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LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2018-20

IDMA BULLETIN

VOL. NO. 51 | ISSUE NO. 39 (PAGES: 40) | 15 TO 21 OCTOBER 2020 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT (APPQM)

A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021

(Details on Page Nos. 4 & 5)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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IDMA BULLETIN

Vol. No. 51 **Issue No. 39** **15 to 21 October 2020**

MBA-STYLE INTERNATIONAL EDUCATIONAL PROGRAM FOR POTENTIAL LEADERS

Empowerment
Through Education
Living A Dream, Building A Future

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021

For further information / queries, please open the below links on our website www.idma-assn.org:

Circular / Covering Note | NSF Presentation | WHY APPQM? By Mr S M Mudda | APPQM 5 Modules | APPQM Series 1 FEEDBACK | REGISTRATION FORM

APPQM FOR DEVELOPING CHANGE AGENTS FOR QUALITY EXCELLENCE

APPQM - Program Modules

1. **Pharmaceutical Quality Management Systems – Best Industry Practices**
   (How to ensure your QMS drives business improvements)
2. **Managing Change: Change Control and Deviations**
   (Advanced problem solving, deviation management, report writing and change management)
3. **Human Factors – Getting people to follow the rules**
   (How to improve performance, reduce human error, embed a quality mind-set & keep your people)
4. **Transforming Data into Information – the Practical Application of Statistics to Transform your Business**
   (The practical application of statistics to transform your business)
5. **Quality by Design, Process Validation and Technology Transfer**
   (Building a foundation for Product Quality and Knowledge Management)

Advantages of NSF's Virtual Training

- NSF's virtual training combines live instructor-led virtual classrooms and self-paced learning online (easy to navigate e-learning) to provide participants with an interactive and engaging learning experience.
- Enhanced Virtual Interactivity – such as polls, etc.
- Virtually managed Break-out rooms - These are as good as physical break out groups
- Use of Team works – specially smaller group sizes
- Use of Tasks and Case Studies
- Courses managed Brilliantly by NSF - Each course is managed on NSF Learning Management System (LMS), with electronic course material
- Time for self-study each day.
- Guest Speakers (including MHRA, US FDA ex-regulators) enhance the modules and motivate the delegates

Additional Benefits:

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees **(from £8000 to £3300)**
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Why APPQM in INDIA?*

When launching the first series of the APPQM, we at IDMA along with NSF, UK reflected on the perceived trust deficit with international regulators despite being regarded as a 'Pharmacy of the World' and offered a global education program APPQM, in collaboration with NSF Health Sciences, UK, as a collective proactive response from the industry. We boldly stated APPQM would be Unique, World-Class and transform the operation efficiency of companies attending. Well, did series one live up to expectations?

Over 40 delegates attended series one.

This is what they thought:

"Transformative", "world-class", "best business investment we've ever made", "life changing", "worth every penny and more", "my company will be sending more delegates to series two", "has helped transform our quality culture" are just some examples of the feedback we've received from APPQM delegates.

Nearly 30 'work placement projects' have been completed by APPQM delegates.These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

*Please visit IDMA website for details of benefits

Current Challenges & APPQM

In this challenging times, the pharmaceutical industry will become competitive only if the 3 factors - **Legacy & Reputation** (License to Operate), **Profit & Efficiency** (Cost Control) and **Customer service** are balanced and managed well.

The COVID-19 pandemic has created unique challenges as well as opportunities for the industry. In the absence of any regulatory inspections happening until quarter III of 2021 and reduced physical oversight by the corporate QA functions, the external interventions on the site will be reduced. There is an urgent need to use this time for building a strong leadership at the site for quality and compliance.

We recommend the virtual APPQM for the site teams for keeping themselves updated with the changing regulatory expectations in the post COVID-19 phase, once the physical inspections start.

The need of the hour is to focus on long term preventive measures aimed at achieving continual improvements rather than short term Compliance-Oriented approach.

Please don't get left behind and register for the second series of APPQM to have a competitive edge in the global market and to be future ready.

REGISTRATION FEE FOR SERIES TWO

The Registration Fee for **APPQM SERIES 2** is restructured at

Rs.3,15,000/- (Rupees Three Lakh Fifteen Thousand Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the Registration Form and send it to

Melvin Rodrigues actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

For further information / queries :

You may also contact **Mr. S. M. Mudda**, @ **mudda.someshwar@gmail.com** / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M MUDDA Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**MAHESH H DOSHI** National President, IDMA	**DR. GEORGE A PATANI** Hon. General Secretary & Vice Chairman, Industry Institution Interaction Committee, IDMA	**DAARA B PATEL** Secretary – General, IDMA

Export of Alcohol Based Hand Sanitizers in containers with dispenser pumps allowed freely – reg.

DGFT Notification No.40/2015-2020, dated 15th October, 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 to the Notification No.08 dated 01.06.2020 related to the export policy of Alcohol based Hand Sanitizers, with immediate effect:

Sr. No.	ITC HS Codes	Description	Present Policy	Revised Policy
207 D	ex3004 ex3401 ex3402 380894	Alcohol Based Hand Sanitizers in containers with dispenser pumps	Prohibited	Free

2. Effect of this Notification:

The Export of Alcohol based Hand Sanitizers in container with dispenser pumps is free for export making export of Alcohol based Hand Sanitizers in any form/packaging freely exportable, with immediate effect.

File No.01/91/180/21/AM20/EC/Part IV/E-21207

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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Electronic filing and Issuance of Preferential CoO for India's Exports under GSP, GSTP, India-Malaysia CECA, India-Singapore CECA w.e.f. 15th October 2020 - reg.

DGFT Trade Notice No.30/2020-2021, dated 13th October, 2020

To,
All Exporters/Members of Trade;
All Designated Issuing Agencies under FTAs/PTAs.

1. In continuation to the earlier Trade Notice(s) 34/2015-2020 dated 19.09.2019, 41/2019- 2020 dated 12.12.2020, 53/2019-2020 dated 02.03.2020 and 01/2020-2021 dated 07.04.2020, it is informed that the electronic platform for Preferential Certificate of Origin(CoO) is being expanded to add four more FTAs/PTAs to facilitate electronic application of CoOs.

2. This given e-platform has been designed as a single-point access for al FTAs/PTAs, all designated Certificate of Origin (CoO) issuing agencies and for all export products, and is accessible at the **URL: https://coo.dgft.gov.in.** It may be noted that the CoO for exports from India under following FTAs/ PTAs are already being applied and issued through the e-platform.

ICPTA	India Chile Preferential Trade Agreement
SAFTA	South Asia Free Trade Agreement
SAPTA	SAARC Preferential Trade Agreement
IKCEPA	India Korea Comprehensive Economic Partnership Agreement

IJCEPA	India Japan Comprehensive Economic Partnership Agreement
AIFTA	ASEAN India Free Trade Agreement
ISFTA	India Sri Lanka Free Trade Agreement
APTA	Asia Pacific Trade Agreement

3. To further this trade facilitation initiative, the Preferential Certificate of Origin for exports to various other countries under the following four trade agreements shall also be applied and issued from the CoO e-platform with effect from 15th October 2020.

GSP	Generalized System of Preferences
GSTP	Global System of Trade Preferences
IMCECA	India Malaysia Comprehensive Economic Cooperation Agreement
ISCECA	India Singapore Comprehensive Economic Cooperation Agreement

4. The given CoO applications for exports from India under GSTP, IMCECA and ISCECA should be submitted through the e-COO platform to the designated issuing agencies. (May please refer to Appendix 2B of the Foreign Trade Policy for details of the designated issuing agencies). No manual application for such a CoO should be submitted to an issuing agency after 15th October 2020. Any manual applications submitted prior to the given date may however be processed by the issuing agencies.

5. CoO applications for exports under GSP may also be submitted through e-CoO platform w.e.f. 15th October 2020. However, the earlier procedure of submitting the manual CoO applications (under GSP) physically to the designated issuing agency shall also be in operation. There shall be a transition period of 3 months when both the online and the physical process shall be operated. Manual submission of GSP CoO applications is accordingly allowed to continue up to 14.01.2021 or until further orders.

6. It is informed that for the applications under the above mentioned FTAs/PTAs, the e-CoO system shall generate all the existing set of CoO copies along with an additional copy i.e. electronic copy. The electronic copy shall bear the image signature of the officer and stamp of the issuing agency. The exporter may however get the remaining copies duly ink-signed by the issuing officer with the stamp from the designated issuing office. The copies of the CoOs so issued may be collected by post or in person, for any submission to the FTAs/PTAs partner countries authorities.

7. The concerned Exporters may please take note of the following additional points with regard to the process being notified herewith:

a. Digital Signature Certificate (DSC) would be required for the purpose of electronic verification. The digital signature would be the same as used in other DGFT applications;

b. The digital signature may be Class II or Class III and should have the IEC of the firm embedded in the DSC;

c. Any new applicant exporter would be required to initially register at the e-platform. The password would be sent on the email and mobile number of the IEC holder. In case the IEC holder desires to update their email on which communication is to be sent, the same may be done by using the 'IEC profile Management' service on the DGFT website **https://dgft.gov.in**

d. Once registration is completed, the IEC branch details would be auto-populated as per the DGFT-IEC database. Applicant is required to ensure that updated IEC details are available in the DGFT system. Necessary steps may be taken to modify the IEC details online, whenever required.

8. For further guidance on registration and application submission, the Help manual & FAQs may be accessed on the landing page at **https://coo.dgft.gov.in.** For any further assistance you may utilize any of the following channels;

i. Raise a service request/suggestion ticket through the DGFT Helpdesk service link on the e- platform home page.

ii. Call the toll-free Helpline number 1800-111-550.

iii. Send an email to **coo-dgft@gov.in**

This issues with the approval of the Competent Authority.

File No.01/02/82/AM-19/EDI

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

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Date of submission of documents for EO fulfilment in Advance Authorisations extended up to 31.12.2020 – reg.

DGFT Public Notice No.26/2015-2020, dated 16th October, 2020

1. In exercise of powers conferred under Paragraph 1.03 of the Foreign Trade Policy 2015-2020, as amended from time to time, the Director General of Foreign Trade makes the following amendments in Para 4.44 of Hand Book of Procedures 2015-2020.

2. A new para 4.44 (g) is inserted as under:-

Para 4.44(g):

(g) For all Advance Authorisations, where Export Obligation period is expiring/has expired between 01.02.2020 and 31.10.2020, as a one-time temporary measure, date of submission of documents for EO fulfilment is extended up to 31.12.2020.

Effect of this Public Notice: Due to COVID 19, Para 4.44 of Handbook of Procedures 2015-20, on Monitoring of Export Obligation stands amended to allow extension in the date of submission of documents for EO fulfilment up to 31.12.2020 for all Advance authorisations, wherever Export Obligation period is expiring/has expired between 01.02.2020 and 31.10.2020.

File No.01/94/180/466/AM20/PC-4

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

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GOVERNMENT NOTIFICATIONS

Time extended upto 30.03.2021 for all proposals for projects/activities in respect of API as B2 category in line with EIA Notification dated 27.03.2020 - reg.

Gazette Notification S.O. 3636(E), dated 15th October 2020

In exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), read with clause (d) of sub-rule (3) of rule 5 of the Environment Protection Rules, 1986, the Central Government after having dispensed with the requirement of notice under clause (a) of sub-section (4) of rule 5 of the said rules in the public interest, hereby makes the following further amendment in the notification of the Government of India in the Ministry of Environment and Forest, Published in the Gazette of India, Part II, Section 3, Sub-section (ii), vide number S.O 1533 (E), dated the 14th September, 2006, namely:-

In the said notification, in the Schedule, in sl. Number 5(f), in column (5), for the figures, letters and word "30th September, 2020", at both the places where they occur, the figures, letters and word **"30th March, 2021"** shall be substituted.

F.No.19-21/2020-IA.III

Geeta Menon, Joint Secretary, Ministry of Environment, Forest and Climate Change, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1533(E), dated the 14th September, 2006 and was last amended vide Number S.O 1562 (E), dated the 21st May, 2020.*

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Notified due dates of filing of FORM GSTR-1 for registered persons having aggregate turnover of up to 1.5 crore rupees in the preceding financial year or the current FY for period October 2020 to March 2021 - reg.

GST-Central Tax Notification No.74/2020, dated 15th October, 2020

1. In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), the Central Government, on the recommendations of the Council, hereby notifies the registered persons having aggregate turnover of up to 1.5 crore rupees in the preceding financial year or the current financial year, as the class of registered persons who shall follow the special procedure as mentioned below for furnishing the details of outward supply of goods or services or both.

2. The said registered persons shall furnish the details of outward supply of goods or services or both in **FORM GSTR-1** under the Central Goods and Services Tax Rules, 2017, effected during the quarter as specified in column (2) of the Table below till the time period as specified in the corresponding entry in column (3) of the said Table, namely:-

TABLE

Sr. No.	Quarter for which details in FORM GSTR-1 are furnished	Time period for furnishing details in FORM GSTR-1
(1)	(2)	(3)
1	October, 2020 to December, 2020	13th January, 2021
2	January, 2021 to March, 2021	13th April, 2021

3. The time limit for furnishing the details or return, as the case may be, under sub-section (2) of section 38 of the said Act, for the months of October, 2020 to March, 2021 shall be subsequently notified in the Official Gazette.

F.No.CBEC-20/06/09/2019-GST

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

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Notified due dates of filing of FORM GSTR-1 for the registered persons having aggregate turnover of more than 1.5 crore rupees in the preceding financial year or current FY for the period October 2020 to March 2021 - reg.

GST-Central Tax Notification No.75/2020, dated 15th October, 2020

1. In exercise of the powers conferred by the second proviso to sub-section (1) of section 37 read with, section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), the Commissioner, on the recommendations of the Council, hereby extends the time-limit for furnishing the details of outward supplies in **FORM GSTR-1** of the Central Goods and Services Tax Rules, 2017, by such class of registered persons having aggregate turnover of more than 1.5 crore rupees in the preceding financial year or the current financial year, for each of the months from October, 2020 to March, 2021 till the eleventh day of the month succeeding such month.

2. The time-limit for furnishing the details or return, as the case may be, under sub-section (2) of section 38 of the said Act, for the months of October, 2020 to March, 2021 shall be subsequently notified in the Official Gazette.

F.No.CBEC-20/06/09/2019-GST

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

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Notified due dates of filing of FORM GSTR-3B for period October 2020 to March 2021 - reg.

GST-Central Tax Notification No.76/2020, dated 15th October, 2020

1. In exercise of the powers conferred by section 168 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this notification referred to as the said Act), read with subrule (5) of rule 61 of the Central Goods and Services Tax Rules, 2017 (hereafter in this notification referred to as the said rules), the Commissioner, on the recommendations of the Council, hereby specifies that the return in **FORM GSTR-3B** of the said rules for each of the months from October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the twentieth day of the month succeeding such month:

Provided that, for taxpayers having an aggregate turnover of up to five crore rupees in the previous financial year, whose principal place of business is in the States of Chhattisgarh, Madhya Pradesh, Gujarat, Maharashtra, Karnataka, Goa, Kerala, Tamil Nadu, Telangana, Andhra Pradesh, the Union territories of Daman and Diu and Dadra and Nagar Haveli, Puducherry, Andaman and Nicobar Islands or Lakshadweep, the return in **FORM GSTR-3B** of the said rules for the months of October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the twenty-second day of the month succeeding such month:

Provided further that, for taxpayers having an aggregate turnover of up to five crore rupees in the previous financial year, whose principal place of business is in the States of Himachal Pradesh, Punjab, Uttarakhand, Haryana, Rajasthan, Uttar Pradesh, Bihar, Sikkim, Arunachal Pradesh, Nagaland, Manipur, Mizoram, Tripura, Meghalaya, Assam, West Bengal, Jharkhand or Odisha, the Union territories of Jammu and Kashmir, Ladakh, Chandigarh or Delhi, the return in **FORM GSTR-3B** of the said rules for the months of October, 2020 to March, 2021 shall be furnished electronically through the common portal, on or before the twenty-fourth day of the month succeeding such month.

2. Payment of taxes for discharge of tax liability as per FORM GSTR-3B: Every registered person furnishing the return in **FORM GSTR-3B** of the said rules shall, subject to the provisions of section 49 of the said Act, discharge his liability towards tax by debiting the electronic cash ledger or electronic credit ledger, as the case may be and his liability towards interest, penalty, fees or any other amount payable under the said Act by debiting the electronic cash ledger, not later than the last date, as specified in the first paragraph, on which he is required to furnish the said return.

F.No.CBEC-20/06/09/2019-GST

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

● ● ●

Filing of optional GST Annual Return for small taxpayers with turnover less than Rs.2 Crores extended for FY 2019-20

GST-Central Tax Notification No.77/2020, dated 15th October, 2020

In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereinafter referred to as the said Act), the Central Government, on the recommendations of the Council, hereby makes the following amendment in the notification of Government of India in the Ministry of Finance, (Department of Revenue), No.47/2019–Central Tax dated the 9th October, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.770(E), dated the 9th October, 2019, namely:-

In the said notification in the opening paragraph, for the words and figures "financial years 2017-18 and 2018-19", the words and figures "financial years 2017-18, 2018-19 and 2019-20" shall be substituted.

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification No.47/2019–Central Tax, dated the 9th October, 2019 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.770(E), dated the 9th October, 2019.*

● ● ●

HSN Codes - digits required on Tax Invoice - Exemption for turnover up to 50 lakhs withdrawn w.e.f. 01.04.2021 - reg.

GST-Central Tax Notification No.78/2020, dated 15th October, 2020

In exercise of the powers conferred by the first proviso to rule 46 of the Central Goods and Services Tax Rules, 2017, the Central Board of Indirect Taxes and Customs, 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.12/2017–Central Tax, dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.660(E), dated the 28th June, 2017, namely:–

In the said notification, with effect from the 01st day of April, 2021, for the Table, the following shall be substituted, namely,-

TABLE

Sr. No.	Aggregate Turnover in the preceding Financial Year	Number of Digits of Harmonised System of Nomenclature Code (HSN Code)
(1)	(2)	(3)
1	Up to rupees five crores	4
2	more than rupees five crores	6

Provided that a registered person having aggregate turnover up to five crores rupees in the previous financial year may not mention the number of digits of HSN Code, as specified in the corresponding entry in column (3) of the said Table in a tax invoice issued by him under the said rules in respect of supplies made to unregistered persons.".

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification number 12/2017–Central Tax, dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.660(E), dated the 28th June, 2017.*

(NOTE: CBIC has issued similar Notification under GST-Integrated Tax Notification No.06/2020, dated 15th October 2020)

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COVID-19 Situation – Supply of Drugs via SPV/Courier Services – Representation from All Kerala Chemists and Druggists Association, Kerala – reg.

ATTENTION MEMBERS

IDMA has received on 20.10.2020 a Communication (Ref. No. A.7454/2020/DC, dated 18.08.2020) from Drugs Controller (I/C), Office of the Drugs Controller, (Drugs Control Department), Red Cross Road, Thiruvananthapuram 695 035, Kerala as reproduced below:

"DCD Communication Ref.No. A.7454/2020/DC, dated 18.08.2020

A copy of the representation mentioned above is enclosed for information and consideration in view of the serious pandemic situation existing in the country.

Yours faithfully,

Drugs Controller (I/C), Office of the Drugs Controller, (Drugs Control Department), Red Cross Road, Thiruvananthapuram 695 035, Kerala.

Request to issue an ADVISORY to manufacturers/C&F & Depots to supply their medicines through SPV/Courier Services during COVID-19 period – reg.

Representation by AKCDA dated 19th June, 2020

To

Shri K J John, Drugs Controller, Thiruvananthapuram.

It is noticed that majority of Pharma Companies are supplying their medicines either through their own vehicles, engaging logistic companies through Special Purpose Vehicle or through Courier Services for reaching the consignments direct to the stockists. But it has been reported to us by our wholesale members that some of the manufacturers are supplying their medicines only through lorry parcel services to save cost even after receiving payments through RTGS. Your good self could understand the plight of such consignments when supplied in regular lorry parcel service along with other commodities and the possible health hazards which may lead to the spread of viruses since such Lorries are generally not sanitized as per Covid Protocol.

Under the above circumstances in the interest of public safety we request you to issue an ADVISORY to Pharma manufacturers operating in the state to effect their supplies either on their own vehicle, SPV or through courier services during Covid period".

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IPC constitutes an Expert Group on Neutraceuticals - reg.

INDIAN PHARMACOPOEIA COMMISSION
(Ministry of Health & Family Welfare, Government of India)
Sector 23, Raj Nagar, Ghaziabad 201 002

F. No. T.13011/01/2017-AR&D **Date:** 16th October, 2020

To,
All Members of 'Expert Working Group-Nutraceuticals'

OFFICE ORDER

Subject: Constitution of 'Expert Working Group-Nutraceuticals'-reg.

Reference to the subject mentioned, I am directed to convey that the competent authority has approved for the constitution of 'Expert Working Group-Nutraceuticals' as under:

S. No.	Name of Member	Organization	Contact Details
1	Sh. Sanjeev Kumar	Central Drugs Standards Control Organization, New Delhi	sanjeevkumar15@cdsco.nic.in Ph. 9868440470
2	Dr. B. Dinesh Kumar	National Institute of Nutrition, Hyderabad	nindineshpct@gmail.com Ph. 9849082088
3	Dr. Parvinder Pal Singh	Indian Institute of Integrative Medicine, Jammu	ppsingh@iiim.res.in Ph. 9419157270
4	Sh. Sunil Bakshi	Food Safety and Standards Authority of India, New Delhi	sbakshi.fssai@gmail.com Ph. 9099146815
5	Sh. Gaurang Oza	Vaibhav Analytical Lab, Ahmedabad	vaibhavlab@hotmail.com Ph. 9824034869
6	Sh. Rajasekhar Akkaraju	M/s Abbott, Mumbai	rajasekhar.akkaraju@abbott.com Ph. 8433992309
7	Sh. Sudam Prasad	M/s Akums, Haridwar	sudama.qcp1@akums.in Ph. 8859004189
8	Sh. Girish Juneja	M/s Mankind, Gurugram	girish.juneja@mankindpharma.com Ph. 9560370076
9	Sh. Deepak Arora	M/s Sun Pharma, Gurugram	deepak.arora@sunpharma.com Ph. 9810210617
10	Sh. Hemal Patel	M/s Torrent Pharma, Ahmedabad	hemalpatel@torrentpharma.com Ph. 9825336469

3. Terms of reference of 'Expert Working Group-Nutraceuticals':

(i) To take decisions on the matters of standards for Nutraceutical drugs for inclusion of their monographs in the Indian Pharmacopoeia.

(ii) If required, Expert Working Group may also consult any other relevant expert(s).

(iii) All members need to sign a duly filled in 'Disclosure Statement' for records of the IPC.

(iv) IPC would provide necessary secretarial assistance for convening the meetings of the Group.

(v) TA/DA will be admissible as per the Govt. rules.

(Manish Jain)
Administrative Officer (I/c)

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Companies (Prospectus and Allotment of Securities) Rules, 2014 amended (1st Amendment of 2020) - reg.

Corporate Affairs Notification No.G.S.R.642(E) dated 16th October 2020

In exercise of the powers conferred by section 26, sub-section (1) of section 27, section 28, section 29, sub-section (2) of section 31, sub-sections (3) and (4) of section 39, sub-section (6) of section 40 and section 42 read with section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Prospectus and Allotment of Securities) Rules, 2014, namely:-

1. Short title and commencement:

(1) These rules may be called the **Companies (Prospectus and Allotment of Securities) Amendment Rules, 2020.**

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

2. In the Companies (Prospectus and Allotment of Securities) Rules, 2014, in rule 14, in sub-rule (1), after third proviso, the following proviso shall be inserted, namely:-

"Provided also that in case of offer or invitation of any securities to qualified institutional buyers, it shall be sufficient if the company passes a previous special resolution only once in a year for all the allotments to such buyers during the year.".

F.No.1/21/2013-CL-V-Part

K V R Murty, Jonit Secretary, Ministry of Corporate Affairs, New Delhi.

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification number G.S.R.251(E), dated the 31st March, 2014 and were subsequently amended:-*

(1) Vide Notification Number G.S.R.424(E), dated the 30th June, 2014;

(2) Vide Notification Number G.S.R.430(E), dated the 7th May, 2018;

(3) Vide Notification Number G.S.R.752(E), dated the 7th August, 2018;

(4) Vide Notification Number G.S.R.853(E), dated the 10th September, 2018;

(5) Vide Notification Number G.S.R.43(E), dated the 22nd January, 2019;

(6) Vide Notification Number G.S.R.130(E), dated the 19th February, 2019; and

(7) Vide Notification Number G.S.R.376(E), dated the 22nd May, 2019.

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CBIC notifies New Exchange Rates w.e.f. 2nd October 2020 - reg.

Notification No.95/2020-Customs (N.T.), dated 1st October, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.88/2020-Customs(N.T.), dated 17th September, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 2nd October, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	54.10	51.75
2.	Bahraini Dinar	201.60	189.25
3.	Canadian Dollar	56.40	54.45
4.	Chinese Yuan	11.00	10.70
5.	Danish Kroner	11.85	11.40
6.	EURO	88.05	84.90
7.	Hong Kong Dollar	9.70	9.35
8.	Kuwaiti Dinar	248.25	233.00
9.	New Zealand Dollar	50.15	47.85
10.	Norwegian Kroner	8.05	7.75
11.	Pound Sterling	96.95	93.60
12.	Qatari Riyal	20.90	19.60
13.	Saudi Arabian Riyal	20.25	19.05
14.	Singapore Dollar	54.95	53.10
15.	South African Rand	4.55	4.25
16.	Swedish Kroner	8.40	8.10
17.	Swiss Franc	81.70	78.55
18.	Turkish Lira	9.85	9.25
19.	UAE Dirham	20.70	19.45
20.	US Dollar	74.50	72.80

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	71.15	68.55
2.	Korean Won	6.55	6.15

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

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

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Atma Nirbhar Bharat Abhiyan

Lok Sabha Unstarred Question No.81

Shri Shrirang Appa Barne:

Shri Bidyut Baran Mahato:

Shri Sudheer Gupta:

Shri Sanjay Sadashivrao Mandlik:

Q. Will the Minister of **FINANCE** be pleased to state;

(a): whether the Government has recently launched *"Atma Nirbhar Bharat Abhiyan"*;

(b): if so, the details thereof along with its aims and objectives;

(c): the details of the initiatives taken by the Government under *Atma Nirbhar Bharat Abhiyan* so far;

(d): the details of various constraints being faced by the Government in this regard; and

(e): the steps being taken by the Government to address these constraints?

Answered on 14th September 2020

A. (a), (b) & (c): Yes, Sir. The Government announced *Atmanirbhar Bharat Abhiyan* - a special economic package of Rs.20 lakh crore on 12.05.2020 with the aim of making the country self-reliant and to focus on local manufacturing, local market and local supply chains. It focuses on preparing the country for tough competition in global supply chains, enhance the ease of doing business, empower MSMEs, attract investments including FDI and strengthen the policies for Make in India. It also aims at supporting agriculture and fisheries reforms and enhancing agriculture and animal husbandry infrastructure. It also contains measures to boost liquidity support for MSMEs, DISCOMS, NBFCs and other businesses. In furtherance of the objective of the above announcement, Ministry of Finance announced various measures/policies/schemes from 13th to 17th May, 2020. The Cabinet Secretariat has also issued Guidelines directing all Ministries/ Departments to indicate in proposals submitted for the consideration of the Cabinet/Cabinet Committees as to how these proposals will help in realizing the goal on *Atmanirbhar Bharat* by encouraging domestic manufacturing, reducing import dependence, increasing exports etc. A Statement indicating the announcements made under *Atmanirbhar Bharat Abhiyan* is at ***Annexure-I.***

(d) & (e): The *Aatma Nirbhar* Package is being implemented by various Ministries/Department. The initiatives and reforms announced are aimed towards addressing various constraints faced in these sectors.

Minister of State (Finance)
(Shri Anurag Singh Thakur)

Annexure-I

Statement referred to in reply to parts (a), (b) & (c) of LSUSQ No.81:

A. Announcements made on 13.05.2020:

1. Rs.3 lakh crore Emergency Working Capital Facility for Businesses, including MSMEs.
2. Rs.20,000 crore Subordinate Debt for Stressed MSMEs.
3. Rs.50,000 crore equity infusion through MSME Fund.
4. New Definition of MSME and other Measures for MSME.
5. No Global tenders for Government tenders of upto Rs.200 crore.
6. Extending the Employees Provident Fund Support for business and organised workers for another 3 months salary for June, July and August 2020.
7. EPF Contribution to be reduced for Employers and Employees for 3 months to 10% from 12% for all establishments covered by EPFO for next 3 months.

8. Rs.30,000 crore Special Liquidity Scheme for NBFC/ HFC/MFIs.
9. Rs.45,000 crore Partial credit guarantee Scheme. 2.0 for Liabilities of NBFCs/MFIs.
10. Rs.90,000 crore Liquidity Injection for DISCOMs.
11. Relief to Contractors given by extension of up to six months for completion of contractual obligations, including in respect of EPC and concession agreements.
12. Relief to Real Estate Projects the registration and completion date for all registered projects will be extended up to six months.
13. Tax relief to business as pending income tax refunds to charitable trusts and non-corporate businesses and professions to be issued immediately.
14. Reduction in Rates of 'Tax Deduction at Source' and 'Tax Collected at Source" by 25% for the remaining period of FY 20-21.
15. Due Dates for various tax related compliances extended.

B. Announcements made on 14.05.2020:

16. Free food grains supply to Migrants for 2 months.
17. Technology system to be used enabling Migrants to access PDS (Ration) from any Fair Price Shops in India by March, 2021-One Nation one Ration Card.
18. Scheme for Affordable Rental Housing Complexes for Migrant Workers and Urban Poor to be launched.
19. 2% Interest Subvention for 12 months for Shishu MUDRA loanees-Relief of Rs. 1500 crore.
20. Rs.5000 crore Credit facility for Street Vendors.
21. Rs.70,000 crore boost to housing sector and middle income group through extension of Credit Linked Subsidy Scheme for MIG under PMAY (Urban).
22. Rs.6,000 crore for Creating employment using CAMPA funds.
23. Rs.30,000 crore Additional Emergency Working Capital for farmers through NABARD.
24. Rs.2 lakh crore concessional credit boost to 2.5 crore farmers under Kisan Credit Card Scheme.

C. Announcements made on 15.05.2020

25. Rs.1 lakh crore Agri Infrastructure Fund for farm-gate infrastructure for farmers.
26. Rs.10,000 crore scheme for formalisation of Micro Food Enterprises (MFE).
27. Rs.20,000 crore for Fishermen through *Pradhan Mantri Matsya Sampada Yojana (PMMSY)*.
28. National Animal Disease Control Programme.
29. Setting up of Animal Husbandry Infrastructure Development Fund - Rs. 15,000 crore.
30. Promotion of Herbal Cultivation: outlay of Rs 4,000 crore.
31. Beekeeping initiatives – Rs.500 crore.
32. From 'TOP' to TOTAL – Rs.500 crore.
33. Measures for Governance and Administrative Reforms for Agriculture Sector:
    i. Amendments to Essential Commodities Act to enable better price realisation for farmers;
    ii. Agriculture Marketing Reforms to provide marketing choices to farmers;
    iii. Agriculture Produce Price and Quality Assurance.

D. Announcements made on 16.05.2020:

34. Commercial Mining introduced in Coal Sector.
35. Diversified Opportunities in Coal Sector.
36. Liberalised Regime in Coal Sector.
37. Enhancing Private Investments and Policy Reforms in Mineral Sector.
38. Enhancing Self Reliance in Defence Production.
39. Policy Reforms in Defence Production.
40. Efficient Airspace Management for Civil Aviation.
41. More World-Class Airports through PPP.
42. India to become a global hub for Aircraft Maintenance, Repair and Overhaul (MRO).
43. Tariff Policy Reform in Power Sector; Privatization of Distribution in UTs.
44. Boosting private sector investment through revamped Viability Gap Funding Scheme in Social Sector.
45. Boosting private participation in space activities.
46. Reforms in Atomic Energy Sector.

E. Announcements made on 17.05.2020:

47. Rs.40,000 crore increase in allocation for MGNREGS to provide employment boost.

48. Increased investments in Public Health and other health reforms to prepare India for future pandemics.

49. Technology Driven Education with Equity post-COVID.

50. Further enhancement of Ease of Doing Business through IBC related measures.

51. Decriminalisation of Companies Act defaults.

52. Ease of Doing Business for Corporates.

53. Public Sector Enterprise Policy for a New, Self-reliant India.

54. Increase borrowing limits of States from 3% to 5% for 2020-21 only & promoting State level reforms.

Impact of Covid-19 on Trade

Lok Sabha Unstarred Question No.105

Shri Manoj Kotak:

Q.Will the Minister of **FINANCE** be pleased to state;

(a): whether the global COVID 19 has become a serious threat to the economy of India;

(b): if so, the details thereof;

(c): whether imports and exports have been badly affected due to COVID-19 and global lockdown;

(d) if so, the details thereof; and

(e): the detail of various measures announced by the Government to tackle the situation and its impact in country?

Answered on 14th September 2020

A. (a) & (b): India, like other nations in the world, imposed a strict lockdown from 25th March, 2020 to combat the spread of COVID-19 and strengthen the country's health infrastructure. From May onwards, the country has been unlocking itself and its positive impact on the economy is seen in high frequency indicators of July and August, 2020.

(c) & (d): In July 2020, merchandise exports of India were estimated at USD 23.6 billion, as against USD 26.3 billion in July 2019, while the merchandise imports were at USD 28.5 billion in July 2020, compared to USD 39.8 billion a year ago. This is in line with the contraction witnessed in world trade in the first four months of 2020-21, due to which exports contracted by (-)30.2% and imports by (-) 46.7%, over the corresponding period of the previous year.

(e): Along with imposition of strict lockdown to contain the spread of COVID-19, Government of India implemented several measures to mitigate the impact of COVID-19 on the economy which, inter-alia, include:

- Relief measures for households such as in-kind (food; cooking gas) and cash transfers to senior citizens, widows, disabled, women Jan Dhan Account holders, farmers; insurance coverage for workers in the healthcare sector; wage increase for MGNREGA workers and support for building and construction workers; collateral free loans to self-help groups and reduction in EPF contributions under *Pradhan Mantri Garib Kalyan Yojana* and employment provision for migrant workers under *Pradhan Mantri Garib Kalyan Rojgar Abhiyaan*, amongst others.
- Relief measures for MSMEs such as collateral-free lending program with 100 percent credit guarantee, subordinate debt for stressed MSMEs with partial guarantee, partial credit guarantee scheme for public sector banks on borrowings of non-bank financial companies, housing finance companies (HFCs), and micro finance institutions, Fund of Funds for equity infusion in MSMEs, additional support to farmers via concessional credit, as well as a credit facility for street vendors (PM SVANidhi), amongst others.
- Regulatory and compliance measures such as postponing tax-filing and other compliance deadlines, reduction in penalty interest rate for overdue GST filings, change in government procurement rules, faster clearing of MSME dues, IBC related relaxations for MSMEs, amongst others.
- Structural reforms announced as part of the *Atmanirbhar* Package which, inter alia, include deregulation of agricultural sector, change in definition of MSMEs, new PSU policy, commercialization of coal mining, higher FDI limits in defence and space sector, development

of Industrial Land/Land Bank and Industrial Information System, revamp of Viability Gap Funding scheme for social infrastructure, new power tariff policy and incentivizing States to undertake sector reforms.

Minister of State in The Ministry of Finance
(Shri Anurag Singh Thakur)

Financial Assistance to States

Lok Sabha Unstarred Question No.186

Shri Krupal Balaji Tumane:

Shri Omprakash Bhupalsinh Alias Pawan Rajenimbalkar:

Q. Will the Minister of **FINANCE** be pleased to state;

(a): the financial assistance provided by the Government to the States particularly Maharashtra to safeguard themselves against covid-19;

(b): whether the Government proposes to provide more central financial assistance to the States in view of the increasing cases of Covid-19 in the country and if so, the details thereof;

(c): whether the State Governments have requested for more financial assistance;

(d): if so, the action taken by the Government in this regard; and

(e): the details of the financial assistance provided by the Union Government for safeguarding against Covid-19; State and amount-wise?

Answered on 14th September 2020

A. (a) to (e): In the view of unprecedented COVID-19 pandemic, the Department of Expenditure has released the central share of State Disaster Response Fund (SDRF) to the States including Maharashtra in the first week of April 2020. A total amount of Rs.11,565.93 crore was released to the States including Rs.1611 cores to the State of Maharashtra. State wise SDRF funds released for the year 2020-21 (upto 31.08.2020) is at ***Annexure-I*** *(not reproduced here).*

Further, to provide additional resources to States to fight against COVID-19 pandemic and considering the request of the States for relaxation of the existing Fiscal Responsibility and Budget Management Act (FRBM) limit of 3 percent of Gross State Domestic Product (GSDP), additional borrowing limit of up to 2 percent of GSDP has been allowed to States for the year 2020-21. Out of the additional borrowing limit of 2 percent of GSDP allowed to States, consent of 0.50 percent of GSDP amounting to Rs. 1,06,830 crore has already been issued to the States including the consent of Rs.15,394 crores to the State of Maharashtra to raise Open Market Borrowing (OMB) during the year 2020-21. State-wise and amount-wise details of additional borrowing consent of 0.50 percent of GSDP issued to the States for the year 2020-21 (upto 31.08.2020) are at ***Annexure-II***. *(not reproduced here)*

Minister of State in the Ministry of Finance
(Shri Anurag Singh Thakur)

Investment by Chinese Companies

Lok Sabha Unstarred Question No.207

Shri S Jagathrakshakan:

Shri A K P Chinraj:

Q. Will the Minister of **FINANCE** be pleased to State:

(a): The total number of Chinese firms/companies which invested in various sectors of India for the last three years;

(b): The total number of Indian firms/companies which invested or are indulged in various business activities/ sectors of China during the said period;

(c): Whether the Government has any proposal to not accord any permission to any Chinese firms to invest in India; and

d): If so, the details thereof?

Answered on 14th September 2020-09-21

A. (a) & (b): **The total FDI inflow from Chinese companies in India during the last three years are as under:**

(Amount in USD Million)

Year	2017-18	2018-19	2019-20
FDI Inflow	350.22	229.00	163.77

(a):: **The details of total Outflow to China are as below:-**

(Amount in USD Million)

Year	2017	2018	2019	2020
Actual Outflow	49.19	12.61	27.57	20.63

A Statement indicating FDI Equity inflow sector wise from China during the last 5 years is at ***Annexure-I*** *(not reproduced here).*

(c) & d):: No. To curb opportunistic takeovers/ acquisitions of Indian Companies due to the current Covid-19 pandemic, Government issued a Press Note 3, 2020 relevant portion of which reads as follows:

"Para 3.1.1: 3.1.1(a): A non-resident entity can invest in India, subject to the FDI Policy except in those sectors/activities which are prohibited. However, an entity of a country, which shares land border with India or where the beneficial owner of an investment into India is situated in or is a citizen of any such country, can invest only under the Government route. Further, a citizen of Pakistan or an entity incorporated in Pakistan can invest, only under the Government route, in sectors/activities other than defence, space, atomic energy and sectors/activities prohibited for foreign investment".

"3.1.1(b): In the event of the transfer of ownership of any existing or future FDI in an entity in India, directly or indirectly, resulting in the beneficial ownership falling within the restriction/purview of the para 3.1.1(a), such subsequent change in beneficial ownership will also require Government approval".

Minister of State (Finance)
(Shri Anurag Singh Thakur)

In Rajya Sabha

Usage of HCQ for the Treatment of Covid-19.

Rajya Sabha Unstarred Question No. 263

Shri Manas Ranjan Bhunia:

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

(a): whether Government had allowed Hydroxychloroquine (HCQ) to be used in treatment of Covid-19 virus; if so, details of using pattern of HCQ among Doctors, Nurses, health workers, and other frontline Corona warriors during the pandemic;

(b): the details of HCQ produced, exported, supplied to States/ UTs and used by them till date;

(c): whether Government did not have any accurate data regarding efficacy of HCQ in treating Covid-19 and despite it permitted use of HCQ in treatment process; and

(d): whether any HCQ study showed increased mortality in COVID-19 patients but the ICMR widened its use in India; if so, details thereof?

Answered on 15th September 2020

A. (a):: Yes, Government has re-purposed the drug Hydroxychloroquine for treatment of mild (but high-risk cases) and for moderate cases. However, the drug is not recommended for severe cases and those with pre-existing cardiac disease. Ministry of Health & Family Welfare does not maintain data on using patterns of Hydroxychloroquine by Doctors, Nurses, health workers, and other frontline corona warriors.

(b):: The details of Hydroxychloroquine supplied by Government of India, procured by the States, actual consumption, available balance is at Annexure. India has exported the drug hydroxychloroquine to more than 140 countries. *(**Annexure** not reproduced here).*

(c) and (d):: Hydroxychloroquine --has demonstrated *in vitro* activity against SARS-CoV2 and was shown to be clinically beneficial in several small single center studies though with significant limitations. Nonetheless, other observational studies with severe methodologic limitations have shown no effect on mortality or other clinically meaningful outcomes. This drug has been used widely in India for other ailments where it is used for prolonged periods of time, with good safety profile.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

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14th Regional Workshop on *"Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries – A Way Forward"* *via* Webinar on October 09, 2020

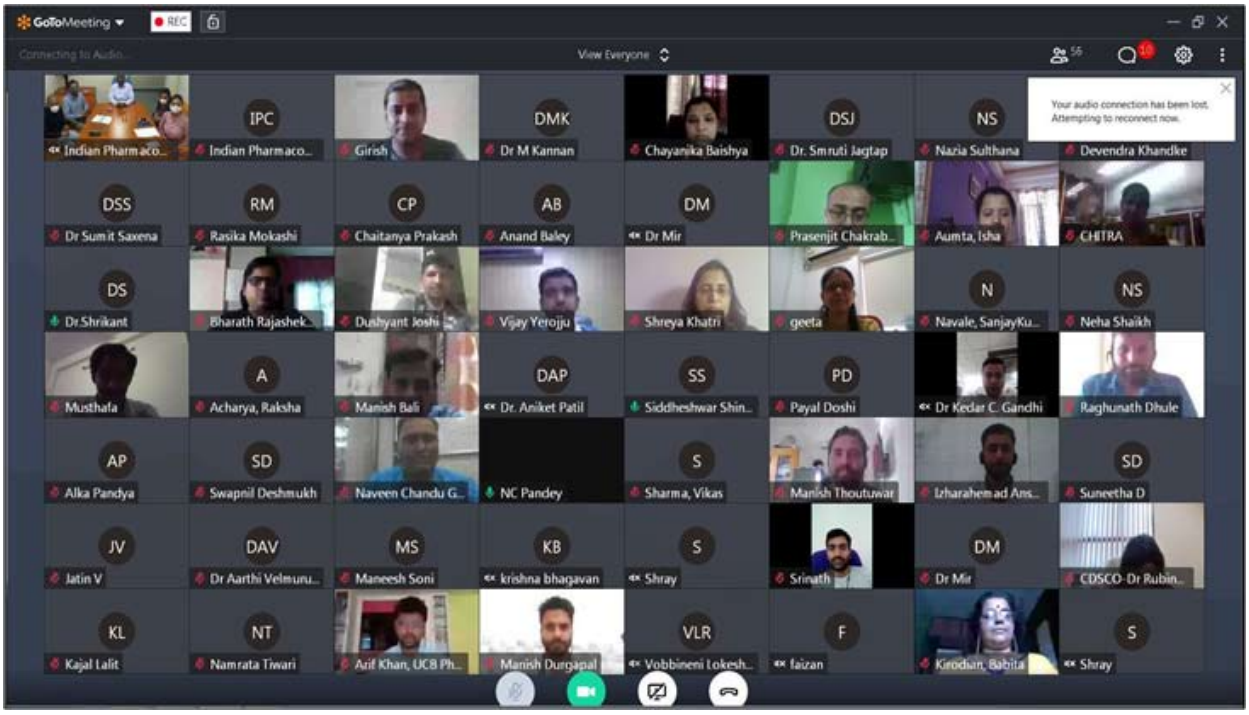

Fig: *Participants from 14th Regional Workshop on "Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries – A Way Forward"*

The Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India has organized **14th Regional Workshop on *"Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries– A Way Forward"*** via webinar on 9th October 2020. The workshop was tailored to regional needs and addressed challenges unique to Pharmacovigilance (PV) and its set up in Pharmaceutical industries. The workshop also addressed the basic concepts of PV & how the PV system can be effectively implemented by the MAHs in Pharmaceutical Industries and also to make them aware about the PV Guidance Document with the major focus on submission of E2B XML ADR related files to PvPI. The workshop was inaugurated by **Dr Jai Prakash**, Secretary-cum-Scientific Director (I/c), IPC & Officer In-charge, PvPI. On behalf of National Coordination Centre for Pharmacovigilance Programme of India, **Dr Shashi Bhushan**, **Mr Rishi Kumar**, **Ms Swati Thapliyal** & **Ms Bhanu Priya** were present in the workshop. More than 48 participants from different pharmaceutical industries and research institute participated in this workshop. **Dr Jai Prakash**; **Dr Rubina Bose**, Deputy Drugs Controller (I), CDSCO, WZ & **Dr Aniket Patil**, Country Safety Lead, Drug Safety Unit-Pfizer India deliberated on topics related to PV. The MAHs assured that they would effectively implement the PV system and train their colleagues in their organization.

Note: Please visit our website **(www.ipc.gov.in)** for regular updates.

Source/Courtesy: Email from NCC.PvPI pvpi.ipc@gov.in*, 12.10.2020*

Protective antibodies persist for months in survivors of serious COVID-19 infections

People who survive serious COVID-19 infections have long-lasting immune responses against the virus, according to a new study led by researchers at Massachusetts General Hospital (MGH). The study, published in Science Immunology, offers hope that people infected with the virus will develop lasting protection against reinfection. The study also demonstrates that measuring antibodies can be an accurate tool for tracking the spread of the virus in the community.

The immune system produces proteins called antibodies in response to SARS-CoV-2, the virus that causes COVID-19. "But there is a big knowledge gap in terms of how long these antibody responses last," says Richelle Charles, MD, an investigator in the Division of Infectious Diseases at MGH and a senior author of the paper. To find out, she and her colleagues obtained blood samples from 343 patients with COVID-19, most of whom had severe cases. The blood samples were taken up to four months after a patient's symptoms emerged. The blood's plasma was isolated and applied to laboratory plates coated with the receptor-binding domain (RBD) of the virus's "spike" protein, which attaches to cells, leading to infection. The team studied how different types of antibodies in the plasma bound to RBD. The results were compared to blood samples obtained from more than 1,500 individuals prior to the pandemic.

The researchers found that measuring an antibody called immunoglobulin G (IgG) was highly accurate in identifying infected patients who had symptoms for at least 14 days. Since the standard PCR (nasal swab) test for SARS-CoV-2 loses sensitivity over time, augmenting it with a test for antibodies in patients who have had symptoms for at least eight days (at which time 50 percent are producing antibodies) will help identify some positive cases that might otherwise be missed, says Charles. The researchers found that IgG levels remained elevated in these patients for four months, and were associated with the presence of protective neutralizing antibodies, which also demonstrated little decrease in activity over time. "That means that people are very likely protected for that period of time," says Charles. "We showed that key antibody responses to COVID-19 do persist." In another finding, Charles and her colleagues showed that people infected with SARS-CoV-2 had immunoglobulin A (IgA) and immunoglobulin M (IgM) responses that were relatively short-lived, declining to low levels within about two and a half months or less, on average. "We can say now that if a patient has IgA and IgM responses, they were likely infected with the virus within the last two months," says Charles. Knowing the duration of the immune response by IgA and IgM will help scientists obtain more accurate data about the spread of SARS-CoV-2, explains Jason Harris, MD, a pediatric infectious disease specialist at MGH and co-senior author of the study. "There are a lot of infections in the community that we do not pick up through PCR testing during acute infection, and this is especially true in areas where access to testing is limited," he says. "Knowing how long antibody responses last is essential before we can use antibody testing to track the spread of COVID-19 and identify 'hot spots' of the disease."

Source: World Pharma News, 08.10.2020 (Excerpts)

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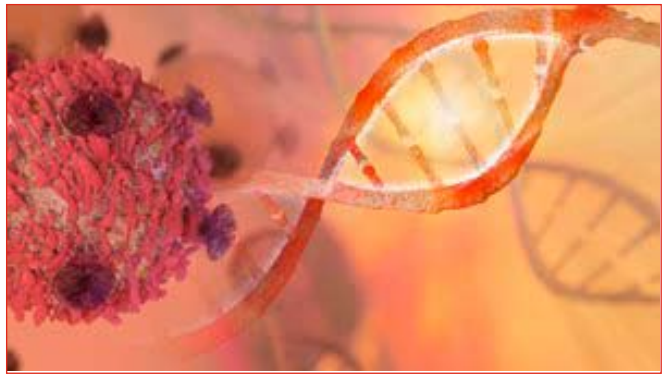
Drug mutagenicity, proarrhythmic potential addressed in pair of FDA Guidances



The US Food and Drug Administration (FDA) has issued two new draft International Council on Harmonisation (ICH) Guidelines for Public Consultation. A question-and-answer (Q&A) guidance on clinical and nonclinical evaluation of QT/QTc interval prolongation and proarrhythmic potential of medicines was published in draft form by FDA on 29 September; the Guidance is currently in ICH Step 2b, awaiting consultation from the Council's participating countries.

The draft Guidelines contain Q&As addressing the ICHE14 Guidance on clinical evaluation of delayed ventricular repolarization and proarrhythmic potential of non-antiarrhythmic drugs; it also includes answers to new

questions regarding the ICH S7B Guidance addressing nonclinical evaluation of drugs that have the potential to cause delayed ventricular repolarization.

The Q&A Guides members of industry through considerations for conducting an integrated nonclinical-clinical risk assessment, "in particular, at later stages of drug development when clinical data are available," said FDA. The Q&A also addresses such scenarios as assessing proarrhythmic and QT prolongation potential of drugs that cannot be safely administered to healthy individuals at supratherapeutic levels, and what strategies to take when placebo control is not possible.

"The draft Guidance is intended to provide a harmonized approach to integrate nonclinical and clinical information for proarrhythmia risk assessment to streamline drug development and provide clarity on regulatory decision making," said FDA, noting that comment is particularly sought on how to define the lack of clinically relevant QT prolongation in the context of cases where a "conventional thorough QT study" may not be feasible.

A second Step 2b ICH Guidance was made available by FDA for public consultation on 28 September after its June 2020 ICH Assembly endorsement. "The draft Q&A Guidance is intended to clarify, promote the convergence of, and improve the harmonization of the considerations for assessment and control of DNA reactive (mutagenic) impurities and of the information that should be provided when developing drugs, completing marketing authorization applications, and using drug master files," said FDA in its notice of the draft Guidance availability.

The Guidance follows the ICH M7 Guideline on considerations for control of mutagenic impurities; it clarifies expectation for evaluation of mutagenic potential of impurities, situations where more extensive genetic toxicity testing are recommended, and which drug products are included in the scope of ICH M7. The draft Guidance also specifies that carcinogenic but non-mutagenic impurities lie outside the M7 scope.

Various scenarios involving Ames-positive impurities are also addressed by the draft guidance, as is guidance on which control strategies are appropriate under what circumstances. Both draft Guidances are open for public comment in the US for 60 days from the date of publication; ICH will gather consultation results from FDA and other international regulators before finalization and eventual implementation by individual participating countries.

Source: Kari Oakes, raps.org, 29.09.2020 (Excerpts)

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NATIONAL NEWS

For MSMEs to thrive, Quality Council of India must play a key role

As efforts gain pace to revive demand in an economy ravaged by COVID-19, the Quality Council of India (QCI) should step up to the plate to ensure that concerns over the quality of offerings of Micro, Small, and Medium Enterprises (MSMEs) — that together contribute nearly 30 percent to the GDP — do not prove a hurdle in the growth recovery process.

As an organisation with participation from both Government and Industry, and a mission to lead the quality movement in India, the QCI must assist companies in the MSME space get their quality act right, so that these businesses may continue to prosper in the 'new normal' marked by volatility, uncertainty, complexity, and ambiguity.

Especially in the light of the desire expressed last month by the Union Minister for Micro, Small and Medium Enterprises Nitin Gadkari about raising the MSME segment's contribution to India's GDP to 50 percent, and create an additional 50 million new jobs in this arena. Gadkari was speaking at the launch of the *Aatmanirbhar Bharat ARISE-Atal* New India Challenge. Besides this, historically, most of the 3 million-plus MSMEs in India, which together employ about 110 million people, have often found the going tough in adopting best practises and international quality standards.

The QCI's intervention could go a long way in enabling countless home-grown MSMEs start living and breathing quality, become more competitive on a global scale, attain a position where they can attract a larger number of better-paying customers from within India and overseas, and, also, significantly gain the muscle to create more well-paying jobs.

Concentrating its focus chiefly on the big boys of Indian industry — of whom most would already be quality-conscious and, have the resources to deploy on improving existing quality systems — can never match the sort of positive transformational impact that QCI can have on the

operations of MSMEs. Gadkari also recently expressed intent of raising the MSME contribution from 49 percent to 60 percent of overall exports. This in itself should be a powerful motivator for the QCI to get more involved with this arena.

That is not all. Prior to the pandemic, many Indian businesses could often bank on the country's large size and population, and low customer awareness levels to get away with products and/or services whose quality often did not merit the prices being charged for the offerings. Now, when customer spend has decreased, companies can no longer get away with the earlier slackness. In such a setting, the QCI, in addition to driving home the quality message, can help the MSMEs realise that several Indian customers — despite their public posturing about being vocal for local — may not necessarily end up buying or paying a premium for a product whose sole USP is its 'desi' tag.

The QCI could make the MSMEs aware that prospective buyers may not always reject a product because the company behind it is foreign and/or may have manufactured the item outside India. In addition to this, the MSMEs must be sensitised to the fact that customers are more likely to choose products that offer a better value proposition. For any organisation, rarely does an opportunity come around to leave a lasting mark on a key segment of the economy on whose progress depends the realisation of self-reliance *(Aatmanirbhar Bharat).*

This will also help India achieve its long-cherished ambition of being recognised as a developed country. For the Quality Council of India, a COVID-19-hit MSME arena presently provides that prospect, and one can only hope that it laps up this chance to become a catalyst for change in the best interests of 1.3 billion Indians.

Source: Sumali Moitra, Moneycontrol.com, 14.10.2020

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Faceless assessment causes delay in Customs Clearance

Industry urges Government to waive off demurrage charges

The Central Board of Indirect Taxes and Customs (CBIC)'s promotion of 'Faceless, Contactless, Paperless Customs' is resulting in delays of import-export shipment clearances. It is envisioned as an initiative to promote ease of doing business with the secure electronic communication of the final Let Export Order (LEO) copy of the Shipping Bill and the Gate pass copy of Shipping Bill, which will help exporters to get the documents updated immediately.

It is being rolled out in a phased manner, and the first phase of it has begun in Chennai and Bengaluru ports, now followed by other ports in the country as well. However, the implementation of faceless assessment is resulting in delays of consignments leading to heavy demurrage charges on companies. Hence, the Pharma industry is requesting the Government authorities to waive off the demurrage charges, until it completely implemented in all the ports. Reportedly, it is taking 15-20 days for a single consignment to clear from the customs against two to three days before the implementation process of faceless assessment.

According to a source from the Mumbai port, though the exact number of tons of cargo pending for want of faceless assessment cannot be ascertained immediately, nearly thousands of tons of cargoes are awaiting assessment. The source informed that the officers are not familiar with the new arrangement and are not keen on assessing the shipment and insisting on submission of more documents. This is delaying the clearance besides compelling the trade to pay heavy demurrage and container detention charges for no fault of theirs.

Therefore, this time the Government must look into this immediately and also address the issue on a war footing, said the source. Dr Dinesh Dua, Chairman, Pharmexcil informed that they have already taken up the issue with the concerned authority at the customs. He cited an incident and said, "In our letter to them, we have communicated that one of our member companies have imported Pulse Oximeter Consignment at Delhi Airport as our regular product to measure check the oxygen level of any COVID-19 infected person.

However, the officer raised several queries and we answered all of their queries, but again and again, they are raising different queries and in spite of answering their queries. Then, the concerned officer of the member company went to meet the officer to address their unit price related queries personally and the officer asked him to arrange the answer of the query, only then will he assess the document.

The company had three documents pending with the officer, one document they have cleared with a hundred percent check, the rest of them is awaiting clearance. He continued," The Pharma industry, which has performed exceedingly well, both in generics and medical devices, in

terms of import and export is faced with a huge dilemma and losses on account of issues faced due to delays caused by customs officials after the partial rollout of faceless assessment effective from October 2020.

During the pre-October period of the consignments, consignments were cleared generally in two to three days' time, but after the introduction of faceless assessment, the delay has gone up to 15-20 days leading to shortages, particularly for COVID–19 related medical equipment and also exports of Pharma to 206 countries in the world. "This is leading to not only losses to Pharma and Medical Devices industry, but it is also creating acute shortages during these challenging times, both in India and overseas.

The Prime Minister, Narendra Modi along with FM and MoS, Finance are trying their best to ensure ease of doing business, but the ground reality is absolutely contrary, particularly in the Customs. The basic essence of digitalisation leading to faceless assessment seems to have been completely neutralised at least for the time being. Therefore, the industry firmly appeals to the Government to waive off the demurrage charges since the industry is not at all responsible for the delay," expressed Dua. Recently, the CBIC has issued a Notification on October 12, communicating that the authority has decided to make all Saturdays (except second Saturday) as working days for all the faceless assessment groups across the country.

Source: Usha Sharma, Express Pharma, 15.10.2020

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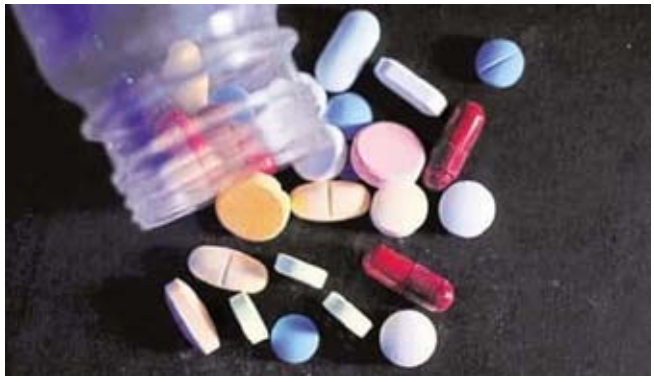
Indian Pharma sector can grow to $ 65 billion industry by 2024: Sadananda Gowda



Glenmark Pharma's current portfolio consists of 135 products authorised for distribution in the US market and 62 Abbreviated New Drug Applications (ANDAs) pending approval with the USFDA. Photo: Pradeep Gaur/Mint

Chemicals and Fertilisers Minister D V Sadananda Gowda has said India is one of the largest manufacturers and exporters of generic medicines across the world. During initial phase, he said, HCQ and Azithromycin was identified as one of medicines under treatment protocol for Covid-19 in emergency cases. Referring to India supplying these medicines to more than 120 countries across the world; he underlined that India thereby earned the reputation of reliable supplier of medicines.

Addressing a video conference 'FICCI LEADS 2020', the Minister highlighted that India is one of the largest manufacturers and exporter of generic medicines across the world. India is the only country with the largest number of US Food and Drug Administration (US FDA) compliant Pharma plants (more than 262 including APIs) outside of USA and exports USD 20 billion worth of Pharma products to various countries, including high standards complying countries like the US and Europe, he added. "We are confident that the Indian Pharma sector can grow to USD 65 billion industry by 2024," Gowda said.

"This is a very very good time to invest and set up manufacturing base in India in Pharma sector. One can enter India market through joint ventures also. The advantage is that you can get access to big markets like domestic Indian market, US, Japan, EU and South East Asia through India as far as Pharma sector is concerned," he said.

Source: Live Mint, 15.10.2020

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IPC rolls out suspected ADR reporting form for voluntary reporting of ADRs by healthcare professionals

In order to report Adverse Drug Reactions (ADRs) for drugs used in prophylaxis for treatment of COVID-19, the Indian Pharmacopoeia Commission (IPC) has rolled out a suspected ADR reporting form for voluntary reporting of ADRs by healthcare professionals.

The Ghaziabad-based IPC, which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has also rolled out medicine side effect reporting form to report ADR for consumers and patients. As a part of the roll out, a Toll Free PvPI Helpline-1800-180-3024 has been launched for public from Monday to Friday between 9:00 am to 5:30 pm. Confidentiality is maintained to protect the patient's identity.

Submission of an ADR report does not have any legal implication on the reporter. It has been recommended that all non-serious, known or unknown, frequent or rare ADRs need to be reported. A reaction is serious when the outcome is death, life-threatening, hospitalization (initial or prolonged). All clinicians, dentists, pharmacists and nurses etc can report ADRs. Duly filled in Suspected ADR Reporting Form can be sent to the nearest ADR Monitoring Centre (AMC) or directly to NCC for PvPI through helpline or mailed at **pvpi.ipc@gov.in** or **pvpi.ipcindia@gmail.com**.

The causality assessment is then carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally, the data is analyzed and forwarded to the Global Pharmacovigilance database managed by WHO Uppsala Monitoring Centre (UMC) in Sweden.

The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines. The signal review panel of PvPI reviews the data and suggests any interventions that may be required. Mandatory fields to be filled for ADR Reporting Form includes patient name with initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

NCC-PvPI has also developed an advanced version of the android mobile app which empowers all the Healthcare Professionals and Consumers for ADR reporting. "Through this application, related images of ADR and lab investigation reports can be attached in a user-friendly manner for clinical assessment and signal detection," said an official associated with the development.

The mobile application by the name "ADR PvPI" Android mobile app for ADR reporting has been developed to have administrative control of data with IPC, NCC-PvPI. This will empower all the healthcare professionals and consumers for ADR reporting with features like support source document and image attachment, healthcare professionals as well as consumer reporting, XML generation and auto filling of report details to save time.

The Union Health Ministry has tasked 311 AMCs existing in the country to establish clinical evidence between the drug and the Adverse Drug Reaction through a robust system of causality assessment. Central Drugs Standard Control Organisation (CDSCO) in collaboration with IPC had in the past also started auditing healthcare institutions through assessment on aspects like SOPs and causality assessment in order to review the functioning of AMCs in the country.

CDSCO under the Union Health Ministry had initiated a nation-wide PvPI in July 2010. To strengthen ADR monitoring, IPC had also come out with Guidelines focused on targeted drugs and events as a part of intensive ADR monitoring exercise under PvPI so that action could be taken on specific drugs involving adverse reactions.

The Health Ministry had in the past also mandated competent institutions in the country based on the ADR monitoring protocol for effective implementation of the projects related to Intensive ADR monitoring. Based on the learnings of these projects, the Government will be equipped in taking regulatory decisions in a timely manner. The exercise has been initiated keeping in view the fact that data from spontaneous reporting of ADRs have generally been mis-spelt.

Source: Shardul Nautiyal, Pharmabiz, 16.10.2020

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Pharma industry lauds RBI's decision to discontinue automatic caution listing

The decision to discontinue the automatic caution-listing by the Reserve Bank of India (RBI) has been appreciated by the pharma industry stakeholders

Under the revised procedure, an exporter would be caution-listed by the Reserve Bank based on the recommendations of the Authorised Dealer (AD) bank concerned, depending upon the exporters track record with the AD bank and investigative agencies. The AD bank would make recommendations in this regard to the regional office concerned in the Foreign Exchange Department of the Reserve Bank in case the exporter has come to the adverse notice of the Enforcement Directorate (ED)/Central Bureau of Investigation (CBI)/Directorate of Revenue Intelligence (DRI)/any such other law enforcement agency and/or the exporter is not traceable and/or is not making sincere efforts to realise the export proceeds.

Similarly, the AD bank would also make recommendations to the Regional Office of the Reserve Bank for de-caution-listing an exporter as per the laid down procedures. **Commenting on the RBI Notification, Mr S V Veerramani, Chairman and MD, Fourrts Laboratories, said, "Earlier, Authorised Dealers (AD) have been given the powers to report under the Export Data Processing and Monitoring System**

(EDPMS) for recommending the exporters under caution list if their export bills are not realised beyond two years. But, this is a welcome move by the RBI, as AD is well aware of the customers' export transaction and sincere efforts of which such long-pending realisation proceeds were initiated. It has now become more exporter friendly and the procedure is simplified."

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association (SMPMA) expressed, "We welcome this step initiated by the Central Government body. It was a long overdue demand of the exporters. The automated caution-listing procedures had a significant negative impact on the industry. Its repercussions were largely faced by many MSME companies that were facing the risk of getting in the caution list of RBI, especially in cases of supplying to the Office of Foreign Assets Control (OFAC) countries and third party payment transactions in those countries where Foreign Remittance is very difficult. The industry is going through a difficult phase due to the COVID-19 pandemic crisis, but this move of the RBI will impart relief to the industry."

Anwar Daud, MD, ZIM Laboratories, opined, "The exporters should also get access to the EDPMS database, which is maintained by RBI. Presently, the database access is limited to banker's head office only, not even the branch. Due to this, it delays the entire process, mainly because of its multiple communication levels, e.g., Exporter -> Bank Branch -> Bank HO -> Bank Branch -> Exporter. Otherwise, it is a welcome step." "The Reserve Bank's decision to discontinue system-based automatic caution-listing of exporters is a big relief in the current times of COVID-19 pandemic.

The Export Data Processing and Monitoring System (EDPMS) which was implemented by RBI in 2014 mandated all banks to bring all transactions with the exporters online. In 2016, RBI introduced system-based automatic caution-listing wherein exporters were put on RBI's caution list if any shipping bill remained open for more than two years in EDPMS. Such listing makes it virtually impossible for an exporter to avail credit and also led to delay in bank documents.

This positive decision will provide a big relief to exporters as in many cases the authorised dealer banks could not update their records due to lockdown and related factors of this pandemic, which threatened inclusion in the caution list. Therefore, such measures will further boost the economy as exports have grown by 5.27 percent year-on-year to $ 27.4 billion in September", informed Sahil Munjal, VP, Pharmexcil.

Dr Dinesh Dua, Chairman, Pharmexcil pointed out, "This RBI circular is a step in the right direction provided it's implemented in the right spirit. Unfortunately, most PSBs have a technology deficit at times when the payments made to exporters' A/C take a lot of time to trace. Exporters have to run from pillar to post to reconcile and provide proof to the dealing hand to trace payments. Proper technology and cooperative personnel can go a long way to facilitate this new provision." He added, "A circular from the apex bank can only succeed if exporters' bankers implement the same robustly.'

The background:

In March 2014, the Governing Authority (RBI) decided to integrate the returns related to the handling of shipping bills for caution listed exporters; delayed utilisation of advances received for exports; and exports outstanding with Export Data Processing and Monitoring System (EDPMS). The objective was to enable AD category–I banks to access the updated list of caution-listed exporters through EDPMS on a daily basis. And the list of all caution listed exporters would also be made available to AD category-I banks through their registered e-mail address.

The laid down criteria for cautioning/de-cautioning of exporters in EDPMS, was:

(1): The exporters would be caution listed if any shipping bill against them remains open for more than two years in EDPMS provided no extension is granted by AD Category–I bank/RBI. Date of shipment will be considered for reckoning the realisation period.

(2): Once related bills are realised and closed or extension for realisation is granted, the exporter will automatically be de-caution listed.

(3): The exporters can also be caution listed even before the expiry of two years period based on the recommendation of AD banks. The recommendation may be based on cases where exporter has come to adverse notice of the Enforcement Directorate (ED)/ Central Bureau of Investigation (CBI/Directorate of Revenue Intelligence (DRI)/any such other law enforcement agency or the case where the exporter is not traceable or not making any serious efforts for realisation of export proceeds. In such cases, AD may

forward its findings to the concerned regional office of RBI recommending the inclusion of the name of the exporter in the caution list.

(4): Reserve Bank will caution/de-caution the exporters in such cases based on the recommendation of AD Category–I banks.

As part of the automation of EDPMS, the 'Caution/ De-caution Listing' of exporters was automated in 2016. And accordingly, the exporters were to be caution-listed automatically, if any shipping bill against them remained outstanding for more than two years in EDPMS and no extension was granted for the realisation of export proceeds against the outstanding shipping bill. However, even after revised procedures, the Reserve Bank will be continuing with caution-listing based on case-specific recommendations provided by the AD bank and related instructions in this regard will be issued shortly.

Source: Usha Sharma, Expres Pharma, 13.10.2020

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Curbs on China skew Bulk Drugs Market

The Government's move to reduce India's dependence on China for crucial raw materials used in medicines has led to the creation of local monopolies in a growing number of product categories. This, experts said, may lead to supply constraints and price increases if left unchecked.

While the situation is not alarming yet, it does warrant the need to expand domestic capacities, they added. "You cannot completely cut China out. If you do, these smaller companies may become near-monopolies and charge higher prices. So competition must always be there," said Vishal Manchanda, an analyst with Nirmal Bang Institutional Equities.

For instance, more than half the vitamin C medicines sold in India is currently controlled by Bajaj Healthcare, data from the Directorate General for Trade Remedies showed. Officials of two vitamin C manufacturers, seeking anonymity, said the price of medicine, which is known to boost immunity, saw a sharp spike during Covid.

Bajaj Healthcare Managing Director Anil Jain said the company had briefly raised prices from Rs.450 per kg to Rs.700 per kg in March and April when the Covid crisis in China disrupted supplies, but then it fell to Rs.550 per kg. "The increase in price is due to raw material, transportation and overhead costs," Jain added. The issue of overpricing of vitamin C from the dominant supplier has been such that at least one firm had moved the National Pharmaceutical Pricing Authority seeking help to find an alternative supplier, a person aware of the development said, seeking anonymity. Last month, the Directorate General of Trade Remedies had initiated a fresh anti-dumping probe against imports of vitamin C from China, following a plea by Bajaj Healthcare. Besides vitamin C, production of potassium fluoride, which is used in manufacturing Covid drug Favipiravir is also dominated by a single company—Navin Fluorine International Ltd.

While there are many makers of the compound, industry officials said domestic manufacturers are dependent on Navin Fluorine for supplies due to quality issues with others. Para-aminophenol, another compound for which demand far exceeds local manufacturing capacity, is used to make paracetamol, the commonly used medicine to treat pain and fever. While para-aminophenol is mostly imported from China, Aarti Industries makes it in India, and Vinati Organics is setting up a plant for it, said analysts. However, the capacity is so low that India imports around $100 million worth of paracetamol annually. Pharma firms, in general, are heavily dependent on China for bulk drugs. In FY20, the domestic industry imported 8,247 crore worth of bulk drugs, of which 72% was from China alone.

Some key Pharma intermediates—the raw material for Active Pharmaceutical Ingredients —for which India is heavily dependent on China is cyanoacetic acid, used to make caffeine; dicyandiamide, used to make metformin; and antibiotic penicillin G, according to a report by PricewaterhouseCoopers in April.

Source: Live Mint, 14.10.2020 (Excerpts)

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BDMA welcomes PLI scheme launched by Central Government to promote API industry in India

The Bulk Drugs Manufacturers Association (BDMA) has welcomed the Production Linked Incentive (PLI) scheme launched by the Central Government recently to boost domestic manufacturing of bulk drugs in the country. The Central Government's move is most significant, as it is going to give a big push to the API and bulk drug sector in the country in the coming days, BDMA President V V Krishna Reddy said.

"The PLI scheme rolled out by the Central Government is a big booster for the Pharma industry particularly for the SMSE sector as it is going to promote the domestic manufacturing. As already we have been importing a large portion of APIs, Key Starting Materials (KSMs) and other Drug Intermediates from China. It is high time we reduce our dependence on other countries and promote our own industry, which is very important for us to build a robust platform which would help India to compete with other Global players in the long run," observed the BDMA President.

He appreciated the PLI scheme as a well balanced scheme in which the aspect for the chemical synthesis part is good. However, he expressed his apprehensions towards fermentation part and said that as there are very few companies in the fermentation segment in India, the scheme may not help attract investors in this segment. Further expressing his reservation about the effective implementation of the PLI scheme, the BDMA President said that despite the Government's initiative to promote industry, the Environment Department is exhibiting its low enthusiasm and it may become a big hindrance in the way to the implementation of the scheme aimed at giving a push to the API sector.

"Though launching the booster PLI scheme is a welcome move by the Government, however to ensure its effective implementation there needs to be increased coordination between the Department of Pharmaceuticals and the Ministry of Environment. I suggest there needs to have a couple of meetings between the two departments which would help boost confidence among the investors," opined Krishna Reddy.

While referring to the initiatives like launching of Pharma parks across the country to boost the Pharma bulk drug sector, the BDMA President felt that other than Pharma parks, there are lot of issues that need to be addressed for opening an industry unit. He mentioned that the timeframe to forward the application is 120 days and the Government will take 90 days to give the letter of intent to the companies which have been selected.

The scheme is from 2022 onwards, and the letters of intent shall be given probably in the first quarter of 2021, hence the companies will only be left with 9 months to one year to set up the factory and start producing. Therefore, approximately the first year would lapse for the company to avail the incentive under the PLI scheme. To overcome such problems in the future, he suggested that the time calculation should be done starting from the day the production begins.

Source: A Raju, Pharmabiz, 14.10.2020

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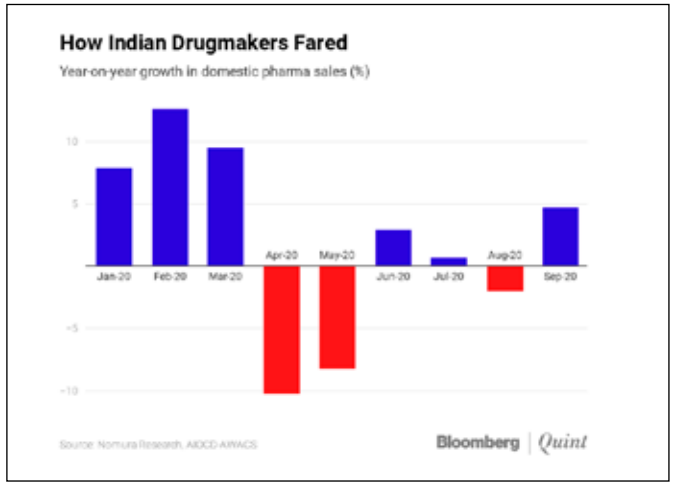
Domestic Pharma Sales Growth jumps to highest in six months



New product growth rose to 3.8% in September, the highest in 36 months. That, according to the brokerage, may be on account of products like Favipiravir and Remdesivir, used for the treatment of Covid-19 that has so far sickened more than 71 lakh Indians and killed over 1.09 lakh. Outperformance of Glenmark Pharmaceuticals Ltd and Cipla Ltd during the month was due to these products, Nomura said.

Glenmark had in June received the Indian drug regulator's approval to manufacture and market a generic of Favipiravir for treating mild to moderate Covid-19. Cipla has received a voluntary non-exclusive licence from Gilead Sciences Inc to manufacture and market the copy-cat version of Remdesivir, used to treat severe symptoms. Nomura also expects Covid-19 drugs to be an important growth driver for Cipla and Glenmark in the quarter ended September.

The brokerage's channel checks of dealers suggest that Remdesivir and Favipiravir are possibly among the top five molecules in India, with monthly sales in excess of Rs.250 crore and Rs.100 crore, respectively. That corroborates with the view of Nirmal Bang Securities. Glenmark and Cipla have outpaced India's Pharma Market Growth, led by their Covid-19 portfolio.

While Cipla is benefiting from Remedesvir and Actemra demand for hospitalised patients, Glenmark dominates the market for Favipiravir. Cipla declined to comment, citing silent period ahead of the earnings announcement. Glenmark is yet to respond to Bloomberg Quint's emailed queries. Volumes, Nomura said, declined 4% year-on-year in September compared with a drop of 9.2% in August, while growth in prices remained in the range of 4-5% for the past six months.

Source: Forum Bhatt, Bloombergquint.com, 14.10.2020 (Excerpts)

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Ayush Ministry clarifies on licensing and approval of various dosage forms of ASU products

The Union Ministry of Ayush has issued a directive to the State Licensing Authorities, clarifying licensing and approval of various dosage forms of ASU formulations and products. Earlier, the Ayush Ministry had received representations from State Licensing Authorities and Ayurveda, Siddha and Unani (ASU) drug manufacturers regarding manufacturing of ASU products in various dosage forms and their licensing or approval under the relevant provisions of Drugs & Cosmetics Rules, 1945.

The issues raised by the stakeholders have been examined in the light of legal definitions of ASU drug/ medicine prescribed in Section 3(a) and (h)i) of the Drugs & Cosmetics Act, 1940 and the Guidelines provided under Rule 158-B of the Drugs & Cosmetics Rules, 1945 for grant of license or approval for manufacturing of various categories and sub-categories of ASU products.

Accordingly, it is observed and hereby clarified that any ASU drug/medicine intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals can be manufactured in any dosage form/drug delivery system except for parenteral route administration, as per the statement issued by the Ministry of Ayush. The State Licensing Authority and the Expert Committee may accordingly examine, process and dispose of the application of the licensed drug manufacturer seeking approval of any ASU formulation/product, it further stated.

Therefore, the standards of the formulation/ingredients are in accordance with the ASU Pharmacopoeias & formularies or in-house standards of the licensed manufacturer and the excipients used in the manufacturing of concerned ASU drug/medicine are in accordance with the Provisions of Rule 169 of Drugs & Cosmetics Rules, 1945 for permitted excipients.

The adequate manufacturing area and infrastructural facilities are available for the manufacturing of applied formulation/product in accordance with Good Manufacturing Practice (GMP) requirements specified in Schedule T under Rule 157 of the Drugs & Cosmetics Rules, 1945.

Source: Neethikrishna, Pharmabiz, 14.10.2020

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Short term PLI scheme to boost domestic mfg of excipients: DoP

We are hopeful of next round of incentivization would be towards excipients

The Department of Pharmaceuticals (DoP) is working on a short term Production Linked Incentive (PLI) scheme to boost domestic manufacturing of excipients. Currently, India imports 95% of its requirements from regulated markets like the US, Europe and China. The DoP has taken initiative to come out with PLI scheme for excipients following an appeal by industry representatives.

The scheme will decrease Indian drug makers' dependency on other countries. Said Dr Dinesh Dua, Chairman, Pharmexcil who is among those who called on DoP seeking extension of PLI scheme to promote domestic manufacturing of excipients, "Introducing PLI scheme to boost domestic manufacturing of APIs is not an end; the scheme needs to be extended to excipient manufacturing as well. India largely imports excipients from regulated markets which is quite expensive.

We should incentivize excipient manufacturing and make sure that this industry comes up concurrently with formulation industry so that right quality excipients would be available at right price in the country." Dr Dua while speaking at a webinar "Pharma Intermediates & APIs: Chemistry of Growth Ingredients" said "We have been assured by the DoP that it would come up with short term PLI scheme to spur domestic manufacturing of excipients."

We are hopeful of next round of incentivization would be towards excipients, he said. Premchand Godha, Chairman and Managing Director of Ipca Laboratories which imports starch from USA, basic material of producing excipients for its formulations marketed there, said "We

lack interest in standardizing manufacturing of excipients at par with regulated markets. Besides incentive scheme, the technology up gradation is required to produce right excipients for the formulations."

Europe and North America account for about 75 percent of the Global excipients market. The excipient manufacturing in India is still at a nascent stage. Some of the leading names in Pharmaceutical excipients in the country are ACG Worldwide, Colorcon, Indchem International, Micro Labs, Dow Chemicals, Lubrizol India, BASF India, SPI Pharma and Merck Groups. A lot of starch based excipients of different commercial grades are produced from starch plants in the country after chemicals or physical processing. Commercial grade microcrystalline cellulose is available from cellulose powder manufacturers, by which chemical and processing are converted to excipients.

However, Indian excipient manufacturers depend on import components. An excipient is a substance formulated alongside the active ingredient of a medication, included for the purpose of long-term stabilization, bulking up solid formulations that contain potent active ingredients (thus often referred to as "bulking agents", "fillers" or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as facilitating drug absorption, reducing viscosity, or enhancing solubility.

Excipients can also be useful in the manufacturing process, to aid in the handling of the active substance concerned such as by facilitating powder flowability or non-stick properties, in addition to aiding *in vitro* stability such as prevention of denaturation or aggregation over the expected shelf life. The selection of appropriate excipients also depends upon the route of administration and the dosage form, as well as the active ingredient and other factors.

Source: The Health Master, 14.10.2020

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Indian Generic Drug Makers to set up Pharmaceutical Cluster in Mexico

Latin America has been an attractive investment area for Indian Pharmaceutical Companies and now six generic drug makers have signed a deal to set up a large pharmaceutical cluster for production and logistics in the Mexican state of Hidalgo. Generic drugs became popular in Latin America only after Indian pharmaceuticals entered the market in the late 1990s.

This put pressure on multinational companies and local Pharma companies to either lower their prices or increase the proportion of generic medicines sold. Medicines, vaccines and other pharmaceutical drugs, have since, become more affordable for Latin America's lower middle class. And this has also helped the Governments in the region to reduce the cost of public healthcare.

During the early days of COVID-19 pandemic, Mexico suffered a shortage of medicines. As such, it identified Indian generic medicines as the best alternative to expensive, branded medicines and raw material that it currently imports from the US and European countries such as Germany, Switzerland, Spain, France, Ireland and Canada.

The Commerce Ministry confirmed that Zydus Cadila, Hetero Drugs, Dr Reddy's Laboratories, Ackerman Pharma, Glenmark Pharmaceuticals and Torrent Pharmaceuticals would be setting up manufacturing facilities in Hidalgo, making Mexico their production and logistics hub. An official said Mexico has stringent regulatory standards, superior to most of its Southern neighbors, and its Pharmaceutical Imports last year stood at $4.3 billion.

In 2019, the Mexican Pharmaceutical Market, which is the second largest in Latin America after Brazil, was worth $10.6 billion. It is the home to about 200 Pharmaceutical Companies, including multinationals. Ravi Ubay Bhaskar, Director General of Pharmaceuticals Export Promotion Council of India (Pharmexcil), revealed that India in the first five months of the ongoing fiscal year till August reported a 67.6 percent growth in drug exports to Mexico.

This was $92 million from about $55 million in the same period last year. Bhaskar said that total exports to Mexico in the previous fiscal year was $160 million. Lakshmi Prasanna, Regulatory Affairs Director at Pharmexcil, pointed out that the Mexican Government has a significant budget for public healthcare and the Government.

Prasanna said the Government procurement of medicines in 2019 was $4.2 billion. Indian Pharma companies are keen on emerging markets for increased growth and business. Pharma exports from India was about $17.27 billion at 2.9 percent growth year-on-year and 3.68 percent CAGR for the period between 2013-14 and 2017-18.

Source: Nandika Chand, mybigplunge.com, 14.10.2020

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Dr Scott Gottlieb: Antibody drugs may be helpful virus treatments, but won't end US epidemic

- *"I think these drugs will make a meaningful difference for people who are the highest risk of having a bad outcome," Dr Scott Gottlieb said of Coronavirus antibody treatments.*
- *"But this is not going to end the epidemic. This is not going to be wildly available to everyone," he told CNBC.*
- *Gottlieb said the US should try to develop a national strategy to expand manufacturing capacity.*

Dr Scott Gottlieb told CNBC on Friday, 09.10.2020 that antibody drugs are likely to be important treatments for the Coronavirus, but he cautioned against considering them a panacea for the nation's Covid-19 outbreak. The former US Food and Drug Administration Commissioner said the lack of supply means not every person who becomes diagnosed with the Coronavirus will be able to receive an antibody treatment — should the FDA grant emergency use authorization to the two companies that recently applied.

"I think these drugs will make a meaningful difference for people who are the highest risk of having a bad outcome," Gottlieb said on "Closing Bell." "But this is not going to end the epidemic. This is not going to be widely available to everyone," he added. Priority would probably be given to Covid-19 patients who are over the age of 65, given they are more likely to become severely ill or die, according to Gottlieb. People who have significant underlying medical conditions also would be higher on the list of patients to receive an antibody treatment, he said.

"We're not going to have this available in the kind of volumes where you'd want to give it to everyone who is at risk and may be even as a prophylaxis for people who are at high risk of contracting the infection like people in nursing homes, front-line health-care providers, front-line workers," he said. This week, Regeneron Pharmaceuticals and Eli Lilly both announced they had submitted emergency use applications to the FDA for their monoclonal antibody treatments for the virus. Both companies have released early data showing the antibody drugs could be promising treatments for Covid-19.

The potential treatments have come into focus in recent days after President Donald Trump received Regeneron's antibody cocktail after he became sick with Covid-19. Trump, who received the treatment on a compassionate use basis, has gone on to tout the experimental drug as "a cure" for Covid-19. However, the President received other treatments for the Coronavirus, such as Gilead Sciences' antiviral Remdesivir, and it is difficult to determine the effectiveness of a single drug outside of a randomized Clinical Trial. Antivirals such as Remdesivir try to stop the virus from replicating, whereas antibody drugs attach to the existing virus in the body and attempt to neutralize it.

Although he cautioned the datasets are still limited, Gottlieb stressed he believes the antibody drugs are likely to provide a benefit for Covid-19 patients. But, he said, the US missed an opportunity to ramp up manufacturing in the spring to ensure there are widespread doses available as the drugs come onto the market. Antibody drugs are difficult to manufacture, and both Regeneron and Eli Lilly teamed up with rival companies to help produce them. In August, Tarrytown, New York-based Regeneron announced an agreement with Swiss drug maker Roche to make and distribute its antibody cocktail.

Indianapolis-based Eli Lilly signed a similar manufacturing agreement for its potential therapy with Amgen, a California biotech firm. The companies "worked hard" to get more production capacity online, said Gottlieb, who led the FDA under Trump from May 2017 to April 2019. "But there really wasn't a national, coordinated strategy to free up manufacturing capacity to be able to produce these at the mass scale that, if we had them at that scale right now, we could effectively use them as a vaccine."

"Remember, these could be not only used potentially to treat people who are infected and prevent them from getting sick, but you could potentially give people a monthly injection of these drugs and prevent them from ever getting infected," he added. "That's how [antibody drugs] were used very successfully in the setting of Ebola." Regeneron said this week that it currently has enough doses of its antibody cocktail for 50,000 patients. It expects to have "doses available for 300,000 patients in total within the next few months," according to a press release. In early February, Regeneron received the US Government's first batch of funding to develop a Covid-19 treatment.

Eli Lilly indicated on Wednesday, 07.10.2020 that it could supply 100,000 doses of its single antibody treatment in October and up to 1 million doses during the fourth quarter of 2020. The company also has a combination antibody treatment and 50,000 doses of it could be available in the fourth quarter. However, Eli Lilly hasn't yet applied for emergency use authorization for the combination therapy. Given the case count in the US, Gottlieb said the current supply of antibody treatments would be insufficient. "You're going to burn through the supply very quickly, even if infection rates stay at the current levels, which I think that they'll probably continue to rise," he said.

Gottlieb said the Government should still consider orchestrating a program to help manufacture more antibody therapies, even though there are high hopes a vaccine may also be ready in the coming months.

"We should be taking steps right now ... to try to make sure we have that supply available in 2021 so we're not constantly struggling to try to get adequate supply of these drugs, if in fact they're demonstrated to be safe and effective," Gottlieb said. "And I think all the early data is encouraging."

(Disclosure: Scott Gottlieb is a CNBC contributor and is a member of the boards of Pfizer, genetic testing start-up Tempus and biotech company Illumina. Pfizer has a manufacturing agreement with Gilead for remdesivir. Gottlieb also serves as co-chair of Norwegian Cruise Line Holdings and Royal Caribbean's "Healthy Sail Panel.")

Source: cnbc.com, 10.10.2020

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Eisai: Joint Development Agreement Aiming for Drug Discovery for COVID-19 Utilizing Eritoran and E6011 Concluded

Eisai Co., Ltd announced that it has entered into a joint research agreement with four research organizations (KAN Research Institute, National Center for Global Health and Medicine, Nagasaki University, and Yokohama City University) in Japan concerning the "Development of Therapeutics to Prevent the Aggravation of the Novel Coronavirus Infectious Disease (COVID-19)" (Grant Number: 20fk0108255), which is a research project with Eisai as the representative research organization. This joint research project "Development of Therapeutics for Novel Coronavirus Infectious Disease (COVID-19)" was adopted for the second public call by the Japan Agency for Medical Research and Development (AMED) as part of its operation for promotion of the Research and Development of innovative treatments for emerging and re-emerging infectious diseases in fiscal year 2020.

In patients with COVID-19 due to the SARS-CoV-2 infection, severe cases such as Acute Respiratory Distress Syndrome (ARDS) and subsequent multiple organ failure have been reported. The involvement of the formation and exacerbation of vasculopathy as well as the cytokine storm in the process of aggravation are assumed. However, at this time, the mechanism of aggravation based on the SARS-CoV-2 infection is not fully understood.

In this collaborative research, a non-clinical animal model of SARS-CoV-2 infection will be constructed. Additionally, TLR (Toll-Like Receptor) 4 antagonist eritoran, discovered by Eisai, and an anti-FKN (fractalkine) antibody E6011, discovered by Eisai's research subsidiary KAN Research Institute, will be evaluated. In addition, this project will promote biomarker research using clinical samples derived from SARS-CoV-2 infected patients. This collaborative research, aims to elucidate the mechanism of COVID-19 aggravation based on SARS-CoV-2 infection and to create drugs that prevent the aggravation of COVID-19.

In the fight against the expansion of COVID-19, based on the human health care (hhc) philosophy, Eisai will continue the development of therapeutics, stable supply of Pharmaceuticals, and support activities in each country.

About TLR4 and Eritoran (E5564):

TLR (Toll-Like Receptor)s are receptors of the innate immune system, and recognize the specific molecular structure of pathogens. It is considered that TLR initiated activation of the innate immune system plays a critical role in eliminating pathogens, causing an inflammatory reaction or an antiviral response. TLR4, one of the TLRs which constitute a family of various receptors, is activated by endotoxins such as lipopolysaccharide released from bacteria. Eritoran is Eisai's in-house discovered and developed TLR4 antagonist created by natural product organic synthesis technology. It is a structural analogue of Lipid A, which is an active pharmacophore of endotoxins. It has been previously observed to have well-tolerated safety profile in 14 clinical studies including a large Phase III randomized trial in severe sepsis.

Eritoran has been shown to have the effects of suppressing cytokine production and improving systemic condition in a mouse influenza virus infection model. It is expected to suppress inflammation and aggravation caused by COVID-19 by inhibiting the activation of TLR4, which is the most upstream of various cytokine gene expression signaling that causes the cytokine-storm. Eritoran has been selected as the therapeutic drug candidate in the international trial REMAP-COVID for hospitalized patients with moderate COVID-19.

About FKN and E6011:

FKN (fractalkine) is a chemokine that has dual functions of cell migration regulation and cell adhesion, which is induced in vascular endothelial cells during inflammation. The FKN receptor (CX3CR1) is mostly expressed in monocytes, macrophages and killer lymphocytes selectively and plays a key role in efficient collection of cells to the inflamed site.

It has been suggested that the FKN-CX3CR1 system relates to various chronic inflammatory diseases including inflammatory bowel disease, rheumatoid arthritis, liver disease, central nervous system disease, arteriosclerosis, dermatosis and others. E6011 is the world's first humanized anti-FKN monoclonal antibody developed by Eisai's research subsidiary KAN Research Institute, Inc., and has a novel action mechanism inhibiting cell invasion by neutralizing activity of fractalkine (FKN), unlike existing cytokine treatments. Currently, a phase II clinical trial in patients with Crohn's disease is being conducted by Eisai's subsidiary for gastrointestinal diseases business EA Pharma Co., Ltd. E6011 inhibits tight binding of CD16+ monocytes (cell populations with high CX3CR1expression), which are important for local inflammatory response, to vascular endothelial cells. E6011 therefore is expected to suppress the initiation and exacerbation of vasculopathy in COVID-19.

Source: itbusinessnet.com, 07.10.2020 (Excerpts)

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FEATURE

What you need to know about Coronavirus right now

Rory Doyle

Regeneron antibodies in demand after Trump treatment

US President Donald Trump said his use of an experimental therapy from Regeneron Pharmaceuticals Inc had allowed him to experience first-hand how effective it could be. "I want to get for you what I got. And I'm going to make it free," Trump said in a video address released on Wednesday, 07.10.2020 at one point calling the unapproved medicine a "cure".

Regeneron's drug is a cocktail of two monoclonal antibodies - manufactured copies of antibodies that are one of the main weapons the immune system generates to fight infections. Patients are asking to join Clinical Trials of antibody-based COVID-19 drugs, though medical experts said more data is needed to assess the treatment's efficacy before wider use should be allowed.

The company said on Wednesday, 07.10.2020 it had submitted a request to the US Food and Drug Administration for an Emergency Use Authorization (EUA) for its antibody combination. Japan to remove travel ban for 12 countries Japan is planning to remove a ban on overseas travel to China and 11 other countries next month, the Yomiuri newspaper reported on Thursday, 08.10.2020. The 11 other countries and regions include Taiwan, Australia, New Zealand, Singapore, South Korea, Vietnam and Malaysia, the Yomiuri said. The Japanese Government, which bans travel to 159 countries and regions, willrecommend that travellers refrain from unnecessary and non-urgent visits to those 12countries, the newspaper said.

Intubation may be less risky for doctors than feared:

Placing a tube in a patient's airway, or removing it, is thought to be one of the highest-risk procedures for medical staff, because of the very close proximity to air being expelled through the mouth of a potentially infected person. But in operating rooms, at least, these procedures might present less of a risk of virus transmission than has been feared.

In operating room experiments with anesthetized patients, intubation and extubation produced far fewer potentially virus-carrying aerosols than expected. Overall, 19 tube insertions generated about one-thousandth of the aerosol generated by a single cough, the researchers reported on Tuesday, 06.10.2020 in the journal Anesthesia.

Fourteen tube removals produced more aerosols, but still less than 25% of that produced by a voluntary cough.

Reassessing travel quarantine period:

Britain is urgently looking at ways to reduce the 14-day quarantine period that applies to some arriving passengers, transport Minister Grant Shapps said on Wednesday, 07.10.2020 adding that a mix of COVID-19 testing and self-isolation was promising.

Virgin Atlantic, easy Jet, London's Heathrow airport and Manchester Airports Group said that a test of a passenger after five days should be the starting point of proposals. But airline body IATA said that 80% of travellers said they would not fly at all if any quarantine was in place. "The proposals on the table do not go as far as we had hoped, "the International Air Transport Association (IATA) said. "A reduction in the length of quarantine is the very minimum needed to restart travel demand."

(Compiled by Karishma Singh; Editing by Robert Birsel)

Source: Reuters, 09.10.2020

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Drug Price Controls Inhibiting Innovation

Charles Boustany

With COVID-19 still raging, it's unlikely trade negotiators from the United States and the United Kingdom will finalize a bilateral agreement before year's end. Hopefully, the delay will afford both parties time to reflect on their priorities. One trade issue that should be at the top of Prime Minister Boris Johnson and US Trade Representative Robert Lighthizer's negotiating list? Changes to the United Kingdom's drug pricing and evaluation regime.

Addressing Pharmaceutical Pricing will be challenging, but it's necessary to safeguard the future of biomedical innovation – especially amid the Coronavirus pandemic. For years, the UK's National Health Service has imposed Government Price Controls on American Pharmaceuticals. That has allowed Britons to freeride off American consumers and taxpayers, instead of shouldering their share of the research and development burden.

And now, during the worst pandemic in 100 years, this unfair pricing regime threatens to undermine the ability of US innovators to continue developing life saving therapies. Fortunately, Ambassador Lighthizer and his team can address this disparity during negotiations with their UK counterparts. Promoting market-based drug pricing in any final US-UK trade deal would benefit American and British patients alike. You don't need to have an advanced degree in behavioral economics to understand that price controls are bad policy.

For starters, they limit pharmaceutical companies' ability to recoup Research and Development costs. This keeps firms from pursuing future Research projects and Developing more new treatments. And unfortunately, scaling back R&D efforts can cause massive layoffs and subsequent economic ruin. When you consider that the US biopharmaceutical industry supports more than 4 million US jobs and contributes $1.1tr illion to our economy each year, it's clear just how much we have to lose by letting price controls endure.

A wealth of research demonstrates the advantages of a world without price controls. According to a 2018 analysis from consultancy Precision Health Economics, lifting price controls in OECD countries could result in eight to 13 new drugs invented each year by 2030. Such new medicines tend to be highly innovative. Fifteen of the 46 new drugs approved by the US Food and Drug Administration in 2017 were first in class, meaning they treat diseases differently from any other existing therapy.

Recent drug advancements have saved millions of lives. For instance, the cancer mortality rate has declined by 26 percent since its peak in the 1990s; new and improved medicines account for nearly 75 percent of that drop. Antiretroviral regimens have transformed HIV/AIDS from a death sentence to a manageable condition. New gene therapies and immunotherapies are restoring sight to the

nearly blind and healing cancer patients who were near death.

It's more important than ever before the United Kingdom stop free-riding on US innovations. American biopharmaceutical firms are hard at work, using their own capital to Research and Develop countless COVID-19 therapies. These firms will continue to feel comfortable making this risky investment only if they remain confident that the price of their discoveries will be dictated by market forces.

The United Kingdom's history of using price controls for drugs challenges this much-needed assurance. And when the UK Government ultimately devalues US COVID-19 therapies, that could lead to fewer active Research and Development projects in the United States and across the globe. President Trump has long sought to reduce other developed nations' use of pharmaceutical price controls. His administration can make this vision a reality by making drug pricing a priority in US-UK trade talks.

Source: thenewsenterprise.com, 20.09.2020 (Excerpts)

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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2018-20
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 21.10.2020

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**