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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 32 (PAGES: 36) | 22 TO 30 AUGUST 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA & APTAR Pharma Webinar

on "Intranasal Immunization: Promises and Challenges"

Date: 2nd September, 2021
Time: 4.30 PM - 6 PM

(Details on Page: 4)

Register now

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 32** **22 to 30 August 2021**

IDMA WEBINAR

IDMA ACTIVITIES:

DoPT MATTERS:

GOVERNMENT COMMUNICATIONS

PARLIAMENT NEWS

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

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

REGISTER NOW - IDMA & APTAR PHARMA WEBINAR on "Intranasal Immunization: Promises and Challenges" for September 2, 4.30 pm to 6 pm

Aptar Pharma and Indian Drug Manufacturers Association (IDMA) is organizing a Webinar on "Intranasal Immunization: Promises and Challenges" on 2nd September 2021, 4.30pm to 6 pm.

Please find the registration link to the webinar on "Intranasal Immunization: Promises and Challenges" for September 2, 4.30pm to 6 pm below:

https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,VjPgRYWeX0GWg7qPokPKGw,vhU8TNwV5kqyzLgXOBFrTg,2jpNZ4u6HEi5FmFxwyYq7A, StN7ioiQ2EmOgoFOGEoeZA, n7i4sv37r0iiFaCew7_LAA?mode=read&tenantId= 5fd74a3e-d57a-410e-8d7c-02c4df062234

The International Speakers for this webinar are

1. **Dr. Julie Suman,** President Next Breath, An Aptar Pharma company
2. **Nektaria Karavas,** Business Development Director, Aptar Pharma

The abstract of the webinar is given below :

Exploring intranasal vaccination for needle-free immunization

Today, there are three marketed nasal vaccines available for human use but many more are in development for both human and veterinary use. Nasal vaccination provides an alternative to the more conventional Injectable drug delivery system. Mucosal immunity can develop via interaction with immune modulators present in the nasal cavity, where the nasal associated lymphoid tissue (NALT) region plays a dominant role.

In this webinar, we will provide an overview of intranasal vaccine formulations for liquid and powder administration. We will then discuss the pros and cons of nasal vaccines, assess intranasal device platforms, logistical considerations that need to be taken into account, as well as present our thoughts on the opportunities that intranasal vaccination can offer.

The webinar shall be of interest to the following people:

- Heads Research Development
- Business Development
- Product Development
- Pharmaceutical Development
- Microbiologists
- Packaging Engineers
- Drug Delivery Scientists
- Formulation Development
- Formulation Scientists
- Process Development
- Quality Control
- R & D
- Research Scientist
- Product Managers
- Innovation Managers
- Virolgists
- Immunologists

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 & S E 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 E-mail : actadm@idmaindia.com / accounts@idmaindia.com Website: www.idma-assn.org	**Aptar Pharma India Private Limited** 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. + 91 22 61951900 / Cell : +91 9892026098 Email : prachi.singhai@aptar.com Website: www.aptar.com

• • •

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Manoj Goyal, Asst. Manager, QC, Wockhardt Ltd., Aurangabad - 13/12/2019

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Asweenkaur Ajmani, Senior Nutrition Executive, Nestle India Ltd. - 19/03/2021

"MDPM programme (DPQCQAM, DDRA, and DAPIMM) gained me details behind issues. This will help me to resolve problems in a better way."
Rakesh Pratap Singh, DGM, Glenmark Pharma, Mumbai - 06/10/2020

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Sujit Ashok More, Executive Supply Chain Management, SRL Limited, – 6/10/2020

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IDMA delegation meets Hon'ble Minister Shri Mansukh L Mandaviya

IDMA Delegation led by Mr. Mahesh H Doshi, National President and Dr. Viranchi Shah, Sr. Vice President greeted Hon'ble Shri Mansukh L Mandaviya ji, Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers during their visit on Monday, 24th August 2021 at New Delhi. In Photo from L : Dr. George Patani, Hon. Gen. Secretary and Mr. Deepnath Roy Chowdhury, Immediate Past National President.

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Inclusion of Chile amongst the countries for ANDA/NDA approval under Clause 4.1 of the Operational Guidelines for PLI Scheme 2.0 - IDMA Suggestion to the Secretary DoP - reg.

IDMA has submitted following representation on 26th August 2021 to Ms. S Aparna, IAS, Secretary, Department of Pharmaceuticals, with a copy to Dr. Sumit Garg, IRS, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on the above subject ;

Respected Madam,

Greetings from IDMA.

We would like to express our appreciation for the initiative that the Department of Pharmaceuticals is taking towards ease of implementation of the PLI scheme and we thank you for inclusion of EMA, BfArm and ANVISA in the list of overseas regulators covered under the Scheme. Given that ANVISA has now been included, we believe that the department is more open to accepting regulatory approvals from other developed nations as well.

We attach herewith a request from our Sr. IDMA Member, Alkem Laboratories Ltd., for inclusion of Chile amongst the countries for ANDA/NDA approval in regards to PLI Scheme 2.0. We, at IDMA, feel that this suggestion is valid & appropriate.

We sincerely look forward to your support for the same.

Yours Sincerely,

For Indian Drug Manufacturers' Association,

Mahesh H Doshi
National President

Encl. : Letter by Alkem Labs Ltd.

ALKEM LABORATORIES LTD.
Regd. Office : ALKEM HOUSE, Senapati Bapat Marg,
Lower Parel (West), Mumbai - 400 013, Maharashtra, India.
• Phone: +91-22-3982 9999 • Fax: 022-2495 2955
• Email: contact@alkem.com • Website: www.alkemlabs.com
• CIN: L00305MH1973PLC174201

Date: 18th August, 2021

Smt. S. Aparna
Secretary
Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Shastri Bhawan
New Delhi – 110001

Sub: Request for inclusion of Chile amongst the countries for ANDA/NDA approval under clause 4.1 of the Operational Guidelines for PLI 2.0

Dear Madam,

Alkem Laboratories Limited ('the Company' or 'Alkem'), is a public company, listed on both The National Stock Exchange of India Limited (NSE) and The Bombay Stock Exchange (BSE). With an experience of over four decades, Alkem is one of India's foremost global pharmaceutical company engaged in the development, manufacture and marketing of pharmaceuticals with footprints across 40+ countries. In India, it has a formidable presence in several therapy segments and consistently features amongst the top ten pharmaceutical companies.

Alkem's products include high-quality branded generics, generic drugs, active pharmaceutical ingredients and nutraceuticals. The Company's product portfolio features over 800+ brands encompassing all major therapeutic segments with over 10 brands having an annual sale of more than INR 1 billion.

Our request

The Company is in the process of making an application under the PLI 2.0 Scheme released by your Department. In this regard, Alkem has also been interacting with your Department in the recent past to showcase and enable a fair chance for maximum participation.

We have noted the latest corrigendum dated 13th August, 2021 which has enhanced the list of countries for ANDA/NDA purposes. While the extension of timelines will allow the industry to better prepare for filing purposes, the selective inclusion of some countries has left us and the industry confused.

During our recent discussions with your Department, we had requested for inclusion of Chile under the list of countries for ANDA/NDA to be eligible under the PLI 20.0 application. While the Department has issued Corrigendum(s) amending clause 4.1 of the Operational guidelines to include ANDA/NDA approvals from countries like Australia, Switzerland, Japan, Brazil and other member countries of PIC/S, such as Vietnam, South Africa, Iran, Cyprus, Israel, Ukraine and the like, our request to include Chile remains unaddressed.

We wish to highlight that Alkem has global supremacy in Chile, considering the fact that Alkem holds 200+ registrations with the Public Health Institute of Chile for its products.

Further, we would like to mention that Chile has a highly regulated pharma sector with a Government Health expenditure of $14,900 mn approx., in the year 2020. The average healthcare spend by Chile amounts to approx. 5% of their GDP on an average as compared to 2-3% in countries like Vietnam and South Africa. Chile also ranks higher on the list of best healthcare systems in the world and stands at #33 as compared to some of the PIC/S countries which have been included in the PLI Scheme (for instance, Iran

stands at #93). This is also reinforced by the confidence that a lot of US based pharma companies are showing in Chile. Companies like Christus Health network, Walgreens Boots Alliance, Nexus, United Health Group and allied have invested heavily in the Chilean healthcare sector.

You would appreciate that India itself not being a PIC/S member country, has quality standards as the backbone of its pharmaceuticals sector and your Department along with CDSCO is constantly improving such standards for our country which are being accepted and appreciated globally. Concomitantly, we believe the Department also views countries like Chile which are not PIC/S members, as countries having robust healthcare system and regulation in place.

We believe that it might not be the intention of your Department to exclude such countries and that the Department would consider such countries having an established healthcare system and framework, on a similar footing as some of the member countries of PIC/S. Accordingly, we request inclusion of Chile amongst the list of the countries for acceptable ANDA/NDA approvals under the PLI 2.0 guidelines.

Looking forward to a favorable response.

Yours sincerely,
For and on behalf of Alkem Laboratories Limited

Name: Mr Rajesh Dubey
Designation: Chief Financial Officer

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Appointments/premature repatriations of officers at Joint Secretary/Joint Secretary equivalent level approved by the Appointments Committee of the Cabinet - reg.

No.33/04/2021-E0(SM-I), dated 23.08.2021

To
All Secretaries to the Government of India.

The Appointments Committee of the Cabinet has approved the following appointments/premature repatriations of officers at Joint Secretary/Joint Secretary equivalent level with pay at Level 14 (₹1,44,200 - 2,18,200/-) of the Pay Matrix:

(1) Appointment of **Ms. Kavita Garg, IDAS (1999)** as **Joint Secretary, Ministry of AYUSH** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Shri PN Ranjit Kumar, IPoS (1993);

(2) Appointment of **Shri Peeyush Kumar, IAS (AP:1997)** as **Joint Secretary, Department of Economic Affairs** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Ms. Sandhya Bhullar, IAS (GJ:2003);

(3) Appointment of **Shri Neelesh Kumar Sah, IA&AS (1997)** as **Joint Secretary, Ministry of Environment, Forest & Climate Change** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Ms. Richa Sharma, IAS (CG:1994);

(4) Appointment of **Ms. Vandana Jain, CSS** as **Joint Secretary, Department of Health & Family Welfare** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Shri Sunil Sharma, IRPS (1985)

(5) (i) Premature Repatriation of **Ms. Rekha Shukla, IRS (IT) (1989),** Joint Secretary, Department of Health & Family Welfare;

(ii) Appointment of **Ms. V Hekali Zhimomi, IAS (UP:1996) as Joint Secretary, Department of Health & Family Welfare** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Ms. Rekha Shukla, IRS (IT) (1989);

(6) (i) Premature repatriation of **Shri Sudhir Garg, IRSEE (1986),** Joint Secretary, Ministry of Micro, Small & Medium Enterprises.

(ii) Appointment of **Ms. Mercy Epao, CSS** as **Joint Secretary, Ministry of Micro, Small & Medium Enterprises** for a tenure of five years from the date of assumption of the charge of the post or until further orders, whichever is earlier, *vice* Shri Sudhir Garg, IRSEE (1986);

(7) Appointment of **Ms. Shruti Singh, IAS (PB:2004)** as **Joint Secretary, Department for Promotion of Industry and Internal Trade (DPIIT)** for an overall tenure of five years upto 18/03/2023 from the date of assumption of the charge of the post or until further orders, whichever is earlier;

(8) **(i)** Premature repatriation of **Ms. Seema Sharma, IRTS (1994), CVO, Bureau of Indian Standards (BIS)** to her parent cadre;

(ii) Premature repatriation of **Dr. Nipun Vinayak IAS (MH:2001)**nt Secretary, Department of Health & Family Welfare to his parent cadre.

Srinivas R Kartikithala,
Secretary,
Appointments Committee of the Cabinet,
Ministry of Personnel,
Public Grievances and Pensions,
Department of Personnel and Training.

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PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce and Industry, Government of India)

PXL/HO/Cir-057/2021-22 Date: 23.08.2021

Hyderabad

IDMA (Indian Drug Manufacturer's Association)

Dear Sir/Madam,

Subject: INDO OCEANIA CONNECT - VIRTUAL PHARMA BSM, 14 - 17 September 2021

Greetings from Pharmexcil

We take pleasure in informing member companies that Pharmexcil is organizing **"INDO -OCEANIA CONNECT - VIRTUAL PHARMA BSM" during 14 - 17th September 2021 with focus nations- Australia, New Zealand, Papua New Guinea, Fiji, Tonga.** The initiative is being undertaken to provide a unique trade platform for Indian exporters and ensure the continuity of interactions with the pharma stakeholders of Oceania region.

Oceania region is one of the emerging markets & Indian pharma Exports to the region amounted to USD 428.29 Million during FY 2021 with a growth rate of 25%. Furthermore, the growing demand for Indian generics is remarkably noted during the last fiscal year. The 4 day event will witness participation of business delegates from Australia, New Zealand, Papua New Guinea, Fiji, Tonga and other adjoining nations from the Oceania region.

The council in close coordination with our missions abroad, local associations and chambers are working together towards the objective to ensure quality buyers during the forthcoming event. Member companies with their existing business operations and ones looking forward to collaborations in the region are invited to exhibit and participate in the unique virtual expo.

Register for virtual BSM as Exhibitor

Participation Charges:

Pharmexcil Members - INR 10,000 + 18 % GST (non - refundable))

Non Members INR 12,000 + 18 % GST (non - refundable))

Post submission of your pre-registration form, you are required to pay the fee in favour of "Pharmaceuticals Export Promotion Council of India" and send us the transaction UTR details to accounts2@pharmexcil.com');" target=_blank >accounts2@pharmexcil.com with a copy to events@pharmexcil.com');" target=_blank >events@pharmexcil.com latest by 1st September 2021. Post confirmation of your payment, you will receive your stall confirmation and login details for setup of your virtual booth and addition of meeting representatives for the scheduled event.

The payment may be made by NEFT/RTGS as per details below:

Beneficiary name	:	Pharmaceuticals Export Promotion Council of India
Bank Name	:	Union Bank of India
Address	:	1st Floor, Door No: 2/A, MIG (581) Near Community Hall, Sanjeev Reddy Nagar Branch, Hyderabad-500038
Current A/c. No	:	510131000001693
IFSC Code	:	UBIN0906701

Inclusions:

Booth Package entitles companies to set up a virtual booth with an online-display of company profile, product images, promotional material like brochure, video, etc. and facility to chat/message/ video meetings (between overseas buyer and exhibitor).

Salient features of the Virtual platform:

The show will be accessed at web browsers and mobile including IOS and android using innovative interactive technology creating user friendly virtual experience/environment.(Exhibitors are recommended to use Google chrome on their PC's to ensure effective and hassle free meetings)

- Seamless match making opportunity (pre-scheduled/approved meetings).
- Artificial Intelligence driven matchmaking process for buyers as per their requirements.
- Products displayed with detailed specifications to facilitate sourcing.
- Availability of Company and product videos for an enhanced experience of meetings.
- Chat and video conferencing facility to help easy interactions.
- Private Meeting rooms and personalised schedules.
- Secure platform to ensure privacy.

Members may like to use this opportunity to connect with quality buyers from Oceania region and are requested to confirm their participation latest by 1st September 2021. For any further clarifications required, kindly write to rodelhi@pharmexcil.com');" target=_blank >rodelhi@pharmexcil.com or contact Mr. Kumar Siddhartha, Sr. Executive Officer at +91-96544 38137.

Regards

Uday Bhaskar
Director General

Manufacturing and Marketing of certain FDCs as per directions of Hon'ble High Court, Maharashtra, Nagpur Bench - reg.

F.No.04-146/2007-DC (Part-I), dated 27th August 2021

To,
All State/UT Drugs Controller

As you are aware while reviewing the directions of the Hon'ble High Court, Maharashtra, Nagpur bench on following FDCs which are already approved by DCG(I) in specific dosage forms and strengths, DTAB in its meeting held on 27.08.2019 also referred these FDCs to the Prof. Kokate Committee :-

Sr. No.	Fixed Dose Combinations (FDCs)
1.	Cefixime + Cloxacillin
2.	Cefixime + Cloxacillin + Lactobacillus
3.	Cefadroxil + Clavulanic acid

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, the above FDCs have been considered as **rational** with certain conditions.

As regard to the FDC of Cefixime + Cloxacillin and FDC of Cefixime + Cloxacillin + Lactobacillus, these have been considered as rational if cloxacillin is in sustained release form in twice daily doses schedule. The indication of the FDC should be restricted to skin and soft tissue infections.

As regard to the FDC of Cefadroxil + Clavulanic acid, firms should prove the efficacy of the combination by conducting in-vitro study in GLP complied laboratory for all the approved indications with respect to the infections caused by susceptible microorganisms including S. aureus. The study should compare cefadroxil alone and in FDC. Accordingly the study protocol should be submitted for approval within 3 months of the notification.

In view of above, you are requested to direct all the manufacturers of above FDCs to manufacture and market the above FDCs at S. No. 2 & 3 only for the indication as mentioned above. Further as regard to the FDC at S.No.1, you are requested to direct manufacturers to submit the protocol for conducting in-vitro study to prove the efficacy of this combination to this office for approval.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, Directorate General of Health Services, (FDC Division), FDA Bhawan, Kotla Road, New Delhi.

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Procedure to be followed for regularisation of 19 FDCs (Fixed Dose Combinations) out of 294 FDCs which require further generation of data which were licensed to manufacture and market by State Licensing Authority (SLA) without prior approval from DCG(I) -reg .

F. No. 04-146/2007-DC (Part-I), dated 27th August 2021

To,
All State/UT Drugs Controller.

This is with reference to this office letter of even number dated 12.04.2019 whereby all the State/UT Drugs Controllers were requested to ask the concerned stakeholders to submit the requisite data/information. The data submitted by the stakeholders was evaluated by the expert committee.

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, there are 19 FDCs which require further generation of data by way of conducting Phase IV trial/ Active Post Marketing surveillance study as the case may be. List of these FDCs along with recommendations of the expert committee is annexed herewith as Annexure-A.

Manufacturers are requested to follow the pathway for clearance of such applications as under:-

1. Form CT 21(duly filled, signed and stamped)
2. Requisite Fees through Bharatkosh.
3. Name and composition of the FDC.
4. Copy of Product Permission issued by SLA to any firm prior to 28.11.2007 as available or the documents in supporting strength and dosage form of FDC.
5. Copy of Manufacturing license of the applied product issued by State Licensing Authority in Form 25/28
6. S. No. of FDC as per the "Annexure-A" and Stability studies data as per earlier communication in this regard.
7. Test specifications of the FDC along with Method of Analysis.
8. Phase IV trial protocol/commitment for conducting Active Post Marketing Surveillance study as the case may be.

In case of applicants who are not holding manufacturing license of the applied product from the State Licensing Authority and want to apply for these FDCs, they can apply with data generated on Form 29 with above pathway.

All the manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not obtain NOC from DCG (I) are required to submit their applications to this Directorate within 06 months.

In view of above, you are requested to direct all concerned stakeholders to follow above procedure for clearance of the cases. You are also requested to ensure that product license in respect of these 19 FDCs are issued after approval of DCG(I) in favour of the applicant.

Dr V G Somani,
Drugs Controller General (India),
Central Drugs Standard Control Organization,
(FDC Division),
Directorate General of Health Services,
New Delhi.

Annexure - A

Sr. no.	Name of the FDC	Recommendations
1.	Aceclofenac + Paracetamol + Chlorzoxazone	Phase IV clinical trial is required to be conducted.
2.	Aceclofenac + Paracetamol + Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) and efficacy should be the primary objective and should be conducted in a statistical significant number of patients.
3.	Aceclofenac + Paracetamol + Tizanidine	Phase IV clinical trial is required to be conducted.
4.	Aceclofenac + Paracetamol+ Tramadol	Phase IV clinical trial is required to be conducted to demonstrate the superiority of this FDC over two drugs approved FDC.
5.	Alprazolam+ Melatonin	Active PMS study on the FDC is required to be conducted.
6.	Alprazolam+ Propranolol	Phase IV clinical trial is required to be conducted.
7.	Calcium dobesilate+ Decusate sodium	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.
8.	Calcium dobesilate+ Lignocaine	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.
9.	Calcium Dobesilate+ Troxerutin	Phase IV clinical trial is required to be conducted to demonstrate the safety and efficacy.

10.	Chlorzoxazone+ Paracetamol + Diclofenac	Phase IV clinical trial is required to be conducted.
11.	Chlorzoxazone+ Paracetamol+ Ibuprofen	Phase IV clinical trial is required to be conducted.
12.	Chlorzoxazone+ Paracetamol+ Nimesulide	Phase IV clinical trial is required to be conducted.
13.	Diclofenac+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
14.	Diclofenac+ paracetamol+ Tizanidine	Phase IV clinical trial is required to be conducted.
15.	Dicyclomine+ Diclofenac Sodium+ Paracetamol	Phase IV clinical trial is required to be conducted.
16.	Ibuprofen+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
17	Nimesulide+ Paracetamol+ Serratiopeptidase	Phase IV clinical trial is required to be conducted provided that paracetamol dose is 325mg. A randomized comparative superiority trial comparing FDC containing serratiopeptidase with the FDC without serratiopeptidase (other ingredients being the same) with efficacy as the primary objective should be conducted in a statistical significant number of patients.
18.	Propranolol+ Diazepam	Phase IV clinical trial is required to be conducted.
19.	Tizanidine+ Nimesulide+ Paracetamol	Phase IV clinical trial is required to be conducted provided that paracetamol dose is 325mg.

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Procedure to be followed for regularisation of FDCs (Fixed Dose Combinations) declared as rational in respect to 294 FDCs by the DTAB which were licensed to manufacture and market by State Licensing Authority (SLA) without prior approval from DCG(I)-reg.

F. No. 04-146/2007-DC (Part-1), dated 27th August 2021

To,
All State/UT Drugs Controller.

This is in continuation to this Directorate letter of even number dated 27.02.2019 and 08.09.2020 whereby a detailed pathway was issued for obtaining permission from this Directorate in respect of 83 FDCs and subsequently 03 FDCs declared as rational.

As per the report of DTAB dated 13.04.2021 and recommendations of subcommittee of DTAB as approved, 31 more FDCs have been considered as rational under 294 FDCs category. The list of these 31 FDCs is enclosed as Annexure - A.

All the manufacturers who are already holding licenses from State Licensing Authorities for such FDCs and did not obtain NOC from DCG (I) are required to submit their applications to this Directorate at the earliest within 06 months.

In view of above, you are requested to direct all concerned stakeholders for submission of application in Form CT-21 as per the defined pathway for clearance of the cases. You are also requested to ensure that product license in respect of these 31 FDCs are issued after the approval of DCG(I) in favour of the applicant.

Dr. V. G. Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, FDC Division, Directorate General of Health Services, New Delhi.

Annexure - A

S. No.	Name of the FDC	Recommendations
1.	Amoxicillin+ Cloxacillin+ Lactic acid bacillus	Rational.
2.	Amoxycillin+ Clavulanic acid+ Lactic acid bacillus	Rational.
3.	Amoxycillin+ Lactic acid bacillus	Rational.
4.	Amoxycillin+ Lactobacillus acidophilus+ Flucloxacillin Sodium	Rational.
5.	Ampicillin+ Cloxacillin+ Lactic acid bacillus	Rational.
6.	Ampicillin+ Lactic acid bacillus	Rational.
7.	Calcium dobesilate+ Lignocaine+ Hydrocortisone	Rational for short term use.
8.	Cefadroxyl+ Lactic acid bacillus	Rational
9.	Cefdinir+ Lactic acid bacillus	Rational
10.	Cefixime+ Lactic acid bacillus	Rational
11.	Cefixime+ Lactobacillus+ Dicloxacillin	Rational if Dicloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections.
12.	Cefpodoxime prozetil+ Lactic acid bacillus	Rational
13.	Cefpodoxime+ Cloxacillin+ Lactobacillus	Rational if Cloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections.
14.	Cefprozil+ Lactobacillus	Rational
15.	Cepodoxime+ Cloxacillin+ Lactic acid bacillus	Rational if Cloxacillin is in sustained release form in twice daily doses schedule and Indication of the FDC should be restricted to skin & soft tissue infections.
16.	Dicyclomine+ Ranitidine	Rational
17.	Domperidone+ Paracetamol	Rational. FDC is indicated for management of acute migraine.
18.	Domperidone+ Paracetamol+ Tramadol	Rational provided that dose of paracetamol is 325mg. FDC is indicated for management of acute migraine.
19.	Doxycycline+ Lactobacillus	Rational
20.	Drotaverine+ Nimesulide	Rational. FDC is indicated for dysmenorrhoea.
21.	Drotaverine+ Paracetamol	Rational. FDC is indicated for dysmenorrhoea.
22.	Lincomycin+ Lactobacillus	Rational
23.	Ofloxacin+ Lactic acid bacillus	Rational
24.	Ondansetron+ Ranitidine	Rational
25.	Torsemide+ Spironolactone	Rational
26.	Allantoin+Dimethicone + Methylparaben+ Propylparaben	Rational
27.	Aloe vera+Vit-e acetate	Rational if FDC is in cream and lotion dosage form only.
28.	Aloe+ Tocopherol	Rational if FDC is in cream and lotion dosage form only.
29.	Aloevera+Glycerine+PEG 100 stearate+Vit E	Rational if FDC is in cream and lotion dosage form only.
30.	Ampicillin+Flucloxacillin Sodium Salt	Rational
31.	Ampicillin+Flucloxacillin Sodium Salt+ Lactobacillus Acidophilus	Rational

In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Monthly Manufacturing Capacity of Covid Vaccine Makers

Rajya Sabha Unstarred Question No.251

Shri Mallikarjun Kharge:

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

(a) the average monthly capacity of production of each manufacturer of COVID vaccine in the country, including Serum Institute and Bharat Biotech;

(b) the break-up of vaccines manufactured in 2021 by each manufacturer, month-wise;

(c) the average import quantity of vaccines from foreign companies;

(d) the procurement of said vaccines by Government or private sector from each manufacturer, month-wise;

(e) the vaccine production capacity planned to be increased in the coming months; and

(f) the plan of action to be taken in case the manufacturers fail to make the promised volume of vaccines?

Answered on 20th July 2021

A. (a) & (b): The current average monthly capacity of production of Covishield by M/s Serum Institute of India is 11 crore doses and of Covaxin by M/s Bharat Biotech International Limited is 2.5 crore doses.

From January 2021 to 16th July 2021 36.01 crore doses of Covishield have been supplied by M/s Serum Institute of India and 5.45 crore doses of Covaxin have been supplied by M/s Bharat Biotech International Limited for the National Covid Vaccination Programme.

(c): During 2021 (till 14th July 2021), a total of 3.3 million doses of Sputnik V (3 million 1st Component and 0.3 million 2nd component) have been imported.

(d): The procurement of COVID-19 vaccines by Government of India, State Government and Private Hospitals is 36.01 crore in respect of Covishield and 5.45 crore in respect of Covaxin from Jan 2021 to 16th Jul 2021.

(e): As communicated by manufacturers, the monthly vaccine production capacity of Covishield is planned to be increased from 11 crore doses per month to more than 12 crore doses per month and production capacity of Covaxin is planned to be increase from 2.5 crore doses per month to 5.8 crore doses per month.

(f): The procurement process of COVID-19 vaccines has adequate in-built mechanisms of financial penalty in case of delay in delivery of vaccines by the manufacturers.

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

Status of Vaccination in the Country

Rajya Sabha Unstarred Question No.257

Shri Ripun Bora:

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

(a) whether it is a fact that only 4.2 per cent of total population, almost 6 crore people in the country has completed full doses of COVID-19 vaccine against 12 per cent of world's average;

(b) if so, the details of full vaccination and report of first dose received by people of the country and the target of Government to achieve 100 per cent vaccination, State-wise; and

(c) the action taken by Government to meet the growing gap between the actual and targeted vaccinations and the availability of vaccines for next six months, company-wise?

Answered on 20th July 2021

A. (a) & (b): As on 15th July'21, against an estimated target of 94 crore eligible beneficiaries, a total of 7.78 crore beneficiaries have been fully vaccinated for COVID-19.

Similarly, 31.35 crore beneficiaries have received at least one dose of COVID-19 vaccine.

The State-wise details of vaccination coverage is at Annexure.

(c): There is no significant gap between the actual and targeted vaccinations and the average daily vaccinations have shown significant increase over the previous months. To sustain the increased pace of vaccination, Government of India is providing advance visibility of vaccine availability at least 15 days in advance to States/UTs with an advice to prepare and widely publicise advance District-wise & CVC-wise plan for accelerating the coverage of COVID-19 vaccination. Further, a communication strategy is in place which is being implemented across all States/UTs with a focus to sustain vaccine confidence. Accessibility of vaccination is also being improved through involving Private COVID-19 Vaccination Centres (CVCs), Workplace CVCs & 'Near to Home' CVCs.

The projected availability of vaccines from 1st August 2021 to 31st December 2021 is 135 crore doses.

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

Annexure

State/UT-wise COVID-19 Vaccination coverage (As on 15th July 2021)

Sr. No.	State/UT	Target population	1st Dose		2nd Dose	
			No.	Percent	No.	Percent
1	A & N Islands	4,33,809	1,77,014	40.8%	69,670	16.1%
2	Andhra Pradesh	5,57,87,608	1,41,91,226	25.4%	38,49,058	6.9%
3	Arunachal Pradesh	9,78,264	6,11,880	62.5%	1,24,519	12.7%
4	Assam	2,30,55,475	70,42,767	30.5%	14,32,392	6.2%
5	Bihar	7,22,85,445	1,64,78,046	22.8%	28,26,509	3.9%
6	Chandigarh	15,75,709	5,20,502	33.0%	1,26,141	8.0%
7	Chhattisgarh	1,89,08,191	87,15,179	46.1%	19,12,960	10.1%
8	Dadra & Nagar Haveli	3,57,480	2,70,992	75.8%	30,330	8.5%
9	Daman & Diu	2,89,154	2,22,220	76.9%	33,360	11.5%
10	Delhi	1,59,50,750	70,02,464	43.9%	21,51,254	13.5%
11	Goa	15,71,030	9,54,703	60.8%	1,90,273	12.1%
12	Gujarat	4,70,72,608	2,19,84,689	46.7%	65,19,179	13.8%
13	Haryana	2,00,23,616	83,23,981	41.6%	18,63,321	9.3%
14	Himachal Pradesh	54,79,377	34,91,953	63.7%	9,55,322	17.4%
15	Jammu & Kashmir	87,31,752	44,12,222	50.5%	8,75,881	10.0%
16	Jharkhand	2,60,86,098	65,85,589	25.2%	13,84,907	5.3%
17	Karnataka	4,72,23,245	2,15,31,799	45.6%	49,53,534	10.5%
18	Kerala	2,87,40,289	1,17,87,897	41.0%	44,18,383	15.4%
19	Ladakh	2,20,448	1,84,350	83.6%	61,717	28.0%
20	Lakshadweep	60,054	48,684	81.1%	11,884	19.8%

21	Madhya Pradesh	5,53,34,785	2,06,54,535	37.3%	39,13,569	7.1%
22	Maharashtra	9,07,32,824	2,95,57,739	32.6%	83,66,620	9.2%
23	Manipur	19,69,137	8,52,513	43.3%	94,504	4.8%
24	Meghalaya	20,82,796	7,46,590	35.8%	1,06,983	5.1%
25	Mizoram	7,87,409	6,00,309	76.2%	1,08,960	13.8%
26	Nagaland	16,32,268	5,28,588	32.4%	1,04,707	6.4%
27	Odisha	3,20,24,612	1,09,95,438	34.3%	28,21,725	8.8%
28	Puducherry	14,33,306	5,06,962	35.4%	1,21,654	8.5%
29	Punjab	2,21,69,872	71,06,538	32.1%	14,57,346	6.6%
30	Rajasthan	5,13,30,937	2,23,38,742	43.5%	51,05,106	9.9%
31	Sikkim	4,63,253	4,51,037	97.4%	1,25,587	27.1%
32	Tamil Nadu	5,59,05,707	1,53,23,595	27.4%	32,26,031	5.8%
33	Telangana	2,20,37,645	1,07,07,196	48.6%	21,33,726	9.7%
34	Tripura	27,59,205	21,09,410	76.4%	6,73,197	24.4%
35	Uttar Pradesh	15,04,98,822	3,26,66,360	21.7%	61,71,492	4.1%
36	Uttarakhand	77,63,594	39,68,239	51.1%	10,56,218	13.6%
37	West Bengal	7,09,53,023	1,81,36,408	25.6%	68,98,498	9.7%
	Miscellaneous	-	17,41,146		15,34,472	
Total		**94,47,09,596**	**31,35,29,502**	**33.2%**	**7,78,10,989**	**8.2%**

Free of Cost Vaccination

Rajya Sabha Unstarred Question No.258

Shri Tiruchi Siva:

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

(a) by when Government aims to have the whole country vaccinated and the details thereof; and

(b) the number of individuals who have been vaccinated free of cost in 18-44 age bracket?

Answered on 20th July 2021

A. (a): The 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. In view of the dynamic and evolving nature of COVID-19 pandemic, no fixed timeline at present can be indicated for the completion of vaccination drive, however, it is expected that all beneficiaries aged 18 years and above will be vaccinated by December 2021.

(b): As on 16th July 2021, a total of 10.91 crore doses have been administered free of cost to the beneficiaries in the age group of 18-44 years at Government COVID-19 Vaccination Centres (CVCs).

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

Steps Taken to Increase the Vaccine Production

Rajya Sabha Unstarred Question No.260

Shri Bikash Ranjan Bhattacharyya:

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

(a) the steps that have been taken by Government to increase production of vaccines;

(b) the present data on production of vaccines;

(c) the precautionary measures that have been taken to combat the third wave of COVID- 19; and

(d) the infrastructural details to meet the requirements during third wave, State-wise?

Answered on 20th July 2021

A. (a): The Department of Biotechnology (DBT), Ministry of Science & Technology, is implementing a scheme 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. Under the Mission, facility augmentation for production of Covaxin is being supported whereby Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad; Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; are being supported.

Additionally, technology transfer of Covaxin production to Consortium of partners including Hester Biosciences and OmniBRx Biotechnologies Pvt. Ltd., led by, Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, is being facilitated by the Department of Biotechnology. These efforts are expected to enhance the production of Covaxin in the coming months.

Government of India has provided 100% advance payment against supply orders placed with vaccine manufacturers to enable them to utilize these funds for capacity augmentation.

Government of India has also provided financial assistance to one of the domestic vaccine manufacturers for 'At-risk manufacturing' of COVID-19 vaccine.

Regulatory norms have also been streamlined for approval of vaccines in India that have received Emergency Use License (EUL) by FDA of United States, MHRA of United Kingdom, PMDA of Japan or WHO-EUL.

(b): Till 17th July 2021, a total of 48.68 crore doses of COVID-19 vaccines have been manufactured in India.

(c) & (d): Ministry of Health & Family Welfare continues to monitor COVID-19 trajectory right up to the District level. The guiding principle to minimize and avert the risk of future resurgence of cases is the 5-fold strategy of test-track-treat-vaccinate and COVID appropriate behaviour. Besides this States are also being provided requisite technical and financial support to prepare for and respond to any exigencies arising out of rapid spurt of cases.

In addition, Government of India has supported the States/UTs with Ventilators, Oxygen cylinders, PSA (Pressure Swing Adsorption) plants, Drugs and Diagnostics as well as financial assistance for augmentation of hospital beds.

In addition to above, a new scheme 'India COVID-19 Emergency Response & Health System Preparedness Package: Phase-II (ERCP-II)' amounting to Rs 23,123 crore has been approved for Financial year 2021-22 that aims to prevent, detect and respond to the continuing threat posed by COVID-19 and strengthen national health systems for preparedness in India for all States/UTs.

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

Delay in Production of DRDO Anti-Covid 2G Drug

Rajya Sabha Unstarred Question No.277

Shri T.G. Venkatesh:

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

(a) whether it is a fact that Government is delaying the production of DRDO Anti-COVID 2G Drug in spite of 40+ drug production companies coming forward to produce it and not even completed the verification of their applications so far;

(b if so, the details thereof; and

(c) the reasons therefor?

Answered on 20th July 2021

A. (a) to (c): No. 2-Deoxy-D-Glucose (2-DG) is a New drug under the provisions of "New Drugs and Clinical Trial Rules, 2019". For manufacturing and marketing of 2-DG, new drug permission is required under the provisions of "New Drugs and Clinical Trials Rules, 2019". Accordingly, the manufacturers are required to submit the application to Central Drugs Standard Control Organization (CDSCO) as per the above rules. Such applications as and when received are processed as per Rules.

Approval for manufacture of 2-Deoxy-D-Glucose (2-DG) was initially granted by CDSCO to Dr. Reddy's Lab. CDSCO has received only four applications subsequently for 2-DG formulations which have been processed by CDSCO under the provisions of New Drugs and Clinical Trials Rules, 2019, and actions like issuance of NOC for lab testing etc. have been taken.

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

Violation of Fixed Price Norms of Vaccines

Rajya Sabha Unstarred Question No.241

Shri K.R. Suresh Reddy:

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

(a) whether it is a fact that COVID-19 vaccine manufacturing companies are fixing the price per dose between ₹700 to ₹1000 per dose in the private market

(b) if so, the details of the rates fixed by the companies

(c) whether it is also a fact that Government has fixed ₹250 per dose of COVID-19 vaccine; and

(d) if so, the action being taken against the companies which are violating norms?

Answered on 20th July 2021

A. (a) & (b): The price of COVID-19 vaccine declared by the two domestic vaccine manufacturers for procurement by private hospitals is INR 600 for Covishield, INR 1200 for Covaxin. In addition INR 948 is the price declared for Sputnik V which is presently imported in the country.

(c): Government of India has fixed a maximum service charge of INR 150 per dose over and above the price of vaccine for vaccine administration at Private COVID-19 Vaccination Centres (CVCs). However, COVID-19 vaccine continues to be provided free of cost to all eligible beneficiaries at Government CVCs.

(d): The vaccine manufacturers are free to fix the price of vaccine for procurement by Private Hospitals. However, the same has to be declared in a transparent manner which has been done by the manufacturers.

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

Absence of VVM on Covid Vaccines

Rajya Sabha Unstarred Question No.242

Dr. Vikas Mahatme:

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

(a) whether it is a fact that COVID vaccines presently available do not have VVM (Vaccine Vial Monitor)

(b) if so, whether they have any other efficacy indicator and in their absence how is the reliability of vaccines determined when it is exposed to high temperature (above 18 degree celsius) during transit or any logistical milestone

(c) the challenges in VVM, when the same has already been incorporated in mass polio drive and

(d) the logistical steps that Government is taking to successfully and safely execute the mass vaccination drive as India being a tropical country with Harsh Weather conditions (High Temperature)?

Answered on 20th July 2021

A. (a) & (b): Yes, the COVID-19 vaccines presently available in the country do not have VVM (Vaccine Vial Monitor). The storage and transportation of

COVID-19 vaccines from the manufacturer up to the site of administration is ensured in a temperature controlled environment at 2-8 degree Celsius.

(c): VVM is manufactured by a single offshore manufacturer and requires end-point studies at various duration to finalize the type of VVM to be used on each vaccine. In view of global urgency to use COVID-19 vaccine upon development, requirement of very high quantity of VVM and limited production capacity, COVID-19 vaccines are being used without VVM across the world.

(d): A robust Cold Chain Network of around 29,000 cold chain points along with insulated/refrigerated vaccine vans is used to ensure storage and transport of COVID-19 vaccines in a temperature controlled environment. Monitoring of storage temperature is also being done on real time basis so as to ensure that vaccines are not exposed beyond the recommended storage temperature.

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

Shutting Down of Business by Companies

Rajya Sabha Un-Starred Question No. 177

Shri Ripun Bora:

Q. Will the Minister of Corporate Affairs be pleased to state:

(a) whether it is a fact that over 13,000 registered big companies and over more than lakhsof small and tiny industries have shut down operations in the financial year 2020-21 including 1200 companies based in North India;

(b) whether it is also a fact that in Haryana itself, about 3000 and in Delhi, over 2450 registered big companies have shut down their business in the last two years; and

(c) if so, the details of companies closed since 2018 to June 2021, State-wise?

Answered on 20th July 2021

A. (a) Ministry of Corporate Affairs (MCA) administers the provisions of the Companies Act, 2013(the Act), the Limited Liability Partnership Act, 2008 and the Insolvency and Insolvency and Bankruptcy Code, 2016. Big companies, small and tiny industries are not defined under the Companies Act, 2013. The term "closed company" is also not defined under the Act. However, pursuant to the provisions of section 248 (1) of the Act where the Registrar has reasonable cause to believe that companies that are not carrying on any business or operation for a period of two immediately preceding financial years and has not made any application within such period for obtaining the status of a dormant company under section 455, shall after following the due processof law, struck off those companies from the Register of Companies.

Further, Companies are also dissolved through amalgamation or otherwise with the approval of the Hon'ble courts. Accordingly, the details of number of such companies are as under:

No. of companies Struck off all over India during 2020- 2021	No. of Companies dissolved in India during 2020-2021	No. of companies Struck off in North India during 2020- 2021	No. of Companies dissolved in North Indiaduring 2020-2021
12889	87	5034	44

Thus it cannot be said that 13000 big companies and lakhs of small and tiny companies have shut down during 2020-2021.

North India comprising of states namely NCT of Delhi, Haryana, Uttar Pradesh, Uttarakhand, Himachal Pradesh, Punjab, UT of Chandigarh, UT of Ladakh and UT of Jammu and Kashmir.

(b): Similarly, No of Companies struck off u/s 248, and Companies dissolved by following dueprocess in Hon'ble Tribunal/Central Government in the last two Financial Years is as under.

No. of companies Struck off in Delhi and Haryana		No. of companies dissolved in Delhi and Haryana	
2019-2020	2020-2021	2019-2020	2020-2021
12653	2396	53	42

(c): Total No. of companies struck off u/s 248 and dissolved State-wise is as under:

Name of the State	No. of Struck off Companies	No. of Dissolved Companies
	2018 to June 2021	2018 to June 2021
RoC-Ahmedabad	9243	191
RoC-Andaman	41	0
RoC-Bangalore	11185	58
RoC-Chandigarh	4908	9
RoC-Chennai	11217	37
RoC-Chhattisgarh	947	0
RoC-Coimbatore	2992	9
RoC-Cuttack	3731	41
RoC-Delhi	45595	160
RoC-Ernakulam	9189	14
RoC-Goa	597	2
RoC-Gwalior	4920	4
RoC-Himachal Pradesh	858	0
RoC-Hyderabad	20488	28
RoC-Jaipur	9222	1
RoC-Jammu	393	0
RoC-Jharkhand	1848	3
RoC-Kanpur	15803	14
RoC-Kolkata	15022	9
RoC-Mumbai	52869	54
RoC-Patna	4683	1
RoC-Pondicherry	191	0
RoC-Pune	5552	5
RoC-Shillong	1256	6
RoC-Uttarakhand	555	0
RoC-Vijayawada	4918	5
Total	238223	651

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State in the ministry of Corprate Affairs (Rao Inderjit Singh)

Appointment of Independent Directors Question

Rajya Sabha Un-Starred Question No.179

Shri Ramkumar Verma:

Q. Will the Minister of **Corporate Affairs** be pleased to state:

(a) whether it is a fact that there is a decline in appointment of Independent Directors since 2018, if so, the details thereof, year-wise, and the reasons therefore and

(b) whether it is also a fact the decline in appointment of Independent directors is mainly due to non-appointment in Public Sector Undertakings (PSUs), if so, the details of the PSUs along with the steps taken or to be taken by Government?

Answered on 20th July 2021

A. (a) and (b): Appointment of Independent Directors is a continuous process. Whenever the posts of Independent Directors fall vacant the respective Companies are required to comply with the provisions of the Companies Act, 2013. The details of Independent Directors are tabulated as below:

Financial Year	Number of Independent Directors appointed
2018-19	30,046
2019-20	29,140
2020-21	21,084

As per section 149 (10) of the Companies Act, 2013, an independent director shall hold office for a term up to 5 consecutive years on the Board of a company.

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State in the Ministry of Corprate Affairs (Rao Inderjit Singh)

Import Duty on Covid-19 Related Goods

Rajya Sabha Unstarred Question No. 193

Shri Prabhakar Reddy Vemireddy:

Q. Will the Minister of Finance be pleased to state:

(a) whether India is levying highest i.e. 15.2% import duty on COVID-19 related goods and inputs;

(b) whether due to above, the treatment cost of COVID-19 also goes up in the country;

(c) the reasons for not making zero import duty on all COVID-19 related goods and inputs which will help poor and middle class in the treatment; and

(d) the reasons that exemptions are only on oxygen-related equipment and COVID-19 vaccine and not on others?

Answered on 20th July 2021

A. (a), (b), (c) and (d): In order to ensure the availability and affordability of goods being used for Covid-19 relief and management, the Government has for specified period provided the following indirect exemptions/concessions on such items:-

(i) Customs Duty including cesses wherever applicable, has been exempted on (a) medicines such as Remdesivir injection, Remdesivir API, Amphotericin B and specified inputs for their manufacturing (b) oxygen and oxygen related equipment (c) Covid-19 Vaccines (d) specified inflammatory diagnostic kits, etc.

(ii) Specified Covid relief items have also been exempted from payment of IGST when imported for donation to Central Government, State Government or any relief agency, entity or statutory body for free distribution.

(iii) GST rate has been reduced on specified goods like Covid-19 related medicines, oxygen, oxygen related equipment, specified Covid-19 testing kits, Pulse oximeters, hand sanitizers, temperature check equipment, Gas/electric furnace for crematorium and ambulances.

The Minister of State in the Ministry of Finance
(Shri Pankaj Choudhary)

GST on Covid Vaccine

Rajya Sabha Unstarred Question No.229

Shri M.V. Shreyams Kumar:

Q. Will the Minister of Finance be pleased to state:

(a) the details of the decision taken by the recently met GST Council regarding GST on vaccination; and

(b) the response of Government to the criticism against the decision not to wave off 5 per cent GST on COVID-19 vaccination?

Answered on 20th July 2021

(A). (a) and (b): GST rates are notified based on the recommendations of the GST Council. A Group of Ministers (GoM) was constituted by the GST Council to recommend GST rate concessions on COVID relief items including COVID vaccines. The GST Council in its 44th Meeting held on 12.06.2021 considered the report of the GoM, discussed in detail the GST rates pertaining to COVID-19 relief items. The Council recommended not to change the GST rate on Vaccines.

The Minister of State in the Ministry of Finance
(Shri Pankaj Choudhary)

Procurement of Sputnik V and Moderna Vaccines

Rajya Sabha Unstarred Question No.259

Shri Tiruchi Siva:

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

(a) the number of vaccine doses administered for Sputnik V in the country; and

(b) the manner in which Government plans allocation of Moderna vaccine and the number of doses to be procured?

Answered on 20th July 2021

A. (a): As on 16th July 2021, a total of 2.61 lakh doses of Sputnik V have been administered in the country.

(b): NEGVAC (National Empowered Group on Vaccine Administration against COVID-19) is in regular dialouge with offshore COVID-19 vaccine manufacturers including Moderna for import of Covid vaccine. However, the exact number of doses to be imported and their manner of allocation has not been finalized yet.

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

In Lok Sabha

Development of Small Scale Industries

Lok Sabha Unstarred Question No. 1706

Shri Dharambir Singh:

Q. Will the Minister of **Micro, Small and Medium Enterprises** be pleased to state:

(a) whether the Government has formulated any scheme in the name of 'Atmanirbhar' to promote MSME;

(b) if so, the criteria followed for the same along with the details thereof;

(c) whether the Government has made or proposes to make any assessment for the development of small scale industries in the country;

(d) if so, the details of the steps taken/proposed to be taken in Haryana State as per the survey conducted as above;

(e) whether the development of technology in respect of small scale industries is highly insufficient here in comparison to that in main countries across the world, particularly in China where small scale industries play an important role in dumping their own product in the markets of various other countries; and

(f) if so, the concrete steps likely to be taken by the Government in this regard?

Answered on 29th July 2021

A. (a) & (b): Yes, Sir. The Government has announced various relief measures for several sectors under the AatmaNirbhar Bharat Abhiyan and has taken a number of initiatives to support the MSME Sector in the country, especially in Covid-19 pandemic situation. Some of them are:

- Rs 20,000 crore Subordinate Debt for Micro Small & Medium Enterprises(MSMEs).
- Rs. 3 lakh crores Collateral free Automatic Loans for business, including MSMEs.
- Rs. 50,000 crore equity infusion through MSME Fund of Funds.
- New revised criteria for classification of MSMEs. Retail and wholesale trades are also included under MSMEs.
- New Registration of MSMEs through 'Udyam Registration' for Ease of Doing Business.
- No global tenders for procurement up to Rs. 200 crores.

(c) & (d): The Ministry of MSME implements various schemes and programmes for growth and development of MSME Sector in the country, including in the State of Haryana. These schemes and programmes include Prime Minister's Employment Generation programme (PMEGP), Scheme of Fund for Regeneration of Traditional Industries (SFURTI), A Scheme for Promoting Innovation, Rural Industry & Entrepreneurship (ASPIRE), Interest Subvention Scheme for Incremental Credit to MSMEs, Credit Guarantee Scheme for Micro and Small Enterprises, Micro and Small Enterprises Cluster Development Programme (MSE-CDP), Credit Linked Capital Subsidy and Technology Upgradation Scheme (CLCS-TUS). Studies have been conducted by National Small Industries Corporation and Khadi and Village Industries Commission to assess the impact of COVID-19 Pandemic on MSMEs, including units set up under PMEGP.

(e) & (f): A Help-Desk & Facilitation Centre has been set up in Directorate General of Trade Remedies, which deals with the trade remedial measures, including anti-dumping measures. This Help Desk & Facilitation Centre is an institutional arrangement to facilitate optimal utilization of available trade remedial measures by different stakeholders.

Its functions inter-alia include:

- Disseminate information to Domestic Industry (DI) regarding various Trade Remedies.
- Hand-hold DI, especially MSMEs, in filing trade remedial petitions.
- Guide MSMEs to remove 'data gaps' while filing applications.
- Guide the Indian exporters facing Trade Remedial Investigations in other countries.
- Provide information regarding available Non-Tariff Measures to Domestic Industry and advise them to avail the same with the support of concerned Administrative Ministry/ Department.
- Provide information regarding estimated time lines for completion of various procedures and for disposal of cases.

Minister of Micro, Small and Medium Enterprises
(Shri Narayan Rane)

● ● ●

Time Govt Scrapped Mandatory CSR

Voluntary CSR is less wasteful, more effective

A Crisil study finds that India Inc's cumulative corporate social responsibility (CSR) spending since 2014 has crossed the ₹1 lakh croremilestone. This is not a mean achievement, although 40% of the spending over the last two years has been on account of companies counting Covid relief measures as CSR. Companies are mandated to spend 2% of average net profit over the past three years on CSR and non-compliance attracts a penalty (thankfully, the offence has been decriminalised). When multiple entities attempt the same task in discrete efforts, there are multiple inefficiencies, ranging from absent economies of scale to diversion of funds to publicity, administration and duplication. The larger the spending on CSR, the greater the wastage. To avoid this, the government must scrap mandated CSR and let companies go back to voluntary CSR.

Companies that are good at carrying out CSR would do it by themselves. Already, investment that takes into consideration environmental, social and governance (ESG) practices creates an incentive for many companies to carry out voluntary CSR.

It would be less wasteful than mandatory CSR, making the case for the government to scrap mandated CSR compelling. Soap makers promoting handwashing and manufacturers spending good money on developing shop floor skills are good examples of CSR that add to, rather than taking away from, the bottomline and benefiting society at large. Profitable companies contribute a lot to society, just by being what they are. They generate jobs and incomes, meet social needs, pay taxes and allow people's savings to be converted into capital that generates returns for capital providers. These firms also nurture the common good by advancing the frontiers of creativity and innovation.

Many companies go beyond and tackle problems of the environment and of social underdevelopment. They become a draw for ethical investors. It helps improve their valuations. Finally, mandating CSR is akin to levying an additional tax and asking the companies to spend the proceeds themselves.

Source : ET Editorials, 26.08.2021

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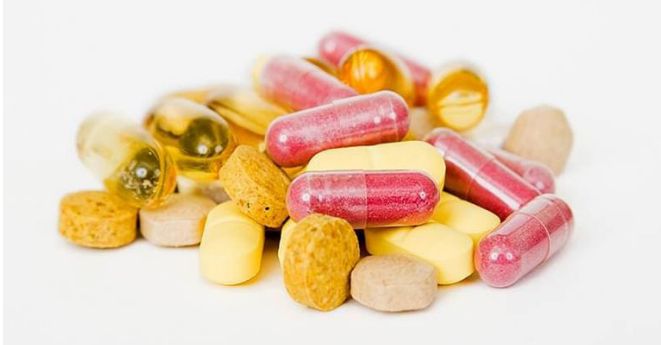
Pharma industry to surpass $60 bn by FY24: Care Ratings



The domestic pharma industry globally ranks third in terms of volume and 13th in value terms, which is primarily because of the predominance of generics, Care Ratings said/ Representational image

The pandemic push will lead to an 11 per cent annual growth for the pharma sector over the next two years and help it surpass $60 billion from around $45 billion in FY21, according to a report.

The domestic pharma industry globally ranks third in terms of volume and 13th in value terms, which is primarily because of the predominance of generics.

As per the report, the industry is expected to grow at about 11 per cent in the next two years to cross the $60-billion-mark in FY24 from $45 billion in FY21.

The report expects this faster growth to be driven by the ability of the domestic industry to leverage the opportunities arising from the expiry of the many patented drugs across the globe, ebbing of regulatory risks, adoption of various de-risk strategies from China dependency for key raw materials, increasing PE investments, and strong fundamentals of the industry.

The domestic industry was $18 billion in FY17, and since then, it has grown at 4.5 per cent per annum and touched $21 billion in FY21. Pharma exports were $17 billion in FY17 and reached $24 billion in FY21, clipping at 10 per cent annually. In FY21, exports grew 18 per cent on the back of pandemic-related drugs. Despite this, the share of exports to overall income has come from 52 per cent in FY17 to 47 per cent in FY21, the report said.

Over the next five years, the patented drugs worth $240 billion will go off-patents globally. This provides a large opportunity for domestic generic formulation companies who are already developing the generic versions of these

patented drugs to cash in on early and are expected to reap $5-6 billion of additional income.

The focus on generics has the domestic country enjoying significant cost advantages in terms of production, R&D and clinical trials over the developed market to the tune of 50, 87 and 90 per cent, respectively.

The country's share in total ANDA approvals has increased from around 40 per cent in 2020 to around 44 per cent as of June 2021. It was 36 per cent in 2017 as it has the largest number of USFDA-compliant pharma plants outside of the US.

The report also expects the R&D expenditure by the domestic pharma companies to remain at about 8 per cent of the total sales for FY23.

Source : The Free Press Journal, 26.08.2021

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Huge Patent opportunity to support pharma sector

Over the next five-six years till 2026, the patented products worth $240 billion are expected to go off-patent

Patent expiry allows the generic drugs to penetrate in the market and diversify product offerings. Representational Image. (PTI)

Chennai: With $240 billion worth patented drugs going off-patent in the next few years, Indian pharma industry has a potential to add $15 billion to become a $60 billion sector in next two years, finds a study. India's share in the new drug application approvals in the US has already gone up in the first half of 2021.

Patent expiry allows the generic drugs to penetrate in the market and diversify product offerings. Over the next five-six years till 2026, the patented products worth $240 billion are expected to go off-patent. This provides a large opportunity for Indian generic formulation companies. Many of the Indian pharma companies are already working to develop the generic version of patented products, finds Care Ratings.

Of the total abbreviated new drug application (ANDA) approvals granted by the US Food and Drug Administration (USFDA), India commands major share in product approvals. India's share in total ANDA approvals has increased to around 40 per cent in CY20 from 36 per cent in CY17. It further went up to 44 per cent in CY21 by June 2021. India also has the distinction of having the largest number of USFDA-compliant pharma plants outside of the US. With the available USFDA compliant infrastructure, it is expected that India will lead the patent cliff opportunity in the US.

Further, most of the companies have increased their spend on research and development in order to produce cost and process-efficient raw materials. The R&D expenditure by the companies may remain at about 8 per cent of the total sales for FY22-FY23. Several global and domestic companies have sought for China +1 supplier base to have diversified supplier base. This, to some extent, has also proved advantageous for Indian pharma API companies.

Source :Sangeetha G, Asian Age, 28.08.2021

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NPPA releases draft version of retail price proposals for six drugs

The National Pharmaceutical Pricing Authority (NPPA) has released the draft version of the proposed price calculation sheet for retail price of six medicine combinations from various players in the country.

Retail price has been fixed for 2.0 ml catridge for pen containing erthropoietin concentrate solution IP 20000 IU with HSA Stabiliser for Wockhardt Ltd, at Rs. 2,054.82 per unit, considering that the only other player in the market, Intas Pharmaceuticals, charges Rs. 1,771.40 per unit for its brand Epofit. The price for Wockhardt includes the amount, added with 16 per cent retailer margin. The moving annual total (MAT) is Rs. 5.72 lakh.

The Authority has fixed retail price for gelatin capsules containing rosuvastatin calcium IP, for Synokem Pharmaceuticals Ltd (manufacturer) and Micro Labs Ltd (marketer) at Rs. 19.87 per unit, considering the average price of Rs. 17.13 along with 16 per cent retailer margin. The reduction in price compared to highest price is 27.38

per cent, when compared to the highest price of Rs. 23.59 per unit, charged by Lupin Ltd for its brand Novastat CV. The prices fixed are excluding GST.

It has also fixed the price of tenofovir disproxil fumarate IP 300 mg, for Cipla Ltd, at Rs. 59.8 per unit, as the only existing player is charging Rs. 51.55 per unit, and for nebbiolo hydrochloride IP for Windlas Biotech Ltd (manufacturer) and Cadila Pharmaceuticals Ltd (marketer), at Rs. 12.96 per unit. The price is Rs. 11.77 per cent lesser than the highest price for the drug in the market.

Retail price of amlodipine besylate IP for Wings Biotech LLP (manufacturer) and Zuventus Healthcare Ltd (marketer), at Rs 5 per unit, considering the average of the prices of 17 companies with market share of one per cent and above. The total MAT for the drug is Rs. 545.46 crore, it said.

Retail price of hard gelatin capsule containing atorvastatin calcium IP equivalent to atorvastatin 20 mg (as pellets) + clopidogrel bisulphate IP equivalent to clopidogrel 75 mg (as pellets) for Synokem Pharmaceuticals Ltd (manufacturer) and Aristo Pharmaceuticals Pvt Ltd (marketer), has been fixed at Rs. 16.55 per unit.\

NPPA, on Thursday, has released draft version of proposed price calculation sheet for retail price of 11 drugs, ranging from paracetamol IP 1000 mg, which has the highest moving annual total (MAT) of Rs.269.2 crore, to levetiracetam IP 500 mg plus sodium chloride IP 820 mg combination with a MAT of Rs. 3.76 lakh.

Source: Pharmabiz, 27.08.2021

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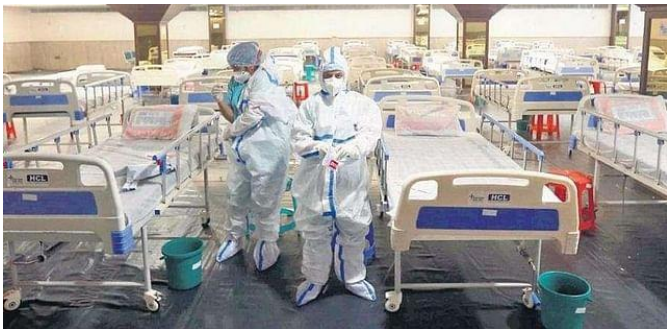
Centre releases Rs 8,093 crore emergency Covid fund for states to plug infra gaps

Last month, the Union Health Ministry had already issued Rs 1,827 crore under this scheme, to be implemented from July this year to March 2022 to the states.



NEW DELHI: The Centre has released around Rs 8,093 crore to states as part of phase 2 of the emergency response & health system preparedness package, approved by the Union cabinet in early July with a corpus of Rs 23,123 crore to prepare rural, tribal and semi-urban areas better.

Last month, the Union Health Ministry had already issued Rs 1,827 crore under this scheme, to be implemented from July this year to March 2022 to the states.

The government said that with the released of 35% more funds, a total of 50% of the fund has now been shared by the states, to ensure implementation of critical activities at the district- levels to prepare the public healthcare systems in response to the evolving pandemic.

The scheme is aimed to accelerate health system preparedness for immediate responsiveness for early prevention, detection and management, with a focus on health infrastructure development including for paediatric care and with measurable outcomes.

Under the ERCP-II, the creation of 827 paediatric units in the districts which will result in the additional creation of 19,030 oxygen supported beds and 10,440 ICU and high dependency unit beds have been planned.

Also, it has been decided to augment 23,056 ICU beds in the public healthcare system out of which 20% will be paediatric ICU beds while to provide care closer to the community due to the ingress of Covid19 in rural, peri-urban and tribal areas, a provision of 8.010 pre-fabricated structures for adding additional beds at government hospitals has been made.

The scheme also looks to establish 203 field hospitals, with 50-100 beds, depending on the requirements posed by the states in tier-II or Tier-III cities and district headquarters which will help in the creation of 13065 oxygen supported beds.

Till April this year, states with supported with Rs 15,000 crore by the Centre for Covid19 preparedness under ERCP-I.

Source: Sumi Sukanya Dutta, Indian Express, 13.08.2021

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Mansukh Mandaviya takes charge as Stop TB Partnership Board chairman

Taking to Twitter, the union minister said, "Honoured to take on as the Chairman of @StopTB Partnership Board

and lead global efforts against TB. I look forward to working with partners and volunteers to take sustained steps to end TB worldwide by 2030 and realise PM @NarendraModiji's vision of ending TB in India by 2025."

New Delhi: Union Health Minister Mansukh Mandaviya on Thursday took charge as the Chairman of Stop TB Partnership Board.

"India's leadership in the global fight against TB continues with Minister @mansukhmandviya's appointment as next Chairperson of @StopTBBoard which supports global efforts in achieving UN goal to end TB by 2030. Leading by example remains committed to ending TB domestically by 2025," tweeted the Permanent Mission of India at the United Nations.

Taking to Twitter, the union minister said, "Honoured to take on as the Chairman of @StopTB Partnership Board and lead global efforts against TB. I look forward to working with partners and volunteers to take sustained steps to end TB worldwide by 2030 and realise PM @NarendraModiji's vision of ending TB in India by 2025."

He also lauded the initiatives of former Health Minister Dr Harsh Vardhan who was charing the board.

"I express my gratitude to the outgoing Chair of Stop TB, @DrHarshVardhan, and appreciate the initiatives taken by the partnership under his guidance. I am also looking forward to working with the incoming Vice-Chair, Austin Arinze, when he takes over on January 1, 2022," added Mandaviya.

The Stop TB Partnership is a United Nations-hosted partnership program that aims to fight against tuberculosis collectively.

Source : ETHealthworld.com from ET, 27.08.2021

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Low-grade imports: DPIIT mulls quality control curbs for 45 more products

The move is part of the ministry's drive to formulate standards/technical regulations or put in place QCOs for 371 key products in the first phase. Imports of these products were to the tune of $128 billion, or a fourth of the total purchases from overseas, in FY19, well before the pandemic struck.

Many countries, especially the big economies, therefore, subject their imports to rigorous technical standards and sanitary and phytosanitary measures.

The commerce and industry ministry is considering quality control orders (QCOs) for 45 more products, ranging from electronics to industrial machinery, as it intends to harden a crackdown on imports of sub-standard products. The move is part of the ministry's drive to formulate standards/technical regulations or put in place QCOs for 371 key products in the first phase. Imports of these products were to the tune of $128 billion, or a fourth of the total purchases from overseas, in FY19, well before the pandemic struck.

"Of the 371 products identified by the commerce ministry, 71 have been allocated to the department for the promotion of industry and internal trade (DPIIT) for the issuance of QCOs. Of these, the DPIIT has notified QCOs for 26 items and the remaining 45 are under consideration," an official source told FE.

However, keeping with the principle of free and fair trade and to ensure domestic consumers have access to quality products, both Indian manufacturers and foreign suppliers will have to conform to the same standard specifications. Importantly, concerned about protectionism by stealth adopted by some nations, Commerce and Industry Minister Piyush Goyal last week asked industry associations to flag non-tariff barriers faced by Indian exporters in various countries so that New Delhi can firm up appropriate responses wherever feasible. Industry sources say the responses could be in the form of subjecting imports to strict quality parameters. So far, QCOs have been issued for a total of 100 products under the BIS Act, the source said. These include air conditioner, toys, footwears, pressure cooker and microwave. Separately, the QCOs for another 15 products, including gas cylinders, valves and regulators,

have been notified under the Indian Explosives Act. The QCOs issued by the government are in sync with the WTO Agreement on Technical Barriers to Trade, said the source. Apart from the QCOs, the government has already firmed up standards as well as technical regulations for hundreds of products across sectors, including consumer electronics, steel, heavy machinery, telecom goods, chemicals, pharmaceuticals, paper, rubber articles, glass, industrial machinery, some metal products, furniture, fertiliser, food and textiles.

Though the move isn't Beijing-specific, it could hurt China, as the second-largest economy is the biggest supplier of low-grade products to India. Government officials maintain that the idea behind the move to enforce standards is not just to curtail low-grade imports but to improve the domestic output of quality products as well. This will, in turn, help boost exports and substitute low-grade imports, in sync with Prime Minister Narendra Modi's push for Atmanirbhar Bharat.

Interestingly, India's move to develop technical specifications for products in recent years marks a shift in its approach to curb the inflows of substandard products (Its earlier approach was to raise tariffs).

Analysts have said India seems to have taken a cue from major developed and developing nations that have effectively employed various non-tariff measures to target non-essential and substandard imports. For instance, the US put in place as many as 8,453 non-tariff measures, followed by the EU (3,119), China (2,971), South Korea (1,929) and Japan (1,881), according to a commerce ministry analysis last year. In contrast, India has imposed only 504 of them. Of course, non-tariff measures are not always aimed at curbing imports (for instance, safety, quality and environmental standards are put in place by all countries for imported products). But what have often worried analysts is that they can be abused for trade protectionism.

Since substandard products are usually imported at much cheaper rates, they not just pose risks to consumer health and environment but also hit domestic manufacturing because of the price-competitiveness. Many countries, especially the big economies, therefore, subject their imports to rigorous technical standards and sanitary and phytosanitary measures.

Source : Financial Express, 31.08.2021

● ● ●

Exports from SEZs up 41.5% to Rs 2.15 lakh crore during Q1 FY22

Export Promotion Council for EoUs and SEZs (EPCES) is the nodal body, set up by the commerce ministry, to promote shipments from these zones.

Exports from special economic zones (SEZs) grew by about 41.5 per cent to Rs 2.15 lakh crore during the April-June quarter of the current fiscal on account of healthy growth in pharmaceuticals, engineering, and gems and jewellery sectors, as per official data. SEZs are key export hubs which contribute about one-fourth of the country's total outbound shipments.

According to commerce ministry data, exports from these zones dipped to Rs 7.56 lakh crore in 2020-21 as against Rs 7.97 lakh crore in 2019-20.

In the first quarter of the current financial year, SEZ exports rose about 41.5 per cent to Rs 2.15 lakh crore.

As many as 427 such zones have been approved by the government, out of which 267 are operational as on June 30.

The data showed that till June 30, Rs 6.25 lakh crore have been invested in these zones and a total of 24.47 lakh people are employed there. Export Promotion Council for EoUs and SEZs (EPCES) is the nodal body, set up by the commerce ministry, to promote shipments from these zones.

The council has announced Bhuvnesh Seth as its new chairman and Srikanth Badiga as the new vice-chairman.

Seth said the council would work on taking the country's exports to USD 400 billion during the current fiscal.

The major export destinations include the United Arab Emirates, US, UK, Australia and Singapore.

Source : ETRetail.com from Economic Times, 30.08.2021

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India's Covid vaccine supply jumps, raising export hopes for the world

The Serum Institute of India (SII), the world's biggest vaccine maker, is now producing about 150 million doses a month.

After donating or selling 66 million doses to nearly 100 countries, India barred exports in the middle of April

India's rising output of COVID-19 vaccines and the inoculation of more than half its adult population with at least one dose are raising hopes the country will return as an exporter within months, ramping up from early next year. After donating or selling 66 million doses to nearly 100 countries, India barred exports in the middle of April to focus on domestic immunisation as infections exploded, upsetting the inoculation plans of many African and South Asian countries.

India's daily vaccinations surpassed 10 million doses on Friday, with national vaccine production more than doubling since April and set to rise again in the coming weeks. New production lines have been set up, a vaccine developed by Cadila Healthcare won recent approval, and commercial production of Russia's Sputnik V is starting in India.

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New production lines have been set up, a vaccine developed by Cadila Healthcare won recent approval, and commercial production of Russia's Sputnik V is starting in India.

The Serum Institute of India (SII), the world's biggest vaccine maker, is now producing about 150 million doses a month of its version of the AstraZeneca shot, more than twice its April output of about 65 million, a source with knowledge of the matter said.

"No fixed timeline on exports but the company hopes to restart in a few months," said the source, who declined to be named without approval to talk on the matter.

SII, which has previously indicated exports could resume by year-end, did not respond to a request for comment. Global vaccine sharing platform COVAX hopes India will restart foreign sales sooner than later.

"With successful national vaccination and the arrival of more products, we are hoping that Indian supply to COVAX will resume as quickly as possible," a spokesperson for the platform's co-lead GAVI told Reuters in an email.

Source : Mint, 30.08.2021

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