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IDMA BULLETIN

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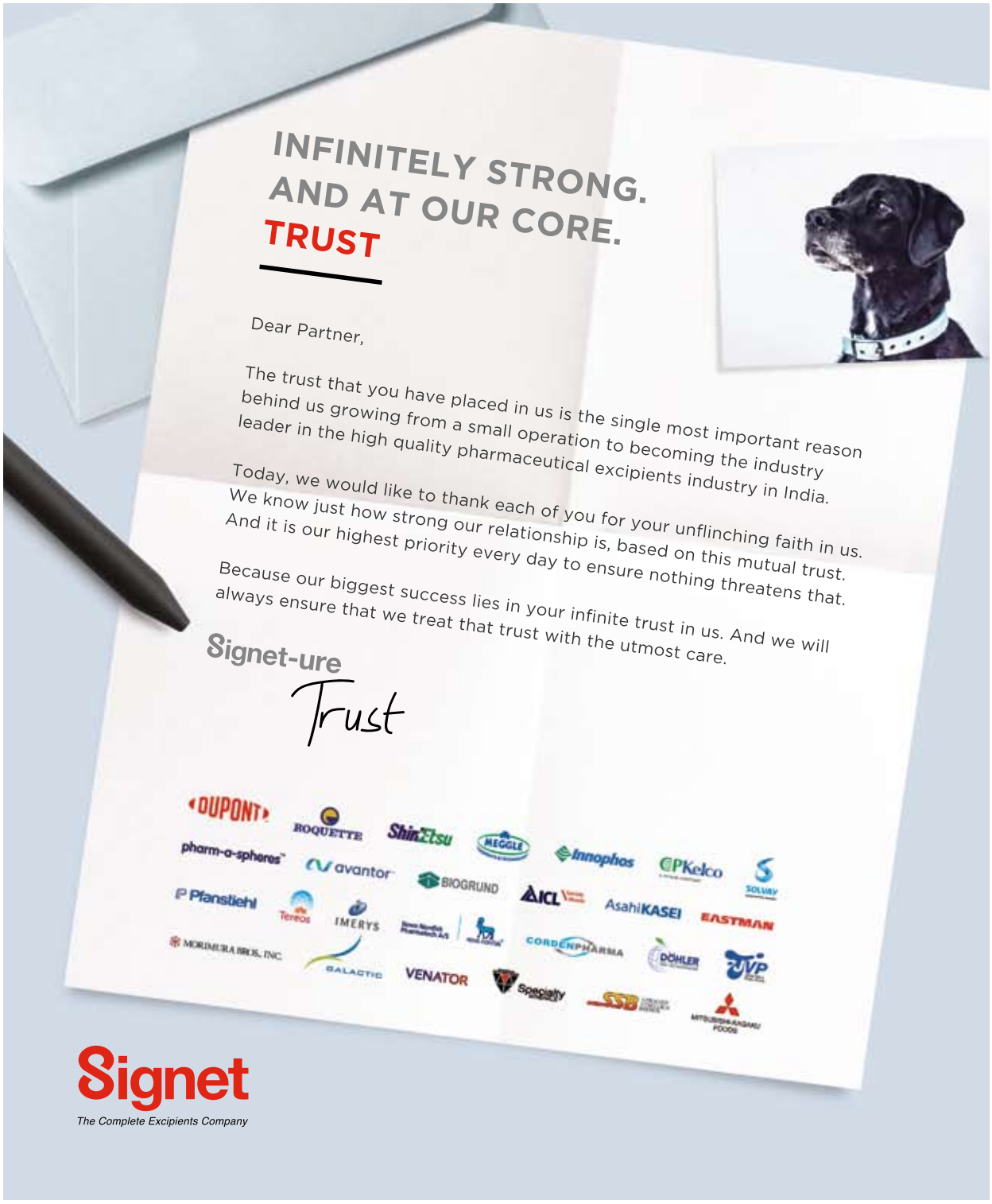
Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS


INFINITELY STRONG.
AND AT OUR CORE.
TRUST
Dear Partner,
The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
Because our biggest success lies in your infinite trust in us. And we will always ensure that we treat that trust with the utmost care.
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ROQUETTE
Shin-Etsu
MEGGLE
Innophos
CPKelco
SOLVAY
pharm-a-spheres
avantor
BIOGRUND
AICL
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EASTMAN
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IDMA BULLETIN

Vol. No. 51 **Issue No. 22** **08 to 14 June 2020**

IDMA-TNPKSB CSR Activities

Association-Tamil Nadu, Puducherry & Kerala State Board (IDMA-TNPKSB) is glad to inform that on 8th June 2020, we donated Rs.18.00 Lakhs worth of these 3 medicines, in the presence of our Deputy Drug Controller-Dr Manivanan, IDMA-TNPKSB-Chairman-Mr Jayaseelan, Vice-Chairman-Mr Sathish & Members Mr Pandian & Mr Rajesh. We were fortunate to have

The Adyar Cancer Institute (WIA), as you are aware, is a public charitable voluntary institute dedicated to the care of cancer for the last 60 years. During these Covid Times, the institute is badly in need of funds/materials (as Covid materials to each health warrior in the hospital is an extra burden to such charitable hospital, but still many patients are dependent on them), as all patients are treated there either free or at a very minimal cost. On the mass request by the Hospital for donors & on a specific request for drugs from the most respected Chairman of the Hospital **Padma Vibhushan Dr V Shanta,** we volunteered to contribute the list of 3 medicines requested by them. Namely ***Neukine***, ***Pegasta*** & ***Peg-Grafeel***. Indian Drug Manufacturers'

Dr Shanta in Person at the time of donating the medicines. She was very thankful to IDMA & all its members. May our service to Humanity Continue as ever...

● ● ●

Have you renewed your **Membership** for the

Year 2019-2020 & 2020-2021

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 / Fax: 022 - 2495 0723

Government imposes provisional anti-dumping duty on import of 1-phenyl-3-methyl-5-Pyrazolone for a period of six months - reg.

Notification No.13/2020-Customs (ADD), dated 9th June, 2020

1. Whereas, in the matter of import of **'I-Phenyl-3-Methyl-5-Pyrazolone'** (hereinafter referred to as the subject goods), falling under tariff heading 2933 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the said Customs Tariff Act), originating in or exported from **China PR** (hereinafter referred to as the subject country) and imported into India, the designated authority *vide* its preliminary findings No. 6/32/2019-DGTR dated the 13th April, 2020, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 13th April, 2020, has come to the conclusion that-

(i) there is substantial increase in imports of subject goods from the subject country in absolute terms as well as in relation to its production and consumption in India, during the Period of Investigation as compared to the previous year;

(ii) the product under consideration has been exported to India from the subject country below the normal value;

(iii) the Domestic Industry has suffered material injury;

(iv) material injury has been caused by the dumped imports of subject goods from the subject country;

and therefore has recommended imposition of provisional anti-dumping duty equal to the difference between the amount indicated in column (7) of the Table appended below and the landed value.

Now, therefore, in exercise of the powers conferred by sub-section (2) of section 9A of the said Customs Tariff Act read with rules 13 and 20 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, the Central Government, on the basis of the aforesaid findings of the designated authority, hereby imposes on the subject goods, the description of which is specified in column (3) of the Table below, falling under tariff heading of the First Schedule to the said Customs Tariff Act as specified in the corresponding entry in column (2), originating in the countries as specified in the corresponding entry in column (4), exported from the countries as specified in the corresponding entry in column (5), produced by the producers as specified in the corresponding entry in column (6), and imported into India, a provisional anti-dumping duty at the rate equal to the difference between the amount as specified in the corresponding entry in column (7) and the landed value of the goods, in the currency as specified in the corresponding entry in column (9) and as per unit of measurement as specified in the corresponding entry in column (8) of the said Table, provided that the landed value is less than the amount indicated in column (7) of the said Table, namely:-

TABLE

Sr. No.	Tariff heading	Description of goods	Country of origin	Country of Export	Producer	Amount	Unit	Currency
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1.	2933	1-phenyl-3- methyl-5-pyrazolone	China PR	China PR	Any	5.01	Kg	USD
2.	2933	1-phenyl-3- methyl-5-pyrazolone	China PR	Any, other than China PR	Any	5.01	Kg	USD
3.	2933	1-phenyl-3- methyl-5-pyrazolone	Any, other than China PR	China PR	Any	5.01	Kg	USD

2. The provisional anti-dumping duty imposed under this notification shall be effective for a period of six months (unless revoked, amended or superseded earlier) from the date of publication of this notification in the Official Gazette and shall be payable in Indian currency.

Explanation 1.- For the purposes of this notification, rate of exchange applicable for the purposes of calculation of such anti-dumping duty shall be the rate which is specified in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), issued from time to time, in exercise of the powers conferred by section 14 of the Customs Act, 1962, (52 of 1962), and the relevant date for the determination of the rate of exchange shall be the date of presentation of the bill of entry under section 46 of the said Customs Act.

Explanation 2.- The landed value of imports for the purpose of this notification shall be the assessable value as determined by the customs under the Customs Act, 1962 and applicable level of custom duties except duties levied under sections 3, 8B, 9, 9A of the said Customs Tariff Act, 1975.

F. No. 354/52/2020–TRU

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

CBIC extends the date for transition under GST on account of merger of erstwhile Union Territories of Daman and Diu & Dadar and Nagar Haveli - reg.

Gazette Notification No.G.S.R.360(E), dated 9th June, 2020

(No.45/2020–Central Tax)

1. In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.10/2020-Central Tax, dated the 21st March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 193(E), dated the 21st March, 2020, namely:—

In the said notification, in the first paragraph, for the figures, letters and words —31st day of May, 2020", the figures, letters and words —**31st day of July, 2020" s**hall be substituted

2. This notification shall come into force with effect from the 20th day of March, 2020.

F. No. CBEC-20/06/03/2020-GST

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note: *The Principal Notification No.10/2020-Central Tax, dated the 21st March, 2020, was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 193(E), dated the 21st March, 2020.*

● ● ●

CBIC extends period to pass order under Section 54(7) of CGST Act - reg.

Gazette Notification No.G.S.R.361(E), dated 9th June, 2020

(No. 46/2020–Central Tax)

1. In exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with section 20 of the Integrated Goods

and Services Tax Act, 2017 (13 of 2017), and section 21 of Union Territory Goods and Services Tax Act, 2017 (14 of 2017), in view of the spread of pandemic COVID-19 across many countries of the world including India, the Government, on the recommendations of the Council, hereby notifies that in cases where a notice has been issued for rejection of refund claim, in full or in part and where the time limit for issuance of order in terms of the provisions of sub-section (5), read with sub-section (7) of section 54 of the said Act falls during the period from the 20th day of March, 2020 to the 29th day of June, 2020, in such cases the time limit for issuance of the said order shall be extended to fifteen days after the receipt of reply to the notice from the registered person or the 30th day of June, 2020, whichever is later

2. This notification shall come into force with effect from the 20th day of March, 2020.

F. No. CBEC-20/06/03/2020-GST

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

CBIC amends Notification No.40/2020 – Central Tax dated 05.05.2020 re. extension of validity of e-way bill generated on or before 24.03.2020 till the 30th day of June 2020 - reg.

Gazette Notification No.G.S.R.362(E), dated 9th June, 2020

(No. 47/2020–Central Tax)

1. In exercise of the powers conferred by section 168A of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with section 20 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), and section 21 of Union Territory Goods and Services Tax Act, 2017 (14 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.35/2020- Central Tax, dated the 3rd April, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 235(E), dated the 3rd April, 2020, namely:-

In the said notification, in the first paragraph, in clause (ii), for the proviso, the following proviso, shall be substituted, namely: -

Provided that where an e-way bill has been generated under rule 138 of the Central Goods and Services Tax Rules, 2017 on or before the 24th day of March, 2020 and whose validity has expired on or after the 20th March, 2020, the validity period of such e-way bill shall be deemed to have been extended till the 30st day of June, 2020.".

2. This notification shall come into force with effect from the 31st day of May, 2020.

F. No. CBEC-20/06/03/2020-GST

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) No. 35/2020-Central Tax, dated the 3rd April, 2020 vide Number G.S.R. 235(E), dated the 3rd April, 2020 and was last amended by Notification No. 40/2020–Central Tax, dated the 5th May, 2020, published in the Gazette of India, Extraordinary vide number G.S.R. 274(E), dated the 5th May, 2020.*

● ● ●

Emergent situation of Corona Virus – reg.

MoEF&CC Letter Ref.D.O.No.22-33/2019-IA-III, dated 13th March 2020

To
Chief Secretaries of All States/Administrators of All UTs,

I write this with a sense of urgency to request your personal intervention in the matter. The Ministry of Environment, Forest and Climate Change had issued a Notification on January 16, 2020 wherein it was clarified that change in raw material-mix or product-mix, change in quantities within products or number of products in the same category, etc will be permitted up to 50% increase in cumulative production and they shall be exempted from the provision of prior Environment Clearance subject to No Increase in Pollution Load Certification from State Pollution Control Board. This provision had proven beneficial for the Pharma Sector, particularly with reference to Active Pharmaceutical Ingredients (API)/Intermediaries. Recently, in a meeting held with representatives of the Pharma Sector, it was pointed out that State Governments have not been granting permission despite this amendment to the Notification.

In view of the current emergent situation of Corona Virus (COVID-19) and the **requirement for availability of drugs/API, you are requested to personally intervene** and **instruct the State Pollution Control Board and other concerned authorities in your State/UT to handle these cases on priority and issue No Increase in Pollution Load' Certificate without delay. You would appreciate that this would be an essential part of the preparedness to combat the impact of COVID-19.**

Hence, given the sense of urgency, I am sure you will instruct all concerned authorities in your State/UT to act swiftly and with responsibility.

C K Mishra, Secretary, Ministry of Environment, Forest and Climate Change, New Delhi.

ITEM NO.8 COURT NO.3 SECTION XVII

S U P R E M E C O U R T O F I N D I A
RECORD OF PROCEEDINGS

CIVIL APPEAL Diary No(s). 8478/2020

(Arising out of impugned final judgment and order dated 10-07-2019 in OA No. 1038/2018 14-11-2019 in OA No. 1038/2018 passed by the National Green Tribunal)

CHAMBER OF SMALL INDUSTRY ASSOCIATIONS Appellant(s)

VERSUS

CENTRAL POLLUTION CONTROL BOARD Respondent(s)

(IA No.42410/2020-EXEMPTION FROM FILING C/C OF THE IMPUGNED JUDGMENT and IA No.42407/2020-EX-PARTE STAY and IA No.42415/2020-INTERVENTION/IMPLEADMENT and IA No.42402/2020-PERMISSION TO FILE APPEAL and IA No.42405/2020-CONDONATION OF DELAY IN FILING APPEAL and IA No.42413/2020-PERMISSION TO FILE ADDITIONAL DOCUMENTS/FACTS/ANNEXURES)

WITH
Diary No(s). 8479/2020 (XVII)
(IA No.42282/2020-CONDONATION OF DELAY IN FILING and IA No.42279/2020-EXEMPTION FROM FILING C/C OF THE IMPUGNED JUDGMENT and IA No.42277/2020-STAY APPLICATION and IA No.42489/2020-INTERVENTION/IMPLEADMENT and IA No.42276/2020-PERMISSION TO FILE APPEAL and IA No.42284/2020-PERMISSION TO FILE ADDITIONAL DOCUMENTS/FACTS/ANNEXURES)

Date : 18-03-2020 These appeals were called on for hearing today.

CORAM :
HON'BLE MR. JUSTICE ROHINTON FALI NARIMAN
HON'BLE MR. JUSTICE S. RAVINDRA BHAT

For Appellant(s) **Mr. Dhruv Mehta, Sr. Adv.**
Mr. Ninad Laud, Adv.
Mr. Ivo D'Costa, Adv.
Mr. Saurabh Kulkarni, Adv.
Ms. Anshula Vijay Kumar Grover, AOR

For Respondent(s)

UPON hearing the counsel the Court made the following

O R D E R

Permission to file appeals is granted.

Delay condoned.

Applications for impleadment are allowed.

Applications seeking exemption from filing certified copy of the impugned order(s) are allowed.

Issue notice.

In the meantime, there shall be stay of operation of the impugned orders dated 10.07.2019 and 14.11.2019 passed by the National Green Tribunal, Principal Bench, New Delhi.

(R. NATARAJAN)
AR-cum-PS

(PARVEEN KUMARI PASRICHA)
BRANCH OFFICER

● ● ●

COVID Emergency Credit Facility covers all companies and not just MSMEs: Finance Minister

Ministry of Finance Press Release dated 8th June 2020

Union Minister for Finance and Corporate Affairs Smt Nirmala Sitharaman said that the COVID Emergency Credit Facility covers all companies and not just MSMEs. Addressing the FICCI National Executive Committee members, Smt Sitharaman assured the industry of all possible Government support with the intent of supporting Indian business and reviving the economy, and said, "We are committed to support/intervene if any of your members have a problem".

On the question of liquidity, the Finance Minister said, "We have fairly - clearly addressed the issue of liquidity. There is definitely the availability of the liquidity. We will look into it if there are still issues." Smt Sitharaman also said that every Government department has been told to clear dues and if there is any issue with any department, the Government will look into it.

The Finance Minister also said that the Government will consider an extension in the deadline for availing the 15% Corporate Tax rate on new investments. "I will see what can be done. We want industry to benefit from the 15% Corporate Tax rate on new investments and I take your point for considering an extension in the deadline of 31st March, 2023," Smt Sitharaman said.

The Finance Minister suggested the industry to submit their recommendations related to the Ministry of Corporate Affairs or SEBI deadlines so that necessary steps could be taken.

With regard to the need for reduction in GST rates in the badly affected sectors, She said, "GST rate reduction will go to the Council. But the council is also looking for revenue. The decision for reduction in rate for any sector has to be taken by the Council".

Finance and Revenue Secretary Mr Ajay Bhushan Pandey informed FICCI members that Income Tax Refund to the Corporates have also started and I-T refunds to the tune of Rs 35,000 crore have been issued in the last few weeks.

The meeting was also attended by the Secretary Expenditure Mr T V Somanathan, Economic Affairs Secretary Mr Tarun Bajaj, Corporate Affairs Secretary Mr Rajesh Verma, Department of Financial Services Secretary Mr Debasish Panda and Chief Economic Advisor Dr K V Subramanian.

FICCI President Dr Sangita Reddy informed the Finance Minister that the chamber is in constant touch with different Government departments to support the implementation of the measures announced to deal with the COVID-19 impact. "FICCI is committed to the common goal of *Atmanirbhar Bharat* and working with the Government in enhancing implementation," Dr Reddy added.

Source: PIB, MoF, Press Relased, 08.06.2020

● ● ●

Recommendations of GST council related to Law & Procedure

Ministry of Finance Press Release dated 12th June 2020

The 40th GST Council met under the Chairmanship of Union Finance & Corporate Affairs Minister Smt Nirmala Sitharaman through video conferencing today, 12.06.2020. The meeting was also attended by Union Minister of State for Finance & Corporate Affairs Shri Anurag Thakur besides Finance Ministers of States & UTs and senior officers of the Ministry of Finance & States/UTs.

The GST Council has made the following recommendations on Law & Procedures changes:

1. Measures for Trade facilitation:

a. Reduction in Late Fee for past Returns:

As a measure to clean up pendency in return filing, late fee for non-furnishing **FORM GSTR-3B** for the tax period from **July, 2017 to January, 2020** has been reduced/waived as under:

i. 'NIL' late fee if there is no tax liability;

ii. Maximum late fee capped at **Rs. 500/- per return** if there is any tax liability.

The reduced rate of late fee would apply for all the GSTR-3B returns furnished between **01.07.2020 to 30.09.2020.**

b. Further relief for small taxpayers for late filing of returns for February, March & April 2020 Tax periods:

For small taxpayers (aggregate turnover upto Rs. 5 crore), for the supplies effected in the month of February, March and April, 2020, the rate of interest for late furnishing of return for the said months beyond specified dates (staggered upto 6th July 2020) is reduced from 18% per annum to 9% per annum till 30.09.2020. In other words, for these months, small taxpayers will not be charged any interest till the notified dates for relief (staggered upto 6th July 2020) and thereafter 9% interest will be charged till 30.09.2020.

c. Relief for small taxpayers for subsequent tax periods (May, June & July 2020):

In wake of COVID-19 pandemic, for taxpayers having aggregate turnover upto Rs. 5 crore, further relief provided by waiver of late fees and interest if the returns in **FORM GSTR-3B** for the supplies effected in the **months of May, June and July, 2020** are furnished by September, 2020 (staggered dates to be notified).

d. One time extension in period for seeking revocation of cancellation of registration:

To facilitate taxpayers who could not get their cancelled GST registrations restored in time, an opportunity is being provided for filing of application for revocation of cancellation of registration up to **30.09.2020**, in all cases where registrations have been cancelled till 12.06.2020.

2. Certain clauses of the Finance Act, 2020 amending CGST Act 2017 and IGST Act, 2017 to be brought into force from **30.06.2020.**

Source: PIB, MoF Press Release, 12.06.2020

● ● ●

New Drugs and Clinical Trials (Amendment) Rules, 2020

The Gazette Notification No.GSR 354(E) issued on 5th June 2020 are the draft rules to NDCTR, 2019. These rules, which have been drafted in consultation with DTAB have been framed to regulate the usage of unapproved new drugs for compassionate use in treatment of patients, be it by import or by manufacture.

Import:

- A medical officer of a hospital or medical institution may apply to import a new drug solely for compassionate use for the treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for an unmet medical need, which has not been permitted in India, but under Phase-III clinical trial in India or in any other country.
- If the requirements under these rules have been met, the Central Licensing Authority (CLA) will grant permission (within 30 days of receipt of application) to import such a new drug in a limited quantity but under clinical trial for compassionate use. The import license shall have a 1 year validity.

Manufacture:

- On similar lines, a manufacturer who intends to manufacture such a new drug for compassionate use in limited quantity, can apply to the CLA to manufacture such a new drug after obtaining the consent in writing from the patient who requires such treatment or his legal heir and the concerned Ethics Committee of the hospital or medical institution.
- As in the above case, if the requirements under these rules are met, CLA will grant permission (within 30 days of receipt of application) to manufacture this new drug in limited quantity. Here too the manufacturing test license shall have a validity for a year.

Adequate checks and balances have been factored under the conditions of the license or permission in the draft rules. No part of the imported/manufactured quantity shall be sold in the market or supplied to any other person, agency or institution and should be used specifically for which the permission would be granted. Inspection of manufacturing sites, suspension of license for non-compliance to rules etc., as stated in NDCTR, 2019 would apply.

Once these draft rules (which are currently open for comments from stakeholders for a period of 15 days) are finally notified, they will facilitate approval of such new drugs to be used in life threatening disease or disease requiring therapy for unmet medical needs in our country like we are presently witnessing. Overall, it's been a decisive and timely move by the Health Ministry and CDSCO in the larger interest of the deprived patients and welcomed by the industry.

Bobby George Ph.D., Group Head, VP Regulatory Affairs, Reliance Life Sciences, Navi Mumbai.

● ● ●

Amendment List-05 to IP 2018 – reg.

IPC Communication Ref. No.T.11013/02/2018-AR&D, dated 3rd June 2020

To,

1. *Drugs Controller General (India),*
2. *CDSCO Zonal Offices,*
3. *All State Drug Controllers,*
4. *Members of Scientific Body of the IPC,*
5. *Members of Sub-Committees of Scientific Body of the IPC,*
6. *Directors of Drugs Testing Laboratories,*
7. *Government Analysts,*
8. *IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations.*

The 8th Edition of Indian Pharmacopoeia (IP) 2018 has become effective from 1" January, 2018. Based on scientific inputs, some IP monographs needed **up-gradation and accordingly Amendment List - 05 to IP 2018** is issued containing such amendments.

This is for notice and compliance with IP 2018.

Dr Jai Prakash, Secretary-cum-Scientific Director (1/c), Indian Pharmacopoeia Commission, Raj Nagar, Ghaziabad, web: **www.ipc.gov.in**

End. Amendment List-05 to IP 2018

Amendment List 05 to IP-2018

Allopurinol. Page 1176
Heavy metals
Change **to: Heavy metals** (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Bisacodyl Gastro-resistant Tablets. Page 4419
Dissolution A. After chromatographic system, line 2
Change **from:** Calculate the content of $C_{22}H_{19}NO_4$ in the medium.
to: Calculate the content of $C_{22}H_{19}NO_4$.

Complies with the acceptance criteria given under acid stage.

Calcium Gluconate. Page 1458
Dose. Line 3
Change **from:** 2.3mmol
to: 2.3mEq

Calcium Gluconate Injection. Page 1459
Usual strengths. Line 4
Change **from:** 0.45mmol
to: 0.45mEq

Citicoline Injection. Page 1639

Para 2

Change **to:** Citicoline Injection contains Citicoline Sodium equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of citicoline, $C_{14}H_{26}N_4O_{11}P_2$.

Assay. Last line

Change **from:** $C_{14}H_{25}N_4O_{11}P_2$

to: $C_{14}H_{26}N_4O_{11}P_2$

Citicoline Prolonged-release Tablets. Page 1639

Para 2

Change **to:** Citicoline Prolonged-release Tablets contain Citicoline Sodium equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of citicoline, $C_{14}H_{26}N_4O_{11}P_2$.

Assay. Last line

Change **from:** $C_{14}H_{25}N_4O_{11}P_2$

to: $C_{14}H_{26}N_4O_{11}P_2$

Citicoline Tablets. Page 1641

Para 2

Change **to:** Citicoline Tablets contain Citicoline Sodium equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of citicoline, $C_{14}H_{26}N_4O_{11}P_2$.

Assay. Last line

Change **from:** $C_{14}H_{25}N_4O_{11}P_2$

to: $C_{14}H_{26}N_4O_{11}P_2$

Ipratropium Bromide. Page 2305

Para 2, line 2

Change **from:** $C_{20}H_{30}BrNO_3, H_2O$

to: $C_{20}H_{30}BrNO_3$,

Water

Change **from:** Not more than 5.0 per cent, determined on 0.5 g.

to: 3.9 per cent to 4.4 per cent, determined on 0.5 g.

Kanamycin Injection. Page 2347

A. Kanamycin Injection (Solution), Para 1

Change **to:** Kanamycin Injection contains Kanamycin Sulphate equivalent to not less than 97.0 per cent and not more than 110.0 per cent of the stated number of Units of kanamycin.

Insert before **Bacterial endotoxins**

Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Lamivudine and Zidovudine Tablets. Page 2381

Related substances

Change **to: Related substances.** Determine by liquid chromatography (2.4.14).

Solvent mixture. 95 volumes of mobile phase A and 5 volumes of mobile phase B.

Test solution. Disperse a quantity of the powdered tablets containing 150 mg of Lamivudine in *water* with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with *water*, filter. Dilute 1.0 ml of the filtrate to 10.0 ml with the solvent mixture.

Reference solution (a). A solution containing 0.015 per cent w/v of *lamivudine RS* and 0.03 per cent w/v of *zidovudine RS* in the solvent mixture.

Reference solution (b). A 0.017 per cent w/v solution of *lamivudine resolution mixture B RS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Inertsil ODS-3v),
- mobile phase: A. a buffer solution prepared by dissolving 1.95 g of *ammonium acetate* in 900 ml of *water*, adjusted to pH 4.0 with *glacial acetic acid* and dilute to 1000.0 ml with *water*,
  B. *methanol*,
  C. *acetonitrile*,
- flow rate: 1ml per minute,
- a gradient programme using the conditions given below,
- spectrophotometer set at 270 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Mobile phase C (per cent v/v)
0	95	5	0
15	95	5	0
30	70	30	0
38	70	30	0
38.1	0	0	100
45	0	0	100
45.1	95	5	0
60	95	5	0

Name	Relative retention time	Correction factor	Acceptance Criteria Not more than (per cent)
Lamivudine-(cytosine)[1, 11]	0.11	---	---
Lamivudine-(uracil)[2, 11]	0.14	---	---
Lamivudine-(carboxylic acid)[11]	0.17	---	0.3
Lamivudine-(S-sulphoxide)[3, 11]	0.20	---	---
Lamivudine-(R-sulphoxide)[4, 11]	0.22	---	---
Zidovudine impurity C[5]	0.27	0.59	1.5
Lamivudine diastereomer[6]	0.50	---	0.2
Lamivudine	0.52	---	---
Zidovudine-(thymidine)[7, 11]	0.60	---	---
Lamivudine-(uracil derivative)[8, 11]	0.70	---	---
Lamivudine-(salicylic acid)[9, 11]	0.80	---	---
Zidovudine	1.0	---	---
Zidovudine impurity B[10, 11]	1.1	---	---
Any other secondary impurity	---	---	0.1
Total lamivudine related impurities	---	---	0.6
Total zidovudine related impurities (The limit includes other impurities)	---	---	2.0

[1] 4-Aminopyrimidin-2(1*H*)-one,
[2] Pyrimidine-2,4(1*H*,3*H*)-dione,
[3] 1-[(2*R*,3*S*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine S-oxide,
[4] 1-[(2*R*,3*S*,5*SS*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine S-oxide,
[5] 5-Methylpyrimidine-2,4(1*H*,3*H*)-dione,
[6] 1-[(2*S*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine,
[7] [1-(2-Deoxy-β-d-ribofuranosyl)]thymine,
[8] (2*R*,5*S*)1-[(2*R*,5*S*)-2-(Hydroxymethyl)-1,3-oxathiolan-5-yl]uracil,
[9] 2-Hydroxybenzoic acid,
[10] 3'-Chloro-3'-deoxythymidine.
[11] These are the process related impurities, monitored in the drug substance,

The relative retention time for lamivudine diastereomer and lamivudine are 0.5 and 0.52 respectively.

Inject reference solution (a) and (b). The test is not valid unless the resolution between lamivudine diastereomer and lamivudine peaks is not less than 1.5 in the chromatogram obtained with reference solution (b) and the relative standard deviation of replicate injections is not more than 2.0 per cent for each component in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the percentage of each lamivudine related impurity in the portion of tablets taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each lamivudine related impurity from the test solution
r_T = sum of the peak responses of lamivudine and all lamivudine related impurities from the test solution

Calculate the percentage of each zidovudine related impurity and other impurity in the portion of tablets taken:

$$\text{Result} = (r_U/r_T) \times (c) \times 100$$

r_U = peak response of each zidovudine related impurity and other secondary impurity from the test solution
r_T = sum of the peak responses of zidovudine, all zidovudine related impurities and other impurities from the test solution
c = correction factor

Lithium Carbonate. Page 2449

Potassium

Change **from:** Dissolve 1.0 g in 10 ml of 7 *M hydrochloric acid,* add sufficient *water* to produce 50 ml and determine by flame photometry (2.4.4), measuring at 766.5 nm, using *potassium solution FP,* suitably diluted with *water,* to prepare the standard solutions (500 ppm).

to: Dissolve 1.0 g in 10 ml of 7 *M hydrochloric acid,* add sufficient *water* to produce 50 ml and determine by Method A of flame photometry (2.4.4) or by Method A for Atomic absorption spectrophotometry (2.4.2), measuring at 767 nm, using *potassium solution FP* or *potassium solution AAS* respectively, suitably diluted with *water,* to prepare the standard solutions (500 ppm).

Sodium

Change **from:** Dissolve 1.0 g in 10 ml of 7 *M hydrochloric acid,* add sufficient *water* to produce 50 ml and determine by flame photometry (2.4.4), measuring at 589 um, using *sodium solution FP,* suitably diluted with *water,* to prepare the standard solutions (500 ppm).

to: Dissolve 1.0 g in 10 ml of 7 *M hydrochloric acid,* add sufficient *water* to produce 50 ml and determine by Method A for flame photometry (2.4.4) or by Method A for atomic absorption spectrophotometry (2.4.2), measuring at 589 nm, using *sodium solution FP* or *sodium solution AAS* respectively, suitably diluted with *water,* to prepare the standard solutions (500 ppm).

Malic Acid. Page 2493

Specific optical rotation. Line 1

Change **from: Specific optical rotation**

to: Optical rotation

Nortriptyline Tablets. Page 2755

Uniformity of content. Last line

Change **from:** $C_{20}H_{23}N$

to: $C_{19}H_{21}N$

Insert after **Storage**
Labelling. The label states the strength in terms of equivalent amount of nortriptyline.

Nystatin. Page2759

Composition. Last para, line 7
Insert after reference solution (a).

Ignore any peak with an area less than the area of the principal peak in the chromatogram obtained with reference solution (c) (0.1 per cent).

Abnormal toxicity
Delete the following requirement

Nystatin intended for oral administration complies with the following additional requirements.
Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity, using a quantity containing not less than 600 Units suspended in not more than 0.5 ml of a 0.5 per cent w/v solution of *acacia* and injecting the suspension intraperitoneally.

Ormeloxifene Hydrochloride Tablets. Page 2795

Identification. C
Change **to:** C. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to peak in the chromatogram obtained with the reference solution.

Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules.

Page 2850
Dissolution
For Pantoprazole Sodium. A. After chromatographic system, line 6
Change **From:** Calculate the content of $C_{16}H_{15}F_2N_30_4S$.
to: Calculate the content of $C_{16}H_{15}F_2N_30_4S$ released in the acid medium by subtracting the content of $C_{16}H_{15}F_2N_30_4S$ in the test solution from the total content of Pantoprazole, $C_{16}H_{15}F_2N_30_4S$ determined in the Assay.

Polyvinyl Alcohol. Page 2960

Insert at the end
Labelling. The label states (1) viscosity in terms of mPas (2) ester value.

Prednisolone Tablets. Page 2980

Assay
Reference solution (b)
Change **to:** *Reference solution (b).* A 0.005 per cent w/v solution of *prednisolone RS* in a mixture of 58 volumes of *methanol* and 42 volumes of *water.*

Raloxifene Hydrochloride. Page 3085

Assay. After chromatographic system, para 1

Change **to:** Inject reference solution (a) and (b).The test is not valid unless the resolution between the raloxifene-N-oxide and principal peak is not less than 2.0 in the chromatogram obtained with reference solution (b), the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 0.7 per cent in the chromatogram obtained with reference solution (a).

Raloxifene Hydrochloride Tablets. Page 3087

Dissolution. After chromatographic system, line 2
Change **from:** tablet.
to: medium.

Assay. After chromatographic system, para 1

Change **to:** Inject reference solution (a) and (b).The test is not valid unless the resolution between the raloxifene-N-oxide and principal peak is not less than 2.0 in the chromatogram obtained with reference solution (a), the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (b).

Ropinirole Prolonged-release Tablets. Page 4501

Related substances. After chromatographic system, para 1, line 5 and 6

Change **from:** not more than 10.0 per cent for ropinirole impurity B in the chromatogram

to: not more than 10.0 per cent in the chromatogram

Streptomycin Sulphate. Page 3265

Para 2

Change **to**: Streptomycin Sulphate has a potency equivalent to not less than 720 µg of streptomycin per mg, calculated on the dried basis.

Sulbactam Sodium. Page 4513

Related substances

Change **to**: **Related substances.** Determine by liquid chromatography (2.4.14).

Buffer solution. A 0.27 per cent w/v solution of *monobasic potassium phosphate,* adjusted to pH 4.0 with *orthophosphoric acid.*

Solvent mixture. 98 volumes of the buffer solution and 2 volumes of *acetonitrile.*

Test solution. Dissolve 77 mg of the substance under examination in 2 ml of *acetonitrile* and dilute to 100.0 ml with the buffer solution.

Reference solution (a). Dissolve 70 mg of *sulbactam RS* in 2 ml of *acetonitrile* and dilute to 100.0 ml with the buffer solution.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

Reference solution (c). A solution containing 0.007 per cent w/v each of *sulbactam related substance A RS, sulbactam related substance D RS, sulbactam related substance E RS* and *sulbactam related substance F RS* in *acetonitrile*. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture (*NOTE- Protect the solution from light*).

Chromatographic system

- a stainless steel column 15 cm x 4.0 mm, packed with octadecylsilane bonded to porous silica (3 µm),
- column temperature: 40°,
- mobile phase: A. a 0.54 per cent w/v solution of *monobasic potassium phosphate,* adjusted to pH 4.0 with *orthophosphoric acid,*
  B. *acetonitrile,*
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 215 nm,
- injection volume: 20 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	98	2
7.5	50	50

8.5	50	50
9.0	98	2
13	98	2

Name	Relative retention time	Correction factor
Sulbactam related compound A[1]	0.4	0.59
Amoxicillin related compound A[2]	0.6	0.50
Sulbactam	1.0	-
6-Bromopenicillanic acid sulfone[3]	1.6	-
Sulbactam related compound D[4]	2.0	0.5
Sulbactam related compound E[5]	2.1	-
Sulbactam related compound F[6]	2.5	0.59

[1]3-Sulfino-D-valine; (2*S*)-2-Amino-3-methyl-3-sulfinobutanoic acid.
[2]6-Aminopenicillanic acid; (2*S*,5*R*,6*R*)-6-Amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.
[3](2*S*,5*R*,6*R*)-6-Bromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.
[4]6-Bromopenicillanic acid; (2*S*,5*R*,6*R*)-6-Bromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.
[5]6,6-Dibromopenicillanic acid sulfone; (2*S*,5*R*)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid 4,4-dioxide.
[6]6,6-Dibromopenicillanic acid; (2*S*,5*R*)-6,6-Dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.

Inject reference solution (b) and (c). The test is not valid unless the resolution between sulbactam related compound D and sulbactam related compound E peaks is not less than 1.5 in the chromatogram obtained with reference solution (c) and the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (b).

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to sulbactam related compound A is not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent), the area of any peak corresponding to 6-bromopenicillanic acid sulfone and sulbactam related compound E, each of is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent), the area of any peak corresponding to amoxicillin related compound A, sulbactam related compound D and sulbactam related compound F, each of is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of areas of all the secondary peaks is not more than 10 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Terazosin Tablets. Page 3334

Related substances

Reference solution (a)

Change **from:** A 0.0003 per cent w/v solution of *terazosin hydrochloride RS* in the mobile phase.

to: A solution of *terazosin hydrochloride RS* in the mobile phase to obtain 0.0003 per cent w/v of terazosin.

Last para, line 4 and 5

Change **from:** any peak due to piperazinyl-ADMQ, chloro ADMQ and bis-ADMQ piperazine

to: any peak corresponding to piperazinyl-ADMQ, chloro ADMQ and bis-ADMQ piperazine, each of,

Trimethobenzamide Hydrochloride. Page 3439

Assay. Line 5

Change **from:** 0.04299 g

to: 0.04249 g

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IPC extends Publication of IP Addendum 2021 by 6 months – reg.

IPC Notice dated 9th June 2020

To

All the Stakeholders of IPC;

As we all are aware that India is passing through Novel Coronavirus Disease (COVID-19) pandemic and in order to protect the country and each of its citizens, the Hon'ble Prime Minister of India announced nationwide lockdown on 24th March, 2020 which is now gradually being relaxed to start normal operations in all sectors. Being an autonomous Institute under the Ministry of Health & Family Welfare, Government of India, Indian Pharmacopoeia Commission (IPC) is actively engaged in providing important healthcare related services to the country. In order to better serve the nation during this health emergency situation due to COVID-19, IPC continues to operate and offering its services to the stakeholders.

IPC has received representations from various stakeholders that due to the nationwide lockdown draft monograph verification at their sites is currently not possible and sourcing/testing of the drug substances and drug products is delayed owing to difficulty in procuring key consumables, reference standards, impurities and, therefore, requested for extension of publication of IP Addendum 2021 for a period of 6 months so that they can review all impacted materials/products and confirm the compliance to provide comments on draft monographs published on IPC website.

Accordingly, considering the inability of the stakeholders' to verify the draft monographs of the IP Addendum 2021 due to current COVID-19 pandemic, IPC has accepted and approved the extension of publication of IP Addendum 2021 by six months.

Dr Jai Prakash, Secretary-cum-Scientific Director (I/c), Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Raj Nagar, Ghaziabad. Website: www.ipc.gov.in.

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DGFT MATTERS

Amendment in Export Policy of Diagnostic Kits/ Laboratory Reagents/Diagnostic Apparatus - reg.

DGFT Notification No.S.O.(E)09/2015-2020-DGFT, dated 10th June 2020

1. In exercise of powers conferred by Section 3 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes the following amendments in the Schedule 2 of the ITCHS Export Policy related to export of Diagnostic Kits, with immediate effect:

A. The export policy of Diagnostic kits/laboratory reagents is revised by **amending the Notification No. 59 dated 04.04.2020 as under:**

Sr. No	ITC HS Codes	Description	Policy
207 G	Ex3822	• VTM kits and reagents • RNA extraction kits and reagents • RT–PCR kits and reagents	Restricted

B. The export policy of following diagnostic instruments/apparatus/reagents is amended to 'Restricted'.

Sr. No	ITC HS Codes	Description	Current Policy	Revised Policy
207 H	Ex39269099 Ex701790 Ex84199090 Ex90189099 Ex3822	15m1 falcon tube or cryovials	Free	Restricted
207 I	Ex300590 Ex3822	Swabs sterile synthetic fibre swabs (Nylon, Polyester, Rayon, or Dacron)		
207 J	Ex90279090 Ex3822	Silicon columns		
207 K	Ex38220090 Ex38220019	Poly adenylic Acid or Carrier RNA		
207 L	Ex38220090 Ex38220019	Proteinase K		
207 M	Ex9027 Ex3822	Magnetic stand		
207 N	Ex38220090 Ex38220019	Beads		
207 0	Ex38220090 Ex38220019	Probes (specific for COVID-19 testing)		
207 P	Ex38220090 Ex38220019	Primers (specific for COVID- 19 testing)		
207 Q	Ex3507 Ex3822	Taq Polymerase enzyme		
207 R	Ex3507 Ex3822	Reverse transcriptase enzyme		
207 S	Ex2934 Ex3822	Deoxy nucleotide triphosphates		

2. All other diagnostic kits/reagents/instruments/apparatus falling under the HS codes above are freely exportable subject to submission of an undertaking, to the concerned Customs Authorities, duly signed by the authorised signatory on the company letterhead, stating the following,

*"The Diagnostic kits/reagents/instruments/apparatus to be exported under the Shipping bill Number – ****** dated DD/MM/YYYY does not contain any item that is restricted for export as per the Notification No. 09/2015-20 dated 10.06.2020" .*

3. Effect of this Notification:

The Notification No. 59 dated 04.04.2020 is amended to the extent that only diagnostic kits/reagents as described in para 1(A) and all diagnostic instruments/apparatus/reagents as described in para 1(B) falling under any HS code, including HS codes specified above, are 'restricted' for exports whether as an individual item or as a part of any diagnostic kits/reagent.

All other diagnostic kits/reagents/instruments/apparatus falling under the HS codes above are freely exportable subject to submission of an undertaking by the exporter to the Customs Authorities at the time of export.

File No. 01/91/180/21/AM20/EC/E-21044

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

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Amendment in Para 2.20(b) of HBP of FTP 2015-20 *re.* revalidation of Export Authorisation/License for Non-SCOMET and SCOMET item - reg.

DGFT Public Notice No.10/2015-20, dated 8th June, 2020

1. In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade (DGFT) hereby makes amendments in Paragraph 2.20(b) of Handbook of Procedures (HBP) with immediate effect.

2. Sub-para (b) of Para 2.20 of HBP of FTP 2015-2020 is amended as under:

Existing Para 2.20(b) of HBP	Revised Para 2.20(b) of HBP
(b) Export Authorisation including for SCOMET items may be revalidated, on merits for a period of six months at a time and maximum upto 12 months by the RA concerned, except for cases in para 2.16(b) of HBP.	(b) Export Authorisation, including for SCOMET items, may be revalidated, on merits for a period of six months at a time and maximum upto 12 months by the DGFT (Hqrs).

3. Effect of this Public Notice

Paragraph 2.20(b) of HBP of FTP 2015-2020 has been amended to allow revalidation of the Export Authorization/ License for Non-SCOMET and SCOMET items from DGFT (Hqrs).

F.No.01/77/180/03/AM20/EC(S)/E-file 18113

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

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Clarification on refund related issues – reg.

GST Circular No.139/09/2020-GST, dated 10th June, 2020

To,

The Principal Chief Commissioners/Chief Commissioners/ Principal Commissioners/Commissioners of Central Tax (All),

The Principal Director Generals/Director Generals (All).

1. Various representations have been received seeking clarification on the issue relating to refund of accumulated ITC in respect of invoices whose details are not reflected in the **FORM GSTR-2A** of the applicant. In order to clarify these issues and to ensure uniformity in the implementation of the provisions of law in this regard across the field formations, the Board, in exercise of its powers conferred by section 168 (1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the issues detailed hereunder:

2. Circular No.135/05/2020–GST dated the 31st March, 2020 states that:

"5. Guidelines for refunds of Input Tax Credit under Section 54(3)

5.1 In terms of para 36 of circular No.125/44/2019-GST dated 18.11.2019, the refund of ITC availed in respect of invoices not reflected in FORM GSTR-2A was also admissible and copies of such invoices were required to be uploaded. However, in wake of insertion of sub-rule (4) to rule 36 of the CGST Rules, 2017 vide Notification No.49/2019-GST dated 09.10.2019, various references have been received from the field formations regarding admissibility of refund of the ITC availed on the invoices which are not reflecting in the FORM GSTR-2A of the applicant.

5.2 The matter has been examined and it has been decided that the refund of accumulated ITC shall be restricted to the ITC as per those invoices, the details of which are uploaded by the supplier in FORM GSTR-1 and are reflected in the FORM GSTR-2A of the applicant. Accordingly, para 36 of the circular No.125/44/2019-GST, dated 18.11.2019 stands modified to that extent."

3.1 Representations have been received that in some cases, refund sanctioning authorities have rejected the *refund of accumulated ITC is respect of ITC availed on Imports, ISD invoices, RCM etc. citing the abovementioned Circular on the basis that the details of the said invoices/ documents are not reflected in* ***FORM GSTR-2A*** *of the applicant.*

3.2 In this context it is noteworthy that before the issuance of Circular No.135/05/2020-GST dated 31st March, 2020, refund was being granted even in respect of credit availed on the strength of missing invoices (not reflected in ***FORM GSTR-2A)*** *which were uploaded by the applicant along with the refund application on the common portal. However, vide Circular No.135/05/2020–GST dated the 31st March, 2020, the refund related to these missing invoices has been restricted. Now, the refund of accumulated ITC shall be restricted to the ITC available on those invoices, the details of which are uploaded by the supplier in* ***FORM GSTR-1*** *and are reflected in the* ***FORM GSTR-2A*** *of the applicant.*

4. The aforesaid circular does not in any way impact the refund of ITC availed on the invoices/documents relating to imports, ISD invoices and the inward supplies liable to Reverse Charge (RCM supplies) etc.. It is hereby clarified that the treatment of refund of such ITC relating to imports, ISD invoices and the inward supplies liable to Reverse Charge (RCM supplies) will continue to be same as it was before the issuance of Circular No.135/05/2020-GST dated 31st March, 2020.

5. It is requested that suitable trade notices may be issued to publicize the contents of this circular.

6. Difficulty, if any, in implementation of this Circular may please be brought to the notice of the Board.

F.No.CBEC-20/06/03-2020-GST

Yogendra Garg, Principal Commissioner, Central Board of Indirect Taxes and Customs, GST Policy Wing, Department of Revenue, Ministry of Finance, New Delhi.

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CBIC specifies the jurisdiction of Commissioner (Appeals) to assessment orders passed by Faceless Assessment Groups - reg.

Notification No.51/2020-Customs (N.T.), dated 5th June, 2020

In exercise of the powers conferred by sub-section (1) of section 4 and sub-section (1) of section 5 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.92/2017-Customs (N.T.) dated 28th September 2017, namely:-

In the said notification, in paragraph 1 after the Table, the following provisos shall be inserted:, namely:-

"Provided that the Commissioner of Customs (Appeals), Bengaluru, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against the serial nos.5 and 6 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial no.7 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act.:

Provided further that the Commissioner of Customs (Appeals-1) Chennai and the Commissioner of Customs (Appeals-II) Chennai, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to the officers as mentioned in column (3) against serial no.7 of the Table above, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officer as mentioned in column (3) against serial nos. 5 and 6 of the Table above and assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act".

F.No.437/48/2014-Cus-IV

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

***Note:-** The Principal Notification No.92/2017-Customs (NT) dated 28th September 2017, was published in the Gazette of India, Extraordinary vide Number G.S.R.1210(E), dated 28th September 2017, and was last amended by Notification No.24/2018-Customs (NT) dated 28th March 2018, published in the Gazette of India, Extraordinary vide number G.S.R.294(E) dated 28.03.2018.*

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CBIC empowers Customs officers as 'proper officers' to conduct faceless or remote assessment of B/E filed u/s 46 of the Customs Act, 1962 for import in another Customs station - reg.

Notification No.50/2020-Customs (N.T.), dated 5th June, 2020

In exercise of the powers conferred by sub-section (1) of section 4 and sub-section (1) of section 5, read with sub-section (34) of section 2 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby, appoints the officers of Customs mentioned in the column (2) of the Table below, posted at any customs station in India, as proper officers for the functions as specified in column (3) of the said Table, in relation to a bill of entry presented electronically under section 46 or section 68 of the said Act, anywhere in India, where, such bill of entry is assigned to them in the Customs Automated System, namely:-

Sr. No.	Designation of the officer	Functions under Section of the Customs Act, 1962
(1)	(2)	(3)
1.	(i) Superintendent of Customs, GST and Central Excise or Appraiser,	(a) under sub-sections (2), (3), and (4) of section 17;
2.	(i) Deputy Commissioner or Assistant Commissioner of Customs.	(a) under sub-section (5) of section 17; (b) Section 18.

F.No.450/26/2019 Cus IV-(Pt)

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

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NEW DEVELOPMENTS

Preventing 'cytokine storm' may ease severe COVID-19 symptoms

For some COVID-19 patients, the body's immune response may be as destructive as the virus that causes the disease. The persistent high fevers, severe respiratory distress, and lung damage seen in some critically ill patients are all signs of an immune system in overdrive.

Now, a new clinical trial will test a treatment that targets this overactive immune response, says Howard Hughes Medical Investigator Bert Vogelstein. He and his team at the Johns Hopkins University School of Medicine are currently recruiting individuals for the trial, which includes patients ages 45 to 85 at the Johns Hopkins Hospital who have COVID-19 but who aren't on a ventilator or in the ICU.Their treatment, a common type of prescription drug called an alpha blocker, might break a cycle of hyper inflammation before it ramps up, their findings from mouse studies and a recent analysis of medical claims data suggest.

"The approach we're advocating involves treating people who are at high risk early in the course of the disease, when you know they're infected but before they have severe symptoms," says Vogelstein. If the trial's results suggest the drug is safe and effective against COVID-19, it could potentially help many people recover safely at home and lessen the strain on hospital resources, he says.

Runaway reaction:

A hyperactive immune response isn't unique to COVID-19. People with autoimmune diseases and cancer patients receiving immunotherapy can experience similar symptoms. These responses are referred to as macrophage activation syndrome, cytokine release syndrome - or simply "cytokine storms."

When macrophages (and some other kinds of immune cells) detect virus particles, they send out alert messages by releasing various proteins known as cytokines. Those cytokines recruit other immune cells to the scene - an inflammatory response that, in moderation, helps the body fight off a virus. But macrophages can also release other signalling molecules, called catecholamines, that amplify this response further, triggering the release of more cytokines. The result is a runaway feedback loop, like a snowball getting bigger as it barrels down a hill.

"It seems that once this process starts, there's this inability to properly switch it off," says Maximilian Konig, a rheumatologist at Hopkins who is helping to coordinate the trial. Before COVID-19 hit, Vogelstein's team was already exploring ways to ease the hyper inflammatory immune response in cancer patients treated with immunotherapy. The researchers were interested in drugs called alpha blockers, which are widely prescribed for prostate conditions and high blood pressure - and also interfere with the cell signalling that triggers cytokine storms. In theory, alpha blockers might stop a cytokine storm before it starts. Giving mice with bacterial infections an alpha blocker lessened cytokine storms and decreased deaths, Vogelstein's team reported in the journal Nature in 2018. And, the researchers found, the treatment didn't seem to harm other aspects of the immune response.

Staving off the storm:

As the COVID-19 pandemic escalated in the United States over the past few months and severely ill patients presented with cytokine storm symptoms, the idea of testing alpha blockers in humans has become more urgent, Vogelstein's team recently argued in the Journal of Clinical Investigation. To obtain approval for an alpha blocker clinical trial, Vogelstein's team first surveyed

medical claims data. They combed through records from people hospitalized for pneumonia and acute respiratory distress and analyzed whether patients' outcomes were better if they had been taking alpha blockers for unrelated conditions. The team's tentative conclusion: taking alpha blocker drugs correlated to a lower risk of death from respiratory distress.

On its own, that's not strong enough evidence to prescribe the drug for a wholly new disease like COVID-19, says Susan Athey, an economist at Stanford University who collaborated with Vogelstein's team on the claims analysis. But it helps bolster the case for the team's clinical trial. In the trial, COVID-19 patients will take gradually increasing doses of an alpha blocker called prazosin, sold under the brand name Minipress, over six days, says Chetan Bettegowda, a neurosurgeon at Hopkins who is helping to design and run the trials. Then, the team will evaluate whether people who received this treatment had a lower ICU admission rate or ventilator use than patients who received the standard treatment. They will follow each patient for 60 days, but preliminary data from the first patients could be available within weeks to months, Bettegowda says. If the trial's results suggest alpha blockers are safe and effective, the team hopes to run a second trial with patients who have been diagnosed with COVID-19 but are not yet hospitalized. They are also encouraging colleagues at other hospitals to join their clinical trial efforts, to gather patient data more quickly. This treatment, if it works, would be a secondary form of prevention, Vogelstein says, mitigating symptoms before they become severe, rather than stopping infection in the first place. "Eventually, hopefully, a vaccine will be produced, and that will be the essence of prevention," he says. "But until vaccines are available, secondary prevention makes a lot of sense."

Source: Science Daily/ World Pharma News, 25.05.2020 (Excerpts)

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Preparing for the new world of drug safety: Embracing cloud and AI

Managing safety cases is becoming more complex due to ever-increasing volume and variety of data. These common but evolving challenges point to the development of common frameworks leading to industry-wide solutions that can be adapted or tailored to specific needs. This webcast, co-hosted by Oracle and ICON, will discuss why, from a CRO perspective, the cloud and AI are important milestones on the journey to the new world of safety. The webcast is moderated by Oracle. In the first half of the webcast, ICON will present its move to the cloud and the reasons behind it. The second half of the presentation will provide a high-level critique of topics such as big data, quality and operational efficiency within the context of automation.

Register for free:https: //www.terrapinn.com/conference/world-drug-safety-us/WB-Embracing-cloud-and-AI.stm

Source: Science Daily/ World Pharma News, 08.06.2020 (Excerpts)

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Maharashtra State Government puts on hold decision to buy drug from Bangladeshi firm

Maharashtra Government has put on hold its decision to purchase investigational drug Remdesivir from Bangladeshi company Eskayef Pharmaceuticals Ltd, that has neither got a licensed agreement with manufacturer Gilead Sciences nor got an approval to sell the drug to any company in India. Senior state officials said they plan to wait for DCGI to approve Indian and foreign companies before initiating procurement procedure for 10,000 vials.

Eskayef Pharma has also quoted a single vial at 2.5 times the retail price announced in Bangladesh. The Pharma's Marketing and Sales Director Dr Mujahidul Islam had informed media in Bangladesh that the retail price of the drug, marketed as Remivir, would be kept at 5,500 Takas per vial (Rs 4,894 INR), however, when they mailed their quotation to Maharashtra Government they priced one vial at $160 (Rs 12,090).

Eskayef has so far not signed a licensed agreement with Gilead to market the drug. In an e-mail response, Gilead Sciences spokesperson told *The Indian Express*, "Gilead has not provided a licence to Eskayef Pharmaceuticals or any other company in Bangladesh to manufacture Remdesivir. Gilead cannot comment on or verify the authenticity or effectiveness of this product as it is not manufactured by Gilead or one of our licensed partners."

A senior Health Ministry official told that no application has been made as yet to import Remdesivir from Bangladesh. Any approvals for imports would be granted only after a proper study of the clinical data. Batches of the products would also have to be submitted to central drug testing laboratories for stability tests, the official added.

In Bangladesh, Eskayef along with few other manufacturers is allowed to manufacture Remdesivir under World Trade Organisation's drug patent waiver. Senior officials in Mantralaya said since the Pharma company's drug efficacy has not been gauged by India's regulatory authority, Maharashtra is not going to perform a stability test to gauge the efficacy of the drug, and will follow procurement procedure only from companies approved by Drug Controller General of India (DCGI).

"We are not going to buy Remdesivir from Eskayef if they do not have necessary approvals," state Health Minister Rajesh Tope said on Sunday, 07.06.2020. So far, DCGI Dr V G Somani, who heads the Central Drugs Standard Control Organization (CDSCO), has only given an approval to Mumbai-based Klinera Global Services to import Remdesivir from three manufacturing sites in the US. Applications submitted by companies like Cipla and Hetero are still under process.

Remdesivir is an anti-viral manufactured in 2014 to treat Ebola. It remains under clinical trials and no conclusive evidence has been found to confirm whether it is able to help in faster recovery of Covid-19 patients. Maharashtra, with over 83,000 cases, accounts for 33 percent of India's Covid-19 burden.

The state has used Remdesivir, so far available on donation, on selected severely ill patients, but even in them a cocktail of other drugs have been used to treat Covid-19. So far National Institute of Allergies and Infectious Diseases (NIAID) trial announced initial results that the drug was reducing recovery period to 11 days. The drug has been given emergency authorisation in India in June, which means that it is being allowed as part of treatment despite clinical trials still ongoing to test its effectiveness.

"There are certain sections, like 47 and 100 of the Patents Act that allow the Government in a national emergency situation to import and use a product despite it being patented in the country.

These provisions are TRIPS compliant," said Murali Neelakantan, former Global General Counsel of Cipla and Glenmark Pharmaceuticals. "These approvals can be granted by the Central Government in a matter of hours." If the Maharashtra Government were to import Remdesivir from Bangladesh, its procurement entity would have to apply to the Central Drugs Standard Control Organisation (CDSCO) for a licence.

"They'll have to give CDSCO the manufacturing and test data which includes production and supply chain records and samples for testing by CDSCO, in order for them to understand the tests done and the process followed by the company to manufacture the drug and to ensure its quality," Neelakantan told.

Source: Tabassum Barnagarwala & Prabha Raghavan, Indian Express, 10.06.2020 (Excerpts)

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Industry welcomes draft New Drugs and Clinical Trials (Amendment) Rules

Recommend measures for more clarity and Impact

The Central Government, in consultation with the Drugs Technical Advisory Board (DTAB), recently issued a draft gazette notification, about making an amendment in the New Drugs and Clinical Trials Rules, 2019 for compassionate use of any new unapproved drug. It has also invited suggestions, objections on the draft guidelines from the industry.

As per the draft Gazette Notification, it is proposed that in Chapter XI, after rule 96, the following shall be inserted:

1) **"96A:** Application for import of unapproved new drug for Compassionate use for the treatment of patients by hospitals or and medical institution.
2) **96B:** Grant of licence for import of new drug for compassionate use.
3) **96C:** Conditions of licence.
4) **96CA:** Suspension or cancellation of license to import new drug for the purpose of compassionate use.
5) **96D:** Application for the permission to manufacture new drug for Compassionate use.
6) **96E:** Grant of the permission to manufacture new drug for Compassionate use.
7) **96F:** Condition of permission.
8) **96G:** Inspection of manufacturing site of new drug for the purpose of compassionate use.
9) **96H:** Suspension or cancellation of permission to manufacture new drug for the purpose of compassionate use.
10) **96I:** Licence to manufacture new drug for compassionate use under the Drugs and Cosmetics Rules, 1945.

And it will come into force on the date of final publication in the Official Gazette in the New Drugs and Clinical Trials Rules, 2019.

The Pharma industry has welcomed the proposed amendments but also share some more recommendations.

Dr Ajit Dangi, President and CEO, Danssen Consulting, pointed out, "The Gazette Notification No.GSR 354(E) issued by the Ministry of Health and Family Welfare is for importing certain lifesaving drugs on compassionate grounds is a good initiative. It is quite comprehensive and has all the checks to ensure the quality and safety of imported drugs. However, there are few issues, which need to be ironed out in consultation with other relevant Government departments." He also cited the following as instances:

1. Inspection of manufacturing facility:

The notification has provision to inspect and approve the manufacturing facility of the overseas manufacturer. Inspecting overseas facilities is not only an expensive affair but also requires technical expertise to do so. For instance, US FDA charges heavy fees under GDUFA, which run into hundreds of thousand US dollars for inspecting and approving the Indian manufacturing facilities which intend to export generic drugs to the US.

2. Storage conditions:

Most of these drugs have stringent storage conditions. Hence, it is important to have a good infrastructure particularly for cold chains throughout the supply chain starting from manufacturing until it reaches the patient. The World Health Organisation estimates that close to 50 percent of the vaccines may be wasted globally every year because of lack of proper temperature control, logistics and shipment related issues. This is all the more important in a tropical country like India.

3. Pricing:

Many of these drugs are quite expensive and often not covered under health insurance. For instance, an injectable, Aflibercept for intravitreal use for Age-related Macular Degeneration of the eye (AMD) is imported into India from Germany and is priced at Rs 60,000/- per unit. The treatment involves a course of a minimum of three injections. The health insurance companies do not reimburse this amount even if one has health insurance as it does not require hospitalisation.

"Some of the issues mentioned above need to be addressed to make this initiative effective on the ground," he added.

Kaushik Desai, Former National General Secretary, Indian Pharmaceutical Association opined, "This is a welcome initiative by the CDSCO, benefitting needy patients in these trying times. The MoH&FW has issued draft Notification specifically keeping COVID-19 pandemic in mind and reduced the period for comments, if any, to

15 days which many times vary from 30 to 90 days. This is a very positive outcome of this pandemic. The onus of deciding the requirement of such medicines which are on phase III trial either in India or abroad is on the hands of doctors from hospitals and medical institutions and they can only justify the need for the patients under their treatment and not for other similar patients from other hospitals hence the quantity requirement may not be very big in number. One can understand the urgency in the import of such medicines but how manufacturing will be taken up needs more clarity and understanding considering formulation development, stability and other criteria associated with it before starting any manufacturing activities locally. There have been cases that some of the phase III trial drugs have not met the expectations, mainly with respect to safety and the Pharma industry will have to take a call if they wish to go ahead with manufacturing for these drugs under phase III trials. This notification may be useful in future to go ahead with local manufacturing, but right now, import of such medicines is of paramount importance to meet unmet medical needs. I foresee long term benefits of this initiative, not only for corona patients but for other ailments too."

Dr P V Appaji, Founder Executive Director and retired Director General, Pharmexcil said, "Making it easy to get new drugs under development (phase III stage) or in use in other countries, is a very proactive initiative. Perhaps, the immediate possibility is for Favipiravir and Remdesivir, which are very essential under present COVID -19 conditions."

A retired Drug Controller from Haryana said, "The published Draft Rules to amend the New Drugs and Clinical Trials Rules, 2019 proposes that a medical officer of a hospital or medical institution may be allowed to import a new drug or the drug may be allowed to be manufactured in India in a limited quantity, for compassionate use for the treatment of patients suffering from life-threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, which has not been permitted in the country so far, but the same is under Phase-III clinical trial in India or in any other country, for diagnosis, treatment, mitigation or prevention of any life-threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need under a treatment protocol.

And the Government has given 15 days' time to the public to send their objections/suggestions to the draft rules. Once, these rules are notified finally, it will pave the way for import of a new drug and also to manufacture a new drug, even when the drug is not approved for marketing in India but a medical officer of a hospital or any medical institution is convinced that the drug can be of use, for diagnosis, treatment, mitigation or prevention any life-threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need under a treatment protocol."

He continued, "Such a New Drug will be allowed to be imported for compassionate use by making an application duly certified by the Medical Superintendent of the hospital or Head of the medical institution, to the Central Licensing Authority i.e. Drugs Controller General of India or a drug can be allowed to be manufactured in India by a manufacturer after seeking permission from DCGI.

Mr S V Veeramani, CMD, Fourrts India Labs and Former, National President, IDMA said, "The Government is proposing the amendments in the New Drugs & Clinical Trials Rules to bring flexibility for compassionate use for the treatment of patients. Especially in the current COVID-19 situation where there is an unmet medical need, it will be timely, since regular approval of a new drug may take years. But they have also built in certain conditions and safeguards for the import or manufacture of the new drug. Further, in the case of a life-threatening disease like cancer these new drugs for India may be lifesaving."

Mr Someshwar M Mudda, Chairman, Regulatory Affairs Committee, Indian Drug Manufacturers' Association (IDMA), "This notification for the importation of medicines on compassionate grounds is a welcome move. It will help patients with access to much-needed medicines. The notification is comprehensively drafted and ensures that quality and safety aspects are controlled while ensuring access. Similarly, the manufacturing of such medicines is proposed to be permitted. However, since some of such medicines are likely to be covered under patent, the impact of this has to be considered."

Dr Kiran Marthak, Consultant, Lambda Therapeutic Research summarised the draft rules and said, "The recently published Gazette in the amendment of Rules for Clinical trials is welcomed by the industry as well as by the medical fraternity and patients. It provides an advantage to the patients in getting the drug which is in Phase III clinical trials abroad. The medical institution or the treating physician can import the drug by applying to the DCGI in a designated form. If all the documents are in order the permission to import the drug will be granted in one month. There is also a provision to manufacture the

drug by applying in a requisite form. Hence, patients will get new drugs particularly for life-threatening conditions, though it is not in the market."

Source: Usha Sharma, Express Pharma, 09.06.2020

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Milan R Patel elected as IDMA-Gujarat State Board's new Chairman

Sumit Jagdish Agrawal of Ishita Pharmaceuticals has also been appointed as the Honorary Secretary for the same tenure

Gujarat State Board of Indian Drug Manufacturers' Association (IDMA), announced that Milan R Patel, Joint Managing Director, Troikaa Pharmaceuticals, has been elected as the new Chairman for IDMA-Gujarat State Board for the tenure of 2020-2021.

IDMA-Gujarat State Board held its 41st Annual General Meeting (AGM) through Video Conferencing, approving the election of Milan R Patel as New Chairman and Sumit Jagdish Agrawal of Ishita Pharmaceuticals as Honorary Secretary for the tenure of 2020-2021 (Calendar Year).

A Chemical Engineer with specialization in process control and automation, Patel, has more than 30 years of in-depth experience in pharmaceutical manufacturing and quality control operations. He has been a key player in establishing various operational and management systems at Troikaa Pharmaceuticals and exercised his expertise and professionalism in 'Good Manufacturing Practices' (GMP) – in Pharma manufacturing operations.

Commenting on his appointment as New Chairman of IDMA-GSB, Patel said "Thanks to all IDMA-GSB members and National IDMA for giving me such a big & important responsibility. This role becomes more crucial as we are in a state – Gujarat, which is the highest contributor to pharmaceutical output in terms of production and export in the Indian Pharma industry". Patel also emphasized the ongoing challenges of corona and vast opportunity for the Pharma sector to tap particularly in the future where the Government spending on healthcare is going to increase.

"The Pharmaceutical Industry is facing paradoxical challenges, because of the challenges raised by corona, but at the same time there will be a huge opportunity which will arise due to higher spending GDP percentage by the Government in the healthcare sector. I am very much sure with the statement coming in from various ministers that the GDP spent on health care, which is hovering around 1.5 percent-2 percent, is going to go up, which means even demand for pharmaceutical medicines is going to go up in the near future."

Patel also insisted that members should focus on sustainability, scalability and quality for long term growth. He also pointed out that members should also look to invest in technology, as with better & high-grade technology, there will be lesser errors and compliance with GMP standards will be easier.

"High-quality product will also bring a lot of pride to the Indian pharma industry, and IDMA-GSB will be the flag bearer of quality," he commented at the virtual AGM session.

Other member's election approved at the 41st AGM is Dr Shrenik Shah (Montage Laboratories) as Sr Vice Chairman, Shri Sanchit Chaturvedi (Halewood Labs Pvt Ltd) & Shri Jay Patel (Astral Stritech Pvt Ltd) as Vice Chairman, Shri Jayesh Pandya (Nucleus Formulations) & Shri Mukesh Vaghasia (Sunvij Drugs Pvt Ltd) as Honorary Joint Secretary and Shri Atul Shah (Ellis Pharmaceuticals) as Honorary Treasurer.

Apart from other 6 office bearers, 10 newly elected Executive Committee Members are Shri Nirav Mehta (Corona Remedies), Shri Vijay Shah (Endurance Healthcare Ltd), Ms Jinkal Patel (Elysium Pharmaceuticals Ltd), Shri Bhavin Patel (Mediwin Pharmaceuticals Ltd), Shri Saurabh Mittal (Mercury Laboratories Ltd), Shri Amish Savla (Asoj Soft Caps Ltd), Shri Jayanti Patel (Baroque Pharmaceuticals Pvt Ltd), Shri Kamlesh Rajnikant Zota (Zota Healthcare Ltd) and Shri Gaurang Oza (Vaibhav Analytical Lab).

Source: EP News Bureau, Express Pharma, 09.06.2020

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Ministry of Health publishes draft New Drugs and Clinical Trials (Amendment) Rules

The Union Health Ministry has come up with draft New Drugs and Clinical Trials (Amendment) Rules, inserting provisions for "compassionate use" of any unapproved drug that is in the phase-III clinical trial, either in India or abroad, by importing or indigenous manufacturing.

The move is aimed at facilitating the availability of new drugs which are in Phase-III clinical trials (human trials) for

severely-ill COVID-19 patients in the country. According to a Gazette Notification of the draft rules published on June 5, a hospital or medical institution may import the new drug for "compassionate use for the treatment of patients suffering from a life-threatening disease or disease-causing serious permanent disability or disease requiring therapy for unmet medical need", which has not been permitted in the country, but under Phase-III clinical trial in the country or abroad, by making an application to the Central Drug Regulator.

Also, if any hospital prescribes a new drug for the same purposes then they may be approved to be manufactured in limited quantity subject to provisions of the rules.

The manufacturer intending to manufacture a new drug will have to obtain the consent in writing from the patient to whom the medicine has been prescribed or his legal heirs and make an application to the Ethics Committee of the hospital or medical institution for obtaining its specific recommendation for the manufacture of such new drug.

After obtaining the recommendation of the Ethics Committee, the manufacturer shall make an application to obtain the permission, to the Central Licencing Authority for manufacturing the new drug for the purpose of compassionate use, the draft rules stated.

"The manufacturer to whom the permission is granted shall make use of the new drug only for the purposes specified in the permission and no part of it shall be sold in the market or supplied to any other person, agency, institution or place," it stated.

The new draft rules will be applicable for 15 days during which people can send their objections and suggestions to be considered by the Central Government after which the final amended rules will be published in the Gazette of India.

The set of new rules have been inserted under section 96 which deals with filing an application, granting the license to the importer or manufacturer, conditions and suspension of such licenses among others.

For both manufacturing and importing, the licence shall remain valid for a period of one year from the date it has been issued. If an importer or the manufacturer to whom the license is granted fails to comply with any provision of the Act and these rules, the Central Licencing Authority, may, after giving an opportunity of being heard, suspend or cancel the license for such period as considered appropriate either wholly or in respect of some of the substances to which the violation relates. The quantity of any new drug manufactured or imported on the basis of permission granted shall not exceed one hundred average dosages per patient, the draft rules stated.

But in exceptional circumstances on the basis of the prescription of the medical officer and the recommendation of the Ethics Committee, the Central Licencing Authority may allow the manufacture of such new drug in larger quantity.

In both cases, for import or indigenous manufacturing, the application should have details including the rationale for the use of the new drug as compassionate use over the available therapeutic options, the criteria for patient selection with a description of the patient's disease or condition and the method of administration of the drug, dose, and duration of therapy.

It should also mention the description of the manufacturing facility and a description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimise its risks among others.

Several drugs across the country are in phase III clinical trials phase for COVID-19. Anti-viral drug Remdesivir, last week, was approved for "restricted emergency use" on severe COVID-19 patients.

Source: Press Trust of India, Express Pharma, 08.06.2020

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AstraZeneca Contacted Gilead over Potential Megamerger

Gilead, AstraZeneca and other drug makers, including Eli Lilly and Co, Pfizer and Merck & Co, are racing to develop vaccines or treatments for COVID-19.

Britain's AstraZeneca has approached US rival Gilead Sciences about a possible merger to form one the world's largest drug companies, Bloomberg News reported on Sunday, 07.06.2020 citing people familiar with the matter. Such a deal would unite two of the drugmakers at the forefront of the industry's efforts to fight the new Coronavirus and could be politically sensitive as Governments seek control over potential vaccines or treatments.

AstraZeneca contacted Gilead last month, but its US rival was not interested in combining with another big pharmaceuticals company, the Bloomberg report said. A spokeswoman for AstraZeneca said the company does not

comment on rumours or speculation. Gilead, the world's largest maker of HIV drugs, declined to comment on the report.

If combined, the two companies would have a market capitalisation of about $232 billion, based on Friday's, 05.06.2020 closing share prices. That would exceed Merck & Co and Pfizer at $207 billion and $200 billion respectively.

Two sources familiar with AstraZeneca's thinking questioned the rationale of a tie-up, telling Reuters that Gilead's Remdesivir drug for COVID-19 patients was insufficient to justify pursuing a multibillion-dollar deal that would detract from AstraZeneca's work on a Coronavirus vaccine.

One of the sources questioned the timing. Given the potential impact a successful vaccine would have on AstraZeneca's share price, it does not need the additional strain of pursuing a record-breaking deal, especially when travel constraints make face-to-face meetings difficult. While Gilead may look cheap with its price-to-earnings ratio of 12 times and AstraZeneca may be attracted by the potential cost-cutting and decent free Cashflow, Jefferies analysts said they do not view a deal as likely.

"We think Gilead believes its HIV business is very underappreciated," they said in a note, adding that the company "would prefer to build value over time and do its own tuck-in deals".

Record Highs:

Gilead's biggest blockbuster drug is HIV drug Biktarvy, with sales of $1.69 billion in the first quarter. AstraZeneca's top-selling product is its lung cancer drug Tagrisso, which generated first-quarter revenue of $982 million.

Both companies' shares have jumped this year as the healthcare sector has drawn fresh investor interest as drugmakers race to develop treatments and vaccines to counter the pandemic. AstraZeneca's shares hit record highs in late April while Gilead's stock is up 20% since the start of the year.

Gilead, AstraZeneca and other drugmakers, including Eli Lilly and Co, Pfizer and Merck & Co, are racing to develop vaccines or treatments for COVID-19, the respiratory illness caused by the novel Coronavirus. More than 6.9 million people have been reported infected with the Coronavirus globally and 399,025 have died, a Reuters tally showed on Sunday, 07.06.2020.

It is unclear whether a vaccine will work, but AstraZeneca's partnership with Oxford University to develop one is among a handful of initiatives US President Donald Trump's COVID task force has backed. Gilead has also been in the vanguard of COVID-19 treatments. Its Remdesivir antiviral is the first drug to lead to improvement in COVID-19 patients in formal clinical trials.

The drug has been cleared for emergency use in COVID-19 patients in countries including the United States and South Korea and could bring in more than $7 billion in annual sales for by 2022 if governments seek to stockpile it against future outbreaks, SVB Leerink has estimated.

Source: Reuters/Business World, 08.06.2020 (Excerpts)

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Covid-19 impact: Pharma Sales down 9% in May

Medicine sales declined 9% year-on-year in May to Rs.10,342 crore as the disruption caused by the covid-19 lockdown continued, with sales of acute drugs under pressure even as panic buying in chronic medicines eased, according to data from market research firm AIOCD-AWACS. "The COVID crisis has impacted the IPM (Indian Pharmaceutical Market) and it continues to show negative growth in May. While there is evidence of revival in some therapies but (overall) IPM continued negative growth of 8.9% in May also," the market research firm said.

Cardiac care medicines reported sales growth of 3.9% against 5.9% in April, while that of anti-diabetic drugs grew 1.1% compared with 6.4% increase in the preceding month. Among the therapeutic areas, anti-infectives were the worst hit. Sales of anti-infective medicines, the largest therapeutic segment, were down by a fifth to Rs.1,104 crore.

Experts have said that the decline in anti-infective sales is due to the lack in visits to doctors and as chances of infections have declined with most people staying at home amid the Covid-19 lockdown. Respiratory drugs sales declined 6% in May to Rs.653 crore after growing 0.3% in April. Kedar Upadhye, Chief Financial Officer of Cipla, one of India's largest respiratory drugs maker, had told Mint in an interview last month that a fall in respiratory drugs was expected as December to March is the peak period for the segment and as lockdown has reduced chances of respiratory allergies, thereby hitting sales. Among Corporates, Cipla was also among the worst hit,

with its sales declining 13% to Rs.459 crore in May, while GlaxoSmithKline Pharmaceuticals, Alkem Laboratories, Emcure Pharmaceuticals and Dr Reddy's Laboratories reported 10-17% fall in sales during the month.

India's largest drug manufacturer Sun Pharmaceutical Industries, largest multinational Abbott group, as well as companies like Lupin, Torrent Pharmaceuticals, Sanofi India, Glenmark Pharmaceuticals and Intas Pharmaceuticals had sales decline in May, as per the data.

Not surprisingly, Ipca Laboratories—the largest manufacturer of Hydroxychloroquine in the India--reported sales growth of 7% to Rs.161 crore. The anti-malarial drug Hydroxychloroquine has been touted as a potential cure for Covid-19 and is currently undergoing trials across the world. The anti-malarial segment also showed a 14% jump in sales, the largest among all therapy areas, to Rs.586 crore during the month.

Source: Leroy Leo, LiveMint, 08.06.2020

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Lockdown brings in uncanny benefit in lesser non-covid infections

Pandemic-induced restrictions may have brought an uncanny benefit for India's public health, which is in the midst of an unprecedented challenge due to rising Covid-19 infections.

A lesser number of people likely fell sick with non-covid 19 infections during this period as data from market research firm AIOCD-AWACS indicated that the disruption caused by the lockdown on the pharmaceutical sector continued, leading to a 9% year-on-year decline in sales of medicines in May to Rs.10,342 crore as people were forced to stay indoors, potentially lowering chances of their contracting infections, industry watchers said.

But it is also possible that lesser number of people had access to medical practitioners during the lockdown, which possibly resulted in a decline in the number of prescriptions drug sales.

"People are taking a lot of precautions, and the chances of contracting infections are lower as they are not going out or eating outside," said Rajeev Singhal, General Secretary of All India Organization of Chemists and Druggists. "Visits to OPDs (out-patient departments) are also down and elective surgeries are postponed. Plus, we had seen panic buying of chronic drugs in April, which was no longer seen in May. All these reasons caused a decline in sales in May," Singhal told Mint in an interview.

Among the therapy areas, data showed anti-infectives were the worst hit, continuing their trend from April. Sales of anti-infective medicines, the largest therapeutic segment, were down by a fifth to Rs.1,104 crore in May.

While chronic therapy areas of cardiac and anti-diabetic drugs did report a growth, it was slower as the previous month had seen panic buying from customers. Cardiac care medicines registered sales growth of 3.9% compared with 5.9% in April, while those of anti-diabetic drugs grew 1.1% compared with 6.4% in the preceding month.

Respiratory drugs sales also declined 6% in May to Rs.653 crore, having grown 0.3% in April. Kedar Upadhye, Chief Financial Officer of Cipla, one of India's largest respiratory drugs maker, had told Mint, in an interview last month, that a fall in respiratory drugs was expected as December to March is a peak period for the segment and as lockdown has reduced the chances of respiratory allergies, thereby hitting medicine sales.

"In the last two or three months, due to the lockdown, people are not going out. They are not eating outside. They are at home. So you don't expect all these infections to happen. Pollution is also down. So respiratory infections are also lower," Ram Shankar Mishra, Director of internal medicine at Max Super Speciality Hospital in Delhi's Saket said. But Mishra added many patients have also been delaying treatment due to fear of contracting Covid-19 at a healthcare facility.

"People who have minor infector don't visit a doctor. Now we see people are coming late. They don't move out when the infection starts but take an antibiotic and sit at home."

Cipla was among the worst hit, with its sales declining 13% to Rs.459 crore in May, while GlaxoSmithKline Pharmaceuticals, Alkem Laboratories, Emcure Pharmaceuticals and Dr Reddy's Laboratories posted 10-17% fall in sales during the month.

India's largest drug manufacturer Sun Pharmaceutical Industries, largest multinational Abbott group, as well as companies like Lupin, Torrent Pharmaceuticals, Sanofi India, Glenmark Pharmaceuticals and Intas Pharmaceuticals had sales decline in May, as per the data.

Interestingly, Ipca Laboratories—the largest manufacturer of Hydroxychloroquine in India--reported a sales growth of 7% to Rs.161 crore. The anti-malarial

drug Hydroxychloroquine has been touted as a potential cure for Covid-19 and is currently undergoing trials across the world.

The anti-malarial segment showed a 14% jump in sales, the largest among all therapy areas, to Rs.586 crore during the month. Singhal said the jump in sales in Hydroxychloroquine (HCQ) reflected the strong demand for the repurposed drug among hospitals and government agencies. "We have told pharmacies to be vigilant about sales of HCQ. The sales growth in May was actually because of the demand from hospitals for use in Covid," he said.

Source: Livemint 09.06.2020

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ICMR, DCGI jointly release guidelines for validation and batch testing of COVID-19 diagnostic kits

The Indian Council of Medical Research (ICMR) and Drugs Controller General of India (DCGI) have jointly come out with guidelines for validation and batch testing of COVID-19 diagnostic kits.

The guidelines were approved at a joint meeting of ICMR and DCGI last week. This is recommendatory and dynamic document without prejudice to statutory provisions, said Dr Lokesh Sharma, Scientist, ICMR.

As per the guidelines, US FDA approved RT-PCR kits, RNA extraction kits and Viral Transport Medium (VTM), rapid antibody test, ELISA and CLIA kits will not require ICMR validation. The manufacturer and supplier of such kits can directly apply for DCGI approval. The first batch of CE-IVD approved, non US FDA approved and indigenous RT PCR kits will require validation from any of 24 ICMR identified validation centres prior to DCGI approval, thereafter for post marketing, additional two batches should be tested as per Medical Devices Rules in four months' time, it stated.

One batch of CE-IVD approved, non US FDA approved, indigenous RNA extraction kits and VTM will require validation from any of ICMR identified validation centres prior to DCGI approval. The testing of three batches of CE-IVD approved, non US FDA approved, indigenous rapid antibody test, ELISA and CLIA kits will be required for validation from any of ICMR identified validation centres prior to DCGI approval, the guidelines said.

The firm will be required to provide batch testing certificate while delivering the consignment. ICMR identified validation centre will undertake random samples testing of batches of kits for quality assurance, said Dr Sharma.

The requests for validation of kits for RT-PCR, RNA extraction, VTM, rapid antibody test, ELISA and CLIA will be sent by the manufacturer, supplier through e-mail (gstoteja@gmail.com) to Dr G S Toteja, Additional Director General, ICMR and national Nodal Officer for validation.

The request from the manufacturer, supplier should mandatorily be accompanied with information viz name of manufacturer, supplier, name of the kit and batch no, first time validation by ICMR, details of last validation along with validation report (if it is not first time validation), difference in kit composition as compared to first validation etc.

The request after receipt and scrutiny will be forwarded to any one of the ICMR identified validation centres depending on the work load and other logistics issue if it is first time validation.

If the kit is for second time validation or subsequent validation or in case of any other issue; the manufacturer has to provide justification which will be reviewed at ICMR, New Delhi and decision will be communicated to manufacturer and supplier within a week. The request for re-validation will only be considered if there is any significant change in the composition or type of reagents in the kit.

Once the kit is delivered to the validation centre with adequate number of test reactions required, reagents, methodology etc, validation report will be sent to the manufacturer, supplier within 15 days, added ICMR scientist.

Till date, 97 RT-PCR kits have been evaluated by ICMR validation centres, and 40 RT PCR kits were found to be satisfactory, he informed.

Some of the kits which were found to be included TaqMan 2019-nCoV Control Kit v1 from ABI (Applied bio-system), United States; AStar Fortitude Kit 2.0 from Accelerate Technologies Pte Ltd (DxD Hub), Singapore; LyteStar 2019-nCoV RT PCR Kit 1.0 from ADT India Ltd, New Delhi; RealStar SARS-CoV-2 RT-PCR kit 1.0 from Altona Diagnostics, Germany; ANGPCR 2019-nCoV from Angstrom Biotech Pvt Ltd, Rajasthan; Biogenix Covid-19 one step RT PCR from Biogenix INC Pvt Ltd, Lucknow etc.

There are 24 centres for validation and batch testing of COVID-19 diagnostic kits which include nine ICMR institutes, five department of biotechnology institutes, three CSIR institutes and seven other institutes.

The seven other institutes are Kasturba Hospital for Infectious Diseases, Mumbai, Institute of Liver and Biliary Sciences, New Delhi, Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh, King George's Medical University (KGMU), Lucknow, National Institute of Biologicals (NIB), Noida, The King Institute of Preventive Medicine and Research, Chennai, Sawai Man Singh Medical College, Jaipur.

Source: Laxmi Yadav, Pharmabiz, 09.06.2020

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IHF Tata Trust designs multi-disease platform solutions to address Public Health Emergency due to COVID-19

To address the public health emergency arising out of COVID-19, India Health Fund (IHF), an initiative of Tata Trust, has designed and conceptualized multi-disease platform solutions which were earlier used for addressing TB screening and diagnosis.

Further, IHF has also repurposed and adapted technologies from its current portfolio of TB and malaria to address COVID-19. IHF has also conducted a nationwide call Quest 2020 searching for innovations and novel approaches on airborne infections and is currently evaluating the path-breaking applications.

The two important tools that are currently being supported for COVID-19 are TruNat Beta COV developed by Molbio Diagnostics and qXR and qScout by Qure.ai respectively. The first tool is the TrueNat Beta COV, an ICMR approved confirmatory RT-PCR test. The device is a portable, battery-operated, easy to use technology which requires minimal training and can be easily deployed in high-burden areas for point-of-care screening. Test results are available within an hour and the cost of each test is Rs. 1,350. This was the second Indian made test for COVID-19 to be approved by ICMR.

"The second technology is qScout, an AI-based X-ray algorithm developed by Qure.ai, the tool allows for progression monitoring of COVID-19 positive patients who have visible lung damage due to COVID-19. The same AI enabled solution had been successful screening of TB patients and bridging gap in delayed diagnosis. Many others continue to be developed and screened, including rapid diagnostics, novel PPE equipment, infection control technologies and apps for contact tracing," informed Jayeeta Chowdhury, Programme Director at IHF, Tata Trusts.

"The Government of India has been proactive in fast-tracking the regulatory approvals for novel technologies and supporting their on-ground deployment. During this crisis, multiple state governments and agencies, such as the Government of Maharashtra and the Municipal Corporation of Greater Mumbai (MCGM), among others have rapidly deployed novel, cutting-edge technologies for tackling COVID-19. This has demonstrated the need for such innovations in the health sector and should pave the way for a more structured rollout of innovative technologies in healthcare in places where they are most needed," Chowdhury added.

The state governments of Goa and Andhra Pradesh have been first to place order of the TrueNat diagnostic platforms and other state governments are in the process of purchasing the same. The Government of Andhra Pradesh had already procured the same platform for TB tests earlier.

Talking about the recent innovations in terms of diagnostics and therapy, Chowdhury informed that there are many ongoing global efforts but given the time drug development takes, accelerating development of screening and diagnostic tool and ensuring access to screening and tests is most crucial now.

Technologies in diagnostics are Quantitative Reverse Transcription-Polymerase Chain Reaction (RT-PCR), Isothermal amplification - eg LAMP assays, Hybrid system combining PCR & advanced detection methods, CRISPER-CAS based technology, DNA sequencing based technology and Rapid tests - Antigenic tests and Serological tests (IgM/IgG antibody based) Innovations in therapy are convalescent plasma therapy, antiviral drug remdesivir, antiviral drug Favilavir, Hydroxychloroquine (Plaquenil) and Chloroquine (Aralen), Lopinavir-ritonavir (Kaletra), oral broad-spectrum antivirals , therapeutics approved for other indications like ivermectin, tocilizumab and open source drug discovery.

Speaking about the environment in India to help adopt technologies in the interest of patient safety, she said that Government of India has created an accelerated pathway for approving healthcare innovations, and this has been improving the testing facilities for COVID-19 patients,

while the need is expanding daily. The rapid approval of technologies for COVID-19 has to continue for tackling equally deadly diseases like tuberculosis.

Regulatory challenges include the turnaround time in obtaining manufacturing license, local approval for antibody test kits, obtaining marketing license to sell the kits commercially in India. Similarly procuring raw materials from outside India takes around 15 to 20 days depending on the global demand.

The Government of India has taken steps to make the environment conducive to adopt technologies for COVID-19. Its initiatives include telemedicine guidelines imports of medical equipment-exemption from customs duty and health cess, (with effect from April 9, 2020 to September 30, 2020) on import of consumables like artificial respiration or other therapeutic respiration apparatus (ventilators), face masks and surgical masks, Personal Protection Equipment (PPE), COVID-19 testing kits and launch of Arogya Setu app.

Source: Shardul Nautiyal, Pharmabiz, 09.06.2020

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Gaining herd immunity the only viable solution for India to tackle COVID-19 pandemic: Dr T R Chandrashekar

India has realized that it has to live with the Coronavirus disease (COVID-19). Gaining herd immunity is the only permanent solution to this pandemic. Vaccination and controlled distribution of the infection through 60% of the population are two ways of gaining herd immunity, said Dr T R Chandrashekar, member, Critical Care Society, Bengaluru and consultant, Institute of Gastroenterology Transplant, Victoria Hospital.

Vaccination is a safer way, with no loss of lives. But a realistic target for the vaccine launch is at least a year away. Hence, gaining herd immunity is the only solution India can afford, economically and socially, with everyone taking on the responsibility to prevent the spread. This will result in loss of lives, which is at 3% to 5% of the infected cases today and is a concern, he added.

If the surge in cases overwhelms the medical infrastructure, it could increase fatalities. The Government will then need to enforce stricter lockdown to control the spread. However, a consolation is that the Indian cohort has shown that 80% to 85% of patients infected run a very mild course of the infection not requiring hospitalization. These patients require self quarantine to avoid infection spread. It is only the 10% to 15% who require supportive care with oxygen. The remaining 5%, who are infected and above 60 years with co-morbidities, is difficult to save. India is a young country with only 10% of the population above 60 years of age, so the mortality rate may be less compared to other parts of the world, Dr Chandrashekar noted.

When the trade-off is between lives and livelihoods, the population is for choosing livelihoods, as a majority of Indian population leads a hand-to-mouth existence.

COVID-19 spreads when an infected person without a mask coughs, generating droplets which contain the virus. These droplets are deposited on surfaces. When a non-infected person touches the surface and then touches his face, he in turn gets infected. The viability of the virus, on different surfaces may be from few hours to one day. By wiping the commonly used surfaces regularly with home bleach solutions or soap and water, the spread can be controlled. Moreover, the virus spread from person to person can be decreased by maintaining physical distancing of at least 6 feet, wearing masks and ensuring hand hygiene.

No Government is capable of monitoring the personal hygiene of the entire population 24x7. Our urban landscape is dotted with overcrowded cities, slums having a lot of civic problems and lack of hygiene. How all these factors play out when we are planning to run the infection through the population has to be factored in by policymakers, he said.

The majority of the population is under the impression that pandemic is done with. This is a dangerous thought which may lead to lowering of the guard, leading to an increase in the spread of the virus. It requires a shift in the way we lead our lives, which has to be brought by awareness campaigns, incentives and enforcement which may take a year or more, said Dr Chandrashekar.

Source: Nandita Vijay, Pharmabiz, 09.06.2020

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DGFT seeks Ministries of Health & Textiles' stand over allowing export of PPEs, surgical masks, textile raw materials

The Directorate General of Foreign Trade (DGFT) has sought direction from Union Ministries of Health and Family Welfare and Textiles to lift export restrictions on

personal protective kits (other than required for health workers), textile raw materials, surgical masks (except N-95) following representations from exporters.

The DGFT has received various representations from exporters of textile fabric, 2/3 ply surgical masks, PPEs, gowns etc requesting it to review the export policy concerning these items, considering sufficient domestic availability. The exporters stated that some of the textile material prohibited (5603 HS codes) under DGFT Notification No. 53 dated March 19, 2020 is not used in making coveralls or masks and therefore must be allowed to be exported.

The FIEO has also requested DGFT to reconsider export policy of PPEs, textile raw materials, 2/3 ply surgical masks (except N-95 masks) to allow their export. FIEO also sought removal of export restriction on all diagnostic kits except COVID-19 test kit.

Following this, DGFT has recently written to Ministries of Health Ministry and textiles to examine the representations and provide their feedback. DGFT in a notification on April 4, 2020 restricted exports of diagnostic kits (diagnostic or laboratory reagents on a backing, preparation diagnostic or laboratory reagents) with immediate effect.

On March 19, 2020 DGFT had put restriction on export of all ventilators, surgical/disposable (2/3 ply) masks and textile raw material for masks and coveralls.

Besides FIEO, the Association of Indian Medical Device Industry (AiMED) has also sought removal of export restriction on nitrile industrial gloves and 3-layer surgical masks other than N95 respirator masks.

AiMED forum coordinator Rajiv Nath in a letter to Dr P D Vaghela, Chairman of empowered committee of essential medical equipment and Secretary, Department of Pharmaceuticals (DoP) and Ravi Capoor, Secretary, Ministry of Textiles on May 19, 2020 stated that besides catering to domestic requirements, 3-layer surgical mask manufacturers in the country have surplus stock. These manufacturers are stopping or slowing down production since last 15-20 days as they have unsold inventory in the wake of falling demand and market prices as public and private healthcare clients are many times preferring to buy low cost 2 and 3 layer masks or nonstandard quality masks without nose clip.

AiMED sought Dr Vaghela and Capoor's intervention in opening up the export of surgical masks to meet global demand in this COVID-19 pandemic. Nath in another letter to Dr Vaghela on May 29, 2020 sought removal of restriction on export of nitrile industrial gloves which has nothing to do with COVID-19 requirement.

Source: Laxmi Yadav, Pharmabiz, 08.06.2020

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N-95 mask manufacturers reduce price upto 47%; NPPA issues list of revised MRPs to ensure compliance

To ensure the availability of N-95 masks at the revised MRPs as per price control compliance, the National Pharmaceutical Pricing Authority (NPPA) has issued a list of price reduction in N-95 masks by four major N-95 mask manufacturers, namely Venus Safety and Health Pvt Ltd, Magnum Health and Safety, Yash Care Life Sciences and Joseph Leslie & Co.

The national drug price regulator has now shared the revised MRPs reported by these manufacturers of N-95 masks with the state drug controllers (SDCs). The list indicates that the makers of N-95 masks reduced the cost of their products, some even up to 47 percent, after NPPA issued an advisory on May 21, 2020 recommending manufacturers to voluntarily lower prices. NPPA had also asked manufacturers, importers, suppliers of the N-95 masks to maintain parity in prices for non-government procurement and make them available at the same reasonable prices.

The reported lowered MRPs of various grades of N-95 masks of the four manufacturers ranges from the earlier MRP of Rs. 160 to current Rs. 95, from the earlier Rs.195 to current Rs. 125, from Rs. 175 to current Rs. 105, from Rs. 225 to current Rs. 135, from Rs. 200 to Rs. 130 and from Rs. 250 to Rs. 165 in case of Venus Safety, from Rs. 175 to current Rs 135 in case of Magnum, from Rs. 238 to Rs. 126 in the case of Yash Care and in case of Joseph Leslie the revised MRP is Rs. 140 from the earlier Rs. 150. The drug pricing regulator had earlier directed manufacturers, importers and suppliers of N-95 masks to maintain parity in prices for non-government procurements and make available the same at reasonable prices to curb black marketing.

"All SDCs have been directed to refer to the Office Memorandum (OM) issued by NPPA office wherein/ importers/ suppliers of the N-95 masks were advised to maintain parity in prices for non-government procurements and to make available the same at reasonable prices. It is further directed that any instance of hoarding, black

marketing and higher pricing of N-95 masks and unethical practices like counterfeit products be viewed seriously and strict action be initiated under the Essential Commodities (EC) Act, 1955," as per the NPPA order.

The NPPA directive comes in the wake of grievances being received regarding hoarding and black marketing and differential higher pricing of N-95 masks in the country. "In the wake of the prevailing situation due to COVID-19, the government is striving to ensure uninterrupted supply of N-95 in adequate quantity of HCWs.

For this Government is procuring N-95 masks directly from the manufacturers, importers and suppliers at bulk rates and at ex-factory prices. However it has been noticed that other procurers (non-government entities) are getting N-95 masks at differential prices," an NPPA order stated.

Maharashtra FDA had on May 15, 2020 also requested NPPA to cap the prices of N-95 masks and PPE kits. It had pointed out that consumers are not aware of the exact MRP of N95 masks and PPEs. Sometimes, the MRP printed by some of the manufacturers is exorbitant and as a result, common public, private doctors, health workers and paramedical staff in private hospitals are forced to pay the said higher printed prices.

As per guidelines issued by the Health Ministry on May 15, 2020, N-95 masks are also to be used in non-COVID areas of treatment such as ENT clinics, emergency rooms, eye clinics, labour rooms, ambulance transfers etc. This has increased the demand for these masks.

Source: Shardul Nautiyal, Pharmabiz, 08.06.2020

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ICMR invites research proposals to address COVID-19 in low and middle income countries

The Indian Council of Medical Research (ICMR) has invited research proposals addressing COVID-19 in Low- and Middle Income Countries (LMICs). This research programme is supported by National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI). The purpose of the call is on understanding the pandemic and mitigating its health impacts in Low and Middle-Income Countries (LMIC) contexts.

The call specification is based on the WHO COVID-19 Global Research Roadmap priorities identified through a consultative process that involved experts from across the world. In addition, it has taken into consideration the African Academy of Sciences research priorities for COVID-19, and input from external experts, for example DHSC's Global Health Research Independent Scientific Advisory Group and MRC's Applied Global Health Research Board.

The focus area of these research proposals are epidemiological studies like identification of groups at characteristics of increased risk of severe infection, determination of susceptibility of children to COVID-19 and their role in transmission of the disease, whether infected asymptomatic, or infected symptomatic and clinical management like to determine interventions that improve clinical outcomes for COVID-19 infected patients (including viral load, disease and transmissibility, markers of protection) and optimal clinical practice strategies to improve the processes of care (including early diagnosis, discharge criteria, optimal adjuvant therapies for patients and contacts).

It also focuses on infection prevention and control including health care workers' protection to optimize the effectiveness of Personal Protective Equipment (PPE), its adaptations in resource-poor/crowded environments and its use in reducing the risk of transmission in health care and community settings and for the implementation of research relating to use of diagnostic tests for containing the epidemic.

Other area of these proposals include social sciences and humanities in the outbreak response on how COVID-19 and the health system response that affects the supply and access to other health care provision (such as maternal health, immunisation, routine surgeries, chronic disease care etc); and determining strategies to mitigate this.

UK institutions include UK Higher Education Institutions, Research Council institutes, and eligible Independent Research Organisations (IROs) are eligible for these proposals.

The GECO Health Research call will have three consecutive rounds on June 22, August 10 and September 28, 2020.

Source: Neethikrishna, Pharmabiz, 08.06.2020

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Scaling up African Pharmaceutical Manufacturing in a Time of COVID-19

John Campbell

Michael Otieno, a pharmacist, dispenses antiretroviral (ARV) drugs at the Mater Hospital in Kenya's capital Nairobi, on September 10, 2015. Thomas Mukoya/Reuters

The COVID-19 pandemic has caused massive disruptions to global supply chains. Africa is particularly vulnerable with respect to pharmaceuticals, both because between 70 and 90 percent are imported and because the continent generally lacks the political sway and bargaining power of other regions. In the shortterm, the most acute issue is the need for huge quantities of quality-assured protective equipment, tests and medicines to treat the symptoms of COVID-19. Significant shortages of other essential medicines could materialize. With access to such essential medical products across the continent challenged, there has been a commensurate uptick in substandard and falsified products related to the testing or treatment of COVID-19.

But many countries in Africa have underutilized capacity to produce quality assured, essential pharmaceutical products locally. In Nigeria, one of the countries with the greatest potential for rapidly scaling up production, pharmaceutical manufacturing production currently utilizes around 40 percent of actual installed capacity. Manufacturing output remains lower than its potential in part due to inconsistent demand, challenges in sourcing active and raw ingredients, unfavorable market conditions, and a lack of available investment to scale up operations, modernize equipment, and resolve local infrastructure limitations. Here are some ways to make use of this potential.

- Insufficient knowledge about the real capacity of local manufacturing sectors, sources of component parts, and expected market demand is hindering efforts to make use of local excess capacity. Pharmaceutical manufacturing associations—along with market intelligence firms, multilateral agencies, and international donors—should lead a comprehensive mapping of the existing technical capacity, resources, and sources of raw materials available on the continent. Meanwhile, governments should work to forecast demand for locally produced products and create a favorable policy environment for local manufacturers to compete with producers from abroad, allowing them to better manage the risk associated with capital investments for scale up.
- Manufacturers and regulators must work to improve quality by applying international public quality standards to gain a competitive foothold, not only locally but in the broader global supply chain.
- The African Medicines Agency (AMA), a continental effort to harmonize medicines regulation, should be fully ratified and quickly scaled up to advance regulatory reliance, mutual recognition, and risk-based regulatory practices. The AMA will help support production of active ingredients in Africa, streamline market access, and reduce barriers to market entry for manufacturers. As of April 30, eleven countries had signed it and two had ratified it.

Progress can already be seen on multiple fronts. Ethiopia and South Africa have developed national strategies and manufacturing roadmaps that address common pitfalls such as sourcing active ingredients; addressing financial barriers; and improving quality in line with international standards. And these plans are starting to translate into specific gains. South Africa and Egypt are beginning to produce active ingredients locally—the first step in overcoming a major hurdle that makes it difficult for African manufacturers to compete with imported products from Asia. Ethiopia, meanwhile, is developing a pharmaceutical manufacturing industrial park to spur national and regional manufacturing activities.

National central banks, such as the Central Bank of Nigeria, are working to stimulate the sector by extending lines of credit to local manufacturers. In addition, Afrexim Bank, the UN Economic Commission for Africa (UNECA), and the African Center for Disease Control recently announced emergency interventions to rapidly respond to

supply and policy gaps, including for medical products. Afrexim Bank further announced a $3 billion funding facility that includes funding to support local production of COVID-19 related health products. As part of this effort, UNECA and Afrexim Bank have compiled a list of fifty local pharmaceutical companies which have the capacity or have shown interest in supplying priority products. COVID-19 is expected to drive countries to enact procurement incentives such as prioritizing and incentivizing the procurement of locally produced products, providing advanced market commitments, and establishing pooled procurement mechanisms such as those being developed by UNECA, the Federation of African Pharmaceutical Manufacturers Associations (FAPMA), and the WHO. Countries should also push global procurement agencies to consider similar incentives to further support the continent's nascent pharmaceutical industry. Scaling up African pharmaceutical capacity will help provide sustainable access to quality medical products and increase health security during the COVID-19 pandemic and beyond.

(Emily Kaine, MD, is the Senior Vice President for Global Health at the U.S. Pharmacopeia. Jude Nwokike is a Vice President for Global Public Health at the U.S. Pharmacopeia).

Source: Blog Post by Guest Blogger for John Campbell, Council on Foreign relations, 22.05.2020 (Excerpts)

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The top 10 Pharma R&D budgets in 2019

Big Pharma contributed less than half of biopharma's 2019 R&D approvals, showing once again that small, emerging firms are consolidating their role as an engine for new drug discovery. (Seventy-four/Getty)

In 2019, the top 10 pharmaceutical R&D spenders collectively plowed a whopping $82 billion into their search for new drugs, diagnostics and vaccines, around $4 billion more than the previous year.

But is 2019 a high-water mark for R&D spending? EvaluatePharma says it just might be, at least when it's measured as a proportion of pharmaceutical revenue. Productivity gains and streamlining could shave away at that percentage, Evaluate figures, but it could also be a victim of Pharma's success. Companies might decide to use less of their revenue to replenish pipelines after a fertile period of new product launches. 2019 was also another big year for FDA approvals. The regulator cleared 45 new drugs, down from a record 59 in 2018 but still the third-biggest annual haul of new molecular entities (NMEs) in the last quarter-century.

While our listing focuses on the largest companies with the deepest pockets, it's worth noting that Big Pharma contributed less than half of the 2019 spending tally, showing once again that small, emerging biopharma companies are consolidating their roles as engines for new drug discovery—and, increasingly, taking drugs to market on their own.

Looking through the main programs across all the top 10 companies, it's immediately clear oncology is still the biggest therapeutic category when it comes to spending. Cancer R&D has traditionally been expensive, but the FDA's willingness to approve treatments on more limited data is cutting costs and offering a quicker path to market. And premium pricing, of course, means returns on investment can be high.

2019 also came to a close before the coronavirus pandemic started to take hold around the world, and it is inevitable that in 2020 it will put a damper on some companies' R&D spending. That was already apparent in the first quarter as drugmakers delayed the start of clinical trials—the most expensive part of the R&D process—and also put the brakes on some projects altogether. But for many top pharmas, the coronavirus has also sparked increased spending—often at-risk—on diagnostic, treatment and vaccine programs for COVID-19, and we've included these as we look ahead to what's coming in 2020.

At the time of writing some companies were suggesting patient enrollment may start to resume in some trials, as lockdowns are relaxed around the world. But with preliminary reports of a spike in new cases in some countries that have started to ease up on social distancing—notably Germany and South Korea—there's no guaranteeing further disruption won't be ahead.

Source: Phil Taylor, FiercePharma, 08.06.2020

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