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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 Issue No. 31 15 to 21 August 2020

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Revised Guidelines regarding discontinuation of Scheduled Formulation under Para 21 (2) of DPCO, 2013 - reg.

NPPA Office Memorandum dated 14th August, 2020

The Authority in its 209th (overall) and 77th meeting held on 06.08.2020 has approved the guidelines for dealing with cases of discontinuation of scheduled formulations under Para 21(2) of DPCO, 2013. These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases.

F No.31(170)/2020/Div.III/NPPA

Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

Enclosed: Revised Guidelines*

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*Revised Guidelines for dealing intimations of discontinuation of Scheduled Formulations under Para 21 (2) of DPCO, 2013

1. Paragraph 21(2) of the DPCO, 2013 provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in **Form-IV** of this order at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with the required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation. A copy of the draft public notice is attached.

2. Taking the above into consideration, the Authority in its **209th** (overall) and **77th** meeting held on **06.08.2020** approved the following guidelines to deal with intimations received in Form-IV (Schedule-II of DPCO, 2013) for discontinuation of production/import of scheduled formulations under Paragraph 21(2) of the DPCO, 2013:

i) Companies may submit duly filled Form-IV (as per Schedule-II of DPCO, 2013) for intimation, duly signed and stamped by Authorised Signatory, for the discontinuation of the production of scheduled formulation with all the requisite documents on email ID: **monitoring-nppa@gov.in,** at least six months prior to the intended date of discontinuation.

ii) Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return e-mail. Incomplete intimation without the requisite documents would be returned for re-submission and the same shall be informed to the applicant via email within 10 working days.

iii) Wherever **Moving Annual Turnover (MAT) of the company is 1% or less than 1% of total MAT value,** company has to inform at least six months prior to the proposed/intended date of discontinuation and to issue public notice in at least one newspaper. Such cases will be noted without issuing any direction to the company and case will be **deemed approved** except where intimation has not been submitted six months prior to the proposed/ intended date of discontinuation or the market share of the company is more than 1%; such cases will be dealt appropriately as per Para-2(iv) of the guidelines.

iv) Wherever Moving Annual Turnover (MAT) of the company is more than 1% of the total MAT Value, company will be directed, with the approval of Chairman, NPPA, within a period of sixty days from the receipt of Form-IV that intimation request has been noted and further directed to issue public notice in the prescribed attached formats in at least two national newspapers one in English and one in Hindi. The company will also be directed to continue production / import and sale of the formulation for a period of *up to twelve months* from the date of issue of public notice and to ensure that

there is no shortage of the formulation during this period.

v) Notwithstanding provisions of Paras 2(iii) & 2(iv) above, whenever concerns regarding shortage is apprehended or a formulation is found to be critical for public health; based on circumstances and also in cases where it is established that the company is intending to discontinue production/ import and sale of a scheduled formulation and has already launched or intends to launch 'a new drug' to evade price control; cases requiring continuance of production/import and sale beyond twelve months or any other case; with the approval of Chairman, NPPA will be referred to a Standing Committee. The Standing committee will comprise of Advisor (Cost), NPPA and representatives from CDSCO and DGHS as Members of the Committee. The recommendation of the Committee will be put up to the Authority.

vi) MAT shall be calculated in 'value terms' as defined in Para 2 (s) of DPCO, 2013, except in cases where market share cannot be calculated by MAT in value, the same will be calculated by MAT in units. Market share is determined from Market Database referred by this office.

vii) The company shall not reduce level of production by more than 25% (of last year production in each quarter) after getting direction from NPPA.

3. The provisions of these guidelines are also applicable to scheduled Medical Devices which have been notified as Drugs by Government of India from time to time.

4. NPPA will upload list of discontinuation of scheduled formulations filed by pharmaceutical companies and approved by competent authority, on the website of NPPA on monthly basis.

5. These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases.

F.No. 31(170)2020/Div III/NPPA

Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

Public Notice

(Under paragraph 21(2) of the Drugs Price Control Order, 2013)

Name of the company
Registered office Address of the company
with their contact details

CIN no.
Website:
E-mail:
Phone no:

Attention of general public is drawn to the fact that (name of company) having regi tered office at aforesaid address is manufacturing / marketing scheduled formulations namely (bra d name) with (composition and strength / dosage) (hereinafter referred to as medicine). (Nan e of company wants to discontinue and stop the manufacture / marketing of the above said p duct after a period of six / twelve months from the date of this notice.
After discontinuation of the above medicine, the same may not be available the market. Therefore, patients using such medicine may consult their doctor for prescr ng alternate medicine. All the doctors / Medical Personals may also make note of this.

<Name of the company Secretary/Authorised person>
Designation
Name of the company

Date:
Place:

Procedure to be followed in cases of manufacturing or other operations undertaken in special warehouses under section 65 of the Customs Act - reg.

Circular No.36/2020-Customs, dated 17th August, 2020

To
All Principal Chief Commissioners/Chief Commissioners of Customs Principal Directors General/Directors General of Customs, Principal Commissioners/Commissioner of Customs.

1. Manufacture and Other Operations in Special Warehouse Regulations, 2020 (hereinafter referred to as the MOOSWR, 2020) have been issued vide Notification No.75/2020-Customs (N.T.) dated 17th August, 2020. These regulations allow manufacturing and other operations in a special warehouse licensed under section 58A of the Customs Act, 1962, with regard to warehoused goods specified in clause (1) of Notification No. 66/2016-Customs (N.T) dated 14th May, 2020 (herein after referred to as, "specified goods").

2. MOOSWR, 2020 and this Circular cover the procedures and documentation for a section 58A warehouse, operating under Section 65 of the Act, in a comprehensive manner including application for seeking permission under section 65, provision of execution of the bond and security by the licensee, receipt, storage and removal of goods, maintenance of accounts, conduct of audit etc.

3. Further, the Special Warehouse (Custody and Handling of goods) Regulations, 2016, which were hitherto governing the procedure for custody and handling of goods deposited in and removed from a Special Warehouse have been amended, vide Notification No.77/2020-Customs (N.T) dated 17th August, 2020, to exclude their application for such warehouses operating under section 65. The said regulations will continue to be applicable for special warehouses, not operating under Section 65.

4. An applicant desirous of manufacturing or carrying out other operations on specified goods in a bonded warehouse under section 65, must have the premises licensed as a special warehouse under section 58A of the Customs Act. The applicants can seek a license under section 58A and permission to operate under section 65 synchronously, or request for permission under section 65, if they already have a warehouse licensed under section 58A.

5. For the sake of uniformity, ease of doing business and exercising due diligence in grant of permission under section 65, the form of application to be filed by an applicant before the jurisdictional Principal Commissioner/Commissioner of Customs is prescribed as in ***Annexure-A.*** The form of application has been so designed that the process for seeking grant of license as a Special Warehouse as well as permission to carry out manufacturing or other operations stands integrated into a single form. The declaration to be made to satisfy regulation 5 of Special Warehouse Licensing Regulations, 2016, and the undertaking to be made by the applicant as per regulation 4 of MOOSWR, 2020, is included in the application format (Part II). The warehouse in which section 65 permission is granted shall also be declared by the licensee as the principal/additional place of business for the purposes of GST.

6. It has also been decided that the licensees manufacturing or carrying out other operations in a bonded warehouse shall be required to maintain records as per the form prescribed under this circular ***Annexure-B****. Regulation 4 of the MOOSWR, 2020, provides that the applicant under section 65 shall undertake to execute a bond in such format as specified. Further, Section 59 of the Customs Act requires the importer of the warehoused goods to furnish security and execute a triple duty bond for the warehoused goods. Thus, the bond prescribed under this Circular as per ***Annexure-C**** serves the requirements of both MOOSWR, 2020 and Section 59 of the Customs Act. Additionally, the licensee will furnish security by way of a bank guarantee equivalent to the duty involved on the warehoused goods.

7. To the extent that the resultant product manufactured or worked upon in a bonded warehouse is **exported,** the licensee shall have to file a shipping bill and pay

any amounts due. A GST invoice shall also be issued for such removal. In such a case, no duty is required to be paid in respect of the imported goods contained in the resultant product as per the provisions of section 69 of the Act.

8. To the extent that the resultant product (whether emerging out of manufacturing or other operations in the warehouse) is cleared for domestic consumption, such a transaction squarely falls within the ambit of "supply" under Section 7 of the Central Goods and Service Tax Act, 2017 (hereinafter referred to as the "CGST Act"). It would therefore be taxable in terms of section 9 of the CGST Act, 2017 or section 5 of the Integrated Goods and Services Tax Act, 2017 depending upon the supply being intra-state or inter-state. The resultant product will thus be supplied from the warehouse to the domestic tariff area under the cover of GST invoice on the payment of appropriate GST and compensation cess, if any. As regards import duties payable on the imported goods contained in so much of the resultant products are concerned, same shall be paid at the time of supply of the resultant product from the warehouse for which the licensee shall have to file an ex-bond Bill of Entry and such transactions shall be duly reflected in the accounts prescribed under ***Annexure-B.*** As per MOOSWR, 2020, the applicant shall also inform the input-output norms for raw materials and final products and shall also inform the revised input-output norms in case of change therein.

8.1 The proper officer should ensure that the goods so cleared are result of manufacturing or other operations. In case the licensee is unable to carry out any manufacturing or other operations on warehoused goods, then the goods may be cleared as such, either for home consumption after the payment of applicable import duties along with the interest accrued upon such goods in terms of Section 61 (2) of the Customs Act, 1962 or may be exported. In such case the provisions of clause (b) of Section 61(1) shall not be applicable.

9. The waste generated during the course of manufacture or other operations of the resultant product may be cleared for home consumption as per clause (b) to sub-section (2) of section 65 of the Customs Act on payment of applicable duties of customs and GST.

10. Where the resultant product is exported, and duty on the waste or refuse is paid as per proviso to clause (a) to sub-section (2) of section 65, the same shall be deposited manually through a Challan. The records maintained as per Annexure-B would be sufficient for accountal of such goods.

11. As per Regulation 3 (2) (e) (i) of the Special Warehouse Licensing Regulations, 2016, the Principal Commissioner or Commissioner has to be satisfied that the site or building of the proposed special warehouse is suitable for secure storage of dutiable goods. Regulation 8 of MOOSWR 2020, requires the licensee to provide such facilities, equipment and personnel as are sufficient to control access to the warehouse, provide secure storage of the goods and ensure compliance to the regulations. Considering the nature of goods to be warehoused in a special warehouse, the Principal Commissioner or Commissioner has to ensure that the structure is fully closed from all sides, gate(s) with access control and personnel to safeguard the premises. It is also to be ensured that there is/are CCTV cameras at the gate(s) and there is a provision of accessing the same by customs officers. The Principal Commissioner/ Commissioners should take into consideration the facilities, equipment and personnel put in place for secure storage of goods, while considering grant of license. Further, office space for bond officer and sufficient space for customs officer for carrying out examination at the time of arrival or removal of goods have to be provided.

12. As per Regulation 4(2)(i) of MOOWSR 2020, a licensee is required to maintain accounts of receipt and removal of goods in digital form in such format as may be specified and furnish the same to the bond officer on monthly basis digitally. This information shall be communicated from the registered email address of a licensee to the designation based official email id accessed by the bond officer. Appointment of any new warehouse keeper should also be intimated along with the monthly returns. Jurisdictional Commissionerate should ensure that such emails are functional and details of same are communicated at the time of issuance of license and also published through public notice.

13. As per Regulation 18(3), the records should be maintained electronically using software which has inter alia features of audit trail and with each event being recorded with time stamp. The licensee is also required to provide details of such software while applying in terms of MOOSWR 2020. At the time of inspection, the proper officer should, through a

demonstration, check and ensure that the software meets the requirements of Regulation 18(3). In case licensee wishes to use any other software after issuance of license, bond officer should be informed in advance along with similar demonstration. Proper officer should record the observations and confirm that the new software meets the requirements of Regulation 18(3).

14. Section 58A provides that the proper officer shall cause a warehouse licensed under section 58A to be locked and no person shall enter the warehouse except in his presence. It is clarified that this requirement shall be applicable for the strong-room where specified goods are warehoused, in terms of regulation 9 of MOOSWR, 2020. This will not apply to the remaining licensed premises.

15. The services of customs officer for supervising various activities prescribed in the MOOSWR, 2020, shall be chargeable on cost recovery or overtime basis, in terms of regulation 4(2)(vi). The licensee shall have to indicate the frequency with which the warehouse has to be operated per day/per week and the expected business hours of such operation, requiring supervision/presence of the bond officer in terms of MOOSWR, 2020.

15.1 The Principal Commissioner/Commissioner shall evaluate the projected requirement and also consider the distance of the warehouse from the customs office to determine which of the modes of recovery of costs needs to be applied and the amount to be paid by the licensee.

16. Clarification required, if any, may be sought from the Board.

F. No.473/03/2020-LC

Dr Swati Bhanwala, OSD (Land Customs), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

(*Annexures B & C not reproduced here)

Annexure-A

Application for License for a special warehouse under section 58A and permission for manufacturing and other operations under section 65 of the Customs Act 1962.

Part I
(to be filled by the applicant)

1. Name of the Applicant:

2. PAN No:

3. GSTIN:

4. IEC:

5. Constitution of business (Tick as applicable and attach copy)

(i) Proprietorship

(ii) Partnership

(iii) Limited Liability Partnership

(iv) Registered Public Limited Company

(v) Registered Private Limited Company

(vi) Registered Trust

(vii) Society/Cooperative society

(viii) Others (please specify)

Note: Copy of certificate of incorporation along with Memorandum of Objects and Article of Association in case of companies and partnership deed in case of partnership firms should be attached.

6. Registered office:

Address:

Tel:

Fax:

E-mail:

7. Bank Account details:

Name of the Bank:

Branch name:

Account Number:

8. Name, Address & DIN (if applicable):
[of Proprietor/Partners/Directors etc.
(Please attach copies of ID proof)].

9. Name & Designation of the Authorized Signatory:
(Please attach copy of Aadhaar Card as proof of ID).

10. Details of existing manufacturing facilities in India and/or Overseas of the applicant firm and of each of its directors/partners/proprietor, as the case may be (please attach separate sheet if required).

Part II
(to be filled by the applicant)

1. Address of the proposed site or building:
2. Boundaries of the warehouse:
   (i) North
   (ii) South
   (iii) West
   (iv) East
3. Details of property holding rights of the applicant (please provide supporting document):
   (i) Owner
   (ii) Lease/rent
4. Contact details at the site/premises:
   (i) Tel:
   (ii) Fax:
   (iii) Email:
   (iv) Website, if any:
5. Details of warehouse license issued earlier to the applicant, if any:
   (i) Date of issue of license:
   (ii) Commissionerate file No.:
   (iii) Attach copy of warehouse license.
6. Whether the applicant is a Licensed Customs Broker? If yes, please provide details:
7. Whether the applicant is AEO? If yes, please provide details.
8. Description of Premises (fill details as applicable to the premises):
   (Please enclose a ground plan of the site/premises indicating all points of exit/entry/area of storage/area of manufacturing/earmarked area of office):

(i) What is floor area?

(ii) Number of stories?

(iii) Total area (or cubic capacity) available for storage of

(a) specified goods, and

(b) other goods

(iv) Identify and mark area(s), occupied by third parties in the ground plan:

(v) What is the type of construction of walls and roof?

(vi) Which year has the building been built? Has it been recently remodelled? If so, when?

(vii) Identify by location and size all accesses to the site / building to pedestrian and vehicles:

(viii) Identify by location and size all other accesses to the building including doors & windows:

(ix) Please indicate whether the premises have been authorized for commercial use by local Government authorities?

9. Goods proposed to be manufactured or other operations proposed to be carried out (if necessary, additional sheets may be attached).

Details of goods:	**Description of goods**	**Classification as per Customs Tariff**	**Briefly detail, input-out norms Please attach any supporting publication / document, if available.**
proposed to be imported			
proposed to be domestically procured			
intermediate product			
final product			
details of waste & scrap			

In case of any change in the nature of operations subsequent to the grant of permission, the same shall be informed to the Jurisdictional Commissioner of Customs within 15 days.

10. SECURITY FACILITIES AT THE PREMISES, EXISTING OR PROPOSED:

(i) Burglar Alarm System:

(ii) CCTV Facility:

a. Is there a CCTV monitoring system installed to cover the surrounding area of the site and storage area?

b. Please indicate the no. of cameras installed:

c. No. of hours/days of recording accessible at any point of time:

(iii) Security Personnel:

a. Details of arrangements for round the clock security provided for the warehouse:

b. Name & details of firm contracted for security services:

c. No. of personnel to be deployed on each shift for round the clock security:

(ix) Fire Security:

(Please enclose a fire safety audit certificate issued by a qualified independent agency)

11. Software which will be used in terms of Regulation 18(3):

11. DECLARATION:

I/ We declare that:

1. I/We are a registered or incorporated entity in India.
2. I / We have not been declared insolvent or bankrupt by a court or tribunal.
3. I/We have not been convicted for an offence under any law.
4. I/We have neither been penalized or convicted nor are being prosecuted for an offence under the Customs Act, 1962 or Central Excise Act, 1944 or Finance Act, 1994 or Central Goods and Services Tax Act, 2017 or Integrated Goods and Services Tax Act,2017 or Goods and Services Tax (Compensation to States) Act, 2017.
5. There is no bankruptcy or criminal proceedings pending against me / us.
6. I/We hereby declare that the information given in this application form is true, correct and complete in every respect and that I am authorized to sign on behalf of the Licensee. I further undertake that if any particulars declared by me/us are proved to be false, the license granted to me/us shall be liable to be cancelled and I/we shall be liable for action under Customs Act, 1962.

12. UNDERTAKING.

I/We undertake to:

(i) maintain accounts of receipt and removal of goods in digital form in such format as may be specified and furnish the same to the bond officer on monthly basis digitally;

(ii) provide facilities, equipment and personnel as required in the Manufacture and Other Operations in Special Warehouse Regulations, 2020;

(iii) execute a bond in such format as may be specified.

(iv) Furnish a security in form of bank guarantee as may be specified;

(v) inform the input-output norms, for raw materials and the final products and to inform the revised input-output norms in case of change therein;

(vi) pay for the services of supervision of the warehouse by officers of customs on cost recovery basis or overtime basis, as may be determined by the Principal Commissioner of Customs or the Commissioner of Customs; and

(vii) comply with such terms & conditions as may be specified by the Principal Commissioner of Customs or the Commissioner of Customs.

(Signature of the applicant/authorized signatory)

Stamp

Date:

Place:

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Manufacture and Other Operations in Warehouse (No.2) Regulations, 2019 amended (1st Amendment of 2020) - reg.

Notification No.76/2020-Customs (N.T.), dated 17th August, 2020

In exercise of the powers conferred by section 157, 143AA read with section 65 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations, to amend the Manufacture and Other Operations in Warehouse (no.2) Regulations, 2019, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Manufacture and Other Operations in Warehouse (no. 2) Amendment Regulations, 2020.**

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

2. In the Manufacture and Other Operations in Warehouse (no. 2) Regulations, 2019, for regulation 3, the following regulation shall be substituted, namely:-

"3. Application: These regulations shall apply to,-

(i) the units that operate under section 65 of the Act, or

(ii) the units applying for permission to operate under section 65 of the Act, in a warehouse licensed under section 58 of the Act.".

F.No.473/03/2020-LC

Gaurav Singh,
Deputy Secretary,
Central Board of Indirect Taxes and Customs,
Department of Revenue,
Ministry of Finance,
New Delhi.

Note: *The Principal Notification No.69/2019-Customs (N.T.), dated the 01st October, 2019.*

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Special Warehouse (Custody and Handling of Goods) Regulations, 2016 amended (1st Amendment of 2020) - reg.

Notification No.77/2020-Customs (N.T.), dated 17th August, 2020

In exercise of the powers conferred by section 157 read with section 58A and subsection (2) of Section 73A of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations to amend the Special Warehouse (Custody and Handling of Goods) Regulations, 2016, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Special Warehouse (Custody and Handling of Goods) Amendment Regulations, 2020.**

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

2. In the Special Warehouse (Custody and Handling of Goods) Regulations, 2016, after regulation 12, the following regulation shall be inserted, namely:-

"13. Non applicability of regulation in certain cases: Nothing contained in these regulations shall apply to a warehouse licensed under Section 58A of the Act and operating under section 65 of the Act.".

F.No.473/03/2020-LC

Gaurav Singh,
Deputy Secretary,
Central Board of Indirect Taxes and Customs,
Department of Revenue,
Ministry of Finance,
New Delhi.

Note: *The Principal Notification No.69/2016-Customs (N.T.), dated the 14th May, 2016 was published in the Gazette of India, Extraordinary, vide number G.S.R.516(E), dated the 14th May, 2016.*

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CBIC New Compliance Information Portal for Imports & Exports

Compliance Information Portal, one-stop-shop for all information required for Imports & Exports as it provides all information related to applicable fees, duties, charges for imports & exports, regulatory requirements like licensing, authorization Online registration available when imported goods arrive at Jawaharlal Nehru Port. No need to approach officer for registration of goods Automated release facility for imported goods launched at Jawaharlal Nehru Customs House. Automated release would help in reducing time as well as cost for clearance process.

Introduction:

CBIC, has endeavored to provide another facilitation tool for the trade and the citizens – **"THE COMPLIANCE INFORMATION PORTAL".** The Site **https://cip.cbic.gov.in/CIP/#/home**

It provides information related to Laws, step by step Procedures and Acts of Customs and all Partner Government Agencies (PGAs) regulating Import and export of commodities of 10000 plus Tariff Headings on a single portal developed by the Central Board of Indirect Taxes and Customs (CBIC).

Features of Compliance Information Portal:

- Once the user login to CIP the information may be obtained by entering either of the following:
  - 4 to 8 digit Customs Tariff Heading,
  - Description of Commodity.
- It covers 3 stages of Import and Export:
  - Prepare for Import and Prepare for Export,
  - Pre-Import and Pre-Export,
  - Import and Export.
- Provides stage-wise detailed process flow chart for all procedures of export for exporting any commodity covered under the Customs tariff Act, 1975.
- The process flow chart covers all basic steps required from preparing for import to Out of Charge from Customs at Import stage.
- The process flow chart covers all basic steps required from preparing for export to Export General Manifest, when the goods are exported.
- The Process flow chart also provides information about requirement of necessary permissions / clearances or requirement of Licenses/Permits/ Certificates/Other Authorizations (LPCOs) to be obtained from any Partner Government Agency (PGA) for imports as well as exports.
- The portal provides weblinks of all Partner Government Agencies whose intervention is required for importing or exporting a commodity at any stage.
- The portal strives to provide every important detail of each step of process flow chart to enable the user to get all necessary information without physically interacting by the Partner Government Agencies. These are:
  - Step description,
  - Requirement description,
  - Laws/Regulations Governing the step,
  - Supporting documents required for the step,
  - Location and Telephone Numbers where the step is carried out.

How does the Portal Work:

The user can search for a commodity on the basis of the following two options:

1. If the Chapter Tariff Heading of commodity is known, the user may enter the CTH.
2. If the user do not know the CTH, search can be made on the basis of description of commodity.

The user is now routed to the page where the Import or Export procedure is to be selected. The user may choose any of the 6 options under Import or 8 options under Export. The options are given below:

Import Procedures:

1. **Bill of Entry for Home Consumption:**

   Procedure for home consumption on payment of duty.

2. **Bill of Entry for Home Consumption Utilizing Export Benefits:**

   Procedure for clearing goods where duty liability is discharged through export incentive scrips.

3. **Bill of Entry for Home Consumption with Duty Deferment:**

   Procedure for home consumption where goods are cleared with deferred duty payment option.

4. **Bill of Entry for Warehousing:**

   Procedure for warehousing goods after assessment for clearance at any subsequent date on payment of duty.

5. **Ex-Bond Bill of Entry for Home Consumption:**

   Procedure for clearing warehoused goods for home consumption on payment of duty.

6. **Ex-Bond Bill of Entry for Home Consumption:**

   Utilizing Export Benefits Procedure for clearing warehoused goods for home consumption where duty liability is discharged through export incentive scrips.

Export Procedures:

1. **Duty Free Shipping Bill**:

   Procedure meant for exporting goods that do not have export duty liability & without availing any export incentive.

2. **Dutiable Shipping Bill:**

   Procedure meant for exporting goods that have export duty liability & without availing any export incentive.

3. **Shipping Bill Linked with Export Benefits:**

   Procedure meant for exporting goods for availing export incentives.

4. **Shipping Bill under Duty Drawback:**

   Procedure meant for exporting goods for availing Duty Drawback.

5. **Duty Free Shipping Bill with self seal option:**

   Procedure meant for exporting goods that do not have export duty liability & without availing any export incentive with self seal option.

6. **Dutiable Shipping Bill with self seal option:**

   Procedure meant for exporting goods that have export duty liability & without availing any export incentive with self seal option.

7. **Shipping Bill Linked with Export:**

   Benefits with self seal option Procedure meant for exporting goods for availing export incentives with self seal option.

8. **Shipping Bill under Duty Drawback with self seal option:**

   Procedure meant for exporting goods for availing Duty Drawback with self seal option.

On selecting the procedure, the user is then routed to the next page which provides stage-wise step by step information for importing/exporting a commodity. The steps have been divided into 3 following stages:

1. Prepare for Import/Export Stage – Steps required to start preparation for Import/Export
2. Pre-Import/Export Stage – Once the steps at prepare stage have been complied with, the user is required to comply with the steps given in this stage.
3. Import/Export Stage – Once the above two steps are complete, the user is now ready to import / export the desired commodity. This stage provides steps to the user for completing import/export of the commodity for which the information has been sought.

- At any given time, the user can check information for any other commodity based on CTH or its description from the Navigation Bar.
- The user is also requested to give feedback and fill the survey form to help CBIC understand your need and to update the portal in a more user friendly manner.

Source: www.facelesscompliance.com, 16.08.2020

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CBIC notifies New Exchange Rates w.e.f. 17th July 2020 - reg.

Notification No.59/2020-Customs (N.T.), dated 16th July, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.55/2020-Customs (N.T.), dated 2nd July, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 17th July, 2020**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods. .

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	53.80	51.50
2.	Bahraini Dinar	206.00	193.45
3.	Canadian Dollar	56.70	54.75
4.	Chinese Yuan	10.90	10.60
5.	Danish Kroner	11.75	11.30
6.	EURO	87.35	84.25
7.	Hong Kong Dollar	9.90	9.55
8.	Kuwaiti Dinar	252.35	236.90
9.	New Zealand Dollar	50.70	48.45
10.	Norwegian Kroner	8.20	7.95
11.	Pound Sterling	96.10	92.85
12.	Qatari Riyal	21.35	20.05
13.	Saudi Arabian Riyal	20.70	19.45
14.	Singapore Dollar	54.95	53.15
15.	South African Rand	4.65	4.35
16.	Swedish Kroner	8.40	8.15
17.	Swiss Franc	81.15	78.05
18.	Turkish Lira	11.30	10.65
19.	UAE Dirham	21.15	19.85
20.	US Dollar	76.10	74.40

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	71.65	69.05
2.	Korean Won	6.45	6.05

F.No. 468/01/2020-Cus.V

Radhakrishnan Ananth, Deputy Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

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Prime Minister Narendra Modi launches platform for "Transparent Taxation - Honouring the Honest"

Tax system aims to be Seamless, Painless, Faceless: PM

Says the number of taxpayers is significantly low with only 1.5 crore paying taxes in a country of 130 crore people

Prime Minister urges people to introspect and come forward to pay Income taxes due on them to build an Atma Nirbhar Bharat

With the launch of the Tax Charter, taxpayer is assured of fair, courteous and rational behavior: PM

Faceless appeal will be available across the country from 25th September i.e. Deen Dayal Upadhyay's Birth Anniversary: PM

"Banking the Unbanked, Securing the Unsecured, Funding the Unfunded and Honoring the Honest" - Focus of the Government: PM

Emphasis is on making every law and policy People Centric and Public Friendly rather than Power Centric: PM

PMO Press Release dated 13th August 2020

Prime Minister Shri Narendra Modi launched a platform for "Transparent Taxation - Honouring the Honest" through video conferencing. Speaking on the occasion he said that the process of Structural Reforms in the country has reached new heights today. The Prime Minister said the platform of "Transparent Taxation - Honouring the Honest, has been launched to meet the requirements of the 21st century taxation system. He elaborated that the platform has major reforms like Faceless Assessment, Faceless Appeal and Taxpayers Charter.

He said that Faceless Assessment and Taxpayers Charter have come into force from today-(13.08.2020), while the facility of faceless appeal will be available for citizens across the country from 25th September i.e. Deen Dayal Upadhyay's Birth Anniversary. The new platform apart from being faceless is also aimed at boosting the confidence of the taxpayer and making him/her fearless.

The PM said that the focus of the Government in the last six years has been "Banking the unbanked, Securing the unsecured and Funding the unfunded" and that the platform of "Honouring the Honest" is in the similar direction. The Prime Minister praised the role of honest taxpayers in nation building and said that making the lives of such taxpayers easy is the responsibility of the Government. "When the life of an honest taxpayer of the country becomes easy, he moves forward and develops, then the country also develops and leaps forward," PM added.

The Prime Minister said the new facilities launched are a part of the Government's resolve to provide maximum Governance with minimum Government. He said that every rule, law and policy are made with an emphasis of them being people centric, public friendly rather than power centric. He said that the use of the new governance model is yielding good results.

The Prime Minister said that an atmosphere is being created where primacy is being given to duty to execute all works. This is the result not because of force and fear of punishment but because of an understanding of the holistic approach that is being adopted. He said the reforms being launched by the Government are not in piecemeal but those aimed at delivering results with holistic perspective.

The Prime Minister said the country's tax structure needed fundamental reforms as the earlier tax

structure was developed from the one created during pre-independent times. Even the several changes made during the post-independent times did not alter its fundamental character, he said.

The Prime Minister said that the complexity of the earlier system made it difficult to conform. He said that simplified laws and procedures make it easy to comply. One such example is the GST, he said, which replaced dozens of taxes. The Prime Minister said that the latest laws reduced the legal burden in the tax system where now the limit of filing cases in the High Court has been fixed at up to 1 crore rupees and up to 2 crores for filing in the Supreme Court. Initiatives like the *'Vivaad Se Vishwas'* Scheme pave the way for most of the cases to be settled out of court.

Prime Minister said that the tax slabs have also been rationalised as a part of the ongoing reforms where there is zero tax upto an income of 5 lakh rupees, while the tax rate has reduced in the remaining slabs too. He said India is one of the countries with lowest Corporate Tax in the World.

The PM said the ongoing reforms aim at making the tax system Seamless, Painless, Faceless. He said the Seamless system works to resolve the problems of a taxpayer instead of entangling him further. By being Painless he said, everything from technology to rules should be simple. Referring to the Faceless system he said there is no need for a direct contact between the Taxpayer and the Income Tax Officer in all matters of scrutiny, notice, survey or assessment.

Referring to the launch of Taxpayers Charter, the Prime Minister said that it is a significant step where the taxpayer is now assured of fair, courteous and rational behavior. He said the charter takes care of maintaining the dignity and sensitivity of the taxpayer and that is based on a trust factor and that the assessee cannot be merely doubted without a basis.

Referring to the reduction of the scrutiny of the cases by at least four times in the last six years from 0.94% in 2012-13 to 0.26% in 2018-19, Prime Minister said this itself is a reflection of the trust that the Government is laying on the returnees. He said in the last 6 years, India has seen a new model of governance evolving in tax administration. Amidst all these efforts, he said the number of people filing income tax returns has increased by about 2.5 crores in the last 6-7 years.

The Prime Minister however said that it can also not be denied that only 1.5 Crore people pay the taxes in a country of 130 crores. Shri Modi urged people to introspect themselves and come forward to pay the taxes due. The Prime Minister said this would help in the making of a Self - Reliant India, *Atma Nirbhar Bharat.*

Source: PIB, PMO Press Release, 13.08.2020

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Scientists identify hundreds of drug candidates to treat COVID-19

Scientists at the University of California, Riverside, have used machine learning to identify hundreds of new potential drugs that could help treat COVID-19, the disease caused by the novel Coronavirus, or SARS-CoV-2. "There is an urgent need to identify effective drugs that treat or prevent COVID-19," said Anandasankar Ray, a Professor of molecular, cell, and systems biology who led the research. "We have developed a drug discovery pipeline that identified several candidates."

The drug discovery pipeline is a type of computational strategy linked to artificial intelligence - a computer algorithm that learns to predict activity through trial and error, improving over time.

With no clear end in sight, the COVID-19 pandemic has disrupted lives, strained health care systems, and weakened economies. Efforts to repurpose drugs, such as Remdesivir, have achieved some success. A vaccine for the SARS-CoV-2 virus could be months away, though it is not guaranteed.

"As a result, drug candidate pipelines, such as the one we developed, are extremely important to pursue as a first step toward systematic discovery of new drugs for treating COVID-19," Ray said. "Existing FDA-approved drugs that target one or more human proteins important for viral entry and replication are currently high priority for repurposing as new COVID-19 drugs. The demand is high for additional drugs or small molecules that can interfere with both entry and replication of SARS-CoV-2 in the body. Our drug discovery pipeline can help."

Joel Kowalewski, a graduate student in Ray's lab, used small numbers of previously known ligands for 65 human proteins that are known to interact with SARS-CoV-2 proteins. He generated machine learning models for each of the human proteins. "These models are trained to identify new small molecule inhibitors and activators - the ligands - simply from their 3-D structures," Kowalewski said.

Kowalewski and Ray were thus able to create a database of chemicals whose structures were predicted as interactors of the 65 protein targets. They also evaluated the chemicals for safety. "The 65 protein targets are quite diverse and are implicated in many additional diseases as well, including cancers," Kowalewski said. "Apart from drug-repurposing efforts ongoing against these targets, we were also interested in identifying novel chemicals that are currently not well studied."

Ray and Kowalewski used their machine learning models to screen more than 10 million commercially available small molecules from a database comprised of 200 million chemicals, and identified the best-in-class hits for the 65 human proteins that interact with SARS-CoV-2 proteins.

Taking it a step further, they identified compounds among the hits that are already FDA approved, such as drugs and compounds used in food. They also used the machine learning models to compute toxicity, which helped them reject potentially toxic candidates. This helped them prioritize the chemicals that were predicted to interact with SARS-CoV-2 targets. Their method allowed them to not only identify the highest scoring candidates with significant activity against a single human protein target, but also find a few chemicals that were predicted to inhibit two or more human protein targets.

"Compounds I am most excited to pursue are those predicted to be volatile, setting up the unusual possibility of inhaled therapeutics," Ray said. "Historically, disease treatments become increasingly more complex as we develop a better understanding of the disease and how individual genetic variability contributes to the progression and severity of symptoms," Kowalewski said. "Machine learning approaches like ours can play a role in anticipating the evolving treatment landscape by providing researchers with additional possibilities for further study. While the approach crucially depends on experimental data, virtual screening may help researchers ask new questions or find new insight."

Ray and Kowalewski argue that their computational strategy for the initial screening of vast numbers of chemicals has an advantage over traditional cell-culture-dependent assays that are expensive and can take years to test. "Our database can serve as a resource for rapidly identifying and testing novel, safe treatment strategies for COVID-19 and other diseases where the same 65 target proteins are relevant," he said.

"While the COVID-19 pandemic was what motivated us, we expect our predictions from more than 10 million chemicals will accelerate drug discovery in the fight against not only COVID-19 but also a number of other diseases."

Ray is looking for funding and collaborators to move toward testing *cell lines, animal models, and eventually Clinical Trials.*

(The research paper, "Predicting Novel Drugs for SARS-CoV-2 using Machine Learning from a >10 Million Chemical Space," appears in the journal Heliyon, an interdisciplinary journal from Cell Press. The technology has been disclosed to the UCR Office of Technology Partnerships, assigned UC case number 2020-249, and is patent pending under the title "Therapeutic compounds and methods thereof.") (Materials provided by University of California - Riverside. Original written by Iqbal Pittalwala. Note: Content may be edited for style and length)..

Source: University of California – Riverside, Science Daily, 12.08.2020 (Excerpts)

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D614G: Malaysia detects new Coronavirus strain that is 10 times more infectious

Malaysia has detected a strain of the new coronavirus that's been found to be 10 times more infectious.

The mutation, earlier seen in other parts of the world and called D614G, was found in at least three of the 45 cases in a cluster that started from a restaurant owner returning from India and breaching his 14-day home quarantine. The man has since been sentenced to five months in prison and fined. The strain was also found in another cluster involving people returning from the Philippines.

The strain could mean that existing studies on vaccines may be incomplete or ineffective against the mutation, said Director-General of Health Noor Hisham Abdullah.

While the rate of increase in Covid-19 new cases and deaths seems to be slowing down, the surge in new cases and fatalities last week (Aug 10-16) made it the deadliest yet in India. Covid-19 cases grew by a little over 4.3 lakh during the week at a rate of 5.9% significantly lower than the 10.9% growth in the previous week. This week reported 6,555 fatalities, a rise of 4.4%.

The mutation has become the predominant variant in Europe and the US, with the World Health Organization saying there's no evidence the strain leads to a more severe disease. A paper published in Cell Press said the mutation is unlikely to have a major impact on the efficacy of vaccines currently being developed.

"People need to be wary and take greater precautions because this strain has now been found in Malaysia," Noor Hisham wrote in a Facebook post on Sunday, 16.08.2020. "The people's cooperation is very needed so that we can together break the chain of infection from any mutation." While Malaysia has largely managed to prevent a resurgence of the virus seen elsewhere in the world, the number of new cases found in the country has been picking up. The country confirmed 26 new cases on Saturday, 15.08.2020, the most since July 28, and added 25 cases on Sunday, 16.08.2020.

Source: Bloomberg/The Times of India, 17.08.2020 (Excerpts)

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The new draft Environment Impact Assessment Bill is rubbing environmentalists the wrong way

One cheerful fact that has come out of the Covid-19 lockdown has been the accounts of the environment becoming cleaner. This, and a growing awareness about air pollution, has made a larger number of Indian's conscious of protecting the surroundings, say environment activists. However, the draft Environment Impact Assessment (EIA) Notification, 2020, released by the Government in March, undermines all these gains, they claim.

The Notification codifies the process to identify and evaluate the environmental effects of proposed development and industrial projects. It provides the basis of a plan to mitigate these effects. The latest draft is the third iteration of the code, first issued in 1994. Environmentalists and citizen groups, however, claim the Notification dilutes the provisions of the 2006 version and undermines the parent law, the Environment Protection Act of 1986. In 2010, the Environment Ministry issued a directive on a pathway to make violating projects comply with the rules.

The Ministry says the latest draft codifies and streamlines the 50 amendments, 230-odd office memorandums and orders of the National Green Tribunal and courts issued over 14 years. But the Chairman of the Parliamentary Standing Committee on Environment, Jairam Ramesh, does not think so. "It is not just a codification and systematisation of all the changes. It goes much beyond that."

A clause-by-clause analysis of the EIA shows the draft mostly does compile the changes, though some of these have been inimical to the environment. However, there are enough reasons to be concerned. Some provisions reduce the categories of projects that require environmental clearance, while others increase the threshold of exemptions.

Environment Minister Prakash Javadekar says it is "just a draft" and the Ministry "will take a call on these views only then the Notification will be finalised." The National Environmental Engineering Research Institute is now compiling and analysing the 17 lakh suggestions and objections received from the public. There has been a lot of criticism on at least two provisions — one deals with projects that violate the norms and the other limits public consultation and participation before a project is approved.

Poor monitoring, reporting and verification have led to non-adherence to environmental norms becoming a consistent problem. The parties concerned often start violating the green norms right from the construction stage. These laws are often forgotten during operations, expansion and modernisation of projects. The draft EIA lays out a process to deal with these violations. But critics say it "regularises" the violations retroactively and can encourage people to break the laws.

Ramesh, a former Environment Minister, says, "These laws have been around for 30 years and are not unknown. So why should there be a violation in the first place? This provision is like opening the door to not following the law, knowing that the Government will regularise the project." The draft gives violators an opportunity to get away with their actions, say some.

But Yasir Ahmad, Partner-Sustainability and Climate Change, PwC India, sees this as a welcome step. "It is a window for them to join the mainstream, with no guarantee that the appraisal process will give an outcome in their favour. This is a welcome step, while not encouraging defaulters."

Since the Notification of EIA 2006, it has become a common practice to allow a project to apply for clearance after committing a violation. The recent draft notes that such violations are recurring and these come to the notice of the authorities only after being committed. Therefore, the Ministry "deems it necessary to lay down the procedure to bring such violation projects under the regulations in the interest of the environment".

That is tantamount to the Government saying the rules aren't enforced properly, claim activists. "This is a big public admission from the Government that the EIA system suffers from a great number of violations and this is systemic," says Kanchi Kohli, Environment and Legal Researcher at the Delhi based Centre for Policy Research.

Another major bone of contention is the limiting of public participation in project clearance. The draft has reduced the number of days set aside for public hearing from 30 to 20. For some kinds of projects, it has barred citizens from reporting violations. Only the Government or the project proponent can report a violation. This is problematic because violators are often brought to the book by the efforts of people in the vicinity of the projects

or by Environmental Groups.

It is really sad, say critics, that the Ministry has missed an opportunity to address critical issues. The draft does not address climate change and biodiversity loss — among the top five risks facing the planet. There is nothing either on critical policy concerns such as resource efficiency or risks of accidents and disasters.

The EIA process needs to appreciate the importance of natural capital, says United Nations Chief Environmental Economist Pushpam Kumar. "There is a growing realisation of the contribution of nature to the economy. Environmental and economic policies must reflect this." It is not too late to make the required changes, says Kohli.

The worry that environmental concerns are taking a back seat becomes valid because of a sense of privileging economic and development activity. The fallout of the pandemic makes economic resurgence all the more urgent. But the legal framework must move beyond the conventional approach that development will cause some environment damage, say activists.

Even industry seems to understand the need to find a balance. "India must, for its own good, find ways to develop without causing permanent environmental damage," says Anirban Ghosh, Chief Sustainability Officer, Mahindra Group. "Our legislation and their implementation must signal that National Development and Environmental Rejuvenation will go hand in hand." It is time for us to be green while looking for green shoots.

Source: The Economic Times, 16.08.2020

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MoU between CSIR and FSSAI for collaborative research on food & nutrition

A Memorandum of Understanding aiming towards collaborative research and information dissemination in the area of food and nutrition was signed by FSSAI and CSIR recently. Dr Harsh Vardhan, Union Minister for Health and Family Welfare, presided the signing of MoU between Food Safety and Standards Authority of India (FSSAI) under Ministry of Health and Family Welfare and Council of Scientific and Industrial Research (CSIR) under Ministry of Science and Technology, in the presence of Ashwini K Choubey, Minister of State (HFW).

Congratulating both FSSAI and CSIR for this innovative step that will merge the potential and faculties of both the premier organisations, the minister stated that this MoU will enable identification of technologies and programmes to be developed in the area of food safety and nutrition research, along with recognition of innovative technologies available with CSIR for deployment by the Indian businesses and/or for regulating compliances.

"It will also seek collection of data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, identification of emerging risks, their mitigation strategies and introduction of rapid alert system. The two organisations will collaborate towards strengthening the quality assurance of laboratory network across the country aimed at development and validation of methods for reliable reporting on quality and safety of food products," Dr Harsh Vardhan stated.

Speaking on the MoU, Dr Harsh Vardhan said, "The MoU is a very significant step that will create a brighter future for India seeking collaborative research and information dissemination in the area of food & nutrition, and food and consumer safety solutions in India. The collaboration between these two premier institutions of India will contribute in fulfilling the vision of New Food System 2050."

The Minister also congratulated FSSAI on being selected as one of the 10 global organisations for the award by Rockefeller Foundation, in partnership with SecondMuse, and OpenIDEO for the 'Eat Right India' movement. The award recognises organisations that have developed an inspiring vision of the regenerative and nourishing food system that they aspire to create by the year 2050. He added that the award is a strong recognition of FSSAI's holistic and pathbreaking approach towards food safety and nutrition. It also provides the vision for its growth path.

"The vision of Health for All can be achieved through the twin measures of ensuring physical exercise and choosing nutritious food in our daily lives. The 'Eat Right India' vision is about creating a culture of safe, healthy and sustainable food involving all stakeholders and leveraging technology in food production, processing, distribution, quality and traceability and to empower consumers to adopt right eating practices," he said.

The Minister highlighted that the envisioned new food system of 2050 will see a surge in demand for healthy, nutritious, plant-based, local, seasonal and indigenous

foods, produced organically. He said it will also see an enhanced focus on climate friendly food production systems, conservation of land and water resources, reduction in food loss and food wastage across the value chain, increase in small-scale production units for self-sustaining local economies, use of environment-friendly packaging alternatives, repurposing of waste.

Choubey congratulated the recipients of the highly respected award launched by Rockefeller Foundation. He said, "The movement envisioned by India will lead to a revival of traditional Ayurvedic wisdom in ancient food practices, a variety of new employment opportunities to bring these measures into practice and support local and rural economies, particularly for women bringing about economic growth and gender equity."

"The MoU with CSIR will enable FSSAI to identify existing and novel technologies and programmes, collect data regarding food consumption, incidence and prevalence of existing emerging risks, develop a rapid-alert system and strengthen the quality assurance laboratory network for this purpose", he added.

Shekhar C Mande, DG-CSIR, Arun Singhal, CEO, FSSAI, and other senior officials of FSSAI and CSIR were also present on the occasion. Dr Amulya K Panda, Dr Sudesh Kumar Yadav of Center of Innovative and Applied Bioprocessing (CIAB, Mohali), an autonomous body under DBT, Dr Addanki Vamsi Krishna, scientist, DBT; and Directors of CSIR labs; KMKS Raghava Rao, Director, Central Food Technological Research Institute (CFTRI, Mysore), Dr Alok Dhawan, Director, Indian Institute of Toxicology Research (IITR, Lucknow), Dr Sanjay Kumar, Director, Institute of Himalayan Bioresource Technology (IHBT, Palampur),

Source: fnbnews.com, 12.08.2020

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Biological E signs pact with J&J for Covid-19 vaccine technology

Indian vaccine manufacturer Biological E, which is currently conducting clinical trials on a Covid-19 vaccine candidate, has signed an agreement with Johnson & Johnson for technology transfer of the latter's Covid-19 vaccine candidate that is now in phase 1/2a clinical trials. Biological E will produce J&J's vaccine at its vaccine production facilities and sell them both in India and export across various global markets.

The Hyderabad headquartered vaccine maker said in the recent years it has embarked on new initiatives for organisational expansion such as developing generic injectable products for regulated markets.

In a statement on Thursday, 12.08.2020 Biological E said it has entered into an agreement with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical firms of Johnson & Johnson, "for drug substance and drug product for Johnson & Johnson's COVID-19 vaccine candidate, Ad26.COV2.S."

Biological E Managing Director Mahima Datla said "Given the magnitude of the COVID-19 pandemic, our ability to mount an effective response will be predicated on the ability to supply the vaccine globally and in significant quantities. This is best achieved through collaboration."

Making it clear that BE will continue clinical trials on its own Covid-19 vaccine candidate, she told that the production capacities of Biological E's own vaccine candidate will be "between 50-80 million doses a month."

The vaccine is developed from a strain of SARSCoV-2 isolated by ICMR-National Institute of Virology, Pune.

Mahima refused to divulge the commercial terms Biological E entered into with J&J or the capacities of J&J to produce the vaccine in India.

Narender Dev Mantena, Director of BioE Holdings Inc., who heads Biological E's novel vaccine initiative, said, "We look forward to deploying our manufacturing infrastructure to support

Johnson & Johnson's commitment to global access for its COVID-19 vaccine."

The Hyderabad headquartered vaccine maker said in the recent years it has embarked on new initiatives for organisational expansion such as developing generic injectable products for regulated markets, exploring synthetic biology and metabolic engineering as a means to manufacture Active Pharmaceutical Ingredients sustainably and developing novel vaccines for global use.

Source: The Economic Times, 14.08.2020

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Bharat Biotech-ICMR developed Covaxin is safe, show preliminary Phase I results

Preliminary results of phase 1 clinical trials of the Bharat Biotech-ICMR developed Covid-19 vaccine, vaccine, Covaxin, suggest that the vaccine is safe, principal investigators conducting the trials told ET.

The vaccine is being tested on 375 volunteers who have enrolled at 12 sites in India. Two doses of the vaccine are being administered to each volunteer.

"The vaccine is safe. We have not observed any adverse events in any of the volunteers at our site," said Savita Verma, Principal Investigator, who is leading the trial at PGI, Rohtak.

While volunteers are being administered with the second dose, investigators are collecting blood samples which will test the immunogenicity of the vaccine.

"As of now we know that it is safe. The second step is to know how effective the vaccine is for which we have started collecting the samples," added Verma. The investigators are expecting to finish the Phase I by August end.

"We are in the process of giving a second dose to the healthy volunteers and so far, we have not seen anything unusual event in patients.

It is safe," said Sanjay Rai, Principal Investigator at All India Institute of Medical Sciences, Delhi. AIIMS had recruited 16 volunteers for testing the Bharat Biotech vaccine.

As the race to secure vaccines begins, the Government is keeping a close eye on developments. Covaxin is India's first vaccine candidate and is developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR). The vaccine is developed from a strain of SARS-CoV-2 isolated by ICMR-National Institute of Virology, Pune.

Once the safety data from all 12 sites shows desirable results, the company will approach the Drug Controller General of India for conducting Phase II trials. "If all goes well, the vaccine may be available in the first half of next year," said another investigator, on the condition of anonymity.

Source: The Economic Times, 14.08.2020

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Spooked by Donald Trump, Indian Pharma cos seeks Government help to woo Capitol Hill

US President Donald Trump has not just spooked the Indian IT companies, even the billion dollar Indian drug industry is rattled by the protectionist noises coming from White House. In a letter written to Arvind Panagariya, Vice Chairman Niti Ayog, the Indian Pharma lobby wants the Commerce Ministry, India's mission in Washington and New York to proactively engage with the Trump administration and lobby the Capitol Hill to seek policy changes that would favour Indian drug companies.

IPA whose members include leading domestic companies like Sun Pharma, Dr Reddy's, Lupin, Cadila Healthcare, Torrent Pharma among others are worried that the Trump Administration might get tough on issues like Intellectual Property Rights, or invoke the Trade Facilitation and Trade Enforcement Act of 2015 to curtail imports of medicines from India.

"The early signals from the Trump Administration do not auger well for the pharmaceuticals. India can look for and may get an opportunity to fill-in the void created by abolition of the Obamacare but it will not come easily. The future is not predictable," said D G Shah, Secretary General, Indian Pharmaceutical Association (IPA) in a letter dated February 28 to Panagariya.

Shah goes on to explain: "Irrespective of which way the Trump Administration moves, it is certain that exports of generics from India would be hit."

The IPA has sought Indian Government's intervention for faster clearances of their drug applications, quicker response of remedial actions after FDA's warning letters and faster resumption of drug supplies. On the back of

Indian Pharma players contributing the most to US FDA's Generic Drug User Fee - the payment generic players pay to US regulators to clear the applications - they expect a preferential treatment to filings from India.

IPA data demonstrates that since 2010, Indian Pharma investment in US has gone up by over 500 percent from Rs.4627 crore to Rs.25,133 crore. Indian drug companies have built their fortunes by making US as one of the key export markets. Today for the top four drug makers of India, over 40% of the revenues comes from the US market.

However in the last few years companies have come under the scrutiny of the US FDA, for non-compliance of Good Manufacturing Practice, some of India's largest companies like Sun and Dr Reddy's are facing an import ban in the US market that has hit their growth. Players like Wockhardt have stopped exports to US altogether after repeated US FDA bans.

Flagship units of Sun and DRL too are facing regulatory scrutiny and import bans. IPA fears that the inspection by the US FDA might only increase in the coming days as according to its data the US regulator has managed to inspect only 30% of the total FDA approved facilities in India.

Going by the statistics in the last six years FDA has consistently increased its scrutiny of Indian firms. Last week, the cream de la crème of Indian Pharma and global regulators including US FDA had congregated in Mumbai for the quality forum, where companies demonstrated their commitment to quality and the various actions they have taken in this direction.

"The quality forum not only brought the industry together towards a common cause of looking at the issues of industry from within, but also helped our company change the way it functions", said Dilip Shanghvi, MD Sun Pharma last week.

However regulators across the world wanted Indian companies to improve their quality checks. We are telling Indian companies that they need to take onus of developing quality products, investigate and follow up," said Mathew Thomas, US FDA India head.

The other issues that drug makers want India to take up with the US are to do with collaboration of Indian regulators with FDA, and a tougher stand regarding Intellectual Property Rights where both the countries have locked horns with each other over the provisions of Trade Related Intellectual Property Rights (TRIPS). To prove its importance, Shah lists out the contribution of Indian drug makers in US, besides providing low cost generics.

Source: The Economic Times, 14.08.2020

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NPPA sets up Price Monitoring and Resource Unit in Karnataka

In coordination with the Karnataka State Drug Control Department, the National Pharmaceutical Pricing Authority (NPPA) has set up a Price Monitoring and Resource Unit (PMRU) in the State. The first Governing Body meeting of this unit is likely to take place by end of this month to chalk out programmes, measures in creating consumer awareness as well as ensuring affordability and accessibility of medicines in the state.

The primary function of PMRUs is to assist the NPPA in monitoring prices of drugs, ensuring the availability of drugs and raising consumer awareness. The NPPA, under its Central Sector Scheme, named Consumer Awareness, Publicity and Price Monitoring (CAPPM), has already set up PMRUs in 12 States/UTs, including; Kerala, Odisha, Gujarat, Rajasthan, Haryana, Nagaland, Tripura, Uttar Pradesh, Punjab, Andhra Pradesh, Mizoram and Jammu & Kashmir.

The Board of Governors of a PMRU includes representatives from the Central, as well as State Government, concerned along with other stakeholders. The PMRU unit of Karnataka consists of a Governing body of seven members, which include; Jawaid Akhtar, Chairman of Karnataka PMRU (Additional Chief Secretary to Government, Health and Family Welfare department, Karnataka); Bhagoji T Khanapure, Vice Chairman of Karnataka PMRU (Drug Controller, Drug Control Department, Government of Karnataka); and Amresh Tumbagi, Member Secretary, (Additional Drug Controller-Drug Control Department, Government of Karnataka); followed by other members; Rajesh K Agrawal, Director, NPPA; Parvati Anand, Goudar, Principal Scientific Officer, Drug Testing Laboratory; Sunil Attavar, President, Karnataka Drug and Pharmaceuticals Manufacturers Association and Suresh Nagpal, President, Karnataka Pharmacy College Management Association.

Commenting on the PMRU unit in the State, Amresh Tumbagi, Member Secretary, PMRU Unit – Karnataka and Additional Drug Controller-Drug Control Department, Government of Karnataka said, “The key objective behind

setting up the unit is to ensure availability, accessibility as well as affordability of medicines in the State.

Although we have been monitoring the prices of medicines across the State, it is equally important to create awareness among the consumers about the fixed prices of medicines by the competent authority. Therefore, through this society, we will be executing several programmes which will help us in creating awareness about the quality as well as the prices of medicines across the State."

He also informed that as per the statutory procedures laid down by the NPPA, two technical staffs along with one coordinator for this centre will also be appointed. He said, "To begin the activities, in the next few days we will be finalising the date of the first Governing Body meeting, which is likely to take place by the end of this month."

Sunil Attavar, President, Karnataka Drug and Pharmaceuticals Manufacturers Association, commented, "Karnataka is the 13 state to set up the price monitoring and resource unit. The unit will provide support to the NPPA and State Drugs Control Department by monitoring the price of medicines, both scheduled and non-scheduled drugs so as to ensure that they are in compliance with the DPCO. The PMRU is a very consumer-centric initiative of the NPPA which will ensure that the consumers are not charged more than the mandated rates.

It could also ensure the availability of essential medicines at the grassroots level. The PMRU will also conduct district-wise programmes for the industry, trade and consumers so that they are updated and well aware." The NPPA also has plans to set up PMRUs in all the 36 States/UTs. Under the CAPPM scheme, the expenses of PMRUs, both recurring and non-recurring are borne by the NPPA.

Source: Usha Sharma, Express Pharma, 14.08.2020

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Indian Consulate holds virtual meet to attract foreign investors for PLI scheme, bulk drugs and medical devices parks

With an aim to facilitate and attract foreign investors for the Central Government announced Production Linked Scheme (PLI), three bulk drug and medical devices parks, the Indian Consulate organised a webinar on ***'India-US Partnership: Healthcare and Medical Research".***

Highlighting the objective and the potential of the recently announced schemes, Dr P D Vaghela, Secretary of Department of Pharmaceuticals, explained the long term benefits of schemes. He informed that foreign investors could also avail the scheme benefits provided they register the firm in India. Besides this, a joint collaboration between foreign firms and Indian companies is also permissible.

During the virtual meeting, Government officials from Himachal Pradesh, Gujarat and Andhra Pradesh presented an overview of the Pharma sector and key offerings to the investors in their respective States.

Development potential in Himachal Pradesh:

Ram Subhag Singh, Additional Chief Secretary, Himachal Pradesh, showcasing the benefits of the state, highlighted that power supply is a key element for the functioning of any industry and the state has a surplus of power supply. He also informed that there is flexibility in rate, which attracts the industry as it offers the lowest rate in the country. To build bulk drugs and medical device parks, the state has enabled the industrial ecosystem to provide Single Window Clearance System with online approval, dedicated nodal officers for projects above $50 million, investment promotion cell for hand holding, self- certification to set up ventures with a turnover up to $35 million, as well online tracking and monitoring by the CM of the state.

In his presentation, Singh highlighted that Himachal Pradesh has Asia's largest Pharma hub and caters up to 38 percent of Asia's demand. Presently, 40 percent of India's total drug formulations are manufactured in the State. The State has 14 US FDA approved, 18 UK MHRA certified and 202 WHO-GMP Pharma facilities. Besides, the state already has three Active Pharmaceutical Ingredients (APIs) clusters, and the Government has acquired approximately 3000 acres of land for setting up bulk drug and medical device parks. Considering the sizeable market for APIs and KSMs in the state, the Government feels that it is an ideal proposition for bulk drug manufacturers to consider Himachal Pradesh as a destination for backward integration.

Growth opportunities in Gujarat:

Informing about the benefits that Gujarat has planned to offer investors, M K Das, Principal Secretary, Gujarat informed that the state has identified 1000 acres of land for setting up a bulk drug park in Bharuch district and GIDC has already initiated the development work. Along with the bulk drug park, the state is also planning to have

a medical device park and has identified a 250-acre land for it in Rajkot.

Talking about the industry-friendly approach initiated by the state Government, he mentioned that a few days back, the Gujarat State Government has released a newindustrial policy. The policy aims to encourage investments in the state and also revive the economy. In the newly released industrial policy, the Government has introduced a new provision for land lease. According to it, the industries will be able to get Government land for projects on a long term lease of up to 50 years, at six percent of market share. Besides, the Government is also offering tailored relocation incentives to industries, but they will be offered on a case-to-case basis.

He informed that Gujarat is also considered as home to MSMEs and according to the MSME Act 2019, the State Government has exempted all MSMEs from obtaining approval for a period of three years, but to avail the benefits, companies need to start operations immediately.

Along with these, for new companies, the state also offers other incentives and it has reduced the base Corporate Fee from 25 percent to 15 percent, provided they start their operations by March 2023. Gujarat has Labour Law Ordinance 2020, and according to that, the State has issued an exemption for new companies from almost all labour laws in the State for a period of 1200 days.

During the presentation, Das mentioned that Gujarat is home to more than 120 US companies across various sectors. And the state's idea is to attract foreign investors. We are the biggest manufacturers as well as exporters in the world, and the State Chief Minister has already instructed to go complete online for all activities. He also assured foreign investors that the state has a legacy of good entrepreneurs and it will also be extending all kinds of support to foreign investors to accelerate growth momentum.

He also mentioned that Pharma and healthcare have been identified as core sectors in which Gujarat has a strong manufacturing base with the potential to accelerate further on a global scale. To encourage research and innovation activities in the state, the Government is extending financial support of up to Rs.50 million to private companies/ institutions for setting up R&D institutions/products.

Advantages in Andhra Pradesh:

Highlighting the growth trajectory of Andhra Pradesh, R Karikal Valaven, Special Chief Secretary, Andhra Pradesh said that the Government of Andhra Pradesh has initiated a Single-Window Clearance System which has benefited the industrial ecosystem. While touching upon the competitive advantage offered by the state Government to industries, he stated that Andhra Pradesh has an abundance of land banks for industrial development. The APIIC has over 300 industrial parks in the state spread over 43,234 acres with the addition of 10 Special Economic Zones. It has 30 Skill Development Centres along with two skill universities.

While divulging details about the Andhra Pradesh industrial policy 2020-23 with key fiscal incentives for manufacturing industries, he informed that the state Government has tailor-made incentives for investment proposals that promise to generate employment for more than 2000 people and offers flexibility for ultra-mega investment that have immense future benefits to the state.

Besides this, the state is also providing other incentives like 100 percent stamp duty reimbursement, power cost reimbursement of one rupee per KwH for five years, investment subsidy of 15 percent to Micro and Small Entities up to Rs. 20 lakhs. For women entrepreneurs and minority communities, it is 35 percent and up to Rs.50 lakhs.

He also mentioned that Andhra Pradesh Med Tech Zone (AMTZ) is India's first integrated medical device manufacturing park, set up on 270 acres of land, which is divided into phases. The aim is to flourish as a hub for medical devices manufacturing, putting India on the global map for high-end medical equipment production and make healthcare products affordable as well as accessible.

He also highlighted the areas of collaboration the medical device parks can offer and informed that for the proposed bulk drug park/API park, the Government has identified land in Kurnool, Nellore and Prakasam districts to accommodate 300 new units.

India-US stakeholder experiences:

Besides Government officials from the above-mentioned states, industry stakeholders like Sanjay Gupta, CEO, Torrent Pharma US; S Sridhar, Managing Director, Pfizer India; Jaswinder Matharu, Board of Director, Cadila Pharmaceuticals; Ravindra Pal Singh Dang, Managing Director, Baxter India and Mike Mehta, President and CEO, Phoenix Healthcare Solutions also shared their business experiences.

Sridhar said that earlier global Pharma markets were considered as hubs for innovation. Now, innovation

activities are also getting translated into the Indian market. However, he also suggested a few areas which need considerable attention from the Government such as fast track regulatory approvals, newer approaches in pricing policy, reforms in healthcare policy etc.

Gupta touched upon the challenges the company faced in India related to the US' regulatory requirements and spoke on the efforts needed to adhere with compliances. He also mentioned that the company is optimistic about the opportunities that exist in the US.

Dang showcased the company's engagement activities with the stakeholders across the healthcare sector. He also highlighted that Baxter India is engaged with the Government and industry bodies to support and shape conversations at policy and regulation levels. Matharu gave an overview of Cadila Pharma and its collaborations with firms in carrying out research activities.

Mehta commented that Phoenix Healthcare Solutions has a positive experience of investing in India, which includes obtaining educated, English-speaking workforce, accessing a large existing domestic market while providing the US clients diversification from dependence upon one country. He further stated that over the years, the supply chain is gradually developing to meet growing demand and helping to grow India-US partnership. He also informed that the company is planning to set up its second manufacturing site in India.

Source: Usha Sharma, Express Pharma, 12.08.2020

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India's shortage of Remdesivir is easing, Goa plant to ramp up production: Cipla

India's supply of antiviral drug Remdesivir and generic equivalents is stabilising after shortages of the vital Covid-19 medicine at hospitals, according to a top executive at one of the country's big drugmakers, Cipla Ltd.

Remdesivir, made by US-based Gilead Sciences Inc, has been in high demand globally, and a handful of companies including Cipla are authorised to make and sell generic versions in 127 developing nations.

Cipla's launch of Remdesivir in late June, along with subsequent launches by others, has helped ease supply bottlenecks in India, Cipla's Global Chief Financial Officer, Kedar Upadhye, told. "Of late, some of the complaints for supplies, and the number of panicky calls that I used to get, have come down dramatically," Upadhye said. "Looks like things have settled."

COVID-19 cases in India, the world's third-worst hit country, have surged in the past month, with new infections topping 50,000 daily. Yet while hospitals previously reported they were struggling to get their hands on the drug, leading to black market sales, Upadhye said the indications from his supply chain were that pressure had eased.

That suggested severe cases had not surged as much as the overall numbers, he said. Government data at the end of July showed about 0.3% of the country's Active Coronavirus patients were on ventilators, while 1.6% on intensive care unit support and 2.3% on oxygen support. Severe cases likely amounted to under 3% of all infections, said Giridhara Babu, an epidemiologist at the Public Health Foundation of India.

India, one of the world's biggest producer of generic drugs, recommends Remdesivir for moderate to severe COVID-19. Doctors also use other drugs, including Favirpiravir, another antiviral approved for the disease. Cipla, which is also free to export the drug, supplies it in South Africa and plans to expand access to "several sub-Saharan African countries", it has said.

India had previously blocked exports of another drug, Hydroxychloroquine, used by some doctors in treating the disease. The ban has since been lifted. Cipla declined to comment on the number of vials of Remdesivir it had shipped so far, but said it had started making the drug at a plant in Goa in western India to ramp up production.

Source: The Economic Times, 12.08.2020

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DoP appoints IFCI as PMA to implement PLI scheme to promote domestic manufacturing of key APIs & Medical devices

The Department of Pharmaceuticals (DoP) has selected IFCI Ltd (the erstwhile Industrial Finance Corporation of India Ltd), a non-banking Finance Company in the public sector, as the Project Management Agency (PMA) for smooth implementation of the Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) as well as medical devices.

IFCI Ltd has created web portals and email IDs for each of the PLI Schemes. It has unveiled web portal **http://plibulkdrugs.ifciltd.com** for implementation of PLI Scheme for promotion of domestic manufacturing of critical KSM/Drug Intermediates and APIs. For execution of PLI Scheme for promotion of domestic manufacturing of medical devices, it has launched another web portal **plimedicaldevices.ifciltd.com.**

The web portals contain relevant information about the Schemes, application forms and contact details, in case of any query of the applicant. The application needs to be submitted through an online portal maintained by the PMA within four months from July 27, 2020, the date of issuance of Guidelines for implementation of PLI Scheme for bulk drugs and medical devices.

IFCI Ltd will be responsible for appraisal of applications and verification of eligibility; examination of claims eligible for disbursement of incentive; compilation of data regarding progress and performance of the scheme including threshold investment and sales of manufactured goods of applicants selected under the scheme. The PMA will have the right to carry out physical inspection of an applicant's manufacturing units and offices through site visit.

An Empowered Committee (EC) chaired by CEO, NITI Aayog will consider applications, as found eligible by the PMA, for approval under the scheme. After receiving approval from the EC, the PMA will issue a letter to the selected applicant within 5 working days. The approval letter will clearly mention the name of applicant, target segment, eligible product(s), proposed investment, baseline (if applicable), scheduled date of commencement of production, ceiling of annual incentive, yearly threshold of cumulative investment and incremental sales of manufactured goods applicable for determining eligibility for incentive.

PLI scheme which is applicable only for Greenfield projects intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reducing India's import dependence in critical APIs. Under the scheme, financial incentives shall be given for six years based on sales made by selected manufacturers for 41 products which cover all the identified 53 APIs. The tenure of the scheme is from FY 2020-21 to FY 2029-30.

For fermentation based products including penicillin G, 7-ACA, erythromycin thiocynate, clavulanic acid, neomycin, gentamycin, betamethasone, dexamethasone, prednisolone, rifampicin, vitamin B1, clindamycin base, streptomycin, tetracycline, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%. The investment threshold limit for fermentation based products ranges from Rs.50 crore to Rs.400 crore.

For chemical synthesis based products--cyclohexane diacetic acid (CDA), 2-methyl-5 nitro-Imidazole (2-MNI), dicyandiamide (DCDA), para amino phenol, meropenem, atorvastatin, olmesartan, valsartan, losartan, levofloxacin, sulfadiazine, ciprofloxacin, ofloxacin, norfloxacin, artesunate, telmisartan, aspirin, diclofenac sodium, levetiracetam, carbidopa, ritonavir, lopinavir, acyclovir, carbamazepine, oxcarbazepine, vitamin B6, levodopa, incentive for FY 2022-23 to FY 2027-28 would be 10%.

The investment threshold limit for chemical synthesis based products ranges from Rs.20 crore to Rs.50 crore. Manufacturers of critical KSMs/DIs and APIs registered in India can apply for the scheme.

The PLI Scheme for promoting domestic manufacturing of medical devices aims to provide financial incentive to boost domestic manufacturing and attract large investments in the medical device sector. Currently the medical device industry depends on imports up to an extent of 86%. Domestic manufacturing is limited to surgical, cardiac stents and general medical devices and consumables.

The Scheme targets four categories of medical devices viz (1) cancer care/radiotherapy medical devices, (2) radiology & imaging medical devices (both ionizing & non-ionizing radiation products) and nuclear imaging devices, (3) anaesthetics & cardio-respiratory medical devices including catheters of cardio respiratory category & renal care medical devices, (4) AU Implants including implantable electronic devices.

The tenure of the Scheme is from financial year 2020-21 to Financial Year 2026-27. It is applicable for Greenfield projects. The companies registered in India and having net worth (of applicant company including that of group companies) not less than Rs.18 crore (i.e.30% of the threshold investment for the first year) as on the date of application are qualified to apply under the Scheme.

A maximum of 28 applicants shall be selected under the Scheme. A maximum of 10 applicants shall be selected under each target segment. A minimum of 3 applicants, if available, shall be selected under each target segment. Expenditure incurred on the new plant, machinery

and equipment shall be considered as investment for determining eligibility under the scheme.

Source: Laxmi Yadav, Pharmabiz, 17.08.2020

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Experts advocate need to assess risk profile of vaccines for COVID-19 amidst WHO disapproving Russian vaccine due to lack of clinical data

Experts have cautioned the Government about the need to assess risk profile of vaccines for COVID-19 amidst reports of World Health Organization (WHO) recently disapproving Russian vaccine 'Sputnik V' for COVID-19 due to lack of clinical data or evidence. History has proven time and again that vaccine trials and manufacturing must be handled with extreme caution to avoid infecting recipients or causing Severe Adverse Effects, they say.

"Whenever there is a discussion of vaccine trials, the infamous 'Cutter Incident' comes to mind which resulted in a major disaster around 40,000 children developed mild polio, 200 were permanently paralyzed and 10 children died. The incidence occurred due to a defective virulent strain of polio which was used in the development of vaccine causing paralysis and death," according to Dr Nitin Malekar, Geneticist and Healthcare Communication Professional.

Russia on August 11, 2020 had launched the COVID-19 vaccine, described by President Vladimir Putin as the world's first. According to WHO, there are six vaccine candidates in phase 3 or phase 2 to 3 combined trials around the world and roughly another 120 in various stages of clinical testing. Vaccine trials are primarily conducted to examine toxicity, immunogenicity, and Serious Adverse Effects (SAEs) of the vaccine agent. The vaccine must pass all the three stages of trial and prove to be safe and effective in target disease conditions before it is sent for regulatory clearance and after approval for the mass production.

The four-stage research study including the 4th stage of market surveillance is essential to gather precise information about the usage, adverse effects, and long-term immunity. Vaccine trials may take months or years to complete since a specific incubation period is necessary to react to the vaccine and develop the required antibodies. For most of the vaccines, single-dose administration is not sufficient to study the immune response, over-all immunity protection and long-term efficacy of the immune response which may eventually require booster doses.

"Once vaccine reaches the market, the important aspect is 'adverse effects', which may not get triggered by the first dose of vaccine but might get triggered or will become evident at the time of booster vaccination. In scientific language, these incidents are known as positive re-exposure," mentioned Dr Malekar. 'WHO' and partners have included nine experimental COVID-19 vaccines within an investment mechanism known as the Covax facility.

Talking with reference to tocilizumab which failed in phase III Clinical Trial recently, the drug which was lately promoted as an effective treatment in severe cases of COVID-19 to calm cytokine storm and reduce mortality, Ahmedabad based Pharma Consultant Dr Sanjay Agrawal argued, "There are absolutely no admissible clinical trials which can show clear evidence that tocilizumab is safe and effective for addressing COVID-19 cases. How regulators have permitted its off-label use and such kind of promotion by bypassing important phase III Clinical Trials is a serious question. Now the drug, having failed in phase III Clinical Trials, has also upset patients and the medical fraternity alike."

Echoing similar views Pharma Consultant Anshu Yadav pinpointed, "Tocilizumab had recently emerged as an alternative therapy for COVID-19 on randomized controlled trial and now did not meet its primary and secondary endpoint of improved Clinical status in patients with COVID-19 casting as persions on its safety and efficacy. In the recent phase III trial, it did not reduce severe respiratory symptoms, intensive care or death compared with standard care. Surprisingly, it is recommended by ICMR for emergency use. This hit and trial measure may cause more harm than good."

The most advanced potential vaccine candidates which have recently moved into clinical development include mRNA-1273 from US-based biotechnology company Moderna, Ad5-nCoV from Chinese biopharma company CanSino Biologicals and INO-4800 from American pharmaceuticals company Inovio. Others in the list include LV-SMENP-DC and pathogen-specific aAPC from Shenzhen Geno – Immune Medical Institute in China.

Source: Shardul Nautiyal, Pharmabiz, 17.08.2020

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NPPA issues final Guidelines for discontinuation of Scheduled Formulations

The National Pharmaceutical Pricing Authority (NPPA) has come out with final Guidelines regarding discontinuation of scheduled formulations under paragraph 21(2) of Drugs Prices Control Order (DPCO), 2013.

The National Drug Pricing Regulator in its 209th (overall) and 77th meeting held on August 6, 2020 has approved the final Guidelines to deal with intimations received in Form-IV (Schedule–II of DPCO, 2013) for discontinuation of production/import of scheduled formulations under para 21(2) of DPCO, 2013.

These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases, stated a circular issued by NPPA on August 14, 2020. Earlier in June 2020 NPPA released draft Guidelines for dealing with cases of discontinuation of scheduled formulations for stakeholders' suggestions.

Para 21(2) of the DPCO, 2013 provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of this order at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with the required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of 60 days of receipt of such intimation.

As per the Guidelines, companies may submit duly filled Form-IV (as per Schedule-II of DPCO, 2013) for intimation, duly signed and stamped by authorized signatory, for the discontinuation of the production of scheduled formulation with all the requisite documents on email ID: **monitoring-nppa@gov.in** at least six months prior to the intended date of discontinuation.

Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return email. Incomplete intimation without the requisite documents would be returned for resubmission and the same shall be informed to the applicant via email within 10 working days.

Wherever Moving Annual Turnover (MAT) of the company is 1% or less than 1% of the total MAT value, the company has to inform at least six months prior to the proposed/intended date of discontinuation and to issue public notice in at least one newspaper. Such cases will be noted without issuing any direction to the company and case will be deemed approved except where intimation has not been submitted six months prior to the proposed/ intended date of discontinuation.

Wherever MAT of the company is more than 1% of the total MAT value, company will be directed, with the approval of the Chairman, NPPA, within a period of 60 days from the receipt of Form-IV that intimation request has been noted and further directed to issue public notice in the prescribed formats in at least two national newspapers one in English and one in Hindi. The company will also be directed to continue production/import and sale of the formulation for a period of up to 12 months from the date of issue of public notice and to ensure that there is no shortage of the formulation during this period.

In spite of above provisions relating to discontinuation of scheduled formulation, whenever concerns regarding shortage is apprehended or a formulation is found to be critical for public health; based on circumstances and also in cases where it is established that the company is intending to discontinue production/import and sale of a scheduled formulation and has already launched or intends to launch a new drug to evade price control; cases requiring continuance of production/import and sale beyond 12 months or any other case; with the approval of Chairman, NPPA will be referred to a standing committee.

The standing committee will consist of Advisor (Cost), NPPA and representatives from CDSCO and Directorate General of Health Services (DGHS) as members of the committee. The recommendation of the committee will be put up to the authority.

MAT shall be calculated in value terms as defined in para 2 (s) of DPCO, 2013, except in cases where market share cannot be calculated by MAT in value, the same will be calculated by MAT in units. Market share is determined from a market database referred by NPPA. The company shall not reduce the level of production by more than 25% (of last year production in each quarter) after getting direction from NPPA.

The provisions of these Guidelines are also applicable to scheduled medical devices which have been notified as drugs by the Government from time to time. NPPA will upload a list of discontinuation of scheduled formulations

filed by pharmaceutical companies and approved by competent authority, on its website on a monthly basis.

Source: Laxmi Yadav, Pharmabiz, 17.08.2020

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Vaccine manufacturers Globally have capacity to produce 2-4 bn doses of COVID-19 vaccines till end of 2021: CEPI survey

Vaccine manufacturers globally have the capacity to produce 2 to 4 billion doses of COVID-19 vaccines till the end of 2021, according to a study by the Coalition for Epidemic Preparedness Innovations (CEPI). CEPI is an alliance to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics.

CEPI, in collaboration with the Bill & Melinda Gates Foundation, The Clinton Health Access Initiative and PATH – undertook a worldwide survey of vaccine manufacturers to understand capabilities, capacities and interest in responding to the pandemic. This finding is important for CEPI's wider COVID-19 response, as it aims to distribute 2 billion doses of COVID-19 vaccine by the end of 2021 through a programme called COVAX.

Between April 3, and June 19, 2020, CEPI invited vaccine manufactures from around the world to take part in a survey to assess what manufacturing capacity was available to produce drug substance and drug product in the coming months, specifically between October 1, 2020, and December 31, 2021.

A key objective of this survey was to understand how COVID-19 vaccine manufacturing could be scaled up without affecting the manufacture of other important vaccines and to identify additional capacity in the global manufacturing system for both drug substance and drug product.

According to the study, India has the largest capacity in the world to make drug substances, which are needed to develop vaccines, followed by Europe and North America. A total of 113 manufacturers from over 30 countries responded to the survey, while 43 respondents were both drug-substance and drug-product manufacturers. Around 56 were drug-substance manufacturers only.

CEPI stated that India has the largest production capacity for drug substances specifically for microbial or yeast expression systems; recombinant protein from suspension cells; recombinant protein from insect cells; viruses; and DNA. For drug product, the base-case estimates showed that China has the largest production capacity, followed by North America, and the rest of Asia and Oceania.

Source: Yash Ved, Pharmabiz, 11.08.2020

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CSIR-IICT urged to promote Industry-Academia Partnership to boost research in Bulk Drugs

The CSIR-Indian Institute of Chemical Technology (CSIR-IICT), Hyderabad has been urged to take a lead in promoting the Industry-Academia Partnership, particularly in the fields of Pharmaceuticals and bulk drugs so that it would help the Department of Pharmaceuticals (DoP), to establish centers of excellence in the bulk drug research in the country.

While taking part in the 77th foundation day programme of CSIR-IICT recently, DoP Secretary Dr P D Vaghela appreciated the initiatives taken by CSIR-IICT in developing the technologies for repurposing of drugs. "CSIR-IICT's efforts to develop new technologies which lead to the repurposing of drugs have enabled the institute to collaborate with lead drug makers like Cipla. This collaboration will soon be launching the Favipiravir drug, which will now be made available at much lower cost," said Dr Vaghela.

He urged CSIR-IICT to Champion, Industry-Academia Partnership and help DoP to establish Centers of Excellence in bulk drug research in three NIPER institutes identified. He requested CSIR and CSIR-IICT in particular to play a dominant role in preparing R&D policy of Government of India for the Pharmaceutical sector.

Dr Vaghela emphasized that the need of the hour is to reduce the dependence on imports of critical chemicals, and expects CSIR-IICT to take significant role in making India self-reliant in Pharmaceutical sector. Currently Key Starting Materials (KSMs) and APIs (Active Pharma Ingredients) that are of critical importance are imported. DoP will come forward to support CSIR-IICT in developing & transferring indigenous technologies for some of these materials.

The Secretary also informed that DoP is planning to allot Rs.1,000 crore to develop Pharma parks in various

states. The companies setting up their units in these parks will be eligible for incentives from the state and central Governments. He said that seamless procedures are required in providing skilled staff, scientists, Academia-Industry relationship for a continuous research in the country.

Such a process can make Pharma products competitive and reduce the dependence on imports. He said that DoP will look upon institutes like CSIR-IICT in helping the State Governments develop common utilities like ETP, steam generation, analytical facilities, pilot plants, etc.

He also felt that there is need to promote industry-academia coordination in the country and the Government is ready to provide funding and planning to propose incentives to encourage scientists, manufacturing sector and the academia.

Dr Shekhar C Mande, Director General, CSIR, also felt that the industry-academia relationship is very important. He assured Dr Vaghela that CSIR will extend all possible collaboration in making India an *Atmanirbhar Bharat* by actively participating in R&D programmes and in building industry-academia relationships.

Dr S Chandrasekhar, Director of CSIR-IICT, said the repurposing of Favipiravir was the beginning and the institute is working to deliver solutions for betterment of the society. "Repurposing of drugs could now become the mainstream of research," he said.

Source: A Raju, Pharmabiz, 10.08.2020

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The MSME Concern

In line with the Central Government's clarion call for making the country *Atma Nirbhar* (self-reliant) in the Pharma sector, the Department of Pharmaceuticals on July 21, 2020 has come out with a notification for Rs.3,000 crore bulk drug parks' promotion scheme and Rs.6,940 crore 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.

It is a fact that India has, over the years, adorned the epithet of 'the Pharmacy of the World' and this has been proved true especially in the ongoing COVID-19 pandemic when India continued to export critical life-saving medicines to the entire world, including developed nations, even during the period of countrywide lockdown which was in force from March 25 and continued till June.

However, despite these achievements, it is a matter of serious concern that India is still critically dependent on Chinese imports for basic raw materials that are used to produce some of the essential medicines. Now, the PLI schemes for promoting domestic manufacturing of KSMs, DIs and APIs will go a long way in boosting domestic manufacturing of 53 bulk drugs, on which India is critically dependent on imports from China. Earlier, a committee on drug security constituted by the DoP had identified 53 APIs for which the country is heavily dependent on imports.

The list of 41 products contained in the scheme Guidelines will enable domestic production of 53 bulk drugs. Under the scheme, financial incentives will be given to a maximum of 136 manufacturers selected under the scheme as a fixed percentage of their domestic sales of these 41 products manufactured locally with the required level of domestic value addition. The incentives would be subject to annual ceilings communicated in the approval letter. The incentives would be given for a period of 6 years.

In the case of fermentation-based products, the rate of incentive is 20% for the first four years, 15% for the fifth year and 5% for the sixth year. In the case of chemically synthesised products, the rate of incentive is 10% for all six years. However, there are murmour of protests from the MSMEs who feel that they are deprived of the benefits under the PLI scheme because of the threshold investment criterion.

As per the scheme, the selected manufacturers will have to make a threshold investment mandated for each product and achieve a prescribed minimum installed capacity before they are eligible to receive incentives. According to the guidelines for the scheme issued by the DoP on July 27, 2020, Rs.20 crore is the threshold investment to become eligible for manufacturing 23 out of the total 53 chemically synthesized KSMs, DIs and APIs.

There are more than 2,000 MSMEs involved in API and drug intermediate manufacturing in the country. Due to Rs.20 crore threshold investment limit, these MSMEs will not become eligible for the PLI scheme. Perturbed over the issue, the *Laghu Udyog Bharati*, an association of MSMEs, has urged the Government to do away with the threshold investment criterion of Rs.20 crore proposed in the Guidelines for the scheme.

It is a fact that the MSMEs played a crucial role in ensuring affordable drugs to the consumers over the last four decades of the pharmaceutical industry's pompous march in the country. They can also play a significant role in making India self-reliant in bulk drug production also. The government should seriously consider the concerns raised by the MSMEs to make them eligible for availing the monetary benefits under PLI scheme.

Source: Ramesh Shankar, Pharmabiz-Editorial, 05.08.2020

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AIOCD seeks PM's intervention to streamline Telemedicine Guidelines as per D&C Act & Pharmacy Act to curtail abuse of prescription drugs

The All India Organisation of Chemists & Druggists (AIOCD), a representative body of around 8.5 lakh chemists across the country, has sought intervention of Prime Minister Narendra Modi to streamline the Telemedicine Guidelines in accordance with provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder and Pharmacy Act, 1948 to prevent misuse of prescription drugs posing a risk to public health.

On March 25, 2020 Telemedicine Guidelines were notified by the Board of Governors in supersession of Medical Council of India by amending the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002.

Welcoming the Guidelines, AIOCD in a letter to the Prime Minister recently stated that telemedicine consultation has the apparent objective to ease access to healthcare for patients. However, in order to make telemedicine consultation effective and protect public health, it should be done in accordance with the provisions of Drugs and Cosmetics Act and Pharmacy Act and Rules made thereunder, said AIOCD President J S Shinde.

Mr Shinde said as per the Telemedicine Guidelines, doctors can in professional discretion prescribe medicines via tele-consultation by sending photo, scan and digital copy of a signed prescription or e-prescription to the patient via email or any messaging platform or by transmitting the prescription directly to a pharmacy. Prescribing drugs digitally is contradictory to D&C Act and Pharmacy Act.

There are ill consequences of prescription drugs if consumed without medical advice and a significant rise in antibiotic resistance is reported due to drug abuse and self-medication. Rule 65(11)(c) of the Drugs & Cosmetics Rules, 1945 provides that at the time of dispensing prescription medicines, the pharmacist should stamp the medicines as dispensed on prescription to stop people from getting the same prescription drugs from multiple pharmacies, he pointed out.

The Telemedicine Guidelines allow doctors to issue prescription by sending photograph of scanned copy of the prescription to patients. The scanned copy of prescription or photograph of prescriptions is not valid under applicable laws since it cannot be stamped to prevent multiple dispensations. In absence of stamping on prescription, there will be multiple dispensing of prescription which can lead to increase in self-medication. This could subsequently result in antibiotic resistance, said AIOCD President.

Outbreaks of a new antimicrobial resistance (AMR) bacteria/superbug will not only cause grave health loss and economic loss to the country but it can also bring disrepute to the country for not taking timely and remedial steps, he cautioned. Antidepressant drug addiction, dependence on sleeping pills, habit forming prescription medicines are well known phenomena in India. Multiple dispensing and over dosages of such medicines can cause impairment of mental faculties and can be fatal.

To obviate this risk, Shinde appealed to the central Government to establish a national portal on which the doctors can email prescription and the patients or the pharmacist can access the prescription by using a unique OTP. The pharmacist can, after dispensing the prescription, either deface it or specify the quantity of medicine dispensed on the national portal itself so that once the medicines are dispensed the prescription cannot be reused. Until this portal is set up, the doctors should not be allowed to issue scanned prescriptions in telemedicine consultation, he stated.

Taking exception to classification of medicines in List O, List A and List B by Telemedicine Guidelines, Rajiv Singhal, General Secretary, AIOCD said "D&C Act which Medical Practitioners and chemists are accustomed with has a different list namely Schedule H, Schedule H1 and Schedule X. The new classification is likely to cause confusion that can lead to wrongful prescribing or wrongful dispensation." Singhal suggested that the List O, List A and List B in the Telemedicine Guidelines should be done away with.

AIOCD expressed concern over the location of doctors offering tele-consultation, saying that doctors should be

allowed to do tele-consultation only in the same city or town where they are practicing as they have better understanding of recent outbreaks or common symptoms in the local population.

The trade body further stated that in case a patient wants to consult a specialist doctor in another city or town, the same should be permitted through a three way consultation between patient, local Medical Practitioner and the specialist. AIOCD has taken exception to tele-medicine consultation offered by e-pharmacies directly or indirectly, saying that the tele-consultation provided by them amounts to solicitation of patients by doctors as internet pharmacies dole out incentives to the physicians to prescribe medicines.

Source: Laxmi Yadav, Pharmabiz, 07.08.2020

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INTERNATIONAL NEWS

Coronavisus: Gilead seeks US Approval for Drug that shortens Covid recovery time

Gilead Sciences Inc has filed an application with the US Food and Drug Administrationseeking full approval for Remdesivir, its experimental COVID-19 drug currently used under emergency authorization, the drugmaker said on Monday-(10.08.2020).

The antiviral drug, which helped shorten the hospital recovery time in a US trial, has been at the forefront of the battle against the pandemic after the FDA granted it Emergency Use Authorization (EUA) in May. The authorization cleared the way for broader use of the drug in more hospitals around the United States, which has recorded over 162,600 COVID-19 deaths and over 5 million infections. But the EUA status is designed to be temporary.

Gilead said its marketing application for Remdesivir, to be sold under brand name Veklury, is supported by data from two late-stage trials conducted by the drugmaker and another by the National Institute of Allergy and Infectious Diseases.

Remdesivir has already been approved by multiple regulatory authorities around the world, including in the European Union, Australia and Japan. The US Government has secured nearly all of Remdesivir's supply through September.

To boost the drug's availability globally, Gilead has signed multiple manufacturing and supply deals, including with Pfizer Inc and Britain's Hikma Pharmaceuticals Plc. A bipartisan group of state attorneys general urged the US Government last week to allow other companies to make Remdesivir to increase its availability and lower prices. Shares of Gilead were down 1.5% in late afternoon trading. Oppenheimer analyst Hartaj Singh said investors are worried that if Gilead cannot secure full approval until at least by the end of the year, it might not be able to meet 2020 sales estimates for the drug.

"On many occasions, Government entities are expressly forbidden from buying or utilizing drugs not approved by the FDA and other regulatory authorities." Consensus sales expectations for remdesivir are up to $2.2 billion for the year, Singh said, after Gilead raised its full-year sales target last month to include revenue from the drug.

(Except for the headline, this story has not been edited by NDTV staff and is published from a syndicated feed.)

Source: Reuters/ndtv.com/world-news, 12.08.2020

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Companies test antibody drugs to treat, prevent COVID-19

With a Coronavirus vaccine still months off, companies are rushing to test what may be the next best thing: antibody drugs that fight the virus right away, without having to train the immune system to do the job.

With a Coronavirus vaccine still months off, companies are rushing to test what may be the next best thing: drugs that deliver antibodies to fight the virus right away, without having to train the immune system to make them. Antibodies are proteins the body makes when an infection occurs; they attach to a virus and help it be eliminated.

Vaccines work by tricking the body into thinking there's an infection so it makes antibodies and remembers how to do that if the real bug turns up. But it can take a month or two after vaccination or infection for the most effective antibodies to form. The experimental drugs shortcut that process by giving concentrated versions of specific ones

that worked best against the Coronavirus in lab and animal tests.

"A vaccine takes time to work, to force the development of antibodies. But when you give an antibody, you get immediate protection," said University of North Carolina virologist Dr Myron Cohen. "If we can generate them in large concentrations, in big vats in an antibody factory, we can kind of bypass the immune system."

These drugs are believed to last for a month or more and could give quick, temporary immunity to people at high risk of infection, such as health workers and housemates of someone with COVID-19. If they proved effective and if a vaccine doesn't materialize or protect as hoped, the drugs might eventually be considered for wider use, perhaps for teachers or other groups.

They are also being tested as treatments, to help the immune system and prevent severe symptoms or death. "The hope there is to target people who are in the first week of their illness and that we can treat them with the antibody and prevent them from getting sick," said Dr Marshall Lyon, an infectious disease specialist helping to test one such drug at Emory University in Atlanta.

Having such a tool "would be a really momentous thing in our fight against COVID," Cohen said. Vaccines are seen as a key to controlling the virus, which has been confirmed to have infected more than 20 million people worldwide and killed more than 738,000. Several companies are racing to develop vaccines, but the results of the large final tests needed to evaluate them are months away.

The antibody drugs are "very promising" and, in contrast, could be available "fairly soon," said Dr Janet Woodcock, a US Food and Drug Administration official who is leading Government efforts to speed Covid-19 therapies. Key studies are underway and some answers should come by early fall.

One company, Eli Lilly, has already started manufacturing its antibody drug, betting that studies now underway will give positive results. "Our goal is to get something out as soon as possible" and to have hundreds of thousands of doses ready by fall, said Lilly's Chief Scientific Officer, Dr Daniel Skovronsky.

Another company that developed an antibody drug cocktail against Ebola — Regeneron Pharmaceuticals Inc — now is testing one for Coronavirus. "The success with our Ebola program gives us some confidence that we can potentially do this again," said Christos Kyratsous, a Regeneron microbiologist who helped lead that work.

Regeneron's drug uses two antibodies to enhance chances the drug will work even if the virus evolves to evade action by one. Lilly is testing two different, single-antibody drugs — one with the Canadian company AbCellera and another with a Chinese company, Junshi Biosciences. In July, Junshi said no safety concerns emerged in 40 healthy people who tried it and that larger studies were getting underway.

Others working on antibody drugs include Amgen and Adaptive Biotechnologies. The Singapore biotech company Tychan Pte Ltd also is testing an antibody drug and has similar products in development for Zika virus and yellow fever. "I'm cautiously optimistic" about the drugs, said the nation's top infectious diseases expert, Dr Anthony Fauci. "I'm heartened by the experience that we had with Ebola," where the drugs proved effective.

What could go wrong?

The antibodies may not reach all of the places in the body where they need to act, such as deep in the lungs. All the antibody drugs are given through an IV and must make their way through the bloodstream to wherever they're needed.

The virus might mutate to avoid the antibody — the reason Regeneron is testing a two antibody combo that binds to the virus in different places to help prevent its escape. Skovronsky said Lilly stuck with one antibody because manufacturing capacity would essentially be cut in half to make two, and "you will have less doses available." If a single antibody works, "we can treat twice as many people," he said.

The antibodies might not last long enough. If they fade within a month, it's still OK for treatment since COVID-19 illness usually resolves in that time. But for prevention, it may not be practical to give infusions more often than every month or two.

A San Francisco company, Vir Biotechnology Inc., says it has engineered antibodies to last longer than they usually do to avoid this problem. GlaxoSmithKline has invested $250 Million in Vir to test them.

Giving a higher dose also may help. If half of antibodies disappear after a month, "if you give twice as much, you will have two months' protection," Lilly's Skovronsky said. The big fear: Antibodies may do the opposite of what's hoped

and actually enhance the virus's ability to get into cells or stimulate the immune system in a way that makes people sicker. It's a theoretical concern that hasn't been seen in testing so far, but large, definitive experiments are needed to prove safety. "As best as we can tell, the antibodies are helpful," Lyon said.

Source: Marilynn Marchione, ABC News, 12.08.2020 (Excerpts)

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Explained: Will Trump's order to buy American medicines impact Indian Pharma Industry?

The US is the largest market for India's Pharmaceutical products. It is said that every third pill sold in America is made in India

Prabha Raghavan

The US, like India, seems to have realised the need to maintain domestic capacities of essential medicines. (Getty Images/Representational)

US President Donald Trump has signed an order aiming to boost domestic production of "essential medicines" and "critical" drug inputs. What would this move mean for India, which is one of the largest overseas suppliers of medicines to the US?

What does Trump's order say?

The US President on Thursday, 06.08.2020 directed each executive department and agency involved in medicine procurement to identify vulnerabilities in supply chains for essential drugs. The order mandates the creation of a list of essential medical products and directs the fast-tracking of regulatory clearances for domestic producers.

Federal agencies are to consider a "variety" of actions to increase their procurement of such products and their critical ingredients from domestic sources while protecting the country's service members, veterans and their families from increases in drug prices. They also have to ensure that the measures they implement do not interfere with America's ability to respond to the Covid-19 outbreak.

Why led to the move?

The US, like most countries, is dependent on countries like China and India for critical products like medicines. This dependence put the Trump administration in a tight spot during the pandemic, which highlighted the extent of their presence in global supply chains.

For instance, when China's Hubei province went into lockdown earlier this year, it strained India's supply of certain critical medicines, including paracetamol, to the world. At that time, India restricted exports of 13 critical key ingredients, ranging from essential antibiotics to vitamins, as well as the medicines made from these. This is because India is heavily dependent on China for these ingredients and wanted to safeguard its own domestic supply until Hubei's lockdown was lifted.

When Trump began touting hydroxychloroquine as a 'miracle' in Covid-19 treatment, India was found to be the largest supplier. Trump in April held calls with Prime Minister Narendra Modi to release stocks of this drug to the US and, at one point even threatened retaliatory action if restrictions were not lifted. Like India, the US seems to have realised the need to maintain domestic capacities of essential medicines.

"These domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID-19," stated Trump's order.

"It is critical that we reduce our dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation's Public Health Industrial Base to respond to these threats".

How important is the US as a Pharma market for India?

The US is the largest market for India's pharmaceutical products. It is said that every third pill sold in America is made in India.

According to the Pharmaceutical Export Promotion Council of India (Pharmexcil) India's pharmaceutical exports to the US are ex-factory valued at around $6 billion. Unlike China, which is heavily present in the global pharmaceutical supply chain as a producer of key drug ingredients, India is known as an exporter of finished pharmaceutical products. Its generic drugs are popular in the US due to their low cost, which makes them more affordable.

How will this order impact Indian drug makers?

Trump's order does not specify any one country, though industry executives and Government officials here claim it will mainly target China. Several experts tracking India's pharmaceuticals industry feel the move could also be posturing by Trump before the presidential election in November.

Regardless of the motive, in the short term, the order is not likely to impact Indian pharmaceutical firms, they say. A major reason is that Indian drugs are "largely" not involved in US Public Procurement Processes, according to Pharmexcil Chairman Dinesh Dua.

"As the USA is a member of the WTO procurement agreement, they don't encourage Indian companies to participate in Public Procurement Processes and mainly involve the US, EU and other members," he said. Another reason is because of some exemptions that the order gives.

For instance, the order will not apply in cases where procuring domestic essential medicines will bring costs for the agency up over 25%. Nor does it apply in cases where there are no sufficient domestic alternatives.

However, some are cautious about possible larger consequences. "This won't be limited to federal procurement. There are other bills being worked on which will mandate CMS (the Centers for Medicare & Medicaid Services) to buy local.

That is a very large segment. This order is just a sense of what is to come," said Public Health Activist Dinesh Thakur, who studies the US and Indian Pharma markets and their regulations.

Source: The Indian Express, 08.08.2020

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We need to build a 'digital culture' for Pharma Research: Sauri Gudlavalleti, Global Head, IPDO, Dr Reddy's Laboratories Ltd

A 2017 McKinsey report describes Digital in healthcare R&D as a $100 bn opportunity. The top 7 Indian generic Pharmaceutical companies spend over $1.5 bn a year in R&D and develop hundreds of products each year. In the current pandemic situation, there is a need to expand Pharmaceutical research efforts while still maintaining lean lab presence for safety reasons.

Digital technologies can help unlock significant resource efficiencies, enable deeper scientific insights, and develop higher quality products. However, achieving these benefits at scale requires the R&D organisation to build a "digital culture", where people not only rapidly adopt, but constantly develop innovative digital solutions to problems. Building such a culture requires four types of interventions.

Start from the top:

An informed and inspired leadership is essential to chart out a clear and coherent digital vision, sponsor digital programs, and communicate their potential value to the

entire organization. Therefore, senior R&D leaders and domain experts must develop an understanding of emerging digital technologies and an appreciation of their potential impact on their own domains. An effective way to achieve this is to draw parallels by taking them on a sensing journey in non-Pharma product development.

For instance, by exploring the similarities between the elimination of bugs in software and the avoidance of deficiencies in regulatory submissions; or, by examining how creating multiple variants of one cellphone chip for multiple cellphone models is similar to using one Active Pharmaceutical Ingredient in multiple formulations.

Showcase impact through early wins:

Creating successful use-cases through the deployment of select tools will help build organizational conviction in the power of digital. Initially, the focus can be on digitizing manual workflows and data collection, simplifying literature search, automating routine data extraction, documentation and verification, and giving more scientists access to a few advanced analytical and modelling techniques. The productivity and convenience

benefits of these tools will encourage adoption. Additionally, they help create "clean data" which will be the foundation for advanced analytics applications in the future. Accelerating R&D while ensuring personnel safety in the current pandemic situation also needs immediate investment in tools that allow scientists to remotely control laboratory equipment, trouble-shoot production issues, and transfer process technologies to distant sites.

Build capability and capacity:

First, a pool of "digital translators" must be built, who can combine domain expertise with an understanding of digital tools. Curious early adopters in R&D domains are ideal for this. They may be taken through a focused digital immersion program that blends online, classroom and experiential learning, followed by "what-if" ideation sessions on how to radically transform their domain activities using digital tools. To build capacity in the larger organization it will be necessary to hand-hold all team members in adopting the initial tools to the fullest extent, as well as to facilitate wider exposure by creating broad-based learning modules and holding lecture/ demonstration events. As the tools gain adoption and clean data begins accumulating, digital translators must start ideating more advanced use cases with predictive capabilities using science-based or artificial intelligence enabled models.

Incorporate in formal processes:

Now, it is time to close the loop and make digital transformation a formal priority. Leaders' annual scorecards must have specific digital transformation deliverables, while a share of the digital translators' time must be dedicated to these programs.

For the rest of the organisation, performance management can incorporate digital skill building, tool adoption and idea generation. Program deliverables must not stop with implementation of digital use cases, but need to go all the way to converting it into value realization in terms of increased number or value of products developed. Digital tools are essential to accelerate scientific solutions, increase resource productivity, improve product quality as well as to generate "clean" data for future applications.

Especially in the current situation which demands faster development amidst multiple physical constraints. It is imperative for Pharma R&D organisations, both generic and innovator, to build a digital culture using a concerted approach.

(DISCLAIMER: The views expressed are solely of the author and ETHealthworld.com does not necessarily subscribe to it. ETHealthworld.com shall not be responsible for any damage caused to any person/organisation directly or indirectly).

Source: ET-Health World, 29.07.2020

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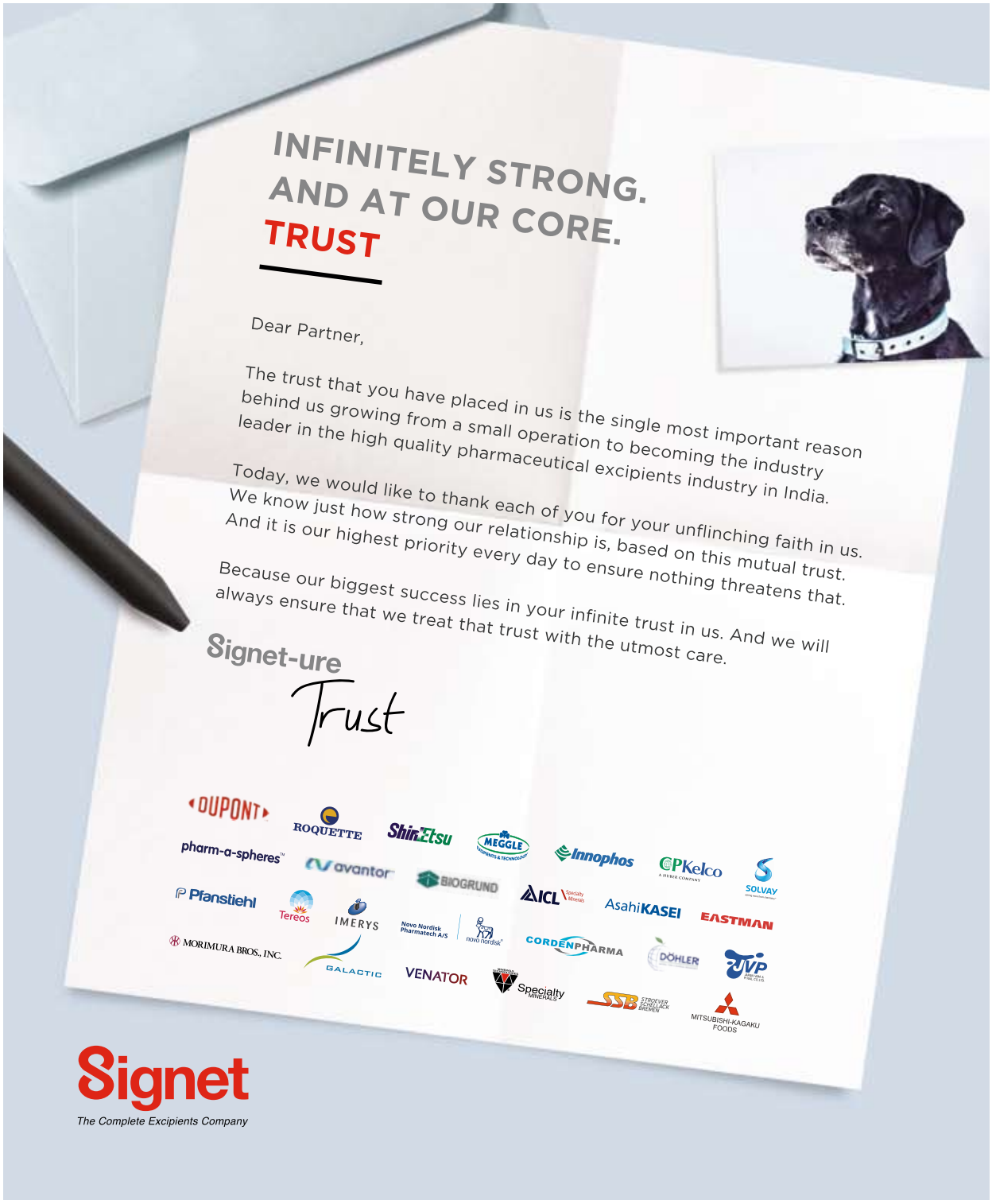
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