.02.2019-Final.pdf.

[2] https://www.nppaindia.nic.in/wp-content/uploads/2021/06/227375.pdf

[3] https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf

undertaking the exercise of trade margin rationalization, as opposed to calculating and fixing the ceiling price or retail price of the said drugs / medical devices.

Therefore, purely from a legal standpoint, the use of any formula and / or the percentage of trade margin, without the sanction of law, can be termed arbitrary and unreasonable, and therefore violative of Article 14 of the Constitution. In a given case, it can be argued that not only has the NPPA acted in excess of the powers conferred upon it, it has adopted methods which are *ultra vires* the DPCO 2013 itself.

Interestingly, the NPPA in its notification by which the trade margins of anti-cancer drugs were capped, concedes that ***there are no laws which control MRP / trade margin***. Without amending the DPCO 2013, invoking Para 19 to issue trade margin rationalization notifications and additionally attaching penal consequences for non-compliance thereof, may not withstand the rigors of Article 14 & 19.

Pertinently, since its notification on May 15, 2013, the DPCO 2013 has been amended 6 times, however no amendment has been made to address the issue of trade margins. This, despite various authorities, including the Department of Pharmaceuticals[4] (in 2016) and the Competition Commission of India[5] (in 2018), highlighting the problem, forming committees and holding stakeholder consultations.

While the object sought to be achieved by capping the trade margins is, without a shadow of doubt, noble and praise-worthy; the same, unfortunately cannot be said of the means employed to accomplish the intent.

[4] https://pharmaceuticals.gov.in/sites/default/files/High%20treade%20margin%20report%20and%20latter%20_0. pdf; accessed on 22.07.2021

[5] http://www.nppaindia.nic.in/wp-content/uploads/2019/03/Notification-25.02.2019-Final.pdf; accessed on 22.07.2021

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