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# IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 30 (PAGES: 40) | 08 TO 14 AUGUST 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

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Date: 26th August, 2021
Time: 3:00 PM - 4:00 PM

(Details on Page: 4)

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Aptar pharma

### IDMA & APTAR PHARMA WEBINAR

on
"Intranasal Immunization: Promises and Challenges"

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

(Details on Page: 5)

## HIGHLIGHTS

- ★ USFDA Officials visited FDCA Gujarat to attend their Regulatory Forum meet for sharing of work done during COVID-19 (Page No. 22)
- ★ Pharma market reports 14% y-o-y growth in July; demand to normalise if pace of vaccination continues: India Ratings (Page No. 25)
- ★ Freight rates jump 250% (Page No. 32)

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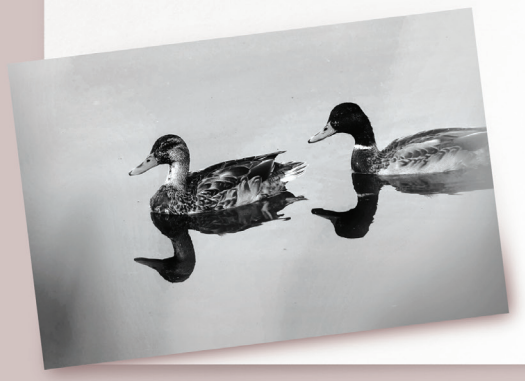

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# IDMA BULLETIN

**Vol. No. 52** **Issue No. 30** **08 to 14 August 2021**

## IDMA WEBINARS:



## GOVERNMENT NOTIFICATIONS:



## PARLIAMENT NEWS:



## FDA MATTERS:



## NATIONAL NEWS:

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## INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

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# 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**<br>*Secretary – General* | **Prachi Singhai**<br>*Manager-Marketing & Communication,*<br>*India & S E Asia* |
|---|---|
| **Indian Drug Manufacturers' Association**<br>102, A Wing, Poonam Chamber, A Wing, 1st Floor, Dr.A.B.Road, Worli, Mumbai-400018. Maharashtra. India.<br>Tel No. 022 24974308 / 24944624<br>Cell: +91 9821868758<br>E-mail : actadm@idmaindia.com / accounts@idmaindia.com<br>Website: www.idma-assn.org | **Aptar Pharma India Private Limited**<br>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.<br>Tel. + 91 22 61951900 / Cell : +91 9892026098<br>Email : prachi.singhai@aptar.com<br>Website: www.aptar.com |


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# The Drugs (Amendment) Rules, 2021 - reg.

**Notification G.S.R. 533(E), dated 3rd August, 2021**

The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and subsection (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

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

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

## DRAFT RULES

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

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

**(2)** In the Drugs Rules, 1945, in rule 90,—

(i) In sub-rule(2), for the words and figures "Form 29", the words and figures "Form 30" shall be substituted;

(ii) After sub-rule(2) so amended, the following sub-rule shall be inserted, namely:—

"(3) The license in Form 29 may be granted by the licensing authority within a period of seven working days from the date of receipt of the application in Form 30 duly completed, and in case where no communication is received by the applicant within the such stipulated period from licensing authority, such licence shall be deemed to have been granted.".

**F.No.X.11014/2/2021-DR**

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

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# The Environment (Protection) Second Amendment Rules, 2021 - reg.

**Notification G.S.R. 541(E), dated 6th August, 2021**

Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules,1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23rd January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

**1. Short title and commencement**. -

(1) These rules may be called the Environment (Protection) Second Amendment Rules, 2021.

(2) They shall come into force after one year from the date of publication of this notification in the Official Gazette.

**2.** In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

| S. No. | Industry | Parameters | Standard |
|---|---|---|---|
| 1 | 2 | 3 | 4 |
| "73. | Bulk Drug and Formulation (Pharmaceutical) | **A. EFFLUENT STANDARDS*** | |
| | | | Limiting value for concentration (in mg/l except for pH and Bio assay) |
| | | **(i) Compulsory Parameters** | |
| | | pH | 6.0 -8.5 |
| | | BOD (3 days 27°C) | 30 |
| | | COD | 250 |
| | | TSS | 100 |
| | | Oil & Grease | 10 |
| | | Ammonical Nitrogen | 100 |
| | | Bio - Assay Test** | 90% Survival of Fish after first 96 hours in 100% effluent |
| | | (ii) Additional Parameters## | |
| | | ***Benzene | 0.1 |
| | | ***Xylene | 0.12 |
| | | ***Methylene Chloride | 0.9 |
| | | ***Chlorobenzene | 0.2 |
| | | Phosphates as P | 5 |
| | | Sulphides as S | 2 |
| | | Phenolic Compounds | 1 |
| | | Zinc | 5 |
| | | Copper | 3 |
| | | Total Chromium | 2 |
| | | Hexavalent Chromium ($Cr^{6+}$) | 0.1 |
| | | Cyanide (as HCN) | 0.1 |
| | | Arsenic | 0.2 |
| | | Mercury | 0.01 |
| | | Lead | 0.1 |
| | | SAR | Less than 26 (applicable only for discharge on land) |

| | | |
|---|---|---|
| | | **(iii) Industry connected with CETP** |
| | | • The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016.<br>• State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions. |
| | | **Note:**<br>The standards in para A is applicable to all discharges except to CETP.<br>*Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose.<br>** The Bio assay test shall be conducted as per IS : 6582-1971<br>## Parameters listed as **"Additional Parameters"** shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/ quarterly as decided by SPCBs<br>****Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.* |
| | | **B. EMISSION STANDARDS**<br>(Tank farm Vents) |

| | | Parameter | Limiting value for concentration(mg/Nm$^3$) |
|---|---|---|---|
| | | Chlorine | 15 |
| | | Hydrochloric acid vapor | 35 |
| | | Ammonia | 30 |
| | | Benzene | 5 |
| | | Toluene | 100 |
| | | Acetonitrile | 1000 |
| | | Dichloromethane | 200 |
| | | Xylene | 100 |
| | | Acetone | 2000 |
| | | C. *The total cumulative losses of solvent should not be more than 5%of the solvent on annual basis from storage inventory* | |
| | | D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans- boundary Movement) Rules, 2016 and shall be subject to the provision made therein. | |

**F. No. Q-15017/12/2018-CPW**

*Naresh Pal Gangwar, Joint Secretary, Ministry Of Environment, Forest And Climate Change, New Delhi.*

**Note :** *The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844(E), dated the 19th November, 1986 and lastly amended vide notification G.S.R. 243(E), dated the 31st March, 2021.*

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# In Lok Sabha & In Rajya Sabha

## LOK SABHA

### Unethical Practice by Pharma Companies

**Lok Sabha Unstarred Question No. 2316**

**Shri Shanmuga Sundaram K:**

**Shri Velusamy P:**

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

(a) whether the doling out of freebies, cruise tickets, paid vacations and sponsorships to educational conference and seminars for doctors by pharmaceutical companies has been banned from January 1, 2014;

(b) if so, whether the Government is aware of the fact that the Mumbai branch of the Income Tax Appellate Tribunal has disallowed an allowance of Rs. 76.55 lakhs paid by a leading pharma company;

(c) the steps taken by the Government to prevent such kind of unethical practice followed by the pharma companies hitherto; and

(d) whether the Government has any proposal to bring out a specific and comprehensive law and if so, the details thereof?

**Answered on 3rd August 2021**

**A.** (a) & (c): No, Sir. However, in the year 2014, Government had prepared a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) to discourage unethical practices employed by Pharmaceutical Companies for promoting sales of their medical products. On 12th December, 2014, it was sent to all the pharmaceutical associations for voluntary implementation with effect from 01.01.2015. Further, as per clause 6.8.1 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, a registered medical practitioner is prohibited to accept Gifts, Travel facilities, Hospitality, Cash or monetary grant from any pharmaceutical or allied health care Industry.

(b): Yes, Sir. The Central Board of Direct Taxes, Department of Revenue has informed that the Income Tax Appellate Tribunal (ITAT), Mumbai has upheld the disallowance of Rs. 76.55 lakhs made by an Assessing Officer in assessment order of a pharmaceutical company for the Assessment Year 2009-2010.

(d): No, Sir

**Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

### Spurious Drugs

**Lok Sabha Unstarred Question No. 2331**

**Shrimati Ranjanben Dhananjay Bhatt:**

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

(a) whether there is excess of spurious drugs in different parts of the country;

(b) if so, whether the Government will consider taking concrete and effective steps to check it;

(c) if so, the details thereof along with the time by which the said steps are likely to be taken; and

(d) if not, the reasons therefor?

**Answered on 3rd August 2021**

**A.** (a) to (d): As per Central Drugs Standard Control Organisation (CDSCO), isolated complaints regarding spurious drugs are received in CDSCO. As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945. The information received from Drugs Controllers of various States/ UTs during last three years and current year in this context is as under:

| Financial Year | No. of drug samples tested | No. of drug samples declared spurious/ adulterated | Percentage of drug samples declared spurious/ adulterated |
|---|---|---|---|
| 2017-18 | 82599 | 236 | 0.28 |
| 2018-19 | 79604 | 205 | 0.27 |
| 2019-20 | 81329 | 199 | 0.24 |
| 2020-21* | 69272 | 139 | 0.20 |

Corresponding information received from various Zonal/Sub-zonal offices of CDSCO is as under:

| Financial Year | No. of drug samples tested | No. of drug samples declared spurious/ adulterated | Percentage of drug samples declared spurious/ adulterated |
|---|---|---|---|
| 2017-18 | 7088 | 2 | 0.028 |
| 2018-19 | 10382 | 5 | 0.048 |
| 2019-20 | 9299 | 12 | 0.12 |
| 2020-21* | 4237 | 1 | 0.02 |

**The information of FY 2020-21 is upto 31st January, 2021 only.*

Further, amidst reports received of fake & spurious Covid-19 management drugs, CDSCO has requested all States/UTs Drugs Controllers through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation.

As per information available from various State Licensing Authorities, in cases of fake & spurious Covid management drugs, various enforcement actions like Drug seizure, Arrests of accused persons / registration of FIR etc. have been carried out by the States/UTs Drugs Controllers. CDSCO and Ministry of Health and Family Welfare have taken various regulatory measures to ensure the quality of medicines distributed in the country which are as under:

(i) The Drugs and Cosmetics Act, 1940 was amended under the Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non- bailable.

(ii) The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 33 States have already set up designated special Courts.

(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.

(iv) The number of sanctioned posts in the Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 492 (in Jan, 2021).

(v) The testing capacities of Central Drugs Testing Laboratories under the CDSCO are being constantly strengthened to expedite testing of drug samples in the country.

(vi) On 3.4.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

(vii) On 27.10.2017, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

Joint inspection of the licensed manufacturing premises by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach is also provided for.

On 10.04.2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory for all drugs, that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of product manufacturing license by the Authority.

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## API Manufacturing

### Lok Sabha Unstarred Question No. 2358

### Shri Mitesh Rameshbhai Patel (Bakabhai):

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

(a) the quantity of Active Pharmaceutical Ingredient (API) manufactured at domestic level including the details thereof;

(b) the details of efforts made by the Government to promote API manufacturing plants in the country; and

(c) whether the Government has set any special target for the coming years in this regard and if so, the details thereof?

### Answered on 3rd August 2021

**A.** (a) The quantity of API manufactured domestically is not readily available. However, the size of API and Intermediates market in India is estimated to be Rs. 96,000 crore in FY 2019-20. Further, as per data maintained by Directorate General of Commercial Intelligence and Statistics (DGCIS), the quantity and value of API imported and exported in FY 2020-21 is given below:

| | Quantity (In MT) | Value (Rs. In crore) |
|---|---|---|
| Imports | 3,90,476 | 28529 |
| Exports | 3,24,331 | 32856 |

(b)to (c): The Department of Pharmaceuticals is implementing the following three (03) schemes for promoting domestic manufacturing of APIs to ensure their sustainable domestic supply and make India Atma Nirbhar (self-reliant):

(I) **Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India:** The scheme provides for financial incentives to manufacturers selected under the scheme for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The incentives will be provided on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure of the scheme is from FY 2020-2021 to 2029-30.

(II) **Scheme for Promotion of Bulk Drug Parks:** The scheme provides for grant-in-aid to three (03) Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total financial outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme is from FY 2020-21 to 2024-25.

(III) **Production Linked Incentive Scheme for Pharmaceuticals:** The scheme provides for financial incentives to manufacturers selected under the scheme for manufacturing of Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) amongst other categories of formulations. The incentives will be provided on incremental sales to selected participants for a period of 6 years. The total financial outlay of the scheme is Rs. 15,000 crore and the tenure of the scheme is from FY 2020-2021 to 2028- 29.

The detailed guidelines of the above three schemes are available on the website of the Department under the tab “schemes”.

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## Pharmaceutical Export

### Lok Sabha Unstarred Question No. 2364

### Ms. Diya Kumari:

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

(a) the details about the existing schemes to promote pharmaceutical exports in the country;

(b) the quantum of pharmaceutical exports over the past three years; category-wise;

(c) the data of drug exporting States, State-wise thereof;

(d) whether the Government is considering to promote exports of pharmaceuticals; and

(e) if so, the details thereof?

## Answered on 3rd August 2021

**A.** The measures taken by Department of Commerce to promote exports include various schemes under the Foreign Trade Policy (FTP), assistance under the Market Access Initiative (MAI) scheme, setting up district export hubs, Transport and Market Assistance Scheme etc. Trade delegations/buyer-seller meets with various countries are regularly organized for the benefit of exporters. Airfare support is also provided to the exporters with a turnover of Rs.30 crore and below to encourage participation in business delegations/trade fairs.

(b): The quantum of pharmaceutical exports of past three years, category-wise is as under:

*(In Million USD)*

| S. No. | Category | 2018-19 | 2019-20 | 2020-21 |
|---|---|---|---|---|
| 1 | Bulk Drugs, Drug Intermediates | 3911 | 3886 | 4430 |
| 2 | Drug Formulations, Biologics | 14389 | 15941 | 19042 |

(c): Data of Drug exporting States/UTs is given in Annexure.

(d) & (e). Department of Commerce, in partnership with other stakeholders, is working towards boosting our presence in under penetrated/potential international markets viz. North East Asia, Africa, Middle East, Latin America, South East Asia etc. The Department is also actively taking up with MoHFW/CDSCO for promotion of newer products such as gene therapy, bio-similars, specialty drugs to drive the next phase of export growth.

*Annexure*

*( In Million USD)*

| State | Principal Commodity | 2018-19 | 2019-20 | 2020-21 |
|---|---|---|---|---|
| ANDAMAN & NICOBAR | BULK DRUGS, DRUG INTERMEDIATES | 0.01 | - | 0.25 |
| | DRUG FORMULATIONS, BIOLOGICALS | 0.06 | - | - |
| ANDHRA PRADESH | BULK DRUGS, DRUG INTERMEDIATES | 432.81 | 441.17 | 481.25 |
| | DRUG FORMULATIONS, BIOLOGICALS | 1191.76 | 1481.54 | 1987.47 |
| ARUNACHAL PRADESH | BULK DRUGS, DRUG INTERMEDIATES | - | - | 0.00 |
| ASSAM | BULK DRUGS, DRUG INTERMEDIATES | - | - | 0.00 |
| | DRUG FORMULATIONS, BIOLOGICALS | 1.32 | 1.61 | 3.94 |
| BIHAR | BULK DRUGS, DRUG INTERMEDIATES | 0.75 | 0.04 | 0.13 |
| | DRUG FORMULATIONS, BIOLOGICALS | 53.02 | 52.05 | 44.39 |
| CHANDI-GARH | BULK DRUGS, DRUG INTERMEDIATES | 0.33 | 1.23 | 1.85 |
| | DRUG FORMULATIONS, BIOLOGICALS | 3.17 | 2.32 | 4.78 |
| CHATTIS-GARH | BULK DRUGS, DRUG INTERMEDIATES | 0.08 | 0.12 | 0.04 |
| | DRUG FORMULATIONS, BIOLOGICALS | 0.44 | 0.04 | 0.05 |
| DADRA & NAGAR HAVELI | BULK DRUGS, DRUG INTERMEDIATES | 0.79 | 0.64 | 2.94 |
| | DRUG FORMULATIONS, BIOLOGICALS | 168.09 | 271.77 | 407.00 |
| DAMAN & DIU | BULK DRUGS, DRUG INTERMEDIATES | 2.59 | 2.07 | 1.27 |
| | DRUG FORMULATIONS, BIOLOGICALS | 206.96 | 249.89 | 205.58 |
| DELHI | BULK DRUGS, DRUG INTERMEDIATES | 15.96 | 11.34 | 13.16 |

| | | | | |
|---|---|---|---|---|
| | DRUG FORMULATIONS, BIOLOGICALS | 113.49 | 131.60 | 166.98 |
| GOA | BULK DRUGS, DRUG INTERMEDIATES | 9.77 | 5.61 | 6.51 |
| | DRUG FORMULATIONS, BIOLOGICALS | 1306.51 | 1221.92 | 1175.22 |
| GUJARAT | BULK DRUGS, DRUG INTERMEDIATES | 762.72 | 838.72 | 969.80 |
| | DRUG FORMULATIONS, BIOLOGICALS | 2689.28 | 3053.53 | 3719.96 |
| HARYANA | BULK DRUGS, DRUG INTERMEDIATES | 101.17 | 108.37 | 110.93 |
| | DRUG FORMULATIONS, BIOLOGICALS | 173.45 | 124.64 | 134.48 |
| HIMACHAL PRADESH | BULK DRUGS, DRUG INTERMEDIATES | 58.77 | 60.34 | 70.98 |
| | DRUG FORMULATIONS, BIOLOGICALS | 703.02 | 822.03 | 1111.81 |
| JAMMU & KASHMIR | BULK DRUGS, DRUG INTERMEDIATES | 1.17 | 0.52 | 2.63 |
| | DRUG FORMULATIONS, BIOLOGICALS | 33.13 | 40.47 | 44.79 |
| JHARKHAND | BULK DRUGS, DRUG INTERMEDIATES | 0.00 | - | - |
| | DRUG FORMULATIONS, BIOLOGICALS | - | - | 0.00 |
| KARNATAKA | BULK DRUGS, DRUG INTERMEDIATES | 202.21 | 199.91 | 261.15 |
| | DRUG FORMULATIONS, BIOLOGICALS | 549.45 | 634.99 | 822.96 |
| KERALA | BULK DRUGS, DRUG INTERMEDIATES | 0.51 | 0.49 | 0.88 |
| | DRUG FORMULATIONS, BIOLOGICALS | 12.23 | 7.12 | 11.49 |
| MADHYA PRADESH | BULK DRUGS, DRUG INTERMEDIATES | 244.28 | 234.29 | 238.47 |
| | DRUG FORMULATIONS, BIOLOGICALS | 1107.67 | 1158.55 | 1443.35 |
| MAHARASH-TRA | BULK DRUGS, DRUG INTERMEDIATES | 779.94 | 733.51 | 821.54 |
| | DRUG FORMULATIONS, BIOLOGICALS | 3071.45 | 3324.78 | 3604.17 |
| MANIPUR | DRUG FORMULATIONS, BIOLOGICALS | 0.05 | - | 0.04 |
| ODISHA | BULK DRUGS, DRUG INTERMEDIATES | 0.06 | 0.12 | 0.10 |
| | DRUG FORMULATIONS, BIOLOGICALS | 0.51 | - | 0.01 |
| PON-DICHERRY | BULK DRUGS, DRUG INTERMEDIATES | 55.30 | 55.59 | 56.95 |
| | DRUG FORMULATIONS, BIOLOGICALS | 101.64 | 96.72 | 99.03 |
| PUNJAB | BULK DRUGS, DRUG INTERMEDIATES | 301.86 | 302.19 | 314.52 |
| | DRUG FORMULATIONS, BIOLOGICALS | 94.63 | 98.91 | 140.13 |
| RAJASTHAN | BULK DRUGS, DRUG INTERMEDIATES | 55.76 | 48.07 | 72.50 |
| | DRUG FORMULATIONS, BIOLOGICALS | 139.46 | 186.02 | 178.43 |
| SIKKIM | BULK DRUGS, DRUG INTERMEDIATES | 0.01 | 0.00 | 0.02 |
| | DRUG FORMULATIONS, BIOLOGICALS | 2.21 | 3.99 | 5.94 |

| | | | | |
|---|---|---|---|---|
| TAMIL NADU | BULK DRUGS, DRUG INTERMEDIATES | 141.57 | 143.42 | 125.89 |
| | DRUG FORMULATIONS, BIOLOGICALS | 279.03 | 335.27 | 419.21 |
| TELANGANA | BULK DRUGS, DRUG INTERMEDIATES | 629.05 | 606.06 | 754.78 |
| | DRUG FORMULATIONS, BIOLOGICALS | 2102.30 | 2353.54 | 2904.11 |
| TRIPURA | DRUG FORMULATIONS, BIOLOGICALS | | | 0.15 |
| UTTAR PRADESH | BULK DRUGS, DRUG INTERMEDIATES | 62.35 | 50.59 | 77.97 |
| | DRUG FORMULATIONS, BIOLOGICALS | 58.59 | 58.72 | 86.45 |
| UTTARANCHAL | BULK DRUGS, DRUG INTERMEDIATES | 17.54 | 21.84 | 19.37 |
| | DRUG FORMULATIONS, BIOLOGICALS | 161.91 | 168.90 | 226.07 |
| WEST BENGAL | BULK DRUGS, DRUG INTERMEDIATES | 16.55 | 15.73 | 14.99 |
| | DRUG FORMULATIONS, BIOLOGICALS | 33.79 | 44.91 | 43.28 |

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## Setting up of Bulk Clusters

### Lok Sabha Unstarred Question No. 2488

### Shrimati Maneka Sanjay Gandhi:

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

(a) whether the Government is planning to set up bulk clusters of public private partnership (PPP) made for production of pharmaceutical drugs;

(b) whether any innovation clusters has been built for this purpose to produce new drugs, if so, the details thereof;

(c) whether the bulk manufacturing units will lead to the reduction in imports of drugs in the country and if so, the details thereof; and

(d) whether the cost burden of raw materials has been seen as an obstacle in the setting up of the production clusters?

### Answered on 3rd August 2021

**A.** (a) to (d): In order to fulfill its mandate for providing assistance to the industries dealt, the Department of Pharmaceuticals has launched an Umbrella scheme for 'Development of Pharmaceutical Industry', which has various components.

(i) One of the sub-schemes, namely Scheme for 'Assistance to Pharmaceutical Industry for Common Facilities' provides financial assistance up to Rs. 20 cr. per cluster or 70% of the project cost, whichever is less, for creation of common facilities in the cluster. The Scheme is implemented in a Public-Private Partnership (PPP) mode.

(ii) Another sub-scheme for 'Promotion' of Bulk Drug Parks' aims to bring down the cost of manufacturing of bulk drugs by creating world class common infrastructure facilities. Under the scheme, financial assistance is provided for creation of Common Infrastructure Facilities (CIF) subject to a maximum limit of Rs. 1,000 crore per park or 70% of the project cost of CIF (90% in case of North Eastern States and Hilly States), whichever is less. The Scheme is to be implemented through State Implementing Agency (SIA) set up by the State Government to implement the Project.

(iii) Another sub-scheme, namely 'Production Link Incentive (PLI) scheme for promoting Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates (Dis)/ Active pharmaceuticals Ingredients (APIs) in India' has been launched to attain self-reliance and reduce import dependence in critical KSMs/ DIs/APIs. Under the Scheme, financial incentives are provided to the selected applicants on incremental sales over the base year for a period of 6 years. On appraisal of the applications received, in total 43 projects have been approved under the scheme, which will result in committed investment of about Rs. 4425.13 cr.

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## Status of NIPERs

### Lok Sabha Unstarred Question No. 2526

**Dr. Umesh G. Jadhav:**

**Shri Annasaheb Shankar Jolle:**

**Shri B.Y. Raghavendra:**

**Shri Gnanathiraviam S.:**

**Shri Sanganna Amarappa:**

**Shri Prathap Simha:**

**Shri Vijayakumar (Alias) Vijay Vasanth:**

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

(a) whether the Union Government proposes to set up a campus of National Institute of Pharmaceutical Education and Research (NIPER) in the States of Karnataka, Tamil Nadu and other parts of the country;

(b) if so, the details thereof including estimated cost, proposed functions, and the locations identified for setting up of the same;

(c) the details of current NIPER Institutes running in the country;

(d) whether it is proposed to grant the status of national importance to the NIPERs in the country; and

(e) if so, the details along with its features thereof and the time by when the above proposal is likely to be implemented?

### Answered on 3rd August 2021

**A.** (a) & (b): Yes Sir. The Government proposes to set up five new National Institutes of Pharmaceutical Education and Research (NIPERs) in the states of Tamil Nadu (Madurai), Chhattisgarh (New Raipur), Maharashtra (Nagpur), Rajasthan (Jhalawar) and Karnataka (Bangalore). A consolidated EFC proposal with an outlay of Rs.4,300 crore for the period 2020-21 to 2024-25 has been sent to the Ministry of Finance for strengthening the existing seven NIPERs and setting up of five new NIPERs. The proposal also includes construction of campuses, up-gradation of laboratories, setting up centres of excellences, salary of faculty & staff, fellowship to students and other administrative and academic expenses. These institutes will fulfill the objectives, as laid in the NIPER Act, 1998, as amended from time to time, mainly relating to imparting postgraduate and doctorate education and conducting high end research in various specializations of pharmaceuticals and medical devices. The estimated cost of setting up of a new NIPER, including recurring expenses for a period of five years is about Rs. 310 cr.

(c): At present, seven NIPERs are functional across the country at SAS Nagar (Mohali, Punjab), Ahmedabad (Gujarat), Guwahati (Assam), Hajipur (Bihar), Hyderabad (Telangana), Kolkata (West Bengal) and Raebareli (Uttar Pradesh).

(d) & (e): Yes Sir. The National Institute of Pharmaceutical Education and Research Act, 1998 (13 of 1998) was enacted to declare NIPER at SAS Nagar (Mohali, Punjab) to be an institute of national importance. The Act was subsequently amended in the year 2007 to empower the Central Government to establish similar institutes in different parts of the country. Thereafter, six new institutes at Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli were established during 2007-08.

NIPER (Amendment) Bill, 2021, presently under consideration of the Parliament, has a provision that the existing six NIPERs as well as any other similar institute established under the NIPER Act shall be institutes of national importance.

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## RAJYA SABHA

## Production of Covaxin and Covishield Vaccines

### Rajya Sabha Starred Question No.154

**Shri Naresh Gujral:**

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

(a) the current capacity to manufacture Covaxin and Covishield in the country today and

(b) the expected capacity going forward from the month of August to December 2021?

### Answered on 3rd August 2021

**A.** (a) & (b) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 154* FOR 03RD AUGUST, 2021**

(a) and (b): ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) is manufactured by M/s Serum Institute of India Pvt., Ltd., Pune, while the Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is manufactured by M/s Bharat Biotech International Limited, Hyderabad.

As communicated by the manufacturers, the monthly vaccine production capacity of Covishield is projected to be increased from 110 Million doses per month to more than 120 Million doses per month and the production capacity of Covaxin is projected to be increased from 25 Million doses per month to around 58 Million doses per month.

Further, Department of Biotechnology under the Ministry of Science & Technology has launched 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of Department of Biotechnology.

Under the mission, facility augmentation of Bharat Biotech and 01 State Public Sector Enterprise and 02 Central Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; for production of Covaxin have been supported.

In addition, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat has also been facilitated.

Further, Government of India has also extended financial assistance to one of the domestic manufacturers for 'At-risk manufacturing', advance payment against the supply orders placed with M/s Serum Institute of India and M/s Bharat Biotech, and streamlining of regulatory norms for approval of vaccines.

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## Acute Shortage of Remdesivir Injection

### Rajya Sabha Starred Question No.157

### 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 there is an acute shortage of Remdesivir injection in the country due to increase in COVID-19 cases day by day;

(b) if so, the steps taken by Government to increase and monitor supply of Remdesivir drug;

(c) whether it is also a fact that the same drug has been selling in the black market; and

(d) if so, the steps taken by Government to control and monitor this?

### Answered on 3rd August 2021

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

**STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 157* FOR 03RD AUGUST, 2021**

(a) & (b): Shortages of Remdesivir in market was noticed in the months of April and May, 2021 due to the sudden surge in demand of the drugs for managing COVID-19 patients. In order to substantially augment the production of Remdesivir, Drugs Controller General (India) granted expeditious approval to 40 new manufacturing sites of the licensed manufactures of Remdesivir. This led to increase in number of Remdesivir manufacturing sites from 22 in mid-April, 2021 to 62 at present. The domestic production capacity of Remdesivir increased from 38.8 lakh vials per month in mid-April to 122.49 lakh vials per month in June, 2021.

Further, in order to supplement the domestic availability of Remdesivir manufactured in the country, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021.

In addition, Department of Pharmaceuticals (DoP) and Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for allocation of available stocks of Remdesivir to all the States/UTs of the country in order to mitigate shortage and to ensure fair and equitable distribution across the country. The total allocation and supply of the drug is given as under:

| Sr. No. | Name of the drug | Allocation to States/ UTs And Central Institutions (in vials) | Supply till 18.07.2021 (in vials) |
|---|---|---|---|
| 1. | Remdesivir Injection | 98,87,000 | 97,03,393 |

In addition to the above, allocation of commercial supplies to States/UTs, the MoHFW has also supplied around 29 Lakh Remdesivir vials, free of cost, to the States/UTs.

As on date, the demand of Remdesivir has come down considerably and the demand supply gap has reversed whereby supply is much more than the demand. Accordingly, Remdesivir was moved from Prohibited to Restricted Category of Exports on 14th June, 2021. The states and UTs have been issued "Guidelines for Buffer Stock Management of Covid-19 Drugs" and advised to procure and maintain buffer stocks of Remdesivir and other Drugs for preparedness to deal with any future requirements. As on date there is no shortage of Remdesivir reported by any States/UTs.

(c) & (d): Central Drugs Standard Control Organization (CDSCO) has requested all States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places on attempts at blackmarketing/hoarding of COVID drugs and to take stringent action against the offenders. As per information available from various State Licensing Authorities, various enforcement actions like seizure, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities.

Further, National Pharmaceuticals Pricing Authority under the Department of Pharmaceuticals had directed that "the State Governments and UTs may closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding. It may also be ensured that there is no violation of provision of Drug (Prices Control) Order, 2013 (DPCO, 2013) with regard to compliance of ceiling prices/permissible increase in prices of scheduled/non-scheduled formulations".

**Minister In The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)**

## CSR Recommending Procedure

### Rajya Sabha Unstarred Question No. 1613

### Shri Deepak Prakash:

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

(a) whether Government has any record of Corporate Social Responsibility (CSR) funds spent by the companies during the last four financial years and the current year, if so, the details thereof, State- wise, especially the funds spent for the development of Jharkhand;

(b) whether a District Collector/ MLA/ MLC or Member of Parliament can officially recommend to the institutions under the CSR fund for the developmment of their area; and

(c) if so, the details thereof and the official procedure of the same?

### Answered on 3rd August 2021

**A:** a) The Government provides the broad framework for Corporate Social Responsibility (CSR) through Section 135 of the Companies Act, 2013 ('Act'), Schedule VII of the Act and Companies (CSR Policy) Rules, 2014. The entire CSR architecture is disclosure based and CSR mandated companies are required to file details of CSR activities annually in MCA21 registry. All data related to CSR filed by companies in MCA21 registry is available in public domain at www.csr.gov.in. As per the filings made by the companies in the MCA21 registry, the State/ UT-wise (including Jharkhand) CSR spent by all Companies for financial years 2016-17, 2017-18, 2018- 19 and 2019-20 respectively is at Annexure.

As per the Act, companies are required to hold Annual General Meeting (AGM) within six months from the end of financial year. Thereafter, financial statements and board report containing disclosure about CSR, are to be filed in MCA21 within 30 days of the AGM. Thus, the CSR data for the financial year 2020-21 is not available and filings for financial year 2021-22 are required to be made only after the end of current financial year.

(b) & (c): No, Sir. Under the Act, CSR is a Board driven process and the Board of the company is empowered to plan, decide, execute and monitor CSR activities based on the recommendation of its CSR Committee. The Government does not issue any specific direction to the companies to spend in any particular activity or area.

***Annexure***

**ANNEXURE REFERRED TO IN REPLY TO RAJYA SABHA UNSTARRED QUESTION NO. 1613 FOR 03.08.2021**

| STATE/UT-WISE CSR EXPENDITURE DETAILS (IN RS. CRORE) | | | | |
|---|---|---|---|---|
| **States/UT** | **FY 2016-17** | **FY 2017-18** | **FY 2018-19** | **FY 2019-20** |
| Andaman And Nicobar | 0.83 | 0.76 | 0.43 | 0.68 |
| Andhra Pradesh | 753.53 | 275.28 | 644.83 | 679.19 |
| Arunachal Pradesh | 24.05 | 12.13 | 24.50 | 16.83 |
| Assam | 269.92 | 86.23 | 206.01 | 752.73 |
| Bihar | 100.77 | 47.49 | 136.47 | 138.15 |
| Chandigarh | 21.99 | 20.51 | 11.72 | 14.24 |
| Chhattisgarh | 84.94 | 71.79 | 146.66 | 156.64 |
| Dadra And Nagar Haveli | 7.58 | 6.93 | 13.48 | 18.92 |
| Daman And Diu | 2.63 | 20.09 | 6.23 | 8.60 |
| Delhi | 521.16 | 558.33 | 674.17 | 643.99 |
| Goa | 37.89 | 53.34 | 46.74 | 43.71 |
| Gujarat | 870.84 | 775.90 | 1,065.90 | 910.13 |
| Haryana | 390.07 | 266.09 | 335.53 | 474.43 |
| Himachal Pradesh | 24.03 | 60.60 | 79.97 | 76.09 |
| Jammu And Kashmir | 42.84 | 46.44 | 35.34 | 24.93 |
| Jharkhand | 95.69 | 45.92 | 70.30 | 139.04 |
| Karnataka | 887.68 | 1,034.33 | 1,224.92 | 1383.65 |
| Kerala | 135.47 | 167.24 | 387.17 | 250.02 |
| Lakshadweep | 0 | 2.07 | 0.39 | 1.00 |
| Madhya Pradesh | 290.60 | 147.25 | 247.15 | 165.47 |
| Maharashtra | 2492.11 | 2,565.59 | 2,864.04 | 2,751.21 |
| Manipur | 12.35 | 4.03 | 7.64 | 10.87 |
| Meghalaya | 10.97 | 5.49 | 17.99 | 17.29 |
| Mizoram | 0.08 | 0.23 | 0.11 | 0.25 |
| Nagaland | 0.92 | 0.36 | 2.11 | 1.64 |
| Odisha | 316.72 | 472.58 | 682.87 | 679.43 |
| Puducherry | 7.43 | 6.53 | 8.30 | 8.63 |
| Punjab | 75.83 | 89.32 | 164.58 | 176.06 |
| Rajasthan | 325.15 | 263.83 | 549.02 | 696.77 |
| Sikkim | 6.83 | 6.84 | 4.58 | 3.94 |
| Tamil Nadu | 550.94 | 627.75 | 829.27 | 919.05 |
| Telangana | 259.88 | 293.53 | 422.39 | 404.97 |
| Tripura | 1.25 | 1.83 | 23.06 | 4.34 |
| Uttar Pradesh | 328.31 | 302.92 | 479.88 | 496.13 |
| Uttarakhand | 102.52 | 86.65 | 173.32 | 105.34 |
| West Bengal | 290.35 | 299.77 | 369.50 | 390.51 |
| NEC/ Not mentioned * | 7.63 | 132.04 | 3.68 | 3.42 |
| PAN India* | 4,990.68 | 5,050.79 | 6,767.74 | 8,662.86 |
| **Grand Total** | **14,342.45** | **13,908.79** | **18,728.01** | **21,231.15** |

*(Data upto 31.03.2021) [Source: National CSR Data Portal]*

**Companies either did not specify the names of States or indicated more than one State where projects were undertaken.*

**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 Corporate Affairs [Rao Inderjit Singh]**

## Mix-And-Match Covid Vaccines

### Rajya Sabha Unstarred Question No. 1686

### Shri Prabhakar Reddy Vemireddy:

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

(a) whether we can mix first and second doses of COVID vaccines and administer them on people who need it;

(b) whether any studies have been carried out or is there any scientific evidence that such mixing would not have any adverse impact on people;

(c) if so, the details thereof;

(d) whether it is a fact that researcher in Spain found that vaccinating people with both Oxford-AstraZeneca

and Pfizer-BioNTech vaccines is safe and producing potent immune system; and

(e) if so, the details of such outcome?

### Answered on 3rd August 2021

**A.** (a) to (e): So far, no recommendation has been made for mixing first and second doses of COVID vaccines by National Technical Advisory Group on Immunization (NTAGI) or National Expert Group on Vaccine Administration for COVID-19 (NEGVAC).

COVID-19 vaccines have been developed recently, therefore, scientific evidence regarding mix and match studies of different vaccines is still evolving.

There is no specific recommendation from World Health Organization presently on mix and match of vaccines.

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

## Study On Post Covid Diseases

### Rajya Sabha Unstarred Question No. 1692

### Dr. V. Sivadasan:

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

(a) whether Government has carried out any study on the different post COVID diseases;

(b) if so, the details thereof;

(c) whether there is any concrete measure or protocols established by Government to counter these different post COVID diseases; and

(d) if so, the details thereof?

### Answered on 3rd August 2021

**A.** (a) to (d) Indian Council of Medical Research (ICMR), an autonomous body under the Department of Health Research, has established a COVID clinical registry at 20 sites across the country to capture clinical treatment and outcomes of COVID-19. This information is only limited to hospitalized patients. Post Covid studies are being carried out on various conditions like aortic and lung inflammation, mucormycosis etc. Although, Health is a State subject, Government of India has advised the States to establish post COVID clinics in their respective appropriate health facilities to cater to the needs of people suffering various post COVID conditions.

Also, expert groups are working on modules/guidelines on various post COVID conditions/issues.

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

## National Task Force for Covid-19

### Rajya Sabha Unstarred Question No.1696

### Shri Digvijaya Singh:

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

(a) the details (including dates) of the meetings of the National Task Force for COVID-19 (NTF), set up to advise Government on its pandemic response, till date;

(b) whether the NTF met during the months of February and March, 2021, when cases across the country were increasing;

(c) if so, the details of the decision taken at these meetings to prepare for and/or respond to the second wave of the pandemic; and

(d) if not, the reason(s) why no meeting of the NTF was convened during this period despite a surge in cases in parts of the country, particularly Maharashtra?

### Answered on 3rd August 2021

**A.** (a) The details of the meetings of National Task Force (NTF) and its Research Groups (including dates) are available at https://www.icmr.gov.in/pdf/covid/techdoc/ICMR_NTF_Meetings_v1.pdf

(b) to (d) During the months of February and March, 2021, there were seven meetings of Research Groups of NTF, the details of which are again available at https://www.icmr.gov.in/pdf/covid/techdoc/ICMR_NTF_Meetings_v1.pdf

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

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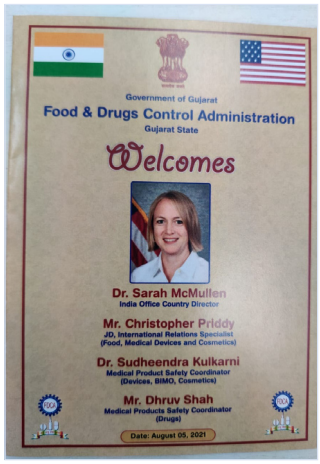
# USFDA Officials visited FDCA Gujarat to attend their Regulatory Forum meet for sharing of work done during COVID-19

US Food and Drug Administration (US FDA) officials visited The Gujarat Food and Drug Control Administration (FDCA) to attend regulatory forum meeting for information sharing and capacity building to tackle Covid-19 pandemic.




This is part of the quarterly review meet of Gujarat FDCA and US FDA regulatory forum.

US FDA-Gujarat FDCA Regulatory Forum was started in the year 2008 to usher in dialogue between senior leaderships of the US FDA and the Gujarat FDCA for future strategic collaborations and knowledge sharing on drug and medical device compliance.

Dr Sarah McMullen, India Office, Country Director, US FDA, Christopher Priddy, JD – International Relations Specialist, Sudheendra Kulkarni, Medical Product Safety Coordinator, US FDA India, Dhruv Shah, Medical Product Safety Coordinator, US FDA participated the meeting.

During the meeting USFDA and FDCA-Gujarat shared with each other about the work done during second wave of COVID-19 pandemic. Prior to this meet, a web meet was done due to prevailing COVID-19 pandemic situation in the country.

"This was Dr. Sarah's first visit to Gujarat after she appointed as Country director, USFDA India office. She is the fifth Country director of India to visit Gujarat FDCA. The first was Bruce Ross who visited in the year 2010. Bruce Ross manages oversees foreign offices of FDA," stated Gujarat FDCA Commissioner Dr H G Koshia.

In the past, a team of USFDA imparted training to all the FDCA-Gujarat officers on various technical aspects of the inspection.

The United States Food and Drug Administration (USFDA) is responsible for protecting and promoting public health through the control and supervision of food safety, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, and veterinary products.

Gujarat FDCA makes optimum use of information technology for achieving excellence in performance. FDCA, Gujarat is the first State to initiate online software for sales and manufacturing licenses.

Gujarat is the largest manufacturer of API amphotericin in India.

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## India in talks to buy 50 million doses of Pfizer vaccine - WSJ

India is in talks to buy 50 million doses of Pfizer Inc (PFE.N) and German partner BioNTech SE's (22UAy.DE) COVID-19 vaccine, the Wall Street Journal reported on Wednesday, citing people familiar with the matter.

A Pfizer spokesperson said it was in talks with the government to supply vaccines, but declined to provide further details. The Indian health ministry did not immediately respond to Reuters request for comment.

To be sure, the drugmaker has not yet sought permission for use of its vaccine in India.

India rolled out one of the world's largest vaccination drives earlier this year and has been relying heavily on the AstraZeneca (AZN.L) vaccine produced by the Serum Institute of India and a home-grown shot produced by Bharat Biotech.

While the coronavirus cases in the country have eased from a devastating peak in April and May, government officials have said the second wave is not over.

Experts have said that large-scale vaccination is India's best bet against the fast-spreading Delta variant of the coronavirus.

The country has fully vaccinated more than 115 million people, which is about 12% of its estimated 944 million adults, according to latest government data. The government aims to vaccinate the entire adult population by December.

Authorities are also in an advanced stage of negotiations with Johnson & Johnson (JNJ.N), which has a deal with India-based Biological E. Ltd, to manufacture as many as 600 million doses, starting as soon as this month, the Journal reported.

Last week, the country approved J&J's one-shot vaccine for emergency use, adding to the vaccines from AstraZeneca, Bharat Biotech, Russia's Gamaleya Institute and Moderna (MRNA.O) that have been granted such approval.

*Source : Financial Express, 12.08.2021*

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## Covid-19 vaccine: DCGI nod to study on mixing of Covishield & Covaxin doses


*The country has administered 52.15 crore vaccines till August 11, of which 45.22 crore were Covishield and 6.41 crore were Covaxin, while the remaining were Sputnik vaccines.*

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO) had a week ago recommended granting a nod for the mix-and-match trial.

The Drugs Controller General of India (DCGI) has granted approval for trials that will mix two different Covid vaccines — Covishield by Serum Institute of India and Covaxin by Bharat Biotech. The study will be conducted by Christian Medical College, Vellore.

The Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO) had a week ago recommended granting a nod for the mix-and-match trial. Combination of the two different vaccines had not been allowed in the country so far as no such trials were conducted and no data was available regarding the safety and efficacy of such combinations. This will be the first-of-its-kind study in the country and will involve 300 participants.

The approval for the study follows an ICMR study in Uttar Pradesh, where 18 people were given two different doses of the Covid-19 vaccine by mistake in May. They had received Covishield as their first dose and were administered Covaxin as the second dose after six weeks. According to the ICMR study, the vaccine combination was safe and there were no adverse reactions. Also, those who got a mixed dosage of the vaccines demonstrated better immunogenicity that those who had got the same vaccine doses.

The country has administered 52.15 crore vaccines till August 11, of which 45.22 crore were Covishield and 6.41 crore were Covaxin, while the remaining were Sputnik vaccines. There is a shortage of Covaxin with Bharat Biotech's capacity ramp-up delayed due to technical glitches. Sputnik, too, has faced supply chain challenges. A mix-and-match approval is expected to help in dealing with shortages.

According to the health ministry, the monthly production of Covaxin was projected to go up to 58 million doses per month, while Covishield production was expected to reach 120 million doses a month from September. SII also has plans to make 300 million doses of the Sputnik vaccine.

There are similar studies being conducted globally to assess the safety and efficacy of combining two different vaccines and to see if combination of vaccines worked better that two doses of the same vaccine. Russia Direct Investment Fund has initiated partnerships with other vaccine producers to conduct joint studies of a combination of the first component of Sputnik V with foreign vaccines. They have completed a study of combining the first shot of Sputnik V vaccine with the AstraZeneca-Oxford University vaccine and the interim analysis on immunogenicity demonstrated high safety. There are studies of single dose of the AstraZeneca vaccine combined with the mRNA vaccines from Pfizer or Moderna as second doses and this was found to be effective.

*Source : Financial Express, 12.08.2021*

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## Biocon-Viatris obtain USFDA nod for first interchangeable insulin


*Research papers have highlighted that the US market witnessed an exponential increase in the prices of all insulins between 2002 and 2016.*

Biocon Biologics, through Viatris, is eligible to have exclusivity for 12 months before the United States Food and Drug Administration (USFDA) can approve another biosimilar interchangeable to Lantus.

Biocon Biologics aims to improve access to affordable insulin for diabetes patients in the US market, as the company, with its partner Viatris, has received approval for Semglee (insulin glargine-yfgn injection) as the first interchangeable biosimilar product.

The interchangeable Semglee product, which will allow substitution of Semglee for the reference product, Lantus, at the pharmacy counter, will be introduced before the end of the year and commercial preparations for that are underway.

Biocon Biologics, through Viatris, is eligible to have exclusivity for 12 months before the United States Food and Drug Administration (USFDA) can approve another biosimilar interchangeable to Lantus.

The "game-changing" approval would allow "pharmacy level substitution" for insulin glargine in the US thereby providing convenient and affordable access to biosimilar insulin glargine, said KiranMazumdar-Shaw, executive chairperson, Biocon Biologics.

This means the interchangeable biosimilar product can be substituted for the reference product by the pharmacist without the intervention of prescriber, akin to how generic drugs are substituted for brand name ones.

"In the US insulin pricing has always been challenging for the uninsured patients and I think we want to make a difference there with this game-changing approval. Therefore, our marketing strategy will also reflect that," said Mazumdar-Shaw, adding, "We are extremely proud to be the first to obtain approval of an interchangeable biosimilar product in the US.

It is a milestone achievement for both Biocon Biologics and our partner Viatris."

Research papers have highlighted that the US market witnessed an exponential increase in the prices of all insulins between 2002 and 2016.

According to a news release on the interchangeability approval by USFDA, biosimilar and interchangeable biosimilar products have the potential to reduce healthcarecostsin the US, a nation with more than 34 million diabetes patients.

"This interchangeability approval for Semglee by the USFDA, another first to our credit, is a testament to our scientific excellence and robust quality comparability data," said ArunChandavarkar, managing director, Biocon Biologics, the biosimilar subsidiary of Biocon.

*Source : Financial Express, 12.08.2021*

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## 'Hello, So are You Vaccinated?'

As we slowly become more sociable and step out with caution en mask, looking left and right before crossing public spaces like never before, one niggling question has been cropping up — what is the social protocol when it comes to determining whether someone has been vaccinated or not?

Asking a friend or family member is easy: you just ask them. But what about bosses, professionals like domestic help, teachers, CAs or even doctors? One easy yet polite way is to quickly bring into the conversation when you had your jab(s). That should elicit a response that will allow you to either continue the meeting or cook up an excuse to bhago. Another way is to crack a joke about it being high time you took your 'third shot'. 'Why stop at two?

Knowing that your vax status will put others at ease, you could start the trend of wearing one or two wrist bands that state — 'Jab we met' for one Covid vaccine taken, and 'Jab-Jab we met' for a double dose. Not only will such a gesture make social distancing less unsociable, but it will also vax-shame laggards into not becoming social pariahs.

Dates, especially blind ones, will benefit from this practice that could be the new determinant for Covid street cred. We must warn suspicious types, though, not to insist on seeing another's CoWin status. That would come across as a bit desperate.

*Source : ET Bureau, 09.08.2021*

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## Zydus completes 'pragmatic trials' for second vax

### ZyCoV-MV likely to provide lasting immunity

Even as ZydusCadila awaits regulatory nod for ZyCoV-D, its plasmid DNA vaccine against Covid , the company has been making further progress on the second vaccine candidate, which is set to provide lasting immunity against the virus. The company has successfully developed a measles virus containing Covid vector.

Zydus has developed a live, attenuated recombinant measles virus-vectored vaccine, ZyCoV-MV, which is believed to provide long-term immunity from the infection. The development is seen as significant in the backdrop of the limited-period immunity provided by most vaccines that are currently available.

Giving an update on the second vaccine candidate, the company informed that it has "completed Pragmatic Clinical Trials (PCT) and that non-human primate immunogenicity study is going on at present".

### Continuous immunity

The recombinant measles virus (rMV), produced by reverse genetics, will express codon-optimised proteins of the novel Coronavirus and induce long-term specific neutralising antibodies. This is believed to create an engine in the body to provide continuous immunity against Covid-19.

This is different from the company's DNA vaccine, in which the plasmid DNA is introduced into the host cells. It is then translated into the viral protein, providing strong immune response mediated by the cellular and humoral arms of the human immune system. This plays a vital role in protection from disease as well as viral clearance.

### Awaits EUA nod

The update on the company's second vaccine candidate comes at a time when Zydus is awaiting a nod for Emergency Use Authorisation (EUA) from the Drug Controller General of India (DCGI) for its plasmid DNA vaccine.

Sources informed that the announcement for grant of EUA is likely to happen anytime this month.

"The Phase-III clinical trials data for 2 mg dose study of ZyCov-D vaccine has also confirmed the safety for children in the age group of 12 to 18 years," the company informed in a presentation to the investors.

*Source : The Hindu Business Line, 11.08. 2021*

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## Pharma market reports 14% y-o-y growth in July; demand to normalise if pace of vaccination continues: India Ratings

India Ratings and Research (Ind-Ra) said on Tuesday that 13.7 per cent y-o-y revenue growth in India's pharmaceutical market during 2021 was led by continued demand normalisation post-high growth months of April and May.

The growth in June was lower at 14.1 per cent. The higher growth in April (51.5 per cent) and May (47.8 per cent) was because of the lower base effect and COVID-induced demand during the second wave.

The lower-though-healthy growth in July was witnessed in therapies which have not benefitted from COVID-led demand in the past.

Therapies which have benefitted from COVID-led demand include anti-infectives, gastro and vitamins.

Ind-Ra expected the demand normalisation to continue if the pace of vaccination remains strong. It expected market revenue growth of over 12 per cent y-o-y for FY22.

During 1Q FY22, pharma market reported growth of 37.2 per cent aided by the lower base effect during 1Q FY21 which was impacted due to the nationwide lockdown.

During July, volumes grew 4.5 per cent, price growth was 5.7 per cent and new products launches were at 3.5 per cent attributed to acute therapy products.

Acute therapies like anti-infectives, analgesic and respiratory witnessed sales growth of 30.2 per cent, 24.1 per cent and 22.8 per cent respectively while gastro grew 19.6 per cent during July.

Growth underperformance was observed in chronic therapies during the month with cardiac and anti-diabetic growing 4.1 per cent and 3.3 per cent respectively.

During moving annual total July, Cipla, Glenmark and Emcure significantly outperformed the market with y-o-y growth of 19.4 per cent, 33.9 per cent and 26.1 per cent respectively.

This was led by higher sales of COVID-19 related products and the continued outperformance of chronic therapies, said Ind-Ra.

*Source : Free Press Journal, 11.08.2021*

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## Kamlesh Kumar Pant appointed as NPPA chairman

In a latest reshuffle in the bureaucratic leadership in the Centre, Kamlesh Kumar Pant, IAS, a 1993 Himachal Pradesh cadre officer has been appointed as the chairman of National Pharmaceutical Pricing Authority (NPPA). He replaces Shubhra Singh, who has been in the chair of the drug price regulator from November, 2018.

Pant, 50, hails from Uttar Pradesh and has been the principal secretary to the Government in Shimla, taking care of education and Human Resource development

from January 2019. He was on deputation with the Central government from 2012 to 2019, during when he worked at the CVO, joint secretary equivalent at ministry of road transport and highways, National Highway Authority of India and joint secretary with the department of defence production, ministry of defence and director at department of revenue, ministry of finance.

He also had a short stint as the Managing Director of Himachal Pradesh Financial Corporation at Shimla and as the managing director of HP State Industrial Development Corporation Ltd.

Pant is taking charge as the chairman of NPPA at a time when the drug price regulator is seeing an increased role in impacting public life by monitoring and controlling the prices of essential medicines and medical devices during the Covid-19 pandemic.

The NPPA has put a cap on trade margin of 42 select non-scheduled anti-cancer medicines under the 'Trade Margin Rationalization (TMR)'.

This has resulted in reduction of up to 90 per cent of maximum retail price (MRP) of 526 brands of these medicines, said an announcement by the ministry of chemicals and fertilisers.

The recent measures include the trade margin rationalisation at price to distributor (PTD) at 70 per cent for five medical devices namely pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer through a Gazette Notification on July 13, 2021. NPPA has said that 91 per cent of the devices that submitted the revised data have shown a price reduction in these cases up to 88 per cent.

The Authority has also brought 106 non-scheduled anti-diabetic and cardiovascular drugs under price control by invoking extraordinary powers in public interest.

The total annual savings on account of revision of ceiling prices of medicines under National List of Essential Medicines (NLEM), price control of anti-diabetic & cardiovascular, fixation of ceiling price of stents, knee implants and capping of TMR on anti-cancer are estimated to the tune of Rs. 12,500 crore.

During the year 2021-22, till July 31, the NPA has fixed price of 85 medicines, including the ceiling price of

one formulation and retail price of 84, while in the full year of 2020-21 it has fixed ceiling prices for 12 and retail prices of 321 formulations. It has also put trade margin rationalisation for six medical devices during the period 2021-22 so far.

*Source: Pharmabiz, 12.08.2021*

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## Key WHO trials to test 3 drugs for use in Covid


*Tedros Adhanom Ghebreyesus, Director General of the World Health Organization (WHO).(via AP)*

"Finding more effective and accessible therapeutics for Covid-19 patients remains a critical need," said WHO director-general TedrosAdhanomGhebreyesus.

The World Health Organization (WHO) on Wednesday announced major international trials of three drugs to see if they improve the condition of hospitalised Covid-19 patients. Artesunate, imatinib and infliximab will be tested on patients in more than 600 hospitals in 52 countries.

"Finding more effective and accessible therapeutics for Covid-19 patients remains a critical need," said WHO director-general TedrosAdhanomGhebreyesus. Artesunate is a treatment for severe malaria; imatinib is a drug used for certain cancers, and infliximab is a treatment for immune system disorders such as Crohn's and rheumatoid arthritis. They were donated for the trial by their manufacturers and are being shipped out to the hospitals involved.

### Thai police halt protest over handling of Covid

Thai police fired water cannon, rubber bullets and tear gas at protesters in Bangkok on Wednesday as demonstrators rallied over the government's handling of the pandemic. Protesters had defied a ban on public gatherings. The slow roll-out of vaccines as well as financial hardship from restrictions are fuelling public anger towards Prime Minister Prayut Chan-O-Cha's government.

### China approves first mixed vaccine trials

China's drug regulator has approved the country's first mixed-vaccine trials as the rapid spread of the Delta variant raises concern about the efficacy of locally produced jabs. The trial will test the efficacy of combining an "inactivated" vaccine made by China's Sinovac with a DNA-based one developed by US pharma company Inovio.

### Quebec to implement Covid vaccine passports

The Canadian province of Quebec will start recognising Covid-19 vaccine passports or passes from September 1, which will limit the public's access to certain facilities such as restaurants and gyms. The details were unveiled by provincial health minister Christian Dubé.

*Source : Hindustan Times, 12.08.2021*

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## Pharma units gear up for third wave, ramp up production

Indore: Home-grown pharmaceutical companies have ramped up production and built up inventories of raw material to prepare for potential third wave of pandemic, likely to spike the demand for drugs used in treatment of Coronavirus.

Drug manufacturers have expanded capacity utilizations to enhance production of Covid-19 related drugs and cold medicines amid apprehension the third wave may strike anytime between rainy to cold season.

Taking cues from the last wave where shortage of raw material had slowed down the production of Covid-19 related drugs, pharmaceutical companies have begun lifting major raw material from the market to rule out vacuum of raw material.

A drug manufacturer DarshanKataria said, "We have started procuring raw material for expected medicines that might be required for treating Covid-19 patients. Last two waves have given some cues about the medicines that are commonly used in the treatment. To ensure availability, we have also roped in vendors and given them some credit to build higher inventory."

Prices of major raw material commonly used by drug companies have already started rising in the market owing to increased lifting.

Cost of most raw material has risen by over 20 per cent including paracetamol, azithromycin, ascorbic acid, ivermectin, doxycycline and methylprednisolone, said drug manufacturers.

*Source :Meenakshi Sharma, TOI-Online, 11.08.2021*

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## Strong measures required to control COVID 19 transmission: AIIMS Dr Wig

New Delhi: Dr Naveet Wig, Head of Department (HoD) of Medicine, iAIIMS, on Wednesday said that strong measures are required to control the COVID-19 transmission that involves micro containment.

Dr Wig, while speaking to ANI, said: "I think we should not go into R-factor or other things. It is important to know how to handle the pandemic. This is both a local problem and a global problem.

It has to be handled locally and globally. How we will handle it locally is very clear, states which have a higher test positivity rate should go under lockdown. We cannot shy away from it, it is the question of containing the virus, and it is the question of mitigating the disease."

"We have to understand that we can make it as a normal flu disease in the next few months, only if we take strong measures. We cannot delay unlocking as well. Wherever numbers of COVID cases are increasing, lock the area for five to ten days, it will pin down the numbers and then you open it up, so please do not shy away whenever you need to take strong measures which include micro containment," he said.

"The formula is very simple. The moment the positivity rate is high in an area declare it a micro containment area, and the moment numbers are down, open it up. We have to keep testing and isolating. Currently, there is no option, more variants will also come. But the treatment and management and containment measures will remain the same until unless everybody gets vaccinated," Dr Wig added.

*Source : ANI, 11.08.2021*

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## Booster covid jab will better protect against future variants: Study

***An additional boost, even using vaccines containing the original strain of coronavirus, will increase protection against variants of concern, revealed the findings published in the journal Science Translational Medicine***

Even as the UK government is planning to give a third Covid vaccine shot to everyone above 50 years of age from next month, scientists confirm that the autumn booster dose will be an effective way to protect people from existing, and potentially future, variants of concern.

The team of experts at the University of Nottingham found that neutralising antibodies generated by a single dose of the Pfizer vaccine were less effective at neutralising key variants of concern, for example the beta (first identified in South Africa) variant.


However, the second dose, especially in those volunteers who had previously been infected with SARS-CoV-2, dramatically increased virus variant neutralising antibody responses (and therefore potential protection) to a level comparable to those seen for the original strain of SARS-CoV-2.

This suggests that an additional boost, even using vaccines containing the original strain of coronavirus, will increase protection against variants of concern, revealed the findings published in the journal Science Translational Medicine.

"We showed that the individuals with past infection produced more antibodies following each dose of vaccine than those who hadn't been exposed. We also showed that this increased antibody response was more effective against some of the variants of concern, such as the Beta and Gamma variants," said Professor Jonathan Ball from the School of Life Sciences at the University.

"In essence, natural infection has mimicked the effects of an additional vaccine dose, and our data clearly shows that this additional antigenic exposure produces an extra boost to the overall virus-killing antibody response that is more effective against variants of concern. Our results support the UK Government's plan to provide a booster jab in the autumn as an effective strategy in protecting people against these variants," he added.

UK Health Secretary Sajid Javid had said the government is awaiting advice from the Joint Committee on Vaccination and Immunisation (JCVI) on the roll out of the booster dose, which will be administered along with flu a jab, the Evening Standard reported on Wednesday.

The booster dose will be prioritised for people who received the Covid shots when the vaccination programmes were first rolled out last December, Javid said.

Meanwhile, the UK government on Tuesday also announced that 75 per cent of adults in the country have received both doses of a Covid-19 jab, while about 47 million people have received their first dose, the Financial Times reported. However, nearly 6 million adults -- roughly one in 10 of the over-18 population -- remain completely unvaccinated, official statistics showed.

*Source : IANS, 11.08.2021*

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## Health Minister Mansukh Mandaviya meets WHO chief scientist Soumya Swaminathan for Covaxin approval

*All documents required for Emergency Use Listing (EUL) have been submitted by Bharat Biotech for Covaxin to the World Health Organization (WHO) as of July 9 and the review process by the global health body has commenced.*

New Delhi: Union Health Minister Mansukh Mandaviya on Thursday (August 12) met World Health Organisation (WHO) Chief Scientist Soumya Swaminathan here to discuss the WHO`s approval for Bharat Biotech`s Covaxin.

Held a meeting with Dr Soumya Swaminathan, Chief Scientist of @WHO. We had a productive discussion on WHO's approval of @BharatBiotech's COVAXIN. @DoctorSoumya also appreciated India's efforts for the contain ment of #COVID19," Mandaviya tweeted.

During the meeting, Swaminathan also discussed the various aspects of the current Covid-19 pandemic among other issues.

Covaxin is developed by Hyderabad-based Bharat Biotech in collaboration with ICMR and the National Institute of Virology, Pune.

All documents required for Emergency Use Listing (EUL) have been submitted by Bharat Biotech for Covaxin to the World Health Organization (WHO) as of July 9 and the review process by the global health body has commenced, said the Minister of State for Health Dr. Bharati Pravin Pawar last month in Rajya Sabha.

Earlier, Covaxin got a certificate of Good Manufacturing Practice (GMP) compliance from the Hungarian authorities. This approval for the vaccine is considered as a step forward in meeting the global standards.

Swaminathan also met Union Minister of State (Independent Charge) Jitendra Singh and discussed issues related to the pandemic.

The Minister told her that with the personal intervention and day-to-day personal monitoring by Prime Minister NarendraModi, India has undertaken the fastest and the largest vaccination drive against COVID19.

Emphasising on the importance of mass vaccination through easy availability and accessibility, Swaminathan said even though the vaccine may not be able to provide absolute protection against different variants of virus, it can certainly reduce the risk of death and complications.

Appreciating India`s comprehensive and cohesive war against COVID-19, Swaminathan said there will be a need to stand on guard in the months to come as well.

The domestically developed Covaxin is effective against the Delta plus variant of COVID-19, claimed the Indian Council of Medical Research (ICMR) in its study last week.

*Source :IANS, 13.08.2021*

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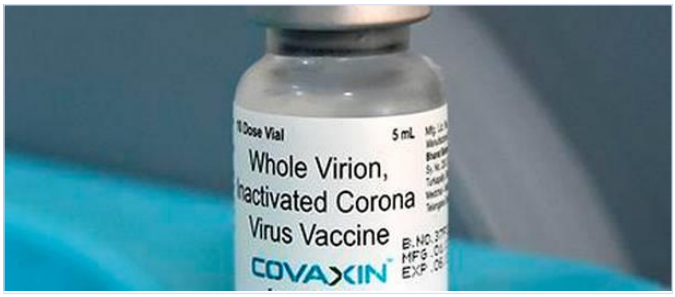
## WHO likely to grant EUL to Covaxin by Sept: Jaishankar

***'My priority is to ensure Indians are able to travel with least restrictions'***




The World Health Organisation (WHO) may decide on giving an emergency authorisation for Covaxin in September, said S Jaishankar, Minister of External Affairs.

The Foreign Minister's statement at the CII Annual Meeting came on the same day WHO's chief scientist Soumya Swaminathan met Health Minister Mansukh Mandaviya to discuss the Emergency Use Listing (EUL) for Covaxin.

EUL is a WHO procedure to streamline the process by which new or unlicensed products can be quickly adopted by multiple countries during public health emergencies. "Typically WHO takes two months...Covaxin filed its application on July 9. So, I am hopeful sometime in September we could get some kind of indication," said Jaishankar.

Earlier, reports from Geneva quoted Mariangela Simao, a WHO Assistant Director General for vaccines, as saying that their assessment of Covaxin was "quite advanced" and that a decision was expected possibly by mid-September.

The Minister further said that India had taken up bilaterally the issue of exempting quarantine for those travellers who had taken certain vaccines.

This exemption had excluded Serum Institute's Covshield. India got the vaccine accepted by a number of countries in Europe through bilateral discussions, he said. "Covaxin is still a problem. I completely understand it. I am hopeful once WHO gives its approval for Covaxin (it will get sorted)," the Minister stated.

Pointing out that regulators worldwide recognised only a limited number of vaccines, Jaishankar said that there was a need for some kind of understanding on vaccination certificates and not vaccines. He said there was a precedence for this, and cited the example of how yellow fever vaccination certificates were accepted for travel without any other specific requirements.

"It is my priority to ensure Indians are able to travel with the least restrictions...," he added.

Meanwhile, Mandaviya, after his meeting with Dr Swaminathan, tweeted: "Held a meeting with Dr SoumyaSwaminathan, Cheif Scientist of @WHO. We had a productive discussion on WHO's approval of @ BharatBiotech'sCovaxin. @DoctorSoumya also appreciated India's efforts for the containment of #COVD19."

**'Efficacy quite high'**

About a month back, Dr Swaminathan had said that the overall efficacy of Covaxin is quite high and that the Phase 3 trials of the vaccine look good. "The overall efficacy is quite high. The vaccine efficacy against the Delta variant is low, but it is still quite good," the scientist was quoted as saying. She had concurred that Covaxin's safety profile so far met the WHO benchmarks.

*Source : The Hindu Business Line, 12.08.2021*

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## AP's 2nd Pharma City coming up near Vizag?

***A pharma cluster is proposed in the land surrendered by NTPC, said an official of the Industries Department***

With North Andhra fast emerging as a prominent pharma hub, the State Government is toying with the idea of establishing a second Pharma City at Pudimadaka, about 50 km from Visakhapatnam-the proposed executive capital of Andhra Pradesh.

The first project named Jawaharlal Nehru Pharma City (JNPC) at Parawada near here has become heavily congested with no space left for allotment to Greenfield investors. JNPC, developed by Ramky under PPP mode, is spread over 2,400 acres with a plotted area of 1,400 acres.

JNPC CEO PP Lal Krishna told Bizz Buzz on Thursday that 86 units are under operation with an estimated turnover of Rs 25,000 crore and a workforce of (direct and contract) 32,000. Space has been allotted to 103 companies as 17 are at various stages of implementation.

An official of the Industries Department, when contacted, said a Pharma Cluster is proposed in the land surrendered by NTPC. The power major shelved its ultra modern coal fired power plant at Pudimadaka, close to the sea, post-bifurcation of the State following change in coal policy by the NDA Government and thrust to encourage solar power plants. Thus, 1,200 acres of land allotted to NTPC is now in possession of AP Industrial Development Corporation.

Though in-principle approval was accorded to develop a steel cluster at the site to avail benefits under the PLI offered to small and medium manufacturers to reduce the cost of steel production, later it has been proposed to shift it to Nakkapalli area. "This was mainly because of the fact that pollution clearance had been obtained in the past for developing a Pharma Cluster in the area," an official said.

Several major pharma units including Reddy's Lab, Divi's Laboratory, Mylan, Pfizer, Aurobindo, Laurus and others have their units at JNPC, Nakkapalli, Duvvada, Ranasthalam and Pydibhimavaram in North Andhra. Bulk Drug Manufacturers of India and Pharmaceutical Exports Promotion Council of India (Pharmexcil) have projected bright prospects for the pharma sector in North Andhra districts of Visakhapatnam, Srikakulam and Vizianagaram.

*Source: Santosh Patnaik, Bizz Buzz, 12.08.2021*

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## Covid: One-dose Sputnik Light set for rollout in September

MUMBAI: India's immunisation plan against Covid-19 may get bolstered soon with the rollout of locally manufactured single-dose Sputnik Light in September.

Panacea Biotec, which had earlier partnered Russian Direct Investment Fund (RDIF), has submitted the dossier for seeking emergency-use authorisation to India's drug regulator recently, sources told TOI.

The vaccine, which will be available in limited quantities initially, is expected to be priced around Rs 750. Till now, the immunisation programme has been using imported two-dose Sputnik V, rolled out by Hyderabad-based Dr Reddy's, RDIF's exclusive distribution partner for India. Shortages in supply of the two-dose Sputnik V could be resolved as early as the month-end, with Dr Reddy's ramping up supplies, sources added. The full rollout of the Sputnik V vaccine was put on hold and is hence lagging, as its imports from Russia were impacted in June. Around five lakh doses of Sputnik V's component 2 vaccine, which have been imported, could be rolled out in India soon.

``We are also working closely with our partners in India for manufacturing readiness. We expect that locally manufactured doses are likely to be available from the September-October period", a Dr Reddy's spokesperson said.

Sputnik Light, developed by Russia's Gamaleya Institute and backed by RDIF, received emergency use authorisation in Russia in May. It is perceived by experts as more 'suitable', given the task of vaccinating a large population even as a possible third wave looms. The Sputnik Light jab has demonstrated nearly 80% efficacy, according to analysed data taken 28 days after the injection was administered in a trial in Russia, an RDIF statement said.

Earlier in July, Panacea Biotec had announced the receipt of a manufacturing license to produce Sputnik V vaccine at its Baddi plant in Himachal Pradesh. The batches manufactured at Baddi have successfully passed the checks for quality parameters both at the GamaleyaCenter in Russia and at the Central Drug Laboratory, Kasauli (Himachal Pradesh). Panacea will produce 100 million doses annually of the vaccine which will be distributed by Dr Reddy's.

Also, an expert panel under the health ministry allowed Dr Reddy's to submit the Russian safety data for approval of the vaccine in India.

"Further, the SEC (subject expert committee) also observed that in view of the safety and immunogenicity data already generated by Dr Reddy's in India on the first dose component of Sputnik V (in other words, Sputnik Light), there was no need for a separate Phase III trial of Sputnik Light in India," it added.

This is in view of the fact that Sputnik Light is the first dose component of Sputnik V. It also recommended that Dr Reddy's should submit safety, immunogenicity and efficacy data from the phase III clinical trial of Sputnik V in Russia to the SEC for its consideration of marketing authorisation of Sputnik Light in India.

*Source: Rupali Mukherjee , TNN, 13.08.2021*

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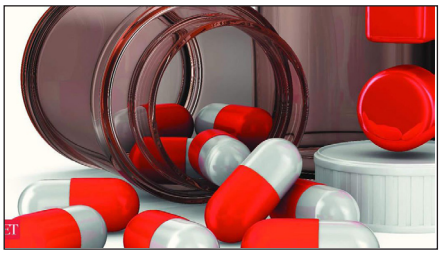
## Green ministry drops antibiotic effluent limits from new rules

***In a debatable transfer, the Green ministry has dropped specification of limits for antibiotic residues/effluents for bulk drug formulation/pharmaceutical business, in its newest set of rules notified this week.***



While this eases off regulatory strain on India's rising pharmaceutical business which is staving off Chinese competitors, the choice comes in opposition to the backdrop of a severe menace of antimicrobial resistance (AMR) in India and the hazards of unchecked antibiotic residues contaminating the water our bodies. Currently, there are not any most limits specified for these antibiotic residues in pharmaceutical effluents. In January 2020, the Union Environment ministry was lauded when it got here up with the draft Environment (Protection) Rules, 1986, for manufacturing bulk medicine. The draft listed out antibiotic residue effluent limits for 121 varieties of antibiotics in its Paragraph D — in all probability the primary such main try, on the planet.

The remaining notification issued on August 6 has dropped Paragraph D and with it – any specification of antibiotic residue effluent limits from the new rules. The new rules as a substitute state that each one the effluents shall merely be labeled as hazardous waste. The new rules will come into impact inside a 12 months from now. ET has learnt that the choice to drop the clause on antibiotic residues has come after intensive consultations with the department of pharmaceuticals and the ministry of well being, moreover different stakeholders. Officials within the know termed it a 'balancing act' maintaining in thoughts the excessive value of compliance for the pharmaceutical business.

It was identified within the discussions that even essentially the most developed nations didn't have any such related requirements and limits on antibiotic residue effluents and imposing them on India's pharma business would put them at an obstacle.

It was strongly argued by the division of prescribed drugs and pharma business associations that specifying antibiotic residue limits will convey appreciable strain on the business which is making an attempt to produce cheap medicine within the nation. The elevated prices might move on to shoppers moreover blunting the aggressive edge India has, it was mentioned .India and China are the most important producers of bulk medicine on the planet and the competitors is stiff. The pandemic has additionally pushed house the significance of the home pharmaceutical business and the necessity for self-dependency, sources informed ET.

ET gathers that sure European nations weighed strongly in favour of specifying limits and wrote to the Indian authorities on the identical. But the ultimate resolution was to drop the clause for now. There is not any readability on whether or not the difficulty shall be reassessed or not.

*Source: Aaj Ka Samachar, 13.08.2021*

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## Govt to Facilitate Easier Access to Affordable Drugs

The government is looking to increase the number of Pradhan Mantri Bhartiya Janaushadhi Kendras to ensure easy access to affordable medicines, Union Health Minister Mansukh Mandaviya said on Thursday. " No one should die because he/she cannot afford medicines, " Mandaviya said at an event organised by CII on Thursday." Today, we have 8,000 Jan Aushadhi stores. Our aim is to increase the uptake of high quality generic medicines at affordable prices."

He said everyday about 2 million people are taking advantage of these stores, as the perception towards generic medicines has changed. Mandaviya said there is a need to make India"atma nirbhar" in the health sector to bring down the cost of healthcare. "Health in India has, so far, not been linked to development. It is, in fact, the most important thing in the progress of the country, If the country needs to progress, its countrymen should be healthy," he said.

*Source : Economic Times, 13.08.2021*

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## Freight rates jump 250%

Freight shipping costs have increased around 250 per cent in the past one year. Overseas buyers have started going light on inventory and this is likely to affect the exports in the coming months, finds the industry.

On an average, shipping cost to different destinations has shot up by 200 to 250 per cent compared to August last year. In cases of Latin American countries and West Africa, the costs are up by 500 to 600 per cent, said Ajay Sahai, director general and CEO of the Federation of Indian Export Organisations (Fieo).

According to him, overseas buyers are going light on their inventory and this is likely to affect exports as well as production in the coming months.

"Earlier, the buyers would hold inventory of up to six months as the freight costs remained almost constant. But now, with costs going over the roof, many buyers are keeping stocks for just two months in the hope that freight costs would come down in the future," he said.

"But this will start affecting our exports soon and in turn our production too will slow down," he added.

Exporters of high volume low-value products are the worst hit as their margins do not support 250 per cent rise in shipping costs.

The freight charges have been going up drastically ever since China revived its exports after getting affected by the pandemic. China has been paying a premium on empty containers and rewarding the shipping lines. Further, the decline in the production of new containers during the pandemic also affected the availability. Fuel prices too are influencing the costs.

Some in the industry have been alleging cartelisation by shipping lines as a reason behind the steep rise in freight charges.

"The increased freight charges at times are much higher than what needs to be levied in such a situation. The shipping lines, most of them being foreign companies, are functioning in an arbitrary manner. The shortages as well as increase in charges are sometimes artificial," said ArunGarodia, vice chairman, EEPC India.

*Source : Sangeetha G, Asian Age, 13.08.2021*

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# FICCI's Event - LEADS 2021 - FUTURE OF PARTNERSHIPS on 14th - 15th September 2021 at New Delhi - An Update

Dear Member,

2nd edition of FICCI's global though leadership initiative - "LEADS", this year it is scheduled on 14th - 15th September 2021, at New Delhi, with an overarching theme of 'Future of Partnerships.

We are delighted to share with you that the event is shaping up well. While Ministry of External Affairs, Govt of India, has consented to support LEADS 2021, we also have consent for keynote addresses from,

- **Mr Piyush Goyal**, Minister of Commerce & Industry, Consumer Affairs & Food & Public Distribution and Textiles, Government of India
- **Mr Jyotiraditya M. Scindia**, Union Minister for Civil Aviation, Government of India
- **Dr. Jitendra Singh**, Minister for Space, Science & Technology, Government of India
- **Dr Rajiv Kumar**, Vice Chairman, Niti Aayog, Government of India
- **Mr. Amitabh Kant**, CEO, Niti Aayog, Government of India.

More Govt. of India Ministers and Parliamentarians from across the world, will follow soon.

We have received an impressive response from global leaders across the world, including some Fortune 500 organisations like **DHL, Panasonic, IKEA, IBM, Mahindra & Mahindra, Australian Space Agency, CITI, Siemens Healthineers, Embraer Defence, NGN Technology, UBER, Airtel, Microsoft, Indigo, Tata Consultancy Services, ERAM Group, Mohsin Haider Darwish, Rakon Ltd, Saber Astronautics, AFK Systema, Ecobank, Vivo, Kidzania, Sojitz, Trigyn Technologies, AFK Systema, Globant etc.**, have already consented to share their thoughts at LEADS 2021. Likewise, participants from 25 countries across the globe have already registered for the programme within few weeks of registrations opening.

**Considering the exclusivity of the program, we will close the Registrations by on 31st August, 2021 depending on limitations of in-person participation.** We shall be grateful if you could kindly send another round of requests to your industry network, to register and benefit from the perspectives of global leaders speaking at LEADS 2021. Your industry members can register at

**www.ficcileads.in**. This site also gives all updates on program outline, speakers, program partners, Institutional partners etc.

In case you have not been registered yet, we request you to do so using the special invitee link below (only for officials of [ORGN] ), **https://registrations.ficci.com/FICCILEADS2021/online-registration-invitee.asp**

We look forward to welcoming you and your members to LEADS 2021 – A FICCI-ERAM group initiative!

With kind regards,
**K S Narayanaswamy**
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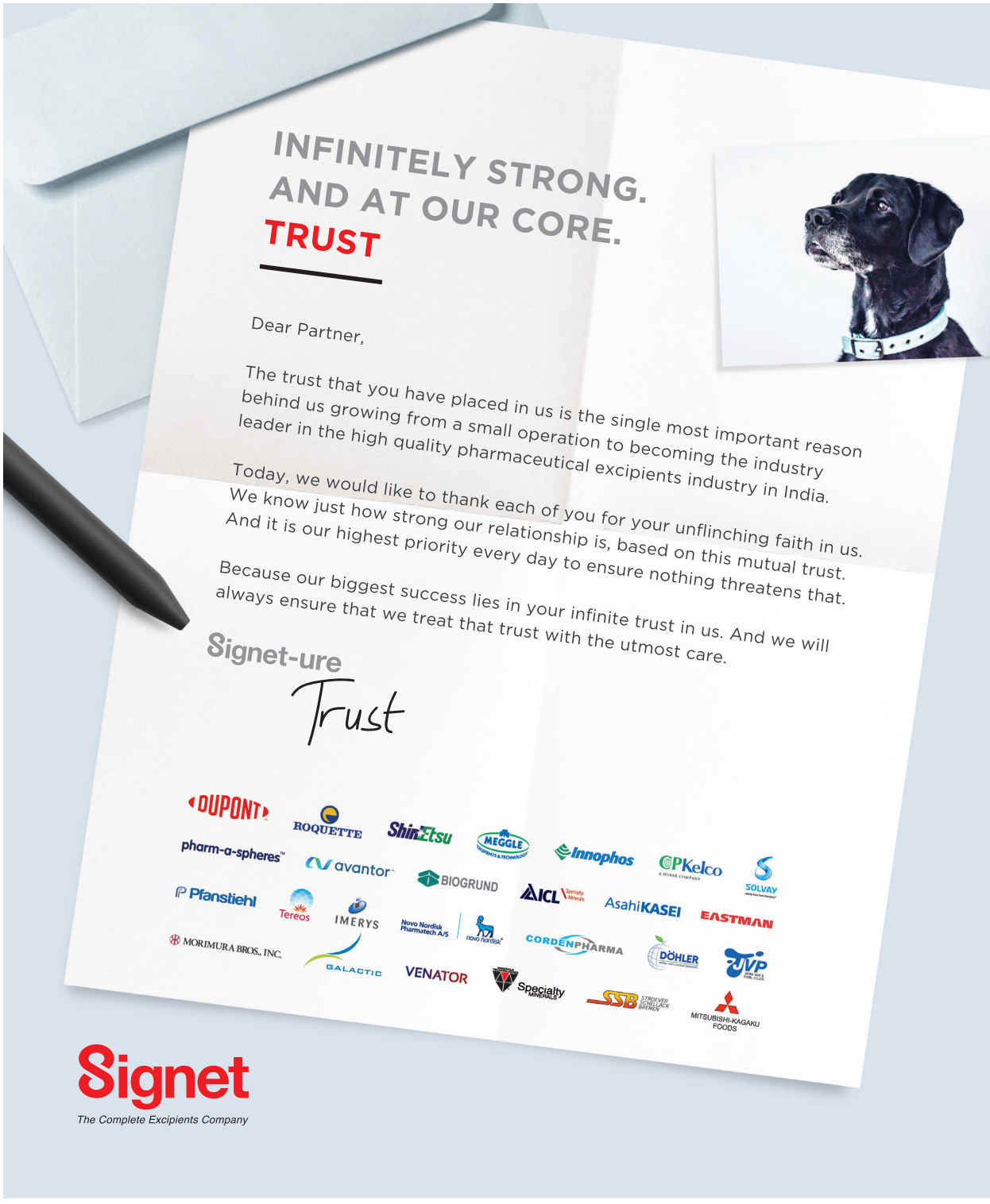
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