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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 16** **22 to 30 April 2021**

NORTH CAROLINA
DEPARTMENT of COMMERCE

Roy Cooper
GOVERNOR

Machelle Baker Sanders
SECRETARY

April 14, 2021

Dear Pharmaceutical Leader:

As North Carolina's newly appointed Secretary of Commerce, allow me to introduce you to our state's esteemed business-friendly environment, including one of the leading pharmaceutical and manufacturing clusters in the United States. It is supported by a top-rated college and university system and is immersed in a rich and diverse culture.

North Carolina has invested in building its life sciences sector since the mid-1980s. The results are apparent today with 775 companies and a diverse and talented workforce of 67,000. This robust ecosystem also includes approximatively 2,500 specialized support companies and suppliers, and several private-sector organizations.

Pharmaceutical and medicine manufacturing is the largest part of our life sciences cluster, with 30,000 skilled people making specialized pharmaceutical and biological products. We're proud to count Accord Healthcare, Aurobindo, Glenmark, and KriGen among those companies, alongside other major pharmas including Baxter, GSK, Novo Nordisk, and Pfizer.

These companies come to North Carolina — and grow here — because of the state's strong business climate and low operating costs. Our building costs, electricity rates, and cost of living all sit below the national average. North Carolina, in fact, ranks as the nation's best state for business in multiple publications including *Forbes*. A 2020 survey by the Boyd Company found the cost of operating a biopharma manufacturing facility in North Carolina's Research Triangle Region was the lowest in the U.S.

These companies wouldn't succeed without trained talent. Our universities graduate 4,900 people with life sciences degrees annually, along with 4,500 engineers. Our NCBioImpact training partnership aligns coursework at universities and community colleges with industry jobs, supporting a strong workforce pipeline. Our state created the first process technician training program to meet the needs of our biopharma manufacturing companies.

Proof of North Carolina's strengths lies in 10 companies announcing new biopharma manufacturing facilities in North Carolina last year. In total, these companies are investing $2.3 billion in facilities to produce pharmaceuticals and biologics. This year is already off to a great start, with three companies announcing more than $300 million in investment.

As a native North Carolinian, I can also personally attest to the strength of this ecosystem through my own education and career. I graduated from public schools, received a biochemistry degree from a public university and worked for more than twenty years as an executive in the life sciences sector in the state before I entered public service. I know what it takes to manage a successful life sciences operation and I am confident you will find all of the necessary components in a North Carolina location.

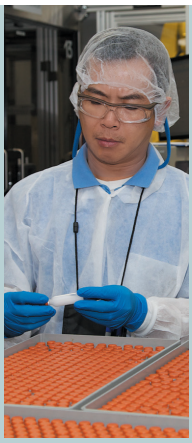
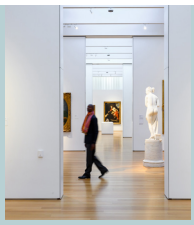
I invite you to take a closer look at North Carolina's talented workforce, strong biopharma manufacturing cluster, and low-cost business climate. To explore doing business in our state, connect to the Economic Development Partnership of North Carolina at edpnc.com/India.

Sincerely,

Machelle Baker Sanders

Machelle Baker Sanders
Secretary, NC Department of Commerce

State of North Carolina | Department of Commerce
301 North Wilmington Street | 4301 Mail Service Center | Raleigh, NC 27699-4301
919 814 4600 T


IT'S ALMOST UNFAIR TO THE OTHER 49 STATES.

Work. Life. And everything that makes both fulfilling. You'll find open minds, open spaces and open opportunities in North Carolina. Ranked #1 for business by Forbes three years running, with the lowest corporate tax rate in the US, low costs of doing business, and cost of living almost 5% below the national average.

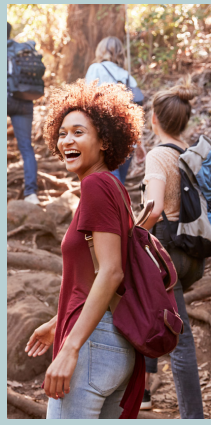
Here you'll find a biotechnology ecosystem that runs deep and wide, across more than 775 companies and 67,000 employees, fueled by a highly educated workforce, major research universities and significant private sector R&D investment.

The EDPNC can connect you with available sites; in-depth workforce, community and infrastructure data; potential supply chain partners; and information on our incentives packages.

Go to EDPNC.com/India or call

Rahul Padmanabha
Director of Investment, India Office
O: +91 9148991212
E: rahul.padmanabha@edpnc.com





ALL IN NORTH CAROLINA

ECONOMIC DEVELOPMENT PARTNERSHIP of NORTH CAROLINA




Need to make Maharashtra again the preferred destination for Bulk Drugs & Intermediates – reg.

ATTENTION MEMBERS

The Association has received the following letter No.MIDC/Dy.CEO-(Env)C17370/2021, dated 28.04.2021 from Dy CEO, MIDC, Maharashtra, Mumbai – in response to joint meeting held on 23rd April 2021 with Dr P Anbalagan, Chief Executive Officer, (CEO), MIDC.

The presentation submitted by Mr Yogin R Majmudar, Chairman, Bulk Drugs Committee, IDMA is also reproduced in the following pages:

"Ref.No.MIDC/Dy.CEO (Env)C17370/2021, dated 28.04.2021

To
Shri Mahesh H Doshi, National President, IDMA

Reference:- Your letter dated 30th March, 2021

During the Webex meeting convened on 23.04.2021 at 12.00 by CEO, MIDC with the you, regarding above mentioned subject, you have raised the issue of making CTE and EC a one step process and informed that MPCB is not following the guidelines/advisory issued by CPCB vide its letter dated 02.02.2017 to all the SPCB/PCC, in order to expediate the process of CTE and have requested CEO MIDC to intervene in the matter.

In this connection I am to inform you as follows:-

1. In order to expediate the process of CTE, CPCB vide letter dated 02.02.2017 issued an advisory to all the SPCBs/ PCCs to follow the modified mechanism for granting consent to various categories of industries as follows:-

"All the projects requiring Environmental Clearance may be exempted from obtaining the Consent to Establish (CTE). Such projects may be directly granted Consent to Operate subject to EC and installation of pollutior control devices."

Further, CPCB issued the direction under Section 18(1) (b) of the Water Act, 1974 and the Air Act, 1981 regarding streamlining of consent mechanism vide Letter No.B-29012/MSMEs/IPC-VI/2017-18/12189-12230 dated 2nd November, 2018.

2. The Hon'ble High Court of Delhi has stayed the directions of the CPCB vide order dated 2nd November, 2018 in W.P. (Civil) 13521 of 2018 in the matter of Social Action for Forest and Environment vs. Union of India and Ors. Further a similar case has also been filed before Hon'ble High Court of Madras (WP No. 3046 of 2019 and WMP No. 3316 & 3320 of 2019).

3. A meeting was convened under Chairmanship of Secretary, Environment, Forest and Climate change with CPCB and after detail deliberations, the Mechanism of one step process of CTE and EC has been decided.

A copy of the mechanism of one step process of CTE and EC decided by MoEF&CC has been issued through OFFICE MEMORANDUM No.F.No.3-3/2019-IA-III, dated 5th February, 2020 and copy of the same is enclosed for your information please. Thanking you, Yours faithfully.

Dy CEO-(Env), MIDC, Andheri, Mumbai-400 093, Maharashtra.

F. No. 3-3/2019-IA.III
Government of India
Ministry of Environment, Forest and Climate Change
Impact Assessment Division
***

Indira Paryavaran Bhawan
Jor Bagh Road, Aliganj
New Delhi – 110003
sharath.kr@gov.in

Date: 5th February, 2020

OFFICE MEMORANDUM

Subject: Modalities for making CTE and EC a one step process - regarding.

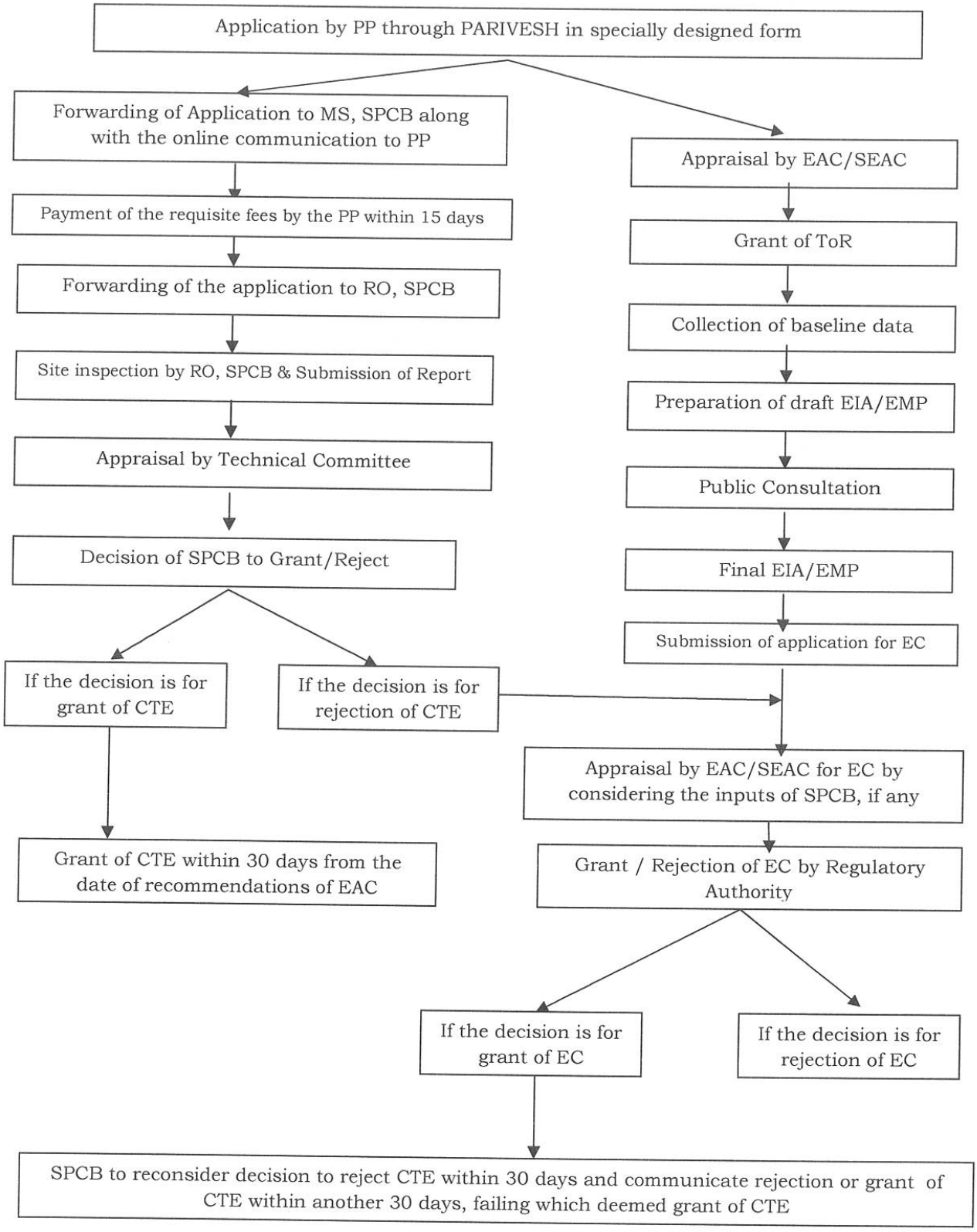
In order to expedite the process of CTE, CPCB vide letter dated 02.02.2017 issued an advisory to all the SPCBs/PCCs to follow the modified mechanism for granting consent to various categories of industries as:-

"All the projects requiring Environmental Clearance may be exempted from obtaining the Consent to Establish (CTE). Such projects may be directly granted Consent to Operate subject to EC and installation of pollution control devices".

2. Further, CPCB issued the directions under Section 18(1)(b) of the Water Act, 1974 and the Air Act, 1981 regarding streamlining of consent mechanism vide Letter No. B-29012/MSMEs/IPC-VI/2017-18/12189-12230 dated 2nd November, 2018.

3. The Hon'ble High Court of Delhi has stayed the directions of the CPCB vide order dated 2nd November 2018 in W.P. (CIVIL) 13521 of 2018 in the matter of Social Action for Forest and Environment vs. Union of India and Ors. The CPCB has further informed that a similar case has also been filed before Hon'ble High Court of Madras (WP No. 3046 of 2019 and WMP No. 3316 & 3320 of 2019).

4. A meeting was convened under chairmanship of Secretary, Environment, Forest and Climate Change with CPCB and after detailed deliberations, the following mechanism of one step process of CTE and EC has been decided.


Application by PP through PARIVESH in specially designed form
Forwarding of Application to MS, SPCB along with the online communication to PP
Payment of the requisite fees by the PP within 15 days
Forwarding of the application to RO, SPCB
Site inspection by RO, SPCB & Submission of Report
Appraisal by Technical Committee
Decision of SPCB to Grant/Reject
If the decision is for grant of CTE
If the decision is for rejection of CTE
Grant of CTE within 30 days from the date of recommendations of EAC
Appraisal by EAC/SEAC
Grant of ToR
Collection of baseline data
Preparation of draft EIA/EMP
Public Consultation
Final EIA/EMP
Submission of application for EC
Appraisal by EAC/SEAC for EC by considering the inputs of SPCB, if any
Grant / Rejection of EC by Regulatory Authority
If the decision is for grant of EC
If the decision is for rejection of EC
SPCB to reconsider decision to reject CTE within 30 days and communicate rejection or grant of CTE within another 30 days, failing which deemed grant of CTE

Provided:-

i. If the PP fails to pay the requisite fee, grant of CTE will be at the discretion of the SPCB/UTPCC concerned;

ii. If the decision for rejection of CTE is not communicated by SPCB/UTPCC to the Ministry or SEIAA, as the case may be, before the meeting of EAC, it will be deemed that there are no specific comments / objections to the SPCB/UTPCC

iii. In case of deemed grant of CTE, the conditions of the EC will also be applicable for the deemed CTE.

iv. The deemed clause may not be applicable for cases, where public consultation is exempted for grant of EC.

5. The above, mechanism may be followed while granting EC and CTE.

6. This issues with the approval of the competent authority.

05/02/2020

(Sharath Kumar Pallerla)
Scientist 'F', IA (Policy) Division

To

1. All the officers of IA Division
2. Chairperson/Member Secretaries of all the SEIAAs/SEACs
3. Chairman of all the Expert Appraisal Committees
4. Chairman, CPCB
5. Chairpersons/Member Secretaries of all SPCBs/UTPCCs

Copy for information:

1. PS to Minister for Environment, Forest and Climate Change
2. PS to MoS (EF&CC)
3. PPS to Secretary(EF&CC)
4. PPS to AS(RSP) / AS (RA)/JS (GM)/ JS (AKN)/ JS (SKB)
5. Website, MoEF&CC and Guard file

Presentation by Mr Yogin R Majmudar, Chairman, Bulk Drugs Committee, IDMA

Presentation for Bringing API Industry Back to Maharashtra

23rd April 2021

Background

- Maharashtra was leader in 60's to 80's in Pharmaceutical manufacturing
- Migration to other States
  - Less militant labour (Gujarat)
  - Tax incentives (Sikkim, Himachal Pradesh, etc)
  - Better infrastructure (AP and Telengana – APIs)
- Currently AP and Tamil Nadu wooing API industry

Pharma Industry Moving Out of Maharashtra

WHO-GMP approved manufacturing units in different States in India

State	2015	2019	Growth in 5 years
Maharashtra	209	229	**<10% increase**
Gujarat	423	684	>50% increase
Telenganga	52	172	>300% increase

Source: CDSCO

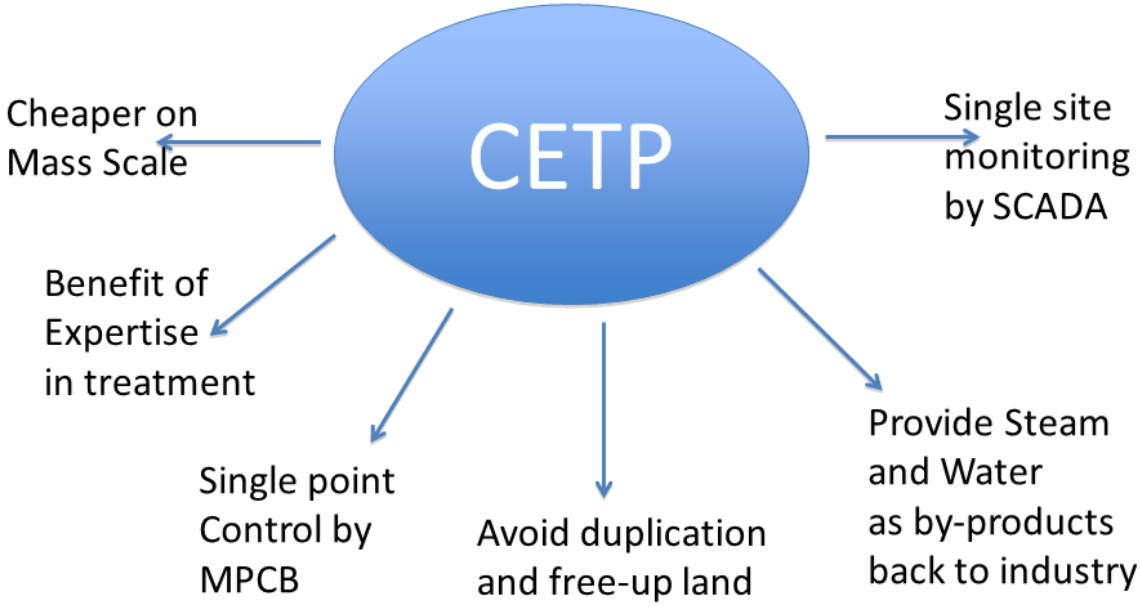
In Maharashtra there are hardly <u>any new</u> Companies in last 5 years compared to other States

Soon Pharma Industry in Maharashtra which was #1 till 1990s will move to down #3

China Fallout

- Since 1990's influx of low priced imports from China – effect also felt in Maharashtra too
- Govt. of India realising overdependence on China as a National Security Risk has among other measures introduced 2 PLI Schemes for this sector
- Need of the hour is cut Costs – Common Facilities
- One possible area – Effluent Treatment which comprises >20% of overall cost of manufacture
- Solution: outsourcing Effluent Treatment to CETPs

Ultimate Solution for Effluent Treatment



32 CETPs in State need up-gradation so individual units are not forced to treat to the same level as output norms applicable to CETPs

Other Areas Needing Improvement

- Need for better infrastructure in MIDC Estates
  - Adequate sized storm water drains for unforeseen rain
  - Better internal roads
  - Better Internet and Telephonic connectivity
  - Single window clearance for expansion
  - Consistent water supply
  - MIDC to provide Infrastructure for final point of discharge of CETP effluent

Request for joint meeting with MPCB to arrive at mutual consensus for future course of action

Operationalisation of DGFT 'COVID-19 Helpdesk' for International Trade related Issues - reg.

DGFT Trade Notice No. 02/2021-2022, dated 26th April 2021

To,
All Exporters/Members of Trade,
All Export Promotion Councils/Commodity Boards.

1. The Department of Commerce, Government of India and DGFT have undertaken to monitor the status of export and imports and difficulties being faced by trade stakeholders in view of the surge of COVID-19 cases. DGFT has accordingly operationalised a **'COVID-19 Helpdesk' to support and seek suitable resolutions to issues arising in respect of International Trade.**

2. This 'COVID-19 Helpdesk' would look into issues relating to Department of Commerce/DGFT, Import and Export Licensing Issues, Customs clearance delays and complexities arising thereon, Import/ Export documentation issues, Banking matters etc. Helpdesk would also collect and collate trade related issues concerning other Ministries/ Departments/Agencies of Central Government and State Governments and will co-ordinate to seek their support and provide possible resolution(s).

3. **EXIM community may submit information on the DGFT website** and submit information relating to their issues on which support is required using the following steps:

i. Navigate to the DGFT Website (https://dgft.gov.in) → Services → DGFT Helpdesk Service

ii. 'Create New Request' and select the Category as 'Covid-19'

iii. Select the suitable sub-category, enter the other relevant details and submit.

Alternatively, you may send your issues to email id: dgftedi@nic.in with the subject header: COVID-19 Helpdesk or call at Toll Free No 1800-111-550

4. The status of resolutions and feedback may be tracked using the Status tracker under the DGFT Helpdesk Services. Email and SMS would also be sent as and when the status of these tickets are updated. Trade Community is requested to kindly make use of the given facilities suitably.

This issues with the approval of the competent authority.

File No. 01/02/08/AM22/EG&TF

Md. Moin Afaque, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

● ● ●

Amendment in Appendix 2E (List of agencies to issue CoO-Non Preferential) *re.* change in address of BCC-CoO (Non-Preferential) - reg.

DGFT Public Notice No.02/2015-2020, dated 26th April 2021

1. In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy 2015-2020, the Director General of Foreign Trade hereby makes the following amendments at Sr.No.7 under the subheading West Bengal in Appendix 2E (List of Agencies authorized to issue Certificate of Origin-Non Preferential) of the Handbook of Procedures, 2015-2020.

Sr. No.	Name of the Agency	Old Address	New Address
7.	Bharat Chamber of Commerce	9, Park Mansions, 2nd Floor, 57A Park Street, Kolkata-16 Tel: 033-2299591/9608 Fax: 033-2204947 E-mail: bcc@cal2.vsnl.net.in	Bharat Chamber of commerce 'BHARAT CHAMBERS' 9/1-Syed Amir Ali Avenue, Kolkata-700017 Tel: 22829591/22839608 Fax: 033-22824947 Email:bharat.chambers@gmail.com

2. Effect of this Public Notice: Address details of Bharat Chamber of Commerce under Appendix 2E of FTP, 2015-2020 is updated.

File No.01/93/180/102/AM-16/PC-2(B)/E-1710

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

● ● ●

GST MATTERS

Central Goods and Services Tax Rules, 2017 amended (2nd Amendment of 2021) - reg.

GST Central Tax Notification No.07/2021, dated 27th April, 2021

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following rules further to amend the Central Goods and Services Tax Rules, 2017, namely:-

1. (1) These rules may be called the **Central Goods and Services Tax (Second Amendment) Rules, 2021.**

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

2. In the Central Goods and Services Tax Rules, 2017, in rule 26 in sub-rule (1), after the third proviso, the following proviso shall be inserted, namely:-

"Provided also that a registered person registered under the provisions of the Companies Act, 2013 (18 of 2013) shall, during the period from the 27th day of April, 2021 to the 31st day of May, 2021, also be allowed to furnish the return under section 39 in **FORM GSTR-3B** and the details of outward supplies under section 37 in **FORM GSTR-1** or using invoice furnishing facility, verified through electronic verification code (EVC).".

Rajeev Ranjan,
Under Secretary,
Central Board of Indirect Taxes and Customs,
Department of Revenue,
Ministry of Finance,
New Delhi.

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification No.3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R.610(E), dated the 19th June, 2017 and last amended Vide Notification No.01/2021-Central Tax, dated the 1st January, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.2(E), dated the 1st January, 2021.*

● ● ●

DPIIT MATTERS

The Intellectual Property Appellate Board established vide section 83 of the Trade Marks Act, 1999 stands dissolved with effect from 04th April 2021 - reg.

Industrial Policy Notification No.S.O.1668(E), dated 22nd April 2021

In Pursuance of the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 vide Notification No.CG-DL-E-04042021-226364 dated 04th April, 2021, the Intellectual Property Appellate Board established vide section 83 of the Trade Marks Act, 1999 stands dissolved with effect from 04th April, 2021.

F.No.P-24017/28/2021-IPR-I

Shailendra Singh, Addl. Secretary,
Department for Promotion of Industry and Internal Trade,
IPR-Estt. Section, Ministry of Commerce and Industry,
New Delhi.

● ● ●

COMPANIES LAW AMENDMENTS

MCA Clarification on spending of CSR funds for setting up makeshift hospitals and temporary COVID Care facilities - reg.

Corporate Affairs General Circular No.05/2021, dated 22nd April 2021

To,
All Stakeholders.

1. In continuation to this Ministry's General Circular No.10/2020 dated 23.03.2020 wherein it was clarified that spending of CSR funds for COVID-19 is an eligible CSR activity, it is further clarified that spending of CSR funds for 'setting up makeshift hospitals and temporary COVID Care facilities' is an eligible CSR activity under item nos. (i) and (xii) of Schedule VII of the Companies Act, 2013 relating to promotion of health care, including preventive health care, and, disaster management respectively.

2. The companies may undertake the aforesaid activities in consultation with State Governments subject to fulfillment of Companies (CSR Policy) Rules, 2014 and the circulars related to CSR issued by this Ministry from time to time.

3. This issues with the approval of competent authority.

E-File No.CSR-10/9/2020-CSR-MCA

Shobhit Srivastava, Deputy Director (CSR Cell), Ministry of Corporate Affairs, New Delhi.

● ● ●

CBIC exempts customs duty on import of Remdesivir injection, Remdesivir API and Beta Cyclodextrin (SBEBCD) used in the manufacture of Remdesivir, up to 31st October, 2021 - reg.

Notification No.27/2021-Customs, dated 20th April 2021

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

Sr. No.	Chapter or heading or sub–heading or tariff item	Description of goods
(1)	(2)	(3)
1.	29	Remdesivir Active Pharmaceutical Ingredients.
2.	29	Beta Cyclodextrin (SBEBCD) used in manufacture of Remdesivir, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.
3.	30	Injection Remdesivir.

2. This notification shall remain in force upto and inclusive of the 31st October, 2021.

F.No.354/3/2021-TRU

Gaurav Singh, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

Expediting Customs Clearances for COVID related imports made by Indian Red Cross society – reg.

Customs Instructions No.08/2021, dated 27th April, 2021

To
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),
All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,
All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),
All Principal Commissioners/Commissioners of Customs & Central tax,
All Principal Director Generals/Director Generals under CBIC.

1. Reference is invited to Board Instruction No.07/2021 dated 24th April 2021 requesting the field formations to give high priority for Customs clearance of import of goods relating to COVID-19 pandemic, including medical grade oxygen, specified equipment for production, transportation and distribution of oxygen, equipment for oxygen therapy to COVID patients and COVID-19 vaccines etc. Donations of COVID related material and medicines from foreign Governments have also started arriving at our ports.

2. In wake of the extraordinary situation owing to the COVID pandemic, the issue of providing seamless clearance to such relief material received from foreign Governments and imported by Indian Red Cross Society was discussed in a meeting chaired by Cabinet Secretary on 27.04.2021. It was decided that in all cases of covid related imports facilitated by Ministry of External Affairs and/or imported by Indian Red Cross society, permissions/licences/ authorizations required from other Government Department/Agencies prior to the clearance of goods, if any, would be deemed to have been given. In other words, such cases need not be referred to those agencies or the requirement may be suitably waived.

3. In view of the above decision, the Customs formations are requested to give the highest priority to these consignments and facilitate their clearance in the shortest possible time.

F.No.450/117/2021-Cus-IV (Pt)

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

● ● ●

CBIC exempts customs duty and health cess on import of oxygen, oxygen related equipment and COVID-19 Vaccines, up to 31st July, 2021 - reg.

Notification No.28/2021-Customs, dated 24th April 2021

1. In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), read with section 141 of Finance Act, 2020 (12 of 2020), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby exempts the goods of the description specified in column (3) of the Table below, falling within the Chapter, heading, sub–heading or tariff item of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) specified in column (2) of the said Table, when imported into India, from the whole of the duty of customs leviable thereon under the said First Schedule and the whole of health cess leviable thereon under section 141 of the said Finance Act, namely:

Table

Sr. No.	Chapter, heading, sub-heading or tariff item	Description
(1)	(2)	(3)
1.	9019 20, 9804	Oxygen concentrator including flow meter, regulator, connectors and tubings.
2.	2804 40	Medical Oxygen
3.	8421 39	Vacuum Pressure Swing Absorption (VPSA) and Pressure Swing Absorption (PSA) oxygen plants, Cryogenic oxygen Air Separation Units (ASUs) producing liquid/gaseous oxygen.
4.	7311	Oxygen canister.
5.	9018	Oxygen filling systems.
6.	7311	Oxygen storage tanks
7.	9018	Oxygen generator
8.	7311	ISO containers for Shipping Oxygen
9.	7311, 8418 or 8419	Cryogenic road transport tanks for Oxygen

10.	7311, 8418 or 8419	Oxygen cylinders including cryogenic cylinders and tanks
11.	Any Chapter	Parts of goods at S.No.1 and 3 to 10 above, used in the manufacture of equipment related to the production, transportation, distribution or storage of Oxygen, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.
12.	9019	Any other device from which oxygen can be generated
13.	9018 or 9019	Ventilators, including ventilator with compressors; all accessories and tubings; humidifiers; viral filters (should be able to function as high flow device and come with nasal canula).
14.	9018	High flow nasal canula device with all attachments; nasal canula for use with the device.
15.	6506 99 00	Helmets for use with non-invasive ventilation.
16.	9019	Non-invasive ventilation oronasal masks for ICU ventilators.
17.	9019	Non-invasive ventilation nasal masks for ICU ventilators.
18.	3002	COVID-19 vaccine.

2. This notification shall remain in force upto and inclusive of the **31st July, 2021.**

F.No.354/3/2021-TRU

Gaurav Singh, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi

● ● ●

Expediting Customs Clearances for import consignments relating to COVID-19 pandemic – reg.

Customs Instructions No.06/2021, dated 24th April, 2021

To
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),
All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,
All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),
All Principal Commissioners/Commissioners of Customs & Central tax,
All Principal Director Generals/Director Generals under CBIC.

1. Reference is invited to letter from Board dated 21.04.2021 wherein it was requested that import of equipments for setting up RT-PCR test labs, medical equipments etc should be cleared on top priority by the Customs.

2. Considering the scourge of COVID 19 and surge of cases in the Country, it is an imperative that import of critical raw materials, life-saving drugs etc reach the intended users/beneficiaries in time for effective fight against the pandemic. Hence, it is requested that all Customs formations may be sensitised of the urgency of this matter and may be directed to give high priority for Customs clearances of import of goods relating to COVID 19 pandemic, including oxygen related equipments etc.

F.No.450/117/2021-Cus-IV

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

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Linear Alkyl Benzene (Quality Control) Order, 2021 notified - reg.

Chemicals & Fertilizers Order S.O.1664(E) dated 15th April 2021

(Published in the Gazette of India on 20th April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), (hereinafter referred to as the said Act), the Central Government, being of the opinion that it is necessary or expedient so to do in the public interest after consultation with the Bureau of Indian Standards, hereby makes the following order, namely:-

1. Short title, commencement and application:

(1) This order may be called the Linear Alkyl Benzene (Quality Control) Order, 2021.

(2) It shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

(3) It shall apply to goods or articles specified in column (1) of the Table below, but shall not apply to such goods or articles meant for export.

2. Conformity to standards and compulsory use of Standard Mark:

Goods or articles specified in column (1) of the Table below shall conform to the corresponding Indian Standard given in column (2) of the said Table and shall bear the Standard Mark under a licence from the Bureau of Indian Standards as per Scheme-I of Schedule-II of the Bureau of Indian Standards (Conformity Assessment) Regulations, 2018.

3. Certification and enforcement authority:

The Bureau of Indian Standards shall be the certifying and enforcing authority in respect of the goods or articles specified in column (1) of the Table.

4. Penalty for contravention:

Any person who contravenes the provisions of this order shall be punishable under the provisions of the said Act.

TABLE

Goods or article	Indian Standard	Title for Indian Standard
(1)	(2)	(3)
Linear Alkyl Benzene	IS 12795:2020	Linear Alkyl Benzene - Specification

F.No.PC-II.46016/6/2020-Tech.CPC–Pt-1

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

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Amendment in the Acetic Acid (Quality Control) Order, 2019 - reg.

Chemicals & Fertilizers Order No.S.O.1676(E), dated 19th April 2021

(Published in the Gazette of India on 23rd April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Acetic Acid (Quality Control) Order, 2019 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **3rd February, 2022."**

F.No.C.II-13012/08/2018-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.2791(E) dated the 5th August, 2019. Subsequently amended vide Notification Number S.O.344(E) dated 24th January, 2020, S.O.2179(E) dated 1st July, 2020 and S.O.3799(E) dated 22nd October 2020.*

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Amendment in the Hydrogen Peroxide (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order No.S.O.1680(E) dated 19th April 2021

(Published in the Gazette of India on 23rd April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Hydrogen Peroxide (Quality Control) Order, 2020 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **13th March, 2022.**

F.No.C.II-13012/28/2019-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.1900(E) dated the 16th June, 2020 and subsequently amended vide Notification Number S.O.4414(E) dated 4th December, 2020.*

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Amendment in the Methanol (Quality Control) Order, 2019 - reg.

Chemicals & Fertilizers Order No.S.O.1681(E) dated 19th April 2021

(Published in the Gazette of India on 23rd April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Methanol (Quality Control) Order, 2019 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **3rd February, 2022.**

F.No.C.II-13012/10/2018-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.2793(E) dated the 5th August, 2019. Subsequently amended vide notification number S.O.345(E) dated 24th January, 2020, S.O.2181 (E) dated 1st July, 2020 and S.O. 3795(E) dated 22nd October 2020.*

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Amendment in the Potassium Carbonate (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order No.S.O.1683(E) dated 19th April 2021

(Published in the Gazette of India on 23rd April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Potassium Carbonate (Quality Control) Order, 2020 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **13th March, 2022."**

F.No.C.II-13012/23/2019-Chem.II

Samir Kumar Biswas,
Addl. Secretary,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi.

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.1895(E) dated the 16th June, 2020 and subsequently amended vide Notification Number S.O.4415(E) dated 4th December, 2020.*

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Amendment in the Sodium Tripolyphosphate (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order No.S.O.1684(E) dated 19th April, 2021

(Published in the Gazette of India on 23rd April, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Sodium Tripolyphosphate (Quality Control) Order, 2020 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **13th March, 2022."**

F.No.C.II-13012/31/2019-Chem.II

Samir Kumar Biswas,
Addl. Secretary,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi.

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.1903(E) dated the 16th June, 2020 and subsequently amended vide Notification Number S.O.4417(E) dated 4th December, 2020.*

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Amendment to the Acrylonitrile (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order S.O.1692(E), dated 26th April 2021

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Acrylonitrile (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement

(1) This order may be called the **Acrylonitrile (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Acrylonitrile (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette".

F.No.PC-II 46016/6/2020-Tech.CPC

N K Santoshi,
Deputy Director General,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi .

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.3999(E), dated the 4th November, 2020.*

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Amendment to the Maleic Anhydride (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order S.O.1693(E), dated 26th April 2021

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Maleic Anhydride (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Maleic Anhydride (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Maleic Anhydride (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette".

F.No.PC-II 46016/6/2020-Tech.CPC

N K Santoshi,
Deputy Director General,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi .

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.4000(E), dated the 4th November, 2020.*

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Amendment to the Methyl Acrylate, Ethyl acrylate, n-butyl Acrylate (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order S.O.1694(E), dated 26th April 2021

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Methyl Acrylate, Ethyl acrylate, n-butyl Acrylate (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Methyl Acrylate, Ethyl acrylate, n-butyl Acrylate (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Methyl Acrylate, Ethyl acrylate, n-butyl Acrylate (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette".

F.No.PC-II 46016/6/2020-Tech.CPC

N K Santoshi,
Deputy Director General,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi .

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.4001(E), dated the 4th November, 2020.*

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Amendment to the Styrene (Vinyl Benzene) (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order S.O.1695(E), dated 26th April 2021

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Styrene (Vinyl Benzene) (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Styrene (Vinyl Benzene) (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Styrene (Vinyl Benzene) (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette".

F.No.PC-II 46016/6/2020-Tech.CPC

N K Santoshi,
Deputy Director General,
Department of Chemicals and Petrochemicals,
Ministry of Chemicals and Fertilizers,
New Delhi .

Note: *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.4002(E), dated the 4th November, 2020.*

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Amendment to the Vinyl Acetate Monomer (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Order S.O.1696(E), dated 26th April 2021

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Vinyl Acetate Monomer (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Vinyl Acetate Monomer (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Vinyl Acetate Monomer (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette".

F.No.PC-II 46016/6/2020-Tech.CPC

N K Santoshi, Deputy Director General, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi .

***Note:** The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification Number S.O.4003(E), dated the 4th November, 2020.*

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In Lok Sabha & In Rajya Sabha

Drug Price Control by NPPA

Lok Sabha Unstarred Question No: 2312

Shri K Shanmuga Sundaram;

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

(a): the details of the total number of drugs which have been placed under price control by the National Pharmaceuticals Pricing Authority (NPPA) as on date;

(b): whether the Government has received any objection from the multinational pharma companies as well as Indian pharma giants and if so, the details thereof;

(c): whether the NPPA order will cover the National List of Essential Medicines (NLEM) as well as nonessential drugs; and

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

Answered on 9th March 2021

A. (a): National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) fixes the ceiling price of scheduled formulations adopted from the National List of Essential Medicines (NLEM) and new drug as per the provisions of para 4, 5 and 6 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The details of medicines under price control are as below:

(i): Ceiling price of 881 scheduled formulation under revised schedule-I of DPCO, 2013.

(ii): Retail price of 1,495 new drugs under the DPCO, 2013.

(iii): Prices of 106 Anti-diabetic and Cardiovascular drugs under Para 19 of the DPCO, 2013 in public interest.

(iv): Ceiling price of Cardiac Stents being scheduled formulation under the DPCO, 2013 affecting price reduction for Coronary Stents, which worked out up to 85% for Bare Metal Stents and 74% for Drug Eluting Stents.

(v): Ceiling price of Orthopaedic Knee Implants under Para 19 of the DPCO, 2013 in Public interest affecting price reduction up to 69%.

(vi): Capped the Trade Margin of non-scheduled formulations of 42 Anti-cancer medicines under "Trade Margin Rationalization" approach as a Pilot for proof of concept, wherein price of more than 500 brands of medicines were reduced up to 90%.

The fixation of the prices has resulted in a notional savings of Rs.12,447 crores per annum to the public after implementation of DPCO, 2013.

(b): The receipt of representations from the Industry and consultations on issues are an ongoing process. NPPA examines any representation received from the companies and Pharma Associations and addresses them suitably.

(c) & (d): NPPA fixes the ceiling prices of scheduled drugs listed in the NLEM and included as Schedule - I of the DPCO, 2013. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA.

A manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation (branded or generic) launched by it. However, as per provisions of the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum.

Minister in The Ministry of Chemicals and Fertilizers (Shri D V Sadananada Gowda)

Life Saving Drugs

Lok Sabha Unstarred Question No: 2314

Shri Ritesh Pandey:

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

(a): the number of life-saving drugs enlisted as essential along with the criteria therefor and the number of such drugs that under price control;

(b): whether the Government proposes to revise the National List of Essential Medicines (NLEM) 2015 and bring in some life-saving medical devices under the said list in order to check their prices;

(c): if so, the details thereof along with the number of medicines/devices identified to be included/excluded in/from NLEM;

(d): whether the Government has received any proposal for inclusion of certain cancer medicines in the NLEM, if so, the details thereof and the action taken by the Government thereon;

(e): whether the Government proposes to link availability of essential medicines with Ayushman Bharat Yojana; and

(f): if so, the details thereof and the financial and operational modalities worked out for the same?

Answered on 9th March 2021

A. (a): The Ministry of Health & Family Welfare publishes the National List of Essential Medicines (NLEM), which are incorporated in the Schedule-I of the Drugs (Price Control) Order. There is no separate categorization in NLEM about life-saving drugs. National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled formulations as per the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The Schedule I of DPCO, 2013 was last amended by adopting NLEM, 2015 consisting of 377 medicines. NPPA has fixed the ceiling prices of 881 scheduled formulations of medicines under NLEM, 2015. The details of price fixed are available on NPPA's website, www.nppaindia.nic.in.

(b) to (d): The Standing National Committee on Medicines (SNCM) has been constituted by the Ministry of Health & Family Welfare on 03.07.2018 to review and revise the National List of Essential Medicines (NLEM), 2015 by way of additions and deletions in existing NLEM. The NLEM revision process consists of consultative mechanism of subject experts from throughout the country and other important stakeholders. Amongst others, the Committee will suggest inclusion of Medical Devices, medical disposables, medical consumables and other products used for health and hygiene of general public in NLEM. The Committee is deliberating the matter to submit its report.

(e) & (f): The health benefits packages defined under Ayushman Bharat Pradhan Mantri – Jan Arogya Yojana (AB PM-JAY) are comprehensive, covering treatment for 25 specialties that include super specialty care like oncology, neurosurgery and cardio-thoracic surgery etc. The health benefits package rate (in case of medical surgical) or defined day-care benefits includes the costs of medicines and drugs from 3 days prior to hospitalization and 15 days post discharge from the hospital. The treatment under AB PM-JAY is provided as per the Standard Treatment Guidelines (if available) and professional judgement of the healthcare provider.

However, there is no proposal with the National Health Authority regarding linking of essential medicines with AB PM-JAY.

Minister in the Ministry of Chemicals and Fertilizers (Shri D V Sadananada Gowda)

Affordable Medical Devices

Lok Sabha Unstarred Question No:2331

Shri Rajendra Dhedya Gavit:

Shri Sanjay Sadashivrao Mandlik:

Shri Ranjeetsinha Hindurao Naik-Nimbalkar:

Shri Sudhakar Tukaram Shrangre:

Shri Shrirang Appa Barne:

Shri Chandra Sekhar Sahu:

Shri Sudheer Gupta:

Shri Bidyut Baran Mahato:

Shri Shivkumar Chanabasappa Udasi:

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

(a): whether the Government has been encouraging the domestic manufacturing of affordable medical devices, bulk drugs and pharmaceuticals under its 'Make in India' initiative and if so, the details thereof;

(b): the extent to which such policies and schemes has boosted India's affordable generics and medical devices sector;

(c): the details of the contribution of the country's export of affordable generics and medical devices;

(d): whether Indian Pharma market is expected to grow to US$ 130 billion by 2030;

(e): if so, the details of the steps taken by the Government to achieve the growth targets of the country; and

(f): the details of employment opportunities likely to be increased in this sector by 2030?

Answered on 9th March 2021

A. (a) & (b): Yes Sir, the Government is encouraging the domestic manufacturing of affordable medical devices, bulk drugs and pharmaceuticals under its 'Make in India' initiative. The Department of Pharmaceuticals has recently launched following two schemes for Medical Devices Sector:

i. Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices: The Scheme has been approved by the Government of India on 20th March, 2020. The revised guidelines for implementation of the scheme has been issued on 29.10.2020. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The tenure of the scheme is from FY 2020-21 to FY 2027-28. The total financial outlay of the Scheme is Rs.3,420 crore. The scheme is under implementation.

ii. Promotion of Medical Device Parks: Recognizing the need for higher levels of investments for the creation of testing and laboratory facilities, this Scheme has been approved by the Government of India on 20th March 2020. The parks will provide common testing and laboratory facilities / centre at one place reducing the manufacturing cost significantly and will help in creating a robust ecosystem for medical device manufacturing in the country. The total financial outlay of the scheme is Rs. 400 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. Financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to Rs. 100 crore. The scheme is under implementation.

Also, the Department of Pharmaceuticals has recently launched following three schemes for promoting domestic manufacturing of critical KSMs/ Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs:

i. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India: Under the scheme, financial incentive is given for manufacturing of 41 eligible products under the four Target Segments viz.:

   a. Fermentation based KSMs/Drug Intermediates.

   b. Fermentation based niche KSMs/Drug Intermediates /APIs.

   c. Key Chemical Synthesis based KSMs/Drug Intermediates.

   d. Other Chemical Synthesis based KSMs/Drug Intermediates/APIs.

   Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940 crore.

ii. Scheme for Promotion of Bulk Drug Parks: To provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

iii. Production Linked Incentive Scheme for Pharmaceuticals: The Union Cabinet in its meeting on 24.02.2021 approved Production Linked Incentive

scheme for Pharmaceuticals with the objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The outlay of the scheme is Rs 15,000 crore and three categories of pharmaceutical goods will be incentivized under the scheme based on their incremental sales. The tenure of the scheme will be from FY 2020-2021 to 2028-29. The Scheme has been notified on 03.03.2021 in the Gazette of India.

(c): The details of generics exports are as follows:

(d): As per economic survey 2020-21, the Pharma Sector is expected to grow to about US $ 120-130 billion by 2030.

(e): The Department of Pharmaceuticals has launched following three schemes to achieve the growth targets of the country:

i. Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India

ii. Promotion of Bulk Drug Parks

iii. Production Linked Incentive Scheme for Pharmaceuticals

(f): Approximately, 2 lakh jobs, direct and indirect, are likely to be created through industry promotion schemes of the Department by 2030.

Minister in The Ministry of Chemicals and Fertilizers (Shri D V Sadananada Gowda)

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Updated results on Coronavirus vaccination effectiveness

Several weeks following the publication of the large real-world COVID-19 vaccine effectiveness study by the Clalit Research Institute in Collaboration with Harvard University in the New England Journal of Medicine (NEJM), additional results focusing on vaccine effectiveness in specific sub-populations have now been published.

While the original publication demonstrated the effectiveness of the Pfizer-BioNTech mRNA vaccine in the general population, outstanding questions remained regarding vaccine effectiveness in specific sub-populations of interest, including the elderly, multi-morbid individuals, and individuals with specific prevalent chronic conditions.

The new study also took place in Israel and evaluated data on approximately 1,400,000 Clalit members, with extended follow-up time compared to the previous study, and additional subpopulations. The advanced methodologies employed meticulous individual matching techniques to enable an as-clean-as-possible analysis of vaccine effectiveness, comparing vaccinated to unvaccinated (control) individuals. The increased sample size and increased follow up time enabled the assessment of vaccine effectiveness in additional sub-populations, which the original vaccine effectiveness study was unable to assess.

The results of the new study make clear that the vaccine is exceedingly effective, with 96% of symptomatic cases and 95% of severe cases prevented (compared with point estimates of 94% and 92% in the previous study). The results also demonstrate that the vaccine is highly effective across all age ranges, with 92% effectiveness in preventing symptomatic disease in individuals 70 years and older.

It is important to note that vaccine effectiveness in prevention of symptomatic disease is slightly lower amongst the multi-morbid population of all ages (88% effective amongst individuals with three or more chronic illnesses or risk factors). Specifically, the effectiveness in preventing symptomatic illness varied in patients with different chronic illnesses: the vaccine was highly effective (96% and 93%) in overweight and obese patients, but slightly less effective in immunosuppressed individuals (84%), patients with heart disease (80%), chronic kidney disease (80%) and diabetes (86%). Effectiveness against severe disease was generally higher.

According to Professor Ran Balicer, Chief Innovation Officer for Clalit and Director of the Clalit Research Institute, "This publication is a direct continuation of the large study published in the New England Journal of Medicine several weeks ago. The updated results based on a larger population with extended follow-up period show that the vaccine is even more effective than previously estimated, preventing 96% of cases and 95% of severe cases of covid-19 in all age groups - a 20 to 25-fold reduction of risk compared to the unvaccinated. Severe disease is dramatically reduced even among patients with some specific chronic conditions, but as suggested in the original study, this protection is mildly reduced among patients with several co-morbidities. These results are very encouraging, as they suggest that most COVID-19 cases will be prevented by vaccination even in the elderly and chronically ill, though there should be expected a somewhat higher rate of infection and severe illness in vaccinated individuals with several comorbidities or immune suppression, compared to the healthy fully vaccinated population.

The main conclusions as we see them: The study further supports the immediate need to vaccinate at any eligible age and especially among those suffering from chronic conditions that are most vulnerable to Covid-19 compilations if not vaccinated. But we also note that these chronically ill vaccinated patients should continue to practice caution in circumstances where a significant risk of infection exists, as they still have somewhat higher residual vulnerability after being vaccinated. We are relieved to note that the risk for such circumstances has been consistently falling in Israel over the last few months, to unprecedented low rates of daily cases - a 50-fold decrease in cases to as low as 10 cases per million per day and less than 1 severe case per million per day - and the numbers are still dropping."

Source: World Phama News, 22.04.2021 (Excerpts)

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Artificial Intelligence model predicts which key of the immune system opens the locks of Coronavirus

The human immune defense is based on the ability of white blood cells to accurately identify disease-causing

pathogens and to initiate a defense reaction against them. The immune defense is able to recall the pathogens it has encountered previously, on which; for example, the effectiveness of vaccines is based. Thus, the immune defense the most accurate patient record system that carries a history of all pathogens an individual has faced. This information however has previously been difficult to obtain from patient samples.

The learning immune system can be roughly divided into two parts, of which B cells are responsible for producing antibodies against pathogens, while T cells are responsible for destroying their targets. The measurement of antibodies by traditional laboratory methods is relatively simple, which is why antibodies already have several uses in healthcare.

"Although it is known that the role of T cells in the defense response against for example viruses and cancer is essential, identifying the targets of T cells has been difficult despite extensive research," says Satu Mustjoki, Professor of Translational Hematology.

AI helps to identify new key-lock pairs:

T cells identify their targets in a key and a lock principle, where the key is the T cell receptor on the surface of the T cell and the key is the protein presented on the surface of an infected cell. An individual is estimated to carry more different T cell keys than there are stars in the Milky Way, making the mapping of T cell targets with laboratory techniques cumbersome.

Researchers at Aalto University and the University of Helsinki have therefore studied previously profiled key-lock pairs and were able to create an AI model that can predict targets for previously unmapped T cells.

"The AI model we created is flexible and is applicable to every possible pathogen - as long as we have enough experimentally produced key-lock pairs. For example, we were quickly able to apply our model to Coronavirus SARS-CoV-2 when a sufficient number of such pairs were available," explains Emmi Jokinen, M.Sc. and a Ph.D. student at Aalto University.

The results of the study help us to understand how a T cell applies different parts of its key to identify its locks. The researchers studied which T cells recognize common viruses such as influenza, HI, and Hepatitis B-virus. The researchers also used their tool to analyze the role of T-cells recognizing hepatitis B, which had lost their killing ability after the progression of Hepatitis to Hepatic cell cancer. The study has been published in the *scientific journal PLOS Computational Biology*.

A new life for published data with novel AI models:

Tools generated by AI are cost-effective research topics. "With the help of these tools, we are able to make better use of the already published vast patient cohorts and gain additional understanding of them," points out Harri Lähdesmäki, Professor of Computational Biology and Machine Learning at Aalto University.

Using the artificial intelligence tool, the researchers have figured out, among other things, how the intensity of the defense reaction relates to its target in different disease states, which would not have been possible without this study.

"For example, in addition to COVID19 infection, we have investigated the role of the defense system in the development of various autoimmune disorders and explained why some cancer patients benefit from new drugs and some do not", reveals M.D. Jani Huuhtanen, a Ph.D. student at the University of Helsinki, about the upcoming work with the new model.

(Story: Materials provided by University of Helsinki. Note: Content may be edited for style and length).

Source: Science Daily, 23.04.2021 (Excerpts)

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Hepatitis C drugs multiply effect of COVID-19 antiviral Remdesivir

When combined with drugs currently used to treat Hepatitis C, the antiviral Remdesivir is 10 times more effective in treating cells infected with SARS-CoV-2, the virus that causes COVID-19.

Published this week in *Cell Reports*, this finding - from Gaetano Montelione, a Professor of Chemistry and Chemical Biology at Rensselaer Polytechnic Institute, and his collaborators at the Icahn School of Medicine at Mount Sinai and the University of Texas at Austin - raises the potential for repurposing available drugs as COVID-19 antivirals in cases where a vaccine isn't practical or effective.

Remdesivir, which blocks viral replication by interfering with a viral polymerase, must be administered intravenously, limiting its use only to patients sick enough to be admitted to a hospital. However, the efficacy of the drug combination would extend to other polymerase inhibitors, of which at least one orally administered version is under development,

making possible an oral drug combination that could be taken at home.

"Nearly 3 million people have died worldwide from COVID-19. There are situations where the vaccine isn't the best option and it would be helpful to have orally available antivirals," said Montelione, a member of the Rensselaer Center for Biotechnology and Interdisciplinary Studies (CBIS). "Here we see a promising synergy that, if confirmed through additional research and clinical trials, could provide a new antiviral to combat COVID-19."

Repurposed drugs, already approved for use as therapeutics for a different disease, could potentially be approved for clinical use more rapidly than newly developed, more specific, and potent drugs. Remdesivir itself is a repurposed antiviral drug, originally developed to treat Hepatitis C, Ebola virus disease, and other viral infections.

"Repurposed drugs have the potential to be tested and approved quickly for safe use, while more effective therapies are under development" said Robert Krug, virologist and Professor emeritus at the University of Texas at Austin, who helped to initiate the collaboration, interpret the results, and write the paper.

The Cell Reports paper identifies four Hepatitis C drugs, simeprevir, grazoprevir, paritaprevir, and vaniprevir, which exhibited a synergistic effect - an effect that is greater than the sum of its parts. For example, when administered at low doses to virus-infected cells in the presence of simeprevir, 10 times less Remdesivir is needed to inhibit 90% of the virus than when Remdesivir is used on its own. Increasing the efficacy of the polymerase inhibitor Remdesivir reduces the dosage required, and therefore could be more effective, and also reduce unwanted side effects in treating COVID-19.

The researchers discovered the synergistic effect as part of an effort to identify existing drugs that could be used against COVID-19. Remdesivir and the Repatitis C drugs inhibit viral replication, but they target different aspects of the process. The RNA that the virus injects into the cell causes it to make two polyproteins, which are then cut into more than two dozen smaller pieces that help to replicate the virus, and make excellent targets for antivirals that block their activity. Remdesivir targets a polymerase cluster, but many antivirals target viral proteases, enzymes that are required for the life cycle of the virus.

In earlier work, Montelione, Krug, and Khushboo Bafna, a postdoctoral fellow at Rensselaer, used a bioinformatics approach to identify existing proteins that resemble the Coronavirus protease structures. The search identified a "striking similarity" with a protease from the Hepatitis C virus, which is the target of several approved drugs. This similarity between the structures of key proteases of the two viruses raised the possibility that existing drugs that bind and block the Hepatitis C protease would have the same effect on at least one of the proteases, called Mpro, in SARS-CoV-2. That possibility was borne out by multiple subsequent studies, including Bafna's docking simulations using supercomputer facilities at the Rensselaer Center for Computational Innovations, predicting the effect of various Hepatitis C drugs on the SARS-CoV-2 Mpro.

In Cell Reports, the team performed protein binding and viral replication studies with the SARS-CoV-2 virus, emdesivir, and 10 hepatitis C drugs, some of which are already approved by the Food and Drug Administration. Seven of the drugs, tested in a secure biocontainment facility at Mount Sinai, inhibit Mpro and suppress the replication of SARS-CoV-2 virus. These studies were enabled by specialized expertise in the laboratories of research collaborators Adolfo García-Sastre and Kris White at Mount Sinai.

But a careful analysis of the data revealed that three hepatitis C drugs were acting not only on Mpro, but also on second viral protease, the papain-like protease, called PLpro. It is this activity that creates the synergy with the polymerase inhibitor Remdesivir. These results indicate that PLpro is an important target for future antiviral drug development, especially for virus variants that are resistant to vaccine-generated antibodies. "The identification of PLpro as an antiviral target that has a synergistic effect with remdesivir is a very important finding. We hope this work will encourage the development of specific SARS-CoV-2 PLpro inhibitors for inclusion in combination therapies with polymerase inhibitors to produce a highly effective antiviral cocktail that will also prevent the rise of resistance mutations," said Kris White, an Assistant Professor at Mount Sinai School of Medicine.

Adolfo García-Sastre, professor of virology at Mount Sinai emphasized, "Combined use of Remdesivir with an inhibitor of the PLpro for the treatment of COVID-19 would also reduce the possibility of selecting SARS-CoV-2 resistant viruses."

Source: World Pharma News, 27.04.2021 (Excerpts)

Industries manufacturing essential goods exempted from Covid restrictions

Industries manufacturing essential commodities and continuous process industries have been exempted from the night curfew and Sunday lockdown Industries manufacturing essential commodities Manufacturing units of drugs, pharmaceuticals, sanitation materials oxygen, medical devices, medical textiles, their raw material components and intermediates; food related or food processing industries including food for poultry, pets and animal husbandry; units engaged in production of agricultural inputs including fertilizers, agricultural machinery and components.

Under the continuous process industries - these are excluded Refineries, large steel plants, cement plants, continuous process chemical industries including paints; sugar mills; fertilizers; float glass plants; large foundries with continuous process; tyre manufacturing plants; large paper mills; electronics industries using surface mount technology, including mobile phones and consumer electronic products; automobile manufacturing units that have large foundries, paint shops or other continuous processes and vertically integrated large textile units.

The GO has also exempted export and their vendor units Manufacturing units that supply components or equipment for the defence sector; manufacturing units of automobiles and components and units producing packaging materials.

Relaxations are also permitted for these units Telecommunications, night shift operations of IT/ ITES companies workforce to operate from the office; maintenance and operations of data centres and other critical IT infrastructure to support back end operations of medical, financial, transport and other critical services; warehousing activities and industries providing maintenance for the purpose of fire safety, machine safety and worker safety will be permitted.

Source: Express News Service, The New Indan Express, 23.04.2021

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PM Modi holds meeting with Pharma companies, asks officials to ramp up vaccine production

File photo of Prime Minister Narendra Modi | Twitter @BJP4India

As the country is witnessing a spike in the COVID-19 cases, Prime Minister Narendra Modi on Monday, 19.04.2021 held a virtual meeting with the top Pharma companies in the country regarding the situation of the pandemic here.

In the COVID-19 review meeting on April 17, PM Modi had stressed that there is no substitute for testing, tracking and treatment.

He also asked the officials to make efforts to utilise the entire national capacity, in the public as well as the private sector, to ramp up vaccine production. Meanwhile, the COVID-19 situation in India continues to deteriorate, as the country yet again reported the highest single-day spike of Coronavirus cases with over 2.73 lakh fresh infections and 1,619 deaths in the last 24 hours.

According to the Health Ministry, there are currently 19,29,329 active cases in the country as of Monday, 19.04.2021. The death toll reached 1,78,769. In the last 24 hours, as many as 1,44,178 people recovered from the virus.

Source: ANI, The Print, 20.04.2021

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'Encourage patients to get Covid vaccine, educate people against rumours'

Prime Minister Narendra Modi on Monday called the vaccine as the biggest weapon in the fight against

COVID-19 and urged doctors to encourage more and more patients to get the jab.

In a virtual interaction with the country's leading doctors on the pandemic situation and vaccination progress earlier today, he also noted that COVID-19 is spreading rapidly in tier-2 and tier-3 cities this time, and asked them to connect with their colleagues working there and give them online consultations to ensure that all protocols are followed correctly.

Urging doctors to educate people against "rumours" on COVID treatment and prevention, Modi said it is very important in these difficult times to not become a victim of panic, an official statement said.

For this, Modi said, along with proper treatment, emphasis must also be on counselling of patients admitted in hospitals.

He also encouraged doctors to use tele-medicine for the treatment of other diseases, in case there is no emergency.

The central government has recently taken many important decisions related to the supply of essential medicines, injections and sufficient availability of oxygen, he said, adding that states have been given necessary guidelines about these.

Amid a massive surge in Coronavirus cases across the country, some Chief Ministers have complained of a shortage of essentials like oxygen supply and medicines like Remdesivir, and sought the Centre's intervention.

Modi said it was due to our doctors' hard work and the nation's strategy that India was able to control the infectious disease, and now that it is facing the second wave, all the doctors and our frontline workers are confronting the pandemic with full force and are saving the lives of millions of people.

He also called for accelerating efforts to upgrade resources in smaller cities. The statement said doctors shared their experiences in dealing with the pandemic and congratulated Modi on his leadership in dealing with the crisis.

They also spoke about how they are augmenting the healthcare infrastructure and reiterated the importance of people wearing a mask & maintaining social distancing.

They also stressed the need for maintaining health infrastructure for non-Covid patients and said they have been sensitising patients against improper use of medicines, it said.

The meeting was also attended by Union Health Minister Harsh Vardhan, his Deputy Ashwini Kumar Choubey, Union Minister of Chemical and Fertilizer D V Sadananda Gowda, his Deputy Mansukh Mandaviya, V K Paul Member of NITI Aayog, and senior bureaucrats.

Source: ANI, The Print, 20.04.2021

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Apex Laboratories gets approval for CleVira as Covid supportive drug

Apex Laboratories said it has got the approval from the Ministry of Ayush for its antiviral drug Clevira as a supporting measure for mild to moderate condition of Covid-19.

Pharma company Apex Laboratories will take the doctor's prescription route for its oral antiviral CleVira tablet that got the Central government's approval as a supporting measure for mild to moderate condition of Covid-19, a senior official said.

Apex Laboratories said it has got the approval from the Ministry of Ayush for its antiviral drug Clevira as a supporting measure for mild to moderate condition of Covid-19.

The company said this is the first of its kind approval in India through various stages of scrutiny at The Central Council for Research in Ayurvedic Sciences and Interdisciplinary Technical Review Committee.

Source: ANI, ET-Healthworld, The Economic Times, 24.04.2021

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Centre Waives Customs Duty on Remdesivir Injection & Its Active Ingredients amid Covid Crisis

Representational image of Remdesivir.

The Centre on Tuesday, 20.04.2021 removed all customs duty on imported Remdesivir injections and the drug's Active Pharmaceutical Ingredients (API) in a bid to boost supplies. The government made the announcement weeks after it banned the export of the antiviral injections till an improvement in the Covid-19 situation in the country.

According to an official release by the Union Finance Ministry, the central government has also exempted customs duty on the import of "Beta Cyclodextrin (SBEBCD)", used in the manufacture of Remdesivir, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.

The move aims to improve the supply of Remdesivir and make it available at cheaper prices as the country reels under the second wave of the Coronavirus pandemic. The Union Health Ministry had directed domestic manufacturers of Remdesivir to ensure easy access of the drug, which is used in the treatment of Coronavirus, to hospitals and patients and advised them to display their stockists and distributes on their websites.

Drugs inspectors and other officers have been directed to verify stocks, check malpractices and also take other effective actions to curb hoarding and black marketing. State Health Secretaries will review this along with drug inspectors of the respective states and UTs, the government statement said.

Seven Indian companies are producing the injection under voluntary licensing agreement with M/s Gilead Sciences, USA. They have an installed capacity of about 38.80 lakh units per month, the ministry said. The Department of Pharmaceuticals has been in contact with the domestic manufacturers to ramp up the drug's production, it added.

The government has also advised states that the extant 'National Clinical Management Protocol for COVID-19', which is based on evidence, has been developed after many interactions by the committee of experts and it is the guiding document for the treatment of COVID-19 patients.

In the protocol, Remdesivir is listed as an investigational therapy, i.e. where informed and shared decision making is essential, besides taking note of contra indications mentioned in the detailed Guidelines, the Ministry said.

States and UTs have been advised that these steps should again be communicated to all hospitals, both in public and private sector, and compliance monitored, it added.

Source: www.news18.com, 22.04.2021

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Health Ministry notifies Government Analysts for all classes of drugs as per D&C Act

The Union Health Ministry has notified one government analyst in respect of all classes of drugs at Central Drugs Testing Laboratory (CDTL), Hyderabad in exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics (D&C) Act, 1940 (23 of 1940) read with Rule 44 of the D&C Rules, 1945. CDTL is one of

the newly established laboratories in the state of Andhra Pradesh (AP) engaged in testing, research and analysis of drugs and cosmetics as per D&C Act, 1940.

As per a Gazette Notification, "Government has appointed Dr Raghuram Reddy Adidala as Analyst at CDTL, Hyderabad in respect of all classes of drugs except for the classes of drugs like sera, solution of serum proteins intended for injection, vaccines (parenteral and oral), toxins, antigens, anti-toxins, sterilized surgical ligature and sterilized surgical sutures, bacteriophages, anti-sera for veterinary use, vaccine for veterinary use, toxoid for veterinary use, diagnostic antigens for veterinary use, VDRL antigen, intra-utrine devices and falope rings, human blood and human blood products, blood grouping reagents and diagnostic kits for Human Immunodeficiency virus, hepatitis B surface antigen and hepatitis C virus and condom."

The Union Health Ministry had earlier in the month of March notified two government analysts in respect of all classes of drugs at Regional Drugs Testing Laboratory (RDTL), Chandigarh.

Name and designation of the government analysts RDTL, Chandigarh are Hitesh Kumar Khare, senior scientific officer-II and Dr Debasis Maiti, senior scientific officer-II.

RDTL, Chandigarh is one of the seven national drugs testing laboratories of Central Drugs Standard Control Organisation (CDSCO), set-up under the requirement for the testing of D&C products, working since November 2007.

The laboratory has been developed for the quality control of D&C products with respect to infrastructure, equipment and manpower for the chemical, instrumentation and microbiological analysis.

The RDTL, Chandigarh is regularly testing number of Legal (Form-18), survey and imported samples of D&C received from the central officers/drugs inspectors of CDSCO North Zone – Ghaziabad, Sub Zone - Baddi, Jammu, Varanasi and Assistant Drugs Controller (India), Indira Gandhi International Airport, New Delhi.

Apart from this, laboratory is notified for the State of Haryana, Himachal Pradesh, Jammu & Kashmir, Union Territories of Chandigarh and Delhi for the analysis of D&C samples drawn by their drug officers. The laboratory is having testing capacity of about 5,000 samples per annum, and is NABL accredited as per ISO/IEC 17025:2005, since 2016.

Union Health Ministry had earlier also notified four government analysts at RDTL, Guwahati in respect of all classes of drugs namely Amar Jyoti Chamuah, junior scientific assistant, Dilip Kumar Sarkar, junior scientific assistant, Rinku Kalita, junior scientific assistant and Arun Kumar Das, junior scientific assistant.

Source: Shardul Nautiyal, Pharmabiz, 24.04.2021

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DCGI seeks daily update from state and UT DCs to curb black marketing and overcharging of Covid drugs

The Drugs Controller General of India (DCGI) has directed all state and Union Territory Drugs Controllers to provide daily update on enforcement activities to stop hoarding, black marketing and overcharging of Covid management drugs— remdesivir, tocilizumab, favipiravir and oxygen cylinder.

In light of present pandemic situation in the country it has been considered necessary to collect the daily information on enforcement activities to prevent black marketing, overpricing with respect to remdesivir, tocilizumab, favipiravir and oxygen cylinder, said DCGI Dr V G Somani.

Dr Somani in a letter to all state and UT drugs controllers recently requested to send the above information as per format on daily basis (by 5 pm) on email—dci@nic.in, enforcecell.div@cvdsco.nic.in, import.regist@cdssco.nic.in.

He asked all zonal, sub zonal offices of CDSCO to coordinate with state and UT drugs control authorities in the matter.

With a sharp rise in Covid-19 cases in the country, the demand for drugs like tocilizumab, favipiravir, antiviral medication remdesivir and oxygen cylinder has also increased. This, in turn, has led to a shortage of these drugs as well as oxygen cylinder and led to black marketing and overcharging.

Tocilizumab, an immunosuppressive drug which was earlier used for treating rheumatoid arthritis, is now being used for treating severe Covid patients. The drug is said to reduce Covid deaths.

The one vial of the drug which is manufactured by Roche, a Switzerland-based company and marketed by Cipla in India, is priced above Rs.40,000. There is an acute shortage of the drug across the country as Cipla has run out of the stock. It is learnt that the Pharma major will get its next consignment of tocilizumab in a week.

Besides this, Remdesivir, a drug that is being used in emergency to treat critical Covid-19 patients who are hospitalized is also in short supply across the country.

Though, the production capacity is being ramped up from current level of 38 lakh vials per month to 74 lakh vials per month, and 20 additional manufacturing sites have been approved, pharmacies across the country have reported shortage of Remdesivir due to the sudden rise in demand.

Export of Remdesivir has also been prohibited on April 11, 2021 to shore up domestic supplies. Now the government has also waived custom duty on import of the drug and its raw material.

Antiviral Favipiravir is also in short supply in the country. Glenmark Pharmaceuticals Ltd, which manufactures the favipiravir brand, FabiFlu, said it has ramped up production capacity to ensure continuous supply of the drug across the country.

Several states have reported shortages of medical oxygen for Covid-19 patients who are in need of oxygen support. When the families of Covid patients are not able to find a hospital bed, doctors advise them to arrange oxygen cylinder at home. Due to rise in demand, the prices of oxygen cylinder have gone up to Rs.20,000 - Rs.25,000 a cylinder in parts of the country. India plans to import 50,000 metric tonnes of medical oxygen to cater to the rising demand. The Union Ministry of Health and Family Welfare has been directed to float a tender for the import.

Source: Laxmi Yadav, Pharmabiz, 23.04.2021

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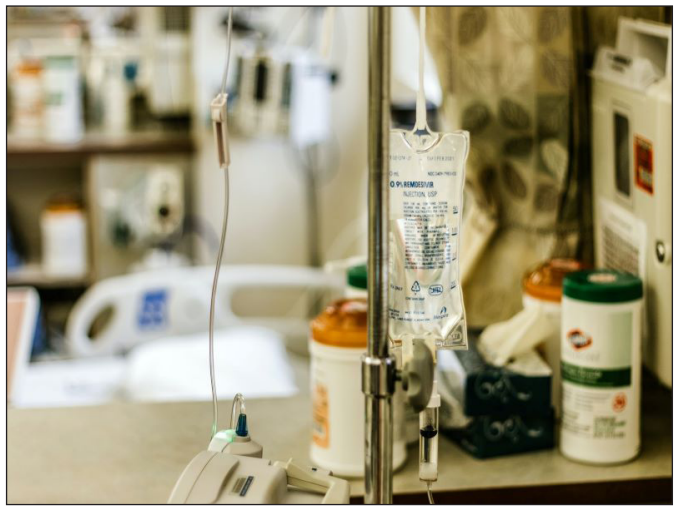
Remdesivir production to double from May, Home Ministry asks states to ensure smooth transport, supply and allocation

India has taken steps to double the production of ant-viral drug Remdesivir from 38.80 lakh units per month to 74 lakh units per month by early next month, the Home Ministry said on Friday, 23.04.2021 and asked the states to ensure smooth transport and supply of the critical drug used in treating Covid-19.



Union Home Secretary Ajay Bhalla, in a letter to Chief Secretaries of all states and Union Territories (UTs), informed that an interim allocation and supply of the life-saving injection to the states/UTs has been scheduled from April 21 to April 30.

"In view of the above, I would urge you to issue necessary instructions to all the authorities concerned to take all measures for compliance with the above allocation and subsequent allocations to be made by MoHFW and DoP in a smooth and timely manner to ensure seamless supply and transport of Remdesivir to States/UTs concerned," he said.

In order to monitor and coordinate the supply of COVID-19 drugs on a daily basis, a mechanism has been set up under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers through the National Pharmaceuticals Pricing Authority (NPPA) and the Drugs Controller General of India, he further said.

"The supply of Remdesivir injection and imported drug Toclizumab is under severe constraint due to sharp increase

in demand. Several steps have been taken to augment the production capacity of the seven licensed manufacturers of Remdesivir injection in the country from 38.80 lakh units per month to 74 lakh units per month by early May 2021," the letter said.

Emphasising the importance of the availability of the drug, Bhall stated that any disruption or hindrance to the movement of this drug, may have an unintended adverse effect to the nation's fight against COVID-19.

"I would also request you to personally monitor the supply of essential medicines required under COVID Treatment Protocol in your UT and appoint Nodal Officers who will be responsible for un-restricted and timely movement of Remdesivir within their UT as per allocation made by MoHFW," he added.

Source: India Blooms News Service, 24.04.2021

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Bharat Biotech's Covaxin demonstrates 100% efficacy against severe Covid-19 disease in Phase 3 interim analysis

Hyderabad-based vaccine manufacturer Bharat Biotech announced second Interim results from Phase 3 trials. Bharat Biotech and ICMR said that Covaxin demonstrated 78 percent vaccine efficacy against Covid-19 disease and 100% efficacy against severe Covid-19 disease with an impact on reduction in hospitalisations.

The interim analysis was based on accruing more than 87 symptomatic cases of Covid-19. Due to the recent surge in cases, 127 symptomatic cases were recorded, resulting in a point estimate of vaccine efficacy of 78% against mild, moderate, and severe Covid-19 disease, the company said.

The efficacy against severe Covid-19 disease was 100%, with an impact on reduction in hospitalizations. The efficacy against asymptomatic Covid-19 infection was 70%, suggesting decreased transmission in Covaxin recipients, the company said in a release.

Source: ET-Health World, The Economic Times, 22.04.2021

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IPC starts verifying testing protocols for DCGI approved drugs

The Indian Pharmacopoeia Commission (IPC) has started verifying the testing protocols for Drugs Controller General of India (DCGI) approved drugs recently introduced in the Indian market.

With reference to the testing protocols, a total 510 of New Drug Samples (NDS) were received from the office of DCGI for verification during the financial year 2019-20 and report for the same has been successfully submitted. Besides this, out of analysis of 2,141 drug samples, 94 were candidate reference material of Indian Pharmacopoeia Reference Substances (IPRS), 510 were NDS and 1,537 were miscellaneous samples.

Ghaziabad-based IPC provides IPRS which act as a fingerprint for the identification of an article under test and its purity as prescribed in Indian Pharmacopoeia (IP).

A total of 1,537 miscellaneous samples received from the Central Drugs Standard Control Organisation (CDSCO), Central Medical Services Society (CMSS) and Inter Laboratory Comparison (ILC) at IPC for the analysis and reports of the same were successfully submitted to the respective offices.

Several representations were made for the test protocols to be made available for drug testing laboratories/regulators of the respective states on demand. Indian pharmacopoeia laboratory has also conducted the testing of new drug molecules received from DCGI office and prepared the protocol bank. The protocols are available on demand.

The financial year 2019-20 was a productive year for the IPC to keep abreast the stakeholders of new scientific developments in the area of setting standards of drugs, promoting rational use of medicinal products through generic approach and to ensure patient safety, their rights and well being through Pharmacovigilance Programme of India (PvPI) and Meteriovigilance Programme of India (MvPI).

During crisis of Covid-19 pandemic, to strengthen the quality of drugs in India, Union Health Ministry released the IP Addendum 2019 to IP 2018 on July 5, 2019 at Nirman Bhawan, New Delhi. The IP Addendum 2019 contains 66 new monographs including those of chemicals category (N=61), herbs and herbal products (N=3), and

radiopharmaceuticals preparations (N=2). It became official from January 1, 2020.

Further, IPC has drafted a total of 64 new monographs for the Addendum 2021 to IP 2018 including 57 chemical monographs, 2 blood and blood related products monographs, 5 herbs and herbal products monograph and 7 general chapters. IP has been recognized formally by the National Department of Regulation of Medicines and Health Products of the Ministry of Public Health of Islamic Republic of Afghanistan and also will be used based on the requirement as reputable pharmacopoeia in the laboratory of medicines and health products quality.

Afghanistan has become the first country to recognize the IP, pursuant to the efforts of the union health ministry and the Union Commerce Ministry of Commerce.

A total number of 94 Reference Standards have been developed during the index period of 2019-20. This includes 13 IPRS, 21 Impurities, and 60 IPRS lot replacements.

Till date, a total of 598 IPRS and 154 Impurity Standards have been developed by the IPC and comprehensive list is available on the website of IPC (www.ipc.gov.in). In addition, a total of 489 numbers of IPRS were retested for their potency and stability.

Also, a total of 211 new candidate materials were received from stakeholders and processed to develop new IPRS. A total of 81 candidate materials are under validation to develop as IPRS and Impurity Standards.

Source: Shardul Nautiyal, Pharmabiz, 27.042021

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Indian healthcare sees cloud computing and data analytics to equip for future emergencies

The Indian healthcare sector has adopted cloud computing and data analytics to maximize the vast amounts of data it generates. While this would improve patient care, collaboration, and research, the hospitals also see that technologies will transform the healthcare sector and equip for future emergencies.

With the adoption of emerging cloud technologies, data analytics will transform the healthcare sector and equip healthcare institutions for future emergencies.

When access to real-time data is crucial in creating strategies to curb the spread of the disease during the pandemic, healthcare and social security departments were able to share, store, and access data through the cloud. Healthcare practitioners are able to make quick decisions based on collected data. Furthermore, collaboration and secure sharing of data proved to be critical for researchers racing to find treatments and vaccines for Covid-19.

Healthcare analytics is a segment of digital healthcare that leverages data from hospitals and other facilities as well as patient records and diagnoses. Although in its nascent stages of adoption in India, healthcare analytics can help medical professionals address many gaps with the help of Artificial Intelligence (AI) and big data analytics.

Cloud computing is not a new concept in the healthcare sector. In the past, IoT devices, wearables, and health-monitoring equipment have collected data that help healthcare institutions gain insights on diagnoses, disease management, treatment, and prevention, Vimal Venkatram, Country Manager, Snowflake told.

By migrating to cloud platforms that offer flexibility and the storage capacity needed to house large volumes of data, healthcare institutions can derive insights that positively impact patient care and hospital operations. With access to real-time information, healthcare professionals and executives are empowered to make informed decisions that improve patient care. By analysing data sets, healthcare professionals and researchers will be able to recommend steps to create disease-control strategies, he added.

With digitalization Mobile Health (mHealth), The Internet of Medical Things (IoMT) Artificial Intelligence (AI), machine learning, and blockchain are seen to enable remote patient monitoring trackers, sensor-enabled hospital beds, medication-tracking systems as, well as medical supplies and equipment inventory tracking systems, said Venkatram.

With mobile health data applications, patients can view their medical records, communicate with care teams, and manage billing and appointments 24 hours a day, seven days a week. Centralised Electronic Health Record (EHR) systems have enabled self-service patient data management, empowering individuals to better track their health.

The expanding digital tech ecosystem is transforming healthcare and improving patient outcomes in India by improving drug management, delivering better patient experiences, accelerate medical research and clinical trial analysis.

On account of the increase in adoption of data analytics, wearable devices, and IoT, we anticipate that cloud technology and its applications to play an important role in the future of the healthcare industry. Cloud technology automates back-end operations and facilitates the creation and maintenance of mobile health apps.

As these medical innovations and technologies continue to evolve and gain traction, the impact of cloud computing in the healthcare industry is expected to grow stronger over the next five years, said Venkatram.

The utilisation of telehealth or Remote Patient Monitoring (RPM) has also seen an increase during the pandemic. Communities with limited access to health services were able to interact with cloud-connected health care professionals and receive appropriate medical advice, noted the Snowflake chief.

Source: Nandita Vijay, Pharmabiz, 27.04.2021

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IPC successfully concludes WHO Biowaiver Project for BCS based classification of APIs

The Indian Pharmacopoeia Commission (IPC) has successfully participated and concluded World Health Organisation (WHO) Biowaiver Project for Biopharmaceutics Classification System (BCS) based classification of Active Pharmaceutical Ingredients (APIs).

The WHO Biowaiver Project classified first set of APIs like tenofovir, dolutegravir, ethionamide and the outcome was finally endorsed by the WHO 53rd Expert Committee on submission.

Further to this, WHO Expert Committee prioritized the second set of APIs (N=15) to scale up the project for BCS based classification. IPC has participated in the WHO Biowaiver Project by contributing in the equilibrium solubility experiments on APIs and results have been communicated to the WHO for compilation of report.

There are certain requirements for a biowaiver study that include allowance of regulatory authorities like the respective Food and Drug Administration (FDA) and WHO. The drugs should have high solubility and high permeability according to BCS. BCS is an experimental model that measures permeability and solubility under prescribed conditions.

A Biowaiver means that *in vivo* bioavailability and/or bioequivalence studies may be waived (not considered necessary for product approval). Instead of conducting expensive and time consuming *in vivo* studies, a dissolution test could be adopted as the surrogate basis for the decision as to whether the two pharmaceutical products are equivalent.

BCS is a regulatory mechanism through which drug developers and generic companies can obtain a waiver of clinical bioequivalence (BE) studies, also called a biowaiver. While BE establishes generic drugs as interchangeable to the branded ones with similar therapeutic and side effect profiles, bioavailability (BA) of drugs signifies the rate and extent to which their active ingredient is absorbed systemically after dosing.

The risk of therapeutic inequivalence of two immediate release products can never be reduced to zero, even if a full clinical study is performed. The conclusion of comparative clinical studies, in vivo bioequivalence studies, in vitro equivalence tests and biowaivers is based on statistics and scientific data that are assumed to be representative for the products at issue. The aim of biowaiver guidance is to reduce the risk of bioinequivalence to an acceptable level.

Pharmaceutical development work aims at reducing the probability of manufacturing inequivalent formulations taking into account the critical aspects of the product at issue. In this context, the absorption phase is regarded as the critical process determining the equivalence of the pharmacokinetic profiles and thereby the therapeutic equivalence of the test and reference product.

Source: Shardul Nautiyal, Pharmabiz, 28.04.2021

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Ayush Ministry issues COVID-19 Guidelines for Ayurveda and Unani Practitioners

The Union Ministry of Ayush has released revised Guidelines for Ayurveda and Unani Practitioners for Covid-19 patients in home isolation and Ayurveda and Unani preventive measures for self-care.

"It is aimed to increase awareness among the citizens regarding the effective home care solutions and recommended Ayush practices, to help them to enhance their immunity along with standard Guideline for Ayurveda & Unani practitioners for management of prophylactic, asymptomatic and mild cases of Covid-19 during home

isolation," the Ministry said. These guidelines and advisories were developed through an extensive consultative process by the empowered committee within the interdisciplinary Ayush Research and Development Task Force setup by Union Ministry of Ayush.

The Ministry said the Project Monitoring Unit for Covid-19 Studies, Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), All India Institute of Ayurveda (AIIA) and National Medicinal Plant Board (NMPB) of this Ministry worked on formulating the advisories and guidelines.

The present guidelines and self-care measures provide clear guidance to Ayurveda & Unani practitioners regarding treatment of Covid-19 patients in different conditions of infection. This brings in uniformity and consistency in the Ayush-based responses to the pandemic across the country. It also helps state/UT governments to plan and incorporate these solutions into the Covid-19 management activities being deployed on the ground. Furthermore, these measures and guidelines contribute to the mainstreaming of Ayush solutions for the management of Covid-19, and will be immensely beneficial to the public since these solutions are easily accessible and will help to alleviate the hardships brought in by the pandemic.

The Ayush Ministry issued an advisory on January 29, 2020 on how to protect oneself from Covid-19 and how to stay healthy. In this context, the ministry has also promoted the use of ready-made formulation like AyushKwath (Ayurveda) which is a simple admixture of four herbal ingredients which are well known in India and outside India for their immunomodulatory and anti-viral activities along with several other health benefits.

It added that keeping a note on the present public health challenges due to the second wave of Covid-19 pandemic, there is a requirement to urgently disseminate information about the guidelines for Ayurveda and Unani Practitioners for the management of Covid-19 patients during home isolation. "The effective evidence-based Ayurveda and Unani formulations/measures such as Ayush-64, Ashwagandha tablets, etc. have been included for the management of asymptomatic and mild cases of Covid-19 during home isolation," it said.

Source: Pharmabiz, 28.04.2021

‘Stickiness’ key to better Diagnostics and Pharmaceuticals

IMAGE: “THE STICKINESS, OR VISCOSITY, OF LIQUIDS IS INCREDIBLY IMPORTANT IN BIOLOGY, “ PROFESSOR BOWEN SAID. view more

Credit: The University of Queensland

The ‘stickiness’, or viscosity, of microscopic liquids can now be measured thousands of times faster than ever before, potentially leading to better understanding of living cells, disease diagnostics and pharmaceutical testing.

University of Queensland’s Professor Warwick Bowen and his colleagues at the Queensland Quantum Optics Lab developed the world-leading technology, technology that uses lasers to track microscale particles with world-record precision.

“The stickiness, or viscosity, of liquids is incredibly important in biology,” Professor Bowen said.

“In living cells, viscosity fluctuations control shape and structure, modulate chemical reactions, and signal whether a cell is healthy or cancerous.

“However, current technologies to measure viscosity are too slow to monitor and track these important changes.

“Our innovative new technology overcomes this by achieving viscosity measurements a thousand times faster than ever before.”

The technology may lead to a fundamental revision of scientists’ understanding of cells.

“It’s thought that fast viscosity fluctuations may occur in our cells - linked to their turbulent or chaotic activity - though they’ve never been observed,” Professor Bowen said.

“Observing them would be re-calibrate our understanding of cells - it would force us to revise our basic models of cellular dynamics.

“These phenomena are predicted to occur on sub-millisecond timescales, far faster than can be measured with previous technology, but completely measurable with ours.

“Cells are the building blocks of life - we could be on the precipice of reimagining how they function.”

Dr Lars Madsen said the discovery may spur advancements in pharmaceutical testing, allowing companies to quality control their drugs faster, and with greater accuracy.

“There are many moving parts when it comes to pharmaceutical manufacture - stirring, pumping, filling,” Dr Madsen said. “These processes need to be incredibly exact, and usually have to be controlled by performing regular viscosity checks with a viscometer.

“We’ve invented an alternative technology, with accuracy and selectivity far beyond existing viscometer technology. “Faster, more accurate testing can create products that are not only be safer, but could offer better storage stability, reduce costs significantly by improving yield, reduce raw material variability and increase delivery reliability.

“We’ve all seen the impacts of pharmaceutical hold-ups this year - speed-to-market is critical in this industry.”

(The research, supported by the Australian Research Council, and the United States Air Force Office of Scientific Research, and published in Nature Photonics. AAAS and EurekAlert! are not responsible for the accuracy of news releases posted to EurekAlert! by contributing institutions or for the use of any information through the EurekAlert system)

Source: EurekAlert, 22.04.2021 (Excerpts)

The application bottleneck, innovation and development of AI in pharmaceutical and chemical fields

Lisa George

With the birth of computer science in the early 21st century, mankind has entered a new era in terms of information storage. Early algorithms are mainly dedicated to liberating repetitive and tedious mathematical and logical operations. But in the following decades, the theoretical basis of related machine learning and various algorithms have been developed by leaps and bounds. Now the organic combination of big data, algorithms and computing power has contributed the application of artificial intelligence in many fields.

Chemistry is a classic discipline of natural sciences, which aims to study the composition, properties, structure and changing laws of matter at the molecular and atomic levels. Chemistry is closely related to human production and life, and plays a vital role in energy, materials, pharmaceuticals and other fields. Traditional chemical research and chemical production rely heavily on experiments guided by theory, requiring a lot of manpower and material resources, and largely depending on the experience and level of practitioners. Then how to apply cutting-edge results in the field of artificial intelligence to the field of chemistry to increase productivity has become an inevitable trend. The resulting cross-discipline of "AI + chemistry" also provides a wide range of exploration space for the vast number of scientific researchers and entrepreneurs.

A series of emerging topics need to be studied: the digitization of chemical molecular structure and physical and chemical properties, automatic prediction of chemical total synthesis or biosynthesis pathways, optimization of industrial production and purification processes of chemical compounds, high-throughput computational screening of drug molecules, drug molecules and proteins prediction and optimization of target binding, prediction of toxicology and metabolic process of drug molecules in vivo. Using Artificial Intelligence to assist the above-mentioned related topics can greatly improve R&D and production efficiency. Compared with the information technology industry, the application of artificial intelligence in the chemical field also encounters a series of challenges.

How Artificial Intelligence plays a role in the pharmaceutical and chemical fields?

AI models can cover more data and obtain information from more data. For example, deep learning models can provide better predictions and generate new molecular structures through the training and learning of big data, which was not possible for the previous classical scientific computing models. Another example: before the use of AI, hundreds of people may discuss together to develop a drug, and hundreds or thousands of molecules may be designed in the end; however, AI allows us to simulate millions of drugs at once as long as the model is appropriate.

Bottlenecks of applying AI in the chemical and pharmaceutical fields?

The first bottleneck encountered is the data problem. In drug development application scenarios, it is difficult to automatically generate data. And without enough data, it may be impossible to do it unless sufficient data has been obtained. In addition, in drug development, many data do not have negative data, but as a machine learning model, negative samples are very important. Without this negative sample, the data is not balanced. This problem always exists and requires a large data system to support it.

The second bottleneck lies in Artificial Intelligence itself. Drug development is an application of Artificial Intelligence, and there are some limitations. Because the drug system itself is very complex, applying a cutting-edge thing to a complex system will create a bottleneck. For example, the learning and inheritance of the experience of pharmaceutical experts is difficult for artificial intelligence to handle.

MedAI is an AI drug R&D company that has successively launched a number of drug discovery prototypes, from the early development stage (AI-driven drug synthesis, drug design, drug activity prediction) to the clinical research stage (AI-driven pharmacovigilance system, registration transaction system, clinical data programming system) and so on, covering a series of key nodes in the whole process of new drug research and development.

Source; Pharmifeb, 21.04.2021

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Our Ref. No. 0117/2021
Dated: April 17, 2021

Kind Attention:
Dr Aseem Vohra, First Secretary,
Embassy of India, Moscow, Russian Federation

PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce and Industry, Government of India)

PXL/HO/Cir-004/2021-22
Date: 22.04.2021
Hyderabad

IDMA (Indian Drug Manufacturer'S Association)

Dear Sir/Madam,

Sub: Commercial Offer for supply of Remdesivir from Russia- Reg

We are glad to inform the members that Pharmexcil has received a communication from the the Indian embassy in Moscow that a Russian manufacturer of pharmaceutical products, PHARMASYNTEZ has offered to export the drug Remdeform (INN Remdesivir) to India of around three to four lakh packs per week.

It is understood that PHARMASYNTEZ group of companies is one of the largest domestic manufacturers in the Russian Federation and it has acquired the rights to produce and sell the "Remdeform" (Remdesivir, lyophilized powder for injection, generic drug of "Veklury" of Gilead Sciences).

It is furthur learned that PHARMASYNTEZ is interested in negotiating the commercial terms directly with buyers from India and is ready to supply "Remdeform: to India" on the following terms. Please find attached the offer received from PHARMASYNTEZ.

. Quantity: 300 000 - 400 000 packs per week

. Estimated delivery Time (Alr: About 8-10 days)

Taking into account severe shortages through indigenous sources, the Indian Pharma importers may like to consider the Russian offer. Members may kindly be aware that import permissions from CDSCO needs to be taken while importing the said product.

Interested members may directly approach the nodal person of PHARMASYNTEZ given below:

Mr. Evgeniy Dubrovin

BD Director

PHARMASYNTEZ Group of Companies

email id: info@pharmasyntez.com

Tel: + 7 3952 55 03 55

Our Director, Regulatory Affairs - Ms.Lakshmi Prasanna (email is: regulatory@pharmexcil.com) would be ready to assist any interested company.

Warm Regards

Udaya Bhaskar

Director General

Encl:
Pharmazyntez

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