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IDMA BULLETIN

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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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IDMA BULLETIN

Vol. No. 51 Issue No. 40 22 to 30 October 2020

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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

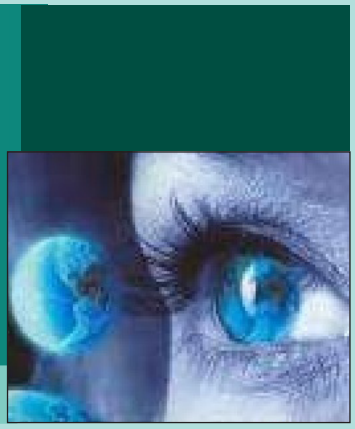
We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

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

IDMA & APTAR PHARMA - Webinar on "Ocular Drug Delivery A Therapeutic Area with an Interesting Past and a Fascinating Future"

on Thursday, 5th November 2020 at 4.00 PM.



APTAR Pharma and **Indian Drug Manufacturers' Association (IDMA)** is organizing a Webinar on ***"Ocular Drug Delivery, A Therapeutic Area with an Interesting Past and a Fascinating Future"*** on the **5th of November, 2020** at **4.00 pm**.

The Webinar shall be presented by:

- **Mr Matthias Birkhoff: Vice President, Business Development, Aptar Germany.**
- **Ms Miriam Faude: Product Manager, Ophthalmic Devices, Aptar Germany.**
- **Dr Degenhard Marx: Director, Scientific Affairs, Aptar Germany.**

This webinar presents available options and discusses future trends, in particular preservatives, debatable additives, but also novel ideas like "Connected Eye Care", an issue that gains even more attraction in the pandemic situation we are all in.

You will learn about the strategies to address patient compliance in both clinical settings and in home care as well as limitations and regulatory hurdles.

Kindly note that there are no registration fees for this webinar but prior registration is compulsory – Please find attached a registration form for the webinar. Request you to kindly forward us your registration form duly filled to:

Ms Prachi Singhai Aptar Pharma prachi.singhai@aptar.com	**Mr Ajay Kumar Singh** IDMA publications@idmaindia.com

Please note that after receipt of your confirmation/registration form, the attendee link will be shared with you.
Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel
Secretary – General, IDMA

Indian Drug Manufacturers' Association
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Mumbai-400018. Maharashtra. India.
Tel No. 022 24974308 / 24944624
Website: www.idma-assn.org

Prachi Singhai
Manager-Marketing & Communication, India & S E Asia
Aptar Pharma
R-854, TTC Industrial Estate, Thane Belapur Road, Rabale,
Mumbai, Maharashtra 400701 India
(Phone) +91 22 6195 1946 | (Mobile) 00 91 9892026098
prachi.singhai@aptar.com | www.aptar.com

REGISTRATION FORM

Webinar on ***"Ocular Drug Delivery: A Therapeutic Area with an Interesting Past and a Fascinating Future"***

November 5, 2020 at 4.00pm

Name :.....

Company :.....

Designation :.....

Address :.....

.....

.....

Contact No :.....

Email ID :.....

RSVP: Ms. Prachi Singhai, Aptar Pharma
prachi.singhai@aptar.com
Mr. Ajay Kumar Singh, IDMA
publications@idmaindia.com

IDMA Representation to DCG(I) on Pathway for Regularization of Kokate Committee approved FDCs including 471 FDCs of Vitamins, Minerals and Micro-nutrients – reg.

The Association has submitted the following representation on 19th October 2020 to Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organisation, New Delhi (in response to DCG(I) letter dated 3rd August 2020) on the above subject :

"Greetings from Indian Drug Manufacturers' Association.

We thank you for notifying the list of 471 FDCs relating to Vitamins, Minerals and Micro-nutrients approved by Prof Kokate Committee. We also appreciate that since 2018, you have notified the list of rational SLA Approved drugs covering 1681 FDCs and 450 FDCs.

We have noted from your above-mentioned letter that for grant of product licenses to subsequent applicants for these 471 FDCs by the SLAs, **the applicants are required to comply with the PSUR requirements as per the new NDCT Rules 2019.**

Several member companies from the MSME sector will be adversely impacted both operationally and financially by this decision that applies the current regulation retrospectively for the existing marketed products, by considering them as 'New Drugs' as defined in the NDCT Rules.

We would like to bring to your kind notice, a brief background of the pathway followed so far for dealing with a typical situation of one of its kind, where all the SLA approved FDCs could be reviewed for their safety and efficacy successfully thereby approving only rational FDCs and withdrawing permission to FDCs found to be not rational.

This exercise could be completed due to the pathway followed for issuing NOCs to the applicants under 18 month Policy and the pathway communicated through various circulars issued by the DCGI office for the subsequent applicants of the FDCs approved by Kokate Committee that is briefly described below:

a): The Circular dated 16th March 2017 described the pathway and provided instructions, among others, for payment of as Rs.15,000/- as the fees and for filing the PSUR, in accordance with the provisions of Schedule Y.

b): The Circular dated 5th June 2017 that followed further clarified the details of the documents to be submitted by the subsequent applicants holding the SLA approved licenses for the approved FDCs and by those who were new manufacturers.

c): The Circular dated 12th December 2018 from the DCG(I) issued after the list of Kokate Committee approved 1681 FDCs was published, specified the fees to be paid as Rs.15,000/- and PSUR to be filed in accordance with Schedule Y, consistent with the previous Circular, while allowing the direct application to the SLA and approval of such FDCs without the submission of the NOC from the DCG(I) office.

The requirements for PSUR filing was also specified similarly in the NOCs issued by the DCG(I) office to individual companies who had submitted the safety and efficacy data for these FDCs.

It is pertinent to note that the drugs reviewed under 18 months policy were already marketed for several years and were not considered as 'New Drugs'. This is evident from the fact that NOCs and not Form 46 were issued to the companies for these products after the FDCs were declared as rational by the Committee.

This pathway was advised (and was modified to facilitate approvals through various Circulars mentioned

above) based on the active engagement and consultation with all the stakeholders, as a practical and acceptable solution for dealing with a unique regulatory situation. Following this pathway, the licenses to the applicants were issued by the SLAs for the applications received for the products cleared so far (1681 + 500) and the companies started filing the PSUR as per Schedule Y as specified in the above mentioned DCG(I) Circulars and also as specified in the NOC letters issued by the DCGI office.

In the meantime, it is observed that the PSUR reviewers at the DCG(I) office have started to write to the manufacturers of such earlier approved FDCs to submit, midway, the PSUR data in accordance with the provisions of the new NDCT Rules 2019.

We have now observed that the recent letter dated 3rd August 2020 has also included this requirement as a condition for regularization of these FDCs that sets aside the PSUR requirement as per Schedule Y specified in the Circulars, dated 16th March 2017 and 12th December 2018 and introduces the requirement of PSUR in accordance with the NDCT Rules.

It is important to note that all the FDCs cleared by the 18 months policy of submission of safety and efficacy data were the existing products and were dealt with this agreed pathway for ensuring that safety and efficacy of the products are established before they are approved for further marketing. This pathway allowed all the manufacturers – the existing, the subsequent applicants and the new manufacturers to follow a uniform procedure considering the special circumstances of approval of such FDCs.

It is therefore difficult to understand as to why this pathway is modified for the fees to be paid and the PSURs to be filed in accordance with the new NDCT Rules by considering them as 'New Drugs'. This requirement is not consistent with the NOCs issued to the manufacturers.

This insistence to follow the stringent PSUR requirements as per new NDCT Rules for the products existing in the market for several years will not serve any useful purpose in terms of benefit to patients. Besides, a compilation of such huge data for these molecules is time-consuming and very expensive, particularly for the MSME sector since they will have to outsource this service from the expert consultants.

Besides this requirement has created a typical situation where the companies have already filed the PSUR for the last 2 years as per Schedule Y are now required to comply with the new NDCT Rules.

You will appreciate that the procedure of review of SLA approved FDCs, that was started in the year 2013, has taken several years to conclude and the products are approved at different intervals of time. In the meantime, new NDCT Rule 2019 has been notified. **However, in our opinion, approval of the FDCs after 2019 cannot be the reason for making applicable new rules because fundamentally these products cannot be considered as 'New Drugs' and secondly, some of the manufacturers will have to pay fees and file detailed PSURs for the same set of the products as per new rules.**

In view of this, we request you to make a Uniform Policy applicable to all manufacturers – for those who were issued NOCs for these FDCs under the 18-month policy and for all the subsequent applicants for all the FDCs cleared under this route regardless of the date approval.

We, therefore, request you to issue a clarification that the pathway prescribed in the DCG(I) Circular dated 12th December 2018 shall be followed for all the FDCs cleared in this route and as specified in the Circular:

1. A fees of Rs.15,000/- shall be charged, and
2. PSURs shall be filed in accordance with Schedule Y (that is also specified in the individual NOCs).

We also request you to withdraw any notices issued for filing PSURs as per new NDCT Rules that will help many small and medium sized companies to comply with the requirements followed by all the previous applicant, uniformly."

● ● ●

Patent (Amendment) Rules 2020 notified – reg.

Patent (Amendment) Rules 2020 have been notified, consequent to circulation of draft Rules and reviewing of responses received. The present amendment relates to:

(1): Priority document formalities relating to Indian National phase of PCT applications.

(2): Working of Patents in India. The Form 27 as originally proposed to be amended, has now been amended and published. It is hoped that the working of Patents in India will be pursued more seriously and diligently than before, having this revised data in Form 27 being sought for. IDMA welcomes this amendment to Patent Rules.

Gazette Notification No.G.S.R. 652(E), dated 19th October, 2020

Whereas the draft rules, namely the Patents (Amendment) Rules, 2019 were published as required under sub-section (3) of section 159 of the Patents Act, 1970 (39 of 1970), vide Notification of the Government of India in the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade) number G.S.R.396(E) dated the 31st May, 2019 in the Gazette of India, Extraordinary, Part II, section 3, subsection (i), for inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And whereas, the copies of the said Gazette notification were made available to the public on the 31st of May, 2019;

And, whereas, the objections and the suggestions received from the public in respect of the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 159 of the Patents Act, 1970 (39 of 1970), the Central Government hereby makes the following rules further to amend the Patents Rules, 2003, namely:-

1. Short title and commencement:

(1) These rules may be called the **Patents (Amendment) Rules, 2020.**

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

2. In the Patents Rules, 2003 (hereinafter referred to as the said rules), for rule 21, the following rule shall be substituted, namely:-

"21. Filing of priority document -

(1) Where the applicant in respect of an international application designating India has not complied with the requirements of paragraphs (a), (b) or (b-bis) of rule 17.1 of the regulations under the Patent Cooperation Treaty, and subject to paragraph (d) of the said rule 17.1 of regulations under the Treaty, the applicant shall file the priority document referred to in that rule before the expiration of the time limit referred to in sub-rule (4) of rule 20 in the Patent Office.

(2) Where sub-paragraph (i) or sub-paragraph (ii) of paragraph (e) of rule 51bis.1 of the regulations under the Patent Cooperation Treaty is applicable, an English translation thereof duly verified by the applicant or the person duly authorised by him shall be filed within the time limit specified in sub-rule (4) of rule 20.

(3) Where the applicant does not comply with the requirements of sub-rule (1) or sub-rule (2), the Patent Office shall invite the applicant to file the priority document or the translation thereof, as the case may be, within three months from the date of such invitation, and if the applicant fails to do so, the claim of the applicant for the priority shall be disregarded for the purposes of the Act.".

3. In the said rules, in rule 131, for sub-rule (2), the following sub-rule shall be substituted, namely:-

"(2) The statements referred to in sub-rule (1) shall be furnished once in respect of every financial year, starting from the financial year commencing immediately after the financial year in which the

patent was granted, and shall be furnished within six months from the expiry of each such financial year."

4. In the said rules, in THE SECOND SCHEDULE, for Form 27, the following Form shall be substituted, namely:-

"FORM 27
THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003

No Fee

STATEMENT REGARDING THE WORKING OF PATENTED INVENTION(S) ON A COMMERCIAL SCALE IN INDIA
[*See* section 146(2) and rule 131(1)]

<table>
<tr><td>1. Insert name, address, nationality, patent number(s).</td><td colspan="3">I/ We, the Patentee(s)/ Licensee ……, in respect of patent number(s) ……, furnish this statement,
(Explanation: One form may be filed in respect of multiple patents, provided all of them are related patents, wherein the approximate revenue / value accrued from a particular patented invention cannot be derived separately from the approximate revenue/value accrued from related patents, and all such patents are granted to the same patentee(s)).</td></tr>
<tr><td>2. State the financial year to which the statement relates.</td><td colspan="3">in respect of the financial year ……</td></tr>
<tr><td rowspan="3">3. Worked / not worked. Please state whether each patent in respect of which this form is being filed is worked or not worked.</td><td>Patent Number(s)</td><td>Worked [Tick (✓) if applicable]</td><td>Not worked [Tick (✓) if applicable]</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td rowspan="3">4. If worked.</td><td colspan="3">(a) Approximate revenue / value accrued in India to the patentee(s)/ licensee furnishing the statement from patent number(s) where the working is through:</td></tr>
<tr><td colspan="2">(1) Manufacturing in India …… (in INR)</td><td>(2) Importing into India ……. (in INR)</td></tr>
<tr><td colspan="3">(b) Brief in respect of (a) above (maximum 500 words)</td></tr>
<tr><td>5. If not worked.</td><td colspan="3">Reasons for not working the patented invention(s) and steps being taken for working of the invention(s).(maximum 500 words)</td></tr>
<tr><td></td><td colspan="3">The facts and matters stated above are true to the best of my/ our knowledge, information and belief.
Dated this ..... day of ..... 20.....</td></tr>
<tr><td>6. To be signed by Patentee(s) / Licensee / Authorised Agent furnishing the statement.</td><td colspan="3">Signature(s) .....

To
The Controller of Patents,
The Patent Office,
at ……</td></tr>
</table>

Note: Every patentee and every licensee (exclusive or otherwise) is required to file this Form; where a patent is granted to two or more persons, all such patentees may file this Form jointly; however, each licensee shall file this Form individually. ".

[F. No. 24027/5/2020-IPR-III]
RAVINDER, Jt. Secy.

Note: The said rules were published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-Section (ii) vide S.O.493 (E) dated the 2nd May, 2003 and lastly amended *vide* notification number G.S.R. 663 (E) dated the 17th September, 2019.

DPIIT appoints Technical Members for Patents, Trademarks and Copyrights in IPAB

DPIIT Gazette Notification No.F.24017/72/2017-IPR-I, dated 20th October, 2020

1. The President of India is pleased to make the following appointments to the posts of Technical Members in Intellectual Property Appellate Board, Chennai, for a period of 4 years from date of appointment or attaining the age of 65 years, or until further orders, whichever is earliest:

Sr. No.	Name	Technical Member	Date of Appointment
1	Shri Birendra Prasad Singh	Patents	21.08.2020 (Forenoon)
2	Ms Lakshmidevi Somanath	Trade Marks	21.08.2020 (Forenoon)
3	Shri M Vijay Kumar	Trade Marks	09.09.2020 (Forenoon)
4	Shri N Surya Senthil	Copyrights	21.08.2020 (Forenoon)
5	Shri S P Chockalingam	Copyrights	21.08.2020 (Forenoon)

2. The salaries and allowances payable to the above officials and the terms and conditions of the service by which they shall be governed, shall be in accordance with the Tribunal, Appellate Tribunal and other Authorities (Qualifications, Experience and other Conditions of Service of Members) Rules, 2020 notified on 12.02.2020.

Sachin Dhania, Deputy Secretary, Department For Promotion of Industry and Internal Trade, IPR-Establishment, Ministry of Commerce and Industry, New Delhi.

● ● ●

Amendment to Notification No.S.O.3721(E), dated the 16th October, 2019 - reg.

Drugs & Cosmetics Notification No.S.O.3722(E), dated 21st October, 2020

In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. S.O.3721(E), dated the 16th October, 2019 published in PART II - Section 3 - Sub-section (ii) of the Gazette of India, Extraordinary, namely,-

In the said notification, for the words and figures "the 1st day of November, 2020", the words and figures "the **1st day of November, 2021"** shall be substituted.

Dr Mandeep K Bhandari, Joint Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, 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.3721(E), dated the 16th October, 2019*

● ● ●

Draft Rules to further amend the Drugs and Cosmetics Rules, 1945 Published - reg.

Drugs & Cosmetics Notification No.G.S.R.656(E), dated 20th October, 2020

(Published in the Gazette of India on 21st October, 2020)

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

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

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi-110011 or emailed at **drugsdiv-mohfw@gov.in**.

DRAFT RULES

1. (1) These rules may be called the **Drugs and Cosmetics (…..Amendment) Rules, 2020.**

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

2. In the Drugs and Cosmetics Rules, 1945, in Schedule H1, after serial number 47 and entry relating thereto, the following serial number and entry shall be inserted, namely:-

"48. Tapentadol"

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

Note: *The Principal Rules were published in the Gazette of India vide Notification number F.28-10/45-H (1), dated the 21st December, 1945.*

● ● ●

Methanol (Quality Control) Order, 2019 amended - reg.

Chemicals & Fertilizers Notification No.S.O.3795(E), dated 22nd October, 2020

(Published in the Gazette of India on 23rd October, 2020)

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

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

"(2) This order shall come into force on the **3rd May, 2021."**

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

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

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

● ● ●

COMPANIES LAW AMENDMENTS

Special Measures under the Companies Act, 2013 and Limited Liability Partnership Act, 2008 in view of COVID-19 outbreak – Extension - reg.

Corporate Affairs General Circular No.36/2020, dated 20th October, 2020

To
The DGCoA,
All Regional Directors,
All Registrar of Companies,
All Stakeholders.

1. In continuation to General Circular No.11/2020 dated 24th March 2020, keeping in view the requests received from various stakeholders seeking relaxation from the residency requirement of 182 days in a year and after due examination, it is hereby clarified that non-compliance of minimum residency in India for a period of at least 182 days in a year, by at least one Director in every company, under section 149 of the Companies Act, 2013 shall not be treated as noncompliance for the financial year 2020-2021 also.

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

File No.2/01/2020-CL-V

K M S Narayanan, Assistant Director (Policy), Ministry of Corporate Affairs, New Delhi.

● ● ●

Central Goods and Services Tax Rules, 2017 amended (Twelveth Amendment of 2020) - reg.

GST-Central Tax Notification No.79/2020, dated 15th October, 2020

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

1. Short title and commencement:

(1) These rules may be called the **Central Goods and Services Tax (Twelveth Amendment) Rules, 2020.**

(2) Save as otherwise provided in these rules, they shall come into force on the date of their publication in the Official Gazette.

2. In the Central Goods and Services Tax Rules, 2017 (hereinafter referred to as the said rules), in rule 46, for the first proviso, the following proviso shall be substituted, namely:-

"Provided that the Board may, on the recommendations of the Council, by notification, specify-

(i) the number of digits of Harmonised System of Nomenclature code for goods or services that a class of registered persons shall be required to mention; or

(ii) a class of supply of goods or services for which specified number of digits of Harmonised System of Nomenclature code shall be required to be mentioned by all registered taxpayers; and

(iii) the class of registered persons that would not be required to mention the Harmonised System of Nomenclature code for goods or services:".

3. In the said rules, for rule 67A, the following rule shall be substituted, namely:-

"67A. Manner of furnishing of return or details of outward supplies by short messaging service facility: Notwithstanding anything contained in this Chapter, for a registered person who is required to furnish a Nil return under section 39 in **FORM GSTR-3B** or a Nil details of outward supplies under section 37 in **FORM GSTR-1** or a Nil statement in **FORM GST CMP-08** for a tax period, any reference to electronic furnishing shall include furnishing of the said return or the details of outward supplies or statement through a short messaging service using the registered mobile number and the said return or the details of outward supplies or statement shall be verified by a registered mobile number based One Time Password facility.

Explanation: For the purpose of this rule, a Nil return or Nil details of outward supplies or Nil statement shall mean a return under section 39 or details of outward supplies under section 37 or statement under rule 62, for a tax period that has nil or no entry in all the Tables in **FORM GSTR-3B** or **FORM GSTR-1** or **FORM GST CMP-08,** as the case may be".

4. In the said rules, in rule 80, in sub-rule (3), for the proviso, the following proviso shall be substituted, namely:-

"Provided that for the financial year 2018-2019 and 2019-2020, every registered person whose aggregate turnover exceeds five crore rupees shall get his accounts audited as specified under subsection (5) of section 35 and he shall furnish a copy of audited annual accounts and a reconciliation statement, duly certified, in **FORM GSTR-9C** for the said financial year, electronically through the common portal either directly or through a Facilitation Centre notified by the Commissioner.".

5. In the said rules, with effect from the 20th day of March, 2020, in rule 138E, after the third proviso, the following proviso shall be inserted, namely:-

"Provided also that the said restriction shall not apply during the period from the 20th day of March, 2020 till the 15th day of October, 2020 in case where the return in **FORM GSTR-3B** or the statement of outward supplies in **FORM GSTR-1** or the statement in **FORM GST CMP-08**, as the case may be, has not been furnished for the period February, 2020 to August, 2020.".

6. In the said rules, in rule 142, in sub-rule (1A),-

(i) for the words "proper officer shall", the words "proper officer may" shall be substituted;

(ii) for the words "shall communicate", the word "communicate" shall be substituted.

7. In the said rules, in **FORM GSTR-1,** against serial number 12, in the Table, in column 6, in the heading, for the words "Total value", the words "Rate of Tax" shall be substituted.

8. In the said rules, for **FORM GSTR-2A**, the following form shall be substituted, namely:-

---

"FORM GSTR-2A
[See rule 60(1)]

Details of auto drafted supplies

(From GSTR 1, GSTR 5, GSTR-6, GSTR-7, GSTR-8, import of goods and inward supplies of goods received from SEZ units/developers)

Year	
Month	

1.	GSTIN		
2.	(a)	Legal name of the registered person	
	(b)	Trade name, if any	

PART A

(Amount in Rs. all Tables)

3. Inward supplies received from a registered person including supplies attracting reverse charge

GSTIN of supplier	Trade/ Legal name	Invoice details				Rate (%)	Taxable value	Amount of tax				Place of supply (Name of State/UT)	Supply attracting reverse charge (Y/N)	GSTR-1/5 period	GSTR-1/5 filing date	GSTR-3B filing status (Yes/ No)	Amend-ment made, if any (GSTIN, Others)	Tax period in which amended	Effective date of Cancella-tion, if any
		No.	Type	Date	Value			Integra-ted tax	Central tax	State/ UT tax	Cess								
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20

4. Amendment to Inward supplies received from a registered person including supplies attracting reverse charge (Amendment to 3)

Details of original Document		Revised details						Rate (%)	Taxable value	Amount of tax				Place of supply (Name of State/ UT)	Supply Attract-ting reverse charge (Y/N)	GSTR-1/5 period	GSTR-1/5 Filing date	GSTR-3B filing Status (Yes/ No)	Amend-ment made (GSTIN, Others)	Tax period of original record	Effective date of cancella-tion if any,
No.	Date	GSTIN	Trade/ Legal name	No.	Type	Date	Value			Integra-ted tax	Central tax	State/ UT tax	Cess								
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22

5. Debit/Credit notes received during current tax period

GSTIN of supplier	Trade/ Legal name	Credit/Debit Note Details					Rate (%)	Taxable value	Amount of tax				Place of supply (Name of State/ UT)	Supply Attract-ting reverse charge (Y/N)	GSTR-1/5 period	GSTR-1/5 filing date	GSTR-3B filing status (Yes/ No)	Amend-ment made, if any (GSTIN, Others)	Tax period in which amended	Effective date of cancella-tion, if any
		No.	Note type	Note supply type	Date	Value			Integra-ted tax	Central tax	State/ UT tax	Cess								
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

6. Amendment to Debit/Credit notes (Amendment to 5)

Details of original document			Revised details							Rate (%)	Taxable value	Amount of tax				Place Of supply (Name Of State/ UT)	Supply attracting reverse charge (Y/N)	GSTR-1/5 period	GSTR-1/5 filing date	GSTR-3B filing status (Yes/ No)	Amendment made (GSTIN, Others)	Tax period of original record	Effective date of cancella-tion if any
Type	No.	Date	GSTIN of Supplier	Trade/ Legal name	No.	Note type	Note supply type	Date	Value			Integrated tax	Central tax	State/ UT tax	Cess								
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24

PART B

7. ISD credit received

GSTIN of ISD	Trade/ Legal name	ISD document details		ISD invoice details (for ISD credit note only)			ITC amount involved				GSTR-6 Period	GSTR-6 filing date	Amendment made, if any	Tax Period in which amended	ITC Eligibility
		Type	No.	Date	No.	Date	Integrated tax	Central tax	State/ UT tax	Cess					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

8. Amendments to ISD credit details

Original ISD Document Details			Revised details					Original ISD invoice details (for ISD credit note only)		ITC amount involved				ISD GSTR-6 Period	ISD GSTR-6 filing date	Amend-ment made	Tax period of original record	ITC Eligibility
Type	No.	Date	GSTIN of ISD	Trade/ Legal name	Type	No.	Date	No.	Date	Integrated Tax	Central Tax	State/ UT Tax	Cess					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19

PART-C

9. TDS and TCS Credit (including amendments thereof) received

GSTIN of Deductor / GSTIN of E-Commerce Operator	Deductor Name/ E- Commerce Operator Name	Tax period of GSTR-7/ GSTR-8 (Original/ Amended)	Amount received/ Gross value (Original/ Revised)	Value of supplies returned	Net amount liable for TCS	Amount (Original/Revised)		
						Integrated tax	Central tax	State / UT tax
1	2	3	4	5	6	7	8	9
9A. TDS								
9B. TCS								

PART-D

10. Import of goods from overseas on bill of entry (including amendments thereof)

ICEGATE Reference date	Bill of entry details				Amount of tax		Amended (Yes/No)
	Port code	No.	Date	Value	Integrated tax	Cess	
1	2	3	4	5	6	7	8

11. Inward supplies of goods received from SEZ units/developers on bill of entry (including amendments thereof)

GSTIN of the Supplier (SEZ)	Trade/ Legal Name	ICEGATE Reference date	Bill of Entry details				Amount of tax		Amended (Yes/No)
			Port code	No.	Date	Value	Integrated tax	Cess	
1	2	3	4	5	6	7	8	9	10

Instructions:

1. Terms Used:-
   a. ITC – Input tax credit
   b. ISD – Input Service Distributor
2. **Important Advisory**: FORM GSTR-2A is statement which has been generated on the basis of the information furnished by your suppliers in their respective FORMS GSTR-1, 5, 6, 7 and 8. It is a dynamic statement and is updated on new addition/amendment made by your supplier in near real time. The details added by supplier would reflect in corresponding FORM GSTR-2A of the recipient irrespective of supplier's date of filing.
3. There may be scenarios where a percentage of the applicable rate of tax rate may be notified by the Government. A separate column will be provided for invoices/documents where such rate is applicable.
4. **Table wise instructions**:

Table No. and Heading	**Instructions**
3 Inward supplies received from a registered person including supplies attracting reverse charge	i. The table consists of all the invoices (including invoices on which reverse charge is applicable) which have been saved/filed by your suppliers in their FORM GSTR-1 and 5. ii. Invoice type: a. R- Regular (Other than SEZ supplies and Deemed exports) b. SEZWP- SEZ supplies with payment of tax c. SEZWOP- SEZ supplies without payment of tax d. DE- Deemed exports e. CBW - Intra-State supplies attracting IGST iii. For every invoice, the period and date of FORM GSTR-1/5 in which such invoice has been declared and filed is being provided. It may be noted that the details added by supplier would reflect in corresponding FORM GSTR-2A of the recipient irrespective of supplier's date of filing. For example, if a supplier files his invoice INV-1 dated 10th November 2019 in his FORM GSTR-1 of March 2020, the invoice will be reflected in FORM GSTR-2A of March, 2020 only. Similarly, if the supplier files his FORM GSTR-1 for the month of November on 5th March 2020, the invoice will be reflected in FORM GSTR-2A of November 2019 for the recipient. iv. The status of filing of corresponding FORM GSTR-3B for FORM GSTR-1 will also be provided. v. The table also shows if the invoice or debit note was amended by the supplier and if yes, then the tax period in which such invoice was amended, declared and filed. For example, if a supplier has filed his invoice INV-1 dated 10th November 2019 in his FORM GSTR-1 of November 2019, the invoice will be reflected in FORM GSTR-2A of November, 2019. If the supplier amends this invoice in FORM GSTR-1 of December 2019, the amended invoice will be made available in Table 4 of FORM GSTR-2A of December 2019. The original record present in Table 3 of FORM GSTR-2A of November 2019 for the recipient will now have updated columns of amendment made (GSTIN, others) and tax period of amendment as December 2019.

	vi. In case, the supplier has cancelled his registration, the effective date of cancellation will be provided.
4 Amendment to Inward supplies received from a registered person including supplies attracting reverse charge (Amendment to table 3)	i. The table consists of amendment to invoices (including invoice on which reverse charge is applicable) which have been saved/filed by your suppliers in their FORM GSTR-1 and 5. ii. Tax period in which the invoice was reported originally and type of amendment will also be provided. For example, if a supplier has filed his invoice INV-1 dated 10th November 2019 in his FORM GSTR-1 of November 2019, the invoice will be reflected in FORM GSTR-2A of November, 2019. If the supplier amends this invoice in FORM GSTR-1 of December 2019, the amended invoice will be made available in Table 4 of FORM GSTR-2A of December 2019. The original record present in Table 3 of FORM GSTR-2A of November 2019 for the recipient will now have updated columns of amendment made (GSTIN, others) and tax period of amendment as December 2019.
5 Debit/Credit notes received during current tax period	i. The table consists of the credit and debit notes (including credit/debit notes relating to transactions on which reverse charge is applicable) which have been saved/filed by your suppliers in their FORM GSTR-1 and 5. ii. If the credit/debit note has been amended subsequently, tax period in which the note has been amended will also be provided. iii. Note Type: o Credit Note o Debit Note iv. Note supply type: o R- Regular (Other than SEZ supplies and Deemed exports) o SEZWP- SEZ supplies with payment of tax o SEZWOP- SEZ supplies without payment of tax o DE- Deemed exports o CBW - Intra-State supplies attracting IGST v. For every credit or debit note, the period and date of FORM GSTR-1/5 in which such credit or debit note has been declared and filed is being provided. It may be noted that the details added by supplier would reflect in corresponding FORM GSTR-2A of the recipient irrespective of supplier's filing of FORM GSTR-1. For example, if a supplier files his credit note CN-1 dated 10th November 2019 in his FORM GSTR-1 of March 2020, the credit note will be reflected in FORM GSTR-2A of March, 2020 only. Similarly, if the supplier files his FORM GSTR-1 for the month of November on 5th March 2020, the credit note will be reflected in FORM GSTR-2A of November 2019 for the recipient. vi. The status of filing of corresponding FORM GSTR-3B of suppliers will also be provided. vii. The table also shows if the credit note or debit note has been amended subsequently and if yes, then the tax period in which such credit note or debit note was amended, declared and filed.

	viii. In case, the supplier has cancelled his registration, the effective date of cancellation will be displayed.
6 Amendment to Debit/ Credit notes (Amendment to 5)	i. The table consists of the amendments to credit and debit notes (including credit/debit notes on which reverse charge is applicable) which have been saved/filed by your suppliers in their FORM GSTR-1 and 5. ii. Tax period in which the note was reported originally will also be provided.
7 ISD credit received	i. The table consists of the details of the ISD invoices and ISD credit notes which have been saved/filed by an input service distributor in their FORM GSTR-6. ii. Document Type : o ISD Invoice o ISD Credit Note iii. If ISD credit note is issued subsequent to issue of ISD invoice, original invoice number and date will also be shown against such credit note. In case document type is ISD Invoice these columns would be blank
7 ISD credit received	iv. For every ISD invoice or ISD credit note, the period and date of FORM GSTR-6 in which such respective invoice or credit note has been declared and filed is being provided. v. The status of eligibility of ITC on ISD invoices as declared in FORM GSTR-6 will be provided. vi. The status of eligibility of ITC on ISD credit notes will be provided.
8 Amendment to ISD credit received	i. The table consists of the details of the amendments to details of the ISD invoices and ISD credit notes which have been saved/filed by an input service distributor in their FORM GSTR-6.
9 TDS/TCS credit received	i. The table consists of the details of TDS and TCS credit from FORM GSTR-7 and FORM GSTR-8 and its amendments in a tax period. ii. A separate facility will be provided on the common portal to accept/reject TDS and TCS credit.
10 & 11 Details of Import of goods from overseas on bill of entry and from SEZ units and developers and their respective amendments	i. The table consists of details of IGST paid on imports of goods from overseas and SEZ units/developers on bill of entry and amendment thereof. ii. The ICEGATE reference date is the date from which the recipient is eligible to take input tax credit. iii. The table also provides if the Bill of entry was amended. iv. Information is provided in the tables based on data received from ICEGATE. Information on certain imports such as courier imports may not be available.

"

9. In the said rules, in **FORM GSTR-5,-**

(i). in the table,**-**

(a) in serial number 2, after entry (c), the following entries shall be inserted, namely: -

"(d)	ARN	Auto Populated
(e)	Date of ARN	Auto Populated.";

(b) in serial number 10,**-**

(A) in the heading, after the words, "Total tax liability", the brackets and words "(including reverse charge liability, if any)", shall be inserted;

(B) after serial number 10B and the entry relating thereto, the following serial number and entry shall be inserted, namely,-

"10C. On account of inward supplies liable to reverse charge					
					.”;

(ii) in the instructions,-

(a) for paragraph 7, the following paragraph shall be substituted, namely:-

"7. Invoice-level information, rate-wise, pertaining to the tax period should be reported as under:

(i.) for all B to B supplies (whether inter-State or intra-State), invoice level details should be uploaded in Table 5;

(ii.) for all inter-state B to C supplies, where invoice value is more than Rs.2,50,000/- (B to C Large) invoice level detail to be provided in Table 6; and

(iii.) for all B to C supplies, other than those reported in table 6, shall be reported in Table 7 providing State-wise summary of such supplies.";

(b) in paragraph 8, in clause (ii), after the words, "invoice value is more than", the word "rupees", shall be inserted;

(c) for paragraph 10, the following paragraph shall be substituted, namely: -

"10. Table 10 consists of tax liability on account of outward supplies declared in the current tax period and negative ITC on account of amendment to import of goods in the current tax period. Inward supplies attracting reverse charge shall be reported in Part C of the table.".

10. In the said rules, in **FORM GSTR-5A**,-

(i) against serial number 4 and entries relating thereto, the following entries shall be inserted, namely:-

"4(a) ARN:
4(b) Date of ARN:";

(ii) for serial number 6, the following shall be substituted, namely: -

"6. Calculation of interest, or any other amount

(Amount in Rupees)

Sr. No.	Description	Place of supply (State/UT)	Amount due (Interest/ Other)	
			Integrated tax	Cess
1	2	3	4	5
1.	Interest			
2.	Others			
	Total			

";

(iii). for serial number 7, the following shall be substituted, namely:-

"7. Tax, interest and any other amount payable and paid

(Amount in Rupees)

Sr. No.	Description	Amount payable		Debit entry no.	Amount paid	
		Integrated tax	Cess		Integrated tax	Cess
1	2	3	4	5	6	7
1.	Tax Liability (based on Table 5 & 5A)					
2.	Interest (based on Table 6)					
3.	Others (based on Table 6)					

".

11. **In the said rules, in FORM GSTR-9,-**

(i) in the Table,-

(a) against serial number 8C, in column 2, for the entry, the following entry shall be substituted, namely:-

"ITC on inward supplies (other than imports and inward supplies liable to reverse charge but includes services received from SEZs) received during the financial year but availed in the next financial year up to specified period";

(b) against Pt. V, for the heading, the following heading shall be substituted, namely:-

"Particulars of the transactions for the financial year declared in returns of the next financial year till the specified period.";

(ii) in the instructions,-

(a) after paragraph 2, the following entry shall be inserted, namely,-

"2A. In the Table, against serial numbers 4, 5, 6 and 7, the taxpayers shall report the values pertaining to the financial year only. The value pertaining to the preceding financial year shall not be reported here."

(b) in paragraph 4,-

(A) after the words, letters and figures, "that additional liability for the FY 2017-18 or FY 2018-19", the word, letters and figures "or FY 2019-20" shall be inserted;

(B) in the Table, in second column, for the letters, figures and word "FY 2017-18 and 2018-19" wherever they occur, the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted;

(c) in paragraph 5, in the Table, in second column,-

(A) against serial number 6B, after the entries, the following entry shall be inserted, namely:-

"For FY 2019-20, the registered person shall report the breakup of input tax credit as capital goods and have an option to either report the breakup of the remaining amount as inputs and input services or report the entire remaining amount under the "inputs" row only.";

(B) against serial number 6C and serial number 6D,-

(i) after the entry ending with the words "entire input tax credit under the "inputs" row only.", the following entry shall be inserted, namely:-

"For FY 2019-20, the registered person shall report the breakup of input tax credit as capital goods and have an option to either report the breakup of the remaining amount as inputs and input services or report the entire remaining amount under the "inputs" row only.";

(ii) in the entry ending with the words, figures and letters "Table 6C and 6D in Table 6D only.", for the letters, figures and word "FY 2017-18 and 2018-19", the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted;

(C) against serial number 6E, after the entry, the following entry shall be inserted, namely:-

"For FY 2019-20, the registered person shall report the breakup of input tax credit as capital goods and have an option to either report the breakup of the remaining amount as inputs and input services or report the entire remaining amount under the "inputs" row only.";

(D) against serial number 7A, 7B, 7C, 7D, 7E, 7F, 7G and 7H, in the entry, for the letters, figures and word "FY 2017-18 and 2018-19", the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted.;

(E) against serial number 8A, after the entry, the following entry shall be inserted, namely:-

"For FY 2019-20, it may be noted that the details from **FORM GSTR-2A** generated as on the 1st November, 2020 shall be auto-populated in this table.";

(F) against serial number 8C, for the entries, the following entry shall be substituted, namely:-

"Aggregate value of input tax credit availed on all inward supplies (except those on which tax is payable on reverse charge basis but includes supply of services received from SEZs) received during the financial year for which the annual return is being filed for but credit on which was availed in the next financial year within the period specified under Section 16(4) of the CGST Act, 2017.";

(d) in paragraph 7,–

(A) after the words and figures "April 2019 to September 2019.", the following shall be inserted, namely: -

"For FY 2019-20, Part V consists of particulars of transactions for the previous financial year but paid in the **FORM GSTR-3B** between April 2020 to September 2020.";

(B) in the Table, in second column,-

(I) against serial number 10 & 11, after the entries, the following entry shall be inserted, namely:-

"For FY 2019-20, Details of additions or amendments to any of the supplies already declared in the returns of the previous financial year but such amendments were furnished in Table 9A, Table 9B and Table 9C of **FORM GSTR-1** of April 2020 to September 2020 shall be declared here.";

(II) against serial number 12,-

(1) in the entry beginning with the word, letters and figures "For FY 2018-19" after the words "for filling up these details.", the following entry shall be inserted, namely:-

"For FY 2019-20, Aggregate value of reversal of ITC which was availed in the previous financial year but reversed in returns filed for the months of April 2020 to September 2020 shall be declared here. Table 4(B) of **FORM GSTR-3B** may be used for filling up these details. For FY 2019-20, the registered person shall have an option to not fill this table.";

(2) in the entry beginning with the word, letters and figures "For FY 2017-18" and ending with the words "an option to not fill this table.", for the letters, figures and word "FY 2017-18 and 2018-19", the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted;

(III) against serial number 13,–

(1) in the entry beginning with the word, letters and figures "For FY 2018-19" after the words, letters and figures "in the annual return for FY 2019-20.", the following entry shall be inserted, namely:-

"For FY 2019-20, Details of ITC for goods or services received in the previous financial year but ITC for the same was availed in returns filed for the months of April 2020 to September 2020 shall be declared here. Table 4(A) of **FORM GSTR-3B** may be used for filling up these details. However, any ITC which was reversed in the FY 2019-20 as per second proviso to sub-section (2) of section 16 but was reclaimed in FY 2020-21, the details of such ITC reclaimed shall be furnished in the annual return for FY 2020-21.";

(2) in the entry beginning with the word, letters and figures "For FY 2017-18" and ending with the words "an option to not fill this table.", for the letters, figures and word "FY 2017-18 and 2018-19", the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted;

(e) in paragraph 8, in the Table, in second column, for the letters, figures and word "FY 2017-18 and 2018-19" wherever they occur, the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted.

12. In the said rules, in **FORM GSTR-9C**, in the instructions,-

(i) in paragraph 4, in the Table, in second column, for the letters, figures and word "FY 2017-18 and 2018-19" wherever they occur, the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted;

(ii) in paragraph 6, in the Table, in second column, for the letters, figures and word "FY 2017 -18 and 2018-19" wherever they occur, the letters, figures and word "FY 2017-18, 2018-19 and 2019-20" shall be substituted.

13. In the said rules, in **FORM GST RFD-01**, in Annexure-1, in Statement-2, in the heading the brackets, word and letters "(accumulated ITC)**"**, shall be omitted.

14. In the said rules, in **FORM GST ASMT-16**, for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax Rate	Turnover	Tax Period		Act	POS (Place of Supply)	Tax	Interest	Penalty	Fee	Others	Total
			From	To								
1	2	3	4	5	6	7	8	9	10	11	12	13
Total												".

15. In the said rules, in **FORM GST DRC-01**, after entry (c), for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax rate	Turnover	Tax Period		Act	POS (Place of Supply)	Tax	Interest	Penalty	Fee	Others	Total
			From	To								
1	2	3	4	5	6	7	8	9	10	11	12	13
Total												**".**

16. In the said rules, in **FORM GST DRC-02**, after entry (c), for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax rate	Turnover	Tax Period		Act	POS (Place of Supply)	Tax	Interest	Penalty	Fee	Others	Total
			From	To								
1	2	3	4	5	6	7	8	9	10	11	12	13
Total												**".**

17. In the said rules, in **FORM GST DRC-07**, after serial number 5, for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax Rate	Turnover	Tax Period		Act	POS (Place of Supply)	Tax	Interest	Penalty	Fee	Others	Total
			From	To								
1	2	3	4	5	6	7	8	9	10	11	12	13
Total												**".**

18. In the said rules, in **FORM GST DRC-08**, after serial number 7, for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax Rate	Turnover	Tax Period		Act	POS (Plac+e of Supply)	Tax	Interest	Penalty	Fee	Others	Total
			From	To								
1	2	3	4	5	6	7	8	9	10	11	12	13
Total												**".**

19. In the said rules, in **FORM GST DRC-09**, for the table, the following table shall be substituted, namely:-

"Act	Tax/Cess	Interest	Penalty	Fee	Others	Total
1	2	3	4	5	6	7
Integrated tax						
Central tax						
State/UT tax						
Cess						
Total						".

20. In the said rules, in **FORM GST DRC-24**, for the table, the following table shall be substituted, namely:-

"Act	Tax	Interest	Penalty	Fee	Other Dues	Total Arrears
1	2	3	4	5	6	7
Central tax						
State/UT tax						
Integrated tax						
Cess						".

21. In the said rules, in **FORM GST DRC-25**, for the table, the following table shall be substituted, namely:-

"Act	Tax		Interest	Penalty	Fee	Other Dues	Total Arrears
1	2		3	4	5	6	7
Central tax							
State/UT tax							
Integrated tax							
Cess							".

".

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 Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide Notification No.3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R.610(E), dated the 19th June, 2017 and last amended vide Notification No.72/2020-Central Tax, dated the 30th September, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.603(E), dated the 30th September, 2020.*

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PARLIAMENT NEWS

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Import of Bulk Drugs/APIs

Lok Sabha Unstarred Question No: 423

Shri Sunil Baburao Mendhe:

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

(a): the details of imports of various Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for producing medicines during the last three years, year-wise;

(b): the total value of imports of such APIs from China during the said period;

(c): whether due to the outbreak of Coronavirus, the imports have been curtailed; and

(d): if so, the steps being taken by the Government to mitigate the shortage of such APIs?

Answered on 15th September 2020

A. (a): As per the available data received from various port offices of the Central Drugs Standard Control Organization, the details of imports of various Bulk Drugs/Active Pharmaceutical Ingredients (APIs) for

producing medicines during the last three years is given as under:-

Year Value	(in Rs crore)
2017-18	5097
2018-19	7066
2019-20	8247

(b): The total value of imports of such APIs from China during the said periods is as under.

Year Value	(in Rs crore)
2017-18	3497
2018-19	4701
2019-20	5970

(c): As per the available information from various port offices of the CDSCO, import of drugs has not been stopped due to outbreak of Corona virus. The CDSCO has not received any report of shortage of stocks at present with the manufacturers.

(d): Central Government has issued notification vide S.O. 2450(E) dated 27.07.2020 which is valid for 6 months providing that if a Registration Certificate holder makes an application for a fresh import registration certificate before the expiry of the existing certificate, the existing registration certificate shall be valid until orders are passed on the application & shall be deemed to be valid for all purposes. With a view to attain self-reliance and reduce import dependence in APIs/ Bulk drugs, the government has rolled out two schemes viz:

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

(ii): "Promotion of Bulk Drug Parks". The scheme guidelines were issued on 27th July, 2020.

Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

Impact of COVID-19 on Pharma Industry

Lok Sabha Unstarred Question No.427

Shri Manoj Kotak:

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

(a): whether the Government has made any assessment of the impact of COVID-19 pandemic on the country's Pharma industry in view of the fact that the country imports 70 percent of raw materials from China for manufacture of medicines;

(b): if so, the Government's plan thereof;

(c): whether the Government has any plan to support Pharma sector to source raw materials for drugs from other countries; and (d) if so, the details thereof?

Answered on 15th September 2020

A. (a) & (b): Many raw materials are imported from China, for manufacturing of medicine. As per available data from the various Port Offices of the Central Drugs Standard Control Organization (CDSCO), the details of the percentage of raw materials imported from China are as under:

Year	Percentage (in terms of value)
2017-18	68.62%
2018-19	66.53%
2019-20	72.40%

The reported restrictions on movement of people, lockdown enforced in various places, logistic issues, etc due to outbreak of Coronavirus in China could have impacted the supply of raw materials from China.

(c) & (d): Under the provisions of the Drugs and Cosmetics Rules, 1945 various sites of different countries are registered by the CDSCO for import of various Active Pharmaceutical Ingredients (API) which are used in the manufacture of drug formulations in the country. CDSCO is reviewing all such applications for import of APIs in an expeditious manner for which India is highly dependent on China. The Government assessed the impact of COVID-19 pandemic on the availability of Active Pharmaceutical Ingredients (API), intermediates and Key Starting Materials (KSM) for which India is critically dependent on China. Accordingly, an inter-ministerial Committee was constituted on 06.02.2020 to address the issue of drug security in the country. The committee submitted its report on 27.02.2020. The Committee observed that there are 58 APIs for which the country is heavily dependent on China. Further, a Technical Committee was also constituted on 02.03.2020 to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. The

Committee also examined the 58 APIs identified by the Drug Security Committee and recommended a scheme for 53 APIs.

On the basis of the recommendations of the committee, the Department has prepared two schemes for promoting domestic manufacturing of Bulk Drugs which were approved by Cabinet on 20.03.2020 viz Production Linked Incentive (PLI) scheme and scheme for Promotion of Bulk Drug Parks. Under the PLI Scheme, financial incentives shall be given based on sales made by selected manufacturers for 41 products which cover all the identified 53 APIs.

The new Schemes are expected to attract substantial investments, increase domestic production of KSMs, DIs and APIs and reduce the country's import dependence to a large extent.

Minister in the Ministry of Chemicals & Fertilizers (Shri D.V.Sadananda Gowda)

In Rajya Sabha

Research on Development of Vaccine For Coronavirus

Rajya Sabha Unstarred Question No. 282

Shri Mallikarjun Kharge:

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

(a): whether India's average overall global health security score continues to be very low compared to several developing countries, if so, the details thereof;

(b): whether India, and other countries are conducting research for developing medicine or vaccine for Coronavirus, if so, the status of outcome and details thereof; and

(c): whether the Government has signed or proposes to sign bilateral or multilateral agreement with other countries to find vaccine/drugs to prevent COVID-19, if so, the details thereof?

Answered on 15th September 2020

A. (a): The globally accepted score to gauge country's capacity to prevent, detect and respond to public health emergencies is mandated by International Health Regulations (IHR) and the scores reported by the World Health Orgainzation through the State party annual reporting tool, wherein India's all capacities average score is more than 78% (global average 64%). A copy of the IHR core capacity score is placed at Annexure. Government of India has not provided any data to GHR project for them to score Indian position in their overall global health security agenda. *(Annexure not reproduced here).*

(b): Yes, India is in the forefront of research for therapeutics, diagnostics and vaccines. Indian Council for Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), Department of Biotechnology (DBT) and Department of Science and Technology (DST) through academia, R&D labs, industry, startups and NGOs are researching on diagnostic kits, vaccines and therapeutics. A number of indigenous diagnostics kits – RTPCR, Antibody and ELISA have been developed and today we have an indigenous production capacity of more than 10 Lakh kits/day. A manufacturing zone was setup at AMTZ Vishakhapatnam to facilitate this process. New inexpensive, rapid and point of care diagnostic methods such as paper based strips and RT-LAMP have been also developed. A major focus has been on facilitating the development of COVID-19 vaccine. More than 30 vaccine candidates have been supported which are in different stages of development, 3 candidates are in advanced stage of Phase I/II/III trials and more than 4 are in advanced pre-clinical development stage. Thirteen Clinical Trials of repurposed drugs and harnessing of traditional knowledge using the modern medicine approach are building a portfolio of therapeutic options for Covid-19 patients. Phase 2 Clinical Trial of immunomodulator Sepsivac with Cadila on critically ill Covid-19 patients has been completed successfully and the Phase III trial will be initiated after regulatory approval. Phase 2 Clinical Trial of the first-ever phytopharmaceutical ACQH is with Sun Pharma is underway. One prophylactic trial of Aswagandha and three trials of Guduchi + Pippali; Yashtimadhu; and polyherbal AYUSH drug (AYUSH-64) are planned on moderately ill Covid19 patients. 5 COVID19 Biorepositories have been setup, which have collected more than 40,000 samples which have been made available to researchers and industry for developing diagnostics, therapeutics and vaccines.

(c): Special international consultations and project calls with USA, Australia, Czech Republic and

BRICS have been initiated by DBT and DST. India partnering with Coalition for Epidemic Preparedness Innovations (CEPI), along with Norway. For vaccine research Indian entities are collaborating with Oxford University, UK; Medical labs in USA and Europe and Thomas Jefferson University, USA with respect to several vaccines in Indian laboratories (Private or Public) and hospitals.

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

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CUSTOMS MATTERS

CBIC Appoints Commissioner (Customs Authority for Advance Rulings), at Delhi and Mumbai - reg.

Notification No.102/2020-Customs (N.T.), dated 23rd October, 2020

1. In exercise of the powers conferred by sub-section (1) of section 28EA of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Tax and Customs hereby appoints-

(i) Commissioner (Customs Authority for Advance Rulings), Delhi; and

(ii) Commissioner (Customs Authority for Advance Rulings), Mumbai, to function as Customs Authority for Advance Rulings, at Delhi and Mumbai, respectively.

2. This notification shall come into force with effect from a date to be notified.

F.No.450/110/2020-Cus IV

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

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GOVERNMENT NOTIFICATIONS

Aniline (Quality Control) Order, 2019 amended - reg.

Chemicals & Fertilizers Notification No. S.O.3796(E), dated 22nd October, 2020

(Published in the Gazette of India on 23rd October, 2020)

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

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

"(2) This order shall come into force on the **3rd May, 2021."**

F.No.C-II.13012/09/2018-Chem.II

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

Note: *The Principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide number S.O.203(E) dated the 15th January, 2020 and was subsequently amended vide Notification Number S.O.2180(E) dated 1st July, 2020.*

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Acetic Acid (Quality Control) Order, 2019 amended - reg.

Chemicals & Fertilizers Notification No.S.O.3799(E), dated 22nd October, 2020

(Published in the Gazette of India on 23rd October, 2020)

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

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

"(2) This order shall come into force on the **3rd May, 2021."**

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

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

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

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NEW DEVELOPMENTS

Salt bridge strategy expands access to Pharmaceutical Cocrystals

Scientists in Belgium have developed a new strategy for making combination drugs, using inorganic salts to glue different Active Pharmaceutical Ingredients together. This method could serve as a powerful tool for making unexplored multi-drug systems with enhanced therapeutic effects.

Combining multiple drugs into a singular dosage can improve patient compliance by reducing their pill load. Multi-drug co-crystallisation is one approach for achieving this goal; however, it is not without its hurdles. In particular, stability plays a significant role, as most compounds preferentially crystallise on their own rather than cocrystallising as a multi-component crystal. Now, Tom Leyssens from the Catholic University of Leuven (KU Leuven) and his colleagues have developed an imaginative strategy to overcome this challenge.

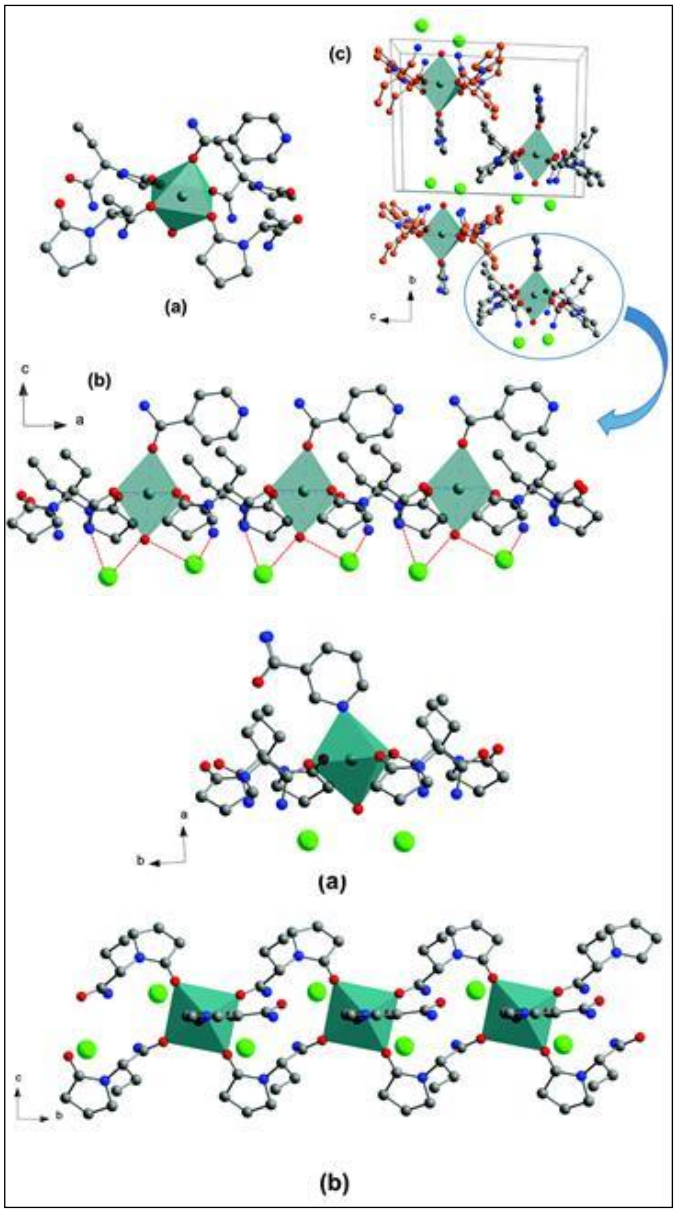
Their strategy creates ternary ionic cocrystals using an inorganic salt bridge to ensure that the intermolecular interactions in the multi-drug cocrystal are more stable that the parent crystals. This allows two drugs to cocrystallise that would not without the linker.

To test their approach the team combined anticovulsant drug levetiracetam and its racemic intermediate etiracetam, with nicotinamide – a form of vitamin B – and its isomer isonicotinamide, using CaCl as the inorganic linker. While each of the four Pharmaceuticals was able to form a binary crystal with CaCl , they found that without, CaCl, levetiracetam or etiracetam would not cocrystallise with nicotinamide or isonicotinamide. Only three of the four potential ternary cocrystals formed successfully. Interestingly, CaCl is unable to link etiracetam and nicotinamide, highlighting the important effect of chirality on the formation of stable cocrystals.

'This strategy will be very useful for a pair of drugs which do not have the direct connecting sites or cannot form into stable cocrystals,' comments team member Lixing Song. 'For example, many drug molecules consist of nitrogen electron-rich groups, such as pyrrolidinone, pyridine or pyrimidine, which all are hydrogen-bonding acceptors, therefore, they cannot cocrystallise successfully. The inorganic salts can serve as the bridge to couple them together.'

To explore the potential of dual-drug ternary ionic cocrystals, the team investigated the solubility of the ternary drug compounds relative to the parent drugs. Mino Caira, Director of the Centre for Supramolecular Chemistry Research at the University of Cape Town in South Africa, says 'it is interesting to note that for the particular systems investigated in the study, the presence of trace water is crucial for the formation of

the desired products, a phenomenon that has been observed previously in other areas of synthetic chemistry.'



Pharmacist Katharina Edkins, of the University of Manchester in the UK, who specialises in the Pharmaceutical solid state, calls the approach interesting and imaginative. 'Whilst the presented combination of model compounds is not directly translatable into a Pharmaceutical product, this study shows a novel approach to generate combination preparations for the treatment of multi-morbid patients. I am looking forward to seeing this approach applied to pharmaceutically relevant drug and dose combinations.'

The team recognises these concerns, however they say that they have used an excellent model system and shown that non-covalent bonding through a central inorganic cation can allow cocrystallisation of two chemically different drug molecules. In the future, the group intend to test their strategy on new and realistic multi-drug systems, and conduct further research into the Pharmacokinetics and Bioavailability of ternary ionic cocrystals.

Source: The Royal Society of Chemistry, Chemistry World, 21.10.2020 (Excerpts)

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This cancer drug can help in Covid-19 treatment

Researchers in the US have discovered that an experimental cancer drug called AR-12 inhibits the Covid-19 virus from infecting cells and replicating.

AR-12 has been studied extensively as both an anti-cancer and anti-viral drug and showed that it is effective against viruses including Zika, mumps, measles, rubella, chikungunya, drug-resistant HIV and influenza.

"AR-12 works in a unique way. Unlike any other anti-viral drug, it inhibits cellular chaperones, which are proteins that are required to maintain the right 3D shape of viral proteins," said study author Paul Dent from the Virginia Commonwealth University in the US. "The shape of the virus is critical to its ability to infect and replicate," Dent added.

According to the study, published in the journal Biochemical Pharmacology, one of the cellular chaperones inhibited by AR-12 is GRP78, which is essential for the reproduction of all viruses. GRP78 acts as a sort of cellular stress sensor and is required for the life cycle of all mammalian viruses. Researcher Andrew Poklepovic, who is leading efforts to translate these exciting findings into a Clinical Trial, said: "AR-12 is an oral therapy that has been well-tolerated in a prior Clinical Trial, so we know that it is safe and tolerable.

"Most Covid-19 drugs are given intravenously, so this would be a unique therapeutic option and potentially suitable for outpatient therapy, similar to the way one would take an antibiotic," Poklepovic added. Poklepovic hopes to begin enrolling patients in early 2021, but several mile stones remain. "For help reaching these significant milestones and moving forward with this research at the accelerated pace that we know is needed, we turned to our colleague at Massey, Said Sebti, who has extensive experience in drug development," said Poklepovic.

"We are working to submit the required information for US FDA approvals, and we are also in discussions with a local pharmaceutical company to manufacture the drug for the trial," the study authors wrote."We are hopeful that AR-12 will emerge as a treatment option for patients suffering from COVID-19, ultimately saving lives and contributing to the global pandemic solution, "they noted.

Source: IANS, ET-Health World, 22.09.2020

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NATIONAL NEWS

Finance Ministry issues Guidelines for implementation of interest waiver on loan

Finance Minister Nirmala Sitharaman

In a festival gift to borrowers, the Finance Ministry on Wednesday, 21.10.2020 approved Guidelines for a scheme for grant of ex-gratia payment of the difference between compound interest and simple interest for six months of loans up to Rs.2 crore. The Guidelines came after the Supreme Court directed the Centre to implement "as soon as possible" interest waiver on loans of up to Rs.2 crore under the RBI moratorium scheme in view of the COVID-19 pandemic.

As per the operational Guidelines issued by Department of Financial Services, the scheme can be availed by borrowers in specified loan accounts for a period from March 1 to August 31, 2020. "Borrowers who have loan accounts having sanctioned limits and outstanding amount of not exceeding Rs.2 crore (aggregate of all facilities with lending institutions) as on February 29 shall be eligible for the scheme," it said.

Housing loan, education loans, credit card dues, auto loans, MSME loans, consumer durable loans and consumption loans are covered under the scheme. As per the scheme, the lending institutions shall credit the difference between compound interest and simple interest with regard to the eligible borrowers in respective accounts for the said period irrespective of whether the borrower fully or partially availed the moratorium on repayment of loan announced by the RBI on March 27, 2020.

The scheme is applicable on those who have not availed the moratorium scheme and continued with the repayment of loans. The lending institutions after crediting the amount will claim the reimbursement from the central Government. According to sources, the Government will have to shell out Rs.6,500 crore for the implementation of the scheme.

Hearing the matter on October 14, the Supreme Court observed that it was concerned about how the benefit of interest waiver would be given to borrowers and said the Centre has taken a "welcome decision" by taking note of plight of the common man, but authorities have not issued any order in this regard. "Something concrete has to be done," a Bench Headed by Justice Ashok Bhushan had said, adding, "Benefits of waivers to borrowers up to Rs.2 crore must be implemented as soon as possible."

The top court, which posted the matter for hearing on November 2, told the advocates appearing for the Centre and banks that "Diwali is in your hand". The Centre recently told the apex court that going any further than the fiscal policy decisions already taken, such as waiver of compound interest charged on loans of up to Rs.2 crore for six months moratorium period, may be "detrimental" to the overall economic scenario, the national economy and banks may not take "inevitable financial constraints".

The top court is hearing a batch of petitions which have raised issues concerning the six-month loan moratorium period announced due to the COVID-19 pandemic. The bench, also comprising Justices R S Reddy and M R Shah, said when authorities have decided something then it has to be implemented.

Source: www.moneycontrol.com, 26.10.2020

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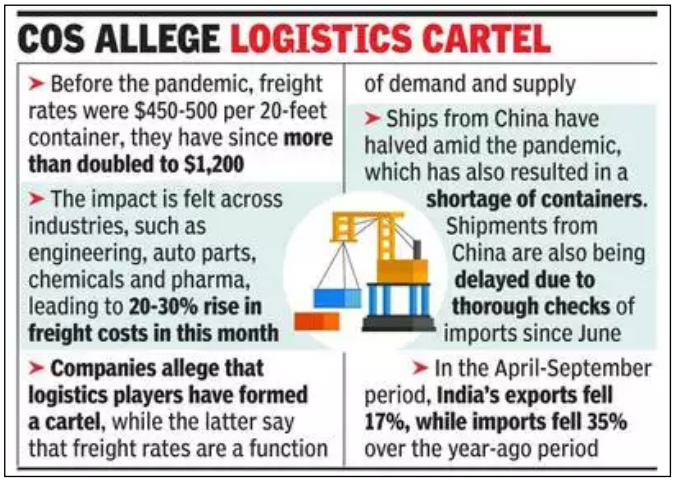
Trade hit by record 60% surge in freight

Trade, both exports and imports, has been badly impacted over the last few weeks after sea freight charges saw one of the highest ever increases of 60% in recent times. The development came after shipping companies hiked rates substantially. To make matters worse, exporters are facing a massive shortage of containers due to lower imports over the last few months.

The cost impact is being felt across industries such as engineering, auto components, chemicals, pharma and devices. There has been an increase in freight costs of 20-30% in October alone. Air freight is also up by 30-40% owing to reduced overseas flights due to the pandemic. For importers, it's a double whammy — in the wake of the increased freight rates, there is a higher outgo in terms of duties, which will impact companies' margins in future, industry experts told.



Federation of Indian Export Organisations (FIEO) President Sharad Kumar Saraf told, "Exports are affected more by sea freight, in which there is a 60% increase in rates for main European ports over the last six months. Similarly, freight rates to Latin American ports have increased by 50%, and for the US it is being increased regularly since February. This is an unprecedented increase and a clear indication of a monopolistic and unfair trade practice."

Freight rate for October has risen sharply from $300 to $800 (per 40ft full container load), particularly for Middle East, European, North and South American ports. Availability of containers has further worsened even at regular ports like Mundra and Nhava Sheva, while the situation in inland container depots is worse. "There is also a huge hold-up of shipments at ports, resulting in inordinate delays and cost-escalation (for industry). Imports are subjected to thorough checks," Pharmaceutical Export Promotion Council of India (Pharmexcil) Chairman Dinesh Dua said. The clearance of shipments currently takes 15-20 days as against nearly a week earlier. This is also being attributed to faceless assessment at ports. Raising the issue with the Government, the industry has sought a regulatory body for shipping companies operating from domestic ports, according to a letter to the Directorate General Shipping.

The letter, a copy of which is with TOI, adds, "Shipping lines are increasing freight (rate) in fortnightly or monthly intervals consistently since July. Besides the increase, the shipments are getting delayed as the vessels are going full. Shipping companies are able to increase the freight by forming cartels." Industries across the board are worried.

"Both air and sea freight have gone up over the last few months, which may have an impact on companies," Indian Drug Manufacturers' Association (IDMA) National President Mahesh H Doshi said. Logistics Company Maersk's MD (South Asia) Steve Felder said, "Freight rates are a function of demand and supply, and they vary based on how these two change. Clearly, Equipment shortages impact supply and we are constantly looking to manage it.

In recent months, we have seen a general shortage of equipment in the market due to an imbalance between imports into and exports out of India. However, our goal is to ensure that we can help our customers in enabling their trade. With exports rising from different parts of the country, we need to position empty containers accordingly across India, thus adding up to the overall cost of logistics."

Source: Rupali Mukherjee, The Times of India, 22.10.2020 (Excerpts)

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BDR Pharma launches generic cancer drug in India

BDR Pharmaceuticals on Wednesday, 21.10.2020 said it has launched the generic version of Lenvatinib drug for the treatment of various types of cancers in India. The generic version of the drug has been launched under the brand name 'Bdfoie' in the country.

The capsules are used for the treatment of differentiated thyroid cancer, advanced liver cancer and advanced kidney cancer, BDR Pharma said in a statement. The results of Clinical Trials showed encouraging results with safety and efficacy on patients with aggressive tumours, it added. The drug is priced at Rs.1,620 (4 mg) and Rs.2,970 (10 mg) for a pack of 10 capsules, the statement said.

"By launching cost-effective therapy options we want to mitigate the challenges faced by Indian patients in seeking access to treatment and finding a timely cure for life threatening diseases," BDR Pharmaceuticals CMD Dharmesh Shah said.

Source: PTI, ET-Health World, 22.10.2020

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AIOCD urges PM to utilize its established supply chain for COVID-19 vaccine distribution

The All India Organisation of Chemists and Druggists (AIOCD) has written a letter to Prime Minister Narendra Modi requesting to utilize the established drug supply chain of the Organisation for vaccines distribution through its around 8.5 lakh Chemists in the country. The AIOCD has also requested the PM to advise concerned Ministries and Departments to issue Guidelines for use of their channel members to distribute COVID-19 vaccines.

"Our country is passing through challenging situations of COVID-19 pandemic. Under your able leadership, crores of Indian citizens have successfully kept fighting against the onslaught like pandemic during the last seven months. We, the 8.5 lakh members of the AIOCD, assured you during an online meeting with the President of AIOCD that our members will actively support by making medicines available without any interruption," stated AIOCD General Secretary Rajiv Singhal in a letter to the PM. Singhal added, "We are proud that our members worked like warriors and maintained smooth supply of essential medicines throughout the country in spite of threats of being infected."

AIOCD, President J S Shinde added, "We appreciate and are grateful to our scientists and pharmaceutical companies for successful development of COVID vaccines. AIOCD brings to the notice of the Prime Minister that vaccines require an unpororus line of cold chain, right from production point to delivery/administration of dose to a person.

So far, all kinds of vaccines have been successfully distributed by our members year-on-year. All required infrastructure is available with the trade members to manage intact cold chain with experience." The AIOCD stated, "We assure our best services to reach out to common citizens in the nook and corner of our country." AIOCD is an apex body of about 8.5 lakh members involved in sale and distribution of medicines across the country.

Source: Yash Ved, Pharmabiz, 23.10.2020

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Anti-parasitic drug ivermectin not to be included for Covid-19 treatment protocol: Health Ministry

The Union Health Ministry has decided not to include ivermectin medicine (anti-parasitic drug) in the National Clinical Management Protocol for Covid-19 for the treatment of virus-infected patients. The move comes after the Central Government's National Task Force for Covid-19 and the Health Ministry's Joint Monitoring Group (JGM) chaired a meeting on Thursday, 22.10.2020 to discuss if the anti-parasitic drug should be included in the national treatment Guidelines or not.

A Government official said, "Many states, for example--Uttar Pradesh, are utilising the drug as off label for treatment purpose and also for prophylaxis use against Covid-19. Now, it has been decided not to recommend ivermectin medicine in the National Clinical Management Protocol for Covid-19 as there is not enough safety and efficacy evidence as per the randomised trials held across the world."

Ivermectin medicine is an inexpensive and safe drug that is used for the treatment of intestinational parasites and scabies. In the fight against Covid-19, the Union Health Ministry has approved the use of several drugs in the treatment of Coronavirus with subject to conditions in the Clinical Management Protocol for Covid-19.The Central Government has already recommended the use of--Remdesivir under "investigational therapies" only for restricted emergency use in moderate Covid-19 cases.

Another drug called--tocilizumab is being used as off-label for the treatment of Covid patients. Meanwhile,

anti-malaria drug Hydroxychloroquine (HCQ) is being utilised inpatients during the initial stage of infection.

Source: ANI, ET-Health World, 23.10.2020

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Government to conduct workshops for regulators and manufacturers on latest technologies for vaccine development

The Union Health Ministry is planning to conduct workshops for regulators and manufacturers in the country for understanding latest technologies for vaccine development. The latest in the series is coding process using MedDRA terminologies which has under its scope products related to vaccines, pharmaceuticals, biologics and drug-device combination products. The terminology is used through the entire regulatory process from pre-marketing to post-marketing, and for data entry, retrieval, evaluation and presentation.

MedDRA is a Clinically-Validated international medical terminology developed under the auspices of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and is used by regulatory authorities and the regulated biopharmaceutical industry. ICH, formerly the International Conference on Harmonisation (ICH), has a 25-year track record of successful delivery of Harmonised Guidelines for Global Pharmaceutical Development as well as their regulation, and a longer standing recognition of the need to harmonise.

The need to harmonise was realized as it was important to have an independent evaluation of medicinal products before they are allowed on the market was reached at different times in different regions. However in many cases the realisation was driven by tragedies, such as that with thalidomide in Europe in the 1960s.

This comes close on the heels of Union Health Ministry also planning to strengthen Pharmacovigilance systems for vaccine Adverse Drug Reaction (ADR) in collaboration with global regulators, Pharmacovigilance Programme of India (PvPI) and immunization programme of India to meet the requirements for reporting vaccine ADRs. "This collectively will be instrumental in achieving vaccine pharmacovigilance right from collecting to coding and finally sending Individual Case Safety Reports (ICSRs) to PvPI," according to an official associated with the development.

Prime Minister Narendra Modi during his keynote speech at the inauguration of Grand Challenges meeting 2020 recently also reiterated that Government is also putting in place a digitised network to deliver the vaccine to its citizens. "This digitised network along with digital health IDs will be used to ensure immunisation of our citizens," he emphasized.

Grand Challenges, which was launched in 2003 by Bill Melinda Gates foundation, fosters innovation to solve key challenges in global health and development. The initiative focuses on fourteen major challenges including vaccine development, development of needle free delivery system for the vaccine, cure for chronic infections among others.

At the inaugural session, Bill Gates also stressed the need for research into three vital fields to remain prepared for the next pandemic – development of vaccine platforms so that vaccines against new infections can quickly be developed and manufactured, monoclonal antibodies and more effective ways of manufacturing it quickly for a pandemic situation and diagnostic platforms that are sensitive and specific and widely available so that huge number of people can be tested and accurately diagnosed.

Vaccine Safety workshop on 'Literature Search and Synthesis on Vaccine Safety' was also organised by World Health Organization (WHO) - India in New Delhi last year to enhance the understanding of all stakeholders on literature search and synthesis on vaccine safety.

Source: Shardul Nautiyal, Pharmabiz, 22.10.2020

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IPC to amend blood thinner Heparin Sodium Monograph in IP 2018

The Indian Pharmacopoeia Commission (IPC) will soon amend the heparin sodium monograph in IP 2018 following an appeal from stakeholders. The decision to this effect was taken by the IPC at a meeting held on September 23, 2020. The meet was attended by IPC officials—Dr Jai Prakash, Senior Secretary-cum-Scientific Director, Dr M Kalaivani, Senior Scientific Officer, Dr Gaurav Pratap Singh, Senior Scientific Officer, Anubhuti Goyal, Scientific Assistant, Sargam Verma, Technical Associate, Rajesh Verma, Assistant Drugs Controller (Biological) at CDSCO, National Institute of Biologicals (NIB) officials, Central Drug Testing Laboratory (CDTL), Mumbai officials, and

Dr Ranjeet Ajmani, Chief Executive Officer, PlasmaGen Biosciences, Bengaluru.

Heparin, a common anti-coagulant drug (that reduces blood clots from forming in the body), is used in treating COVID-19 patients. It is included in the "Guidelines on Clinical management of COVID-19", released by the Directorate General of Health Services, Ministry of Health & Family Welfare. The blood-thinning drug has reduced hospitalisation rates, improved recovery rates, and even reduced the rate of sudden deaths by 90 percent.

At the meet, stakeholders requested for amendment only in heparin sodium monograph not in heparin injection monograph of IP 2018, as amendment in potency value of the bulk does not have any impact on usual strength of injection. Currently, there are two potency value of heparin sodium mentioned in its monograph in IP 2018 i.e. a potency of not less than 180 IU per mg in parenteral preparations containing heparin sodium and a potency of not less than 120 IU per mg in non-parenteral preparations containing heparin sodium.

With the proposed amendment to heparin sodium monograph in IP 2018, a potency of not less than 150 IU per mg in parenteral preparations containing heparin sodium will be included in the monograph. The data/supporting documents (certificate of analysis Brazilian manufacturers) submitted by Biological E Ltd and Bacto Chem Lab supports the potency value of not less than 150 IU/mg.

The manufacturers have expressed difficulty in achieving the potency value of not less than 180 IU/mg in parenteral preparations comprising heparin sodium, said a Senior Scientific Official at IPC. At present, heparin sodium monograph in IP 2018 mentions that heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 180 IU per mg and heparin sodium not intended for the use in the parenteral preparation contains not less than 120 IU per mg, calculated on the dried basis.

Once the proposed amendment is introduced to heparin sodium monograph, it will read as follows, "Heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 180 IU per mg for Heparin obtained from the intestinal mucosa or other suitable tissues of domestic mammals used for food by man except bovine source. Heparin sodium intended for use in the manufacture of parenteral preparation contains not less than 150 IU per mg obtained from the intestinal mucosa or other suitable tissues of bovine and heparin sodium not intended for the use in the parenteral preparation contains not less than 120 IU per mg, calculated on the dried basis."

At present heparin sodium monograph mentions method A to perform assay test to the bulk drug obtained from porcine/ bovine sources. With the proposed amendment, method B will be reintroduced to the monograph of heparin sodium in IP 2018 to perform assay test to the bulk drug obtained from bovine source. Thus assay using method A or B can be performed on heparin sodium obtained from bovine source. For heparin sodium obtained from porcine source, assay using method A is required to be performed.

Earlier heparin sodium monograph in IP 2014 contained method B to perform assay test to the bulk drug, it was not included in IP 2018 following stakeholders' request. The method B comprises assay, method of assay such as test solution, reference solution, preparation of plasma etc. As per the assay mentioned in method B, the potency of heparin sodium can be determined by comparing the concentration necessary to prevent the clotting of sheep or goat or human plasma with the concentration of the reference solution of heparin sodium necessary to give the same effect.

The proposed amendment will be introduced to heparin sodium monograph in IP 2018 after receiving suggestions from the industry stakeholder, stated the senior scientific official.

The stakeholder is required to submit comparative data of chromogenic method and clotting method for at least 25 batches within three months to IPC for further discussion, the official said. Three out of four manufacturers of heparin sodium bulk drug are manufacturing from bovine source in India. Five importers are importing porcine heparin sodium from other countries. The dependency on China is more for importing heparin sodium.

Source: Laxmi Yadav, Pharmabiz, 22.10.2020

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Russian Sputnik V Covid-19 vaccine to be tested on 100 Indian Volunteers

The Russian Sputnik V vaccine against Covid-19 will be tested in India on 100 volunteers, the Indian Central Drugs Standard Control Organisation's Drug Controller General

(DCGI) told Sputnik on Thursday, 22.10.2020. DCGI has granted permission to pharmaceutical giant Dr Reddy's Laboratories for conducting tests. However, the date and time of the test will be determined by the company.

Sputnik quoted the organisation as saying that the vaccine will be tested in the second phase of its Clinical Trials before moving on to phase 3. Last week, the expert committee of DCGI had recommended granting permission to Dr Reddy's Laboratories for conducting phase 2 Clinical Trials of Russian Covid-19 vaccine candidate, Sputnik V, in India.

According to a Government official, Dr Reddy's Lab has stated that in phase 2 Clinical Trial--"would include 100 subjects and for phase 3, it would take 1400 subjects. "Once the Pharma company would submit the safety and immunogenicity data of phase2, it would be analysed by the expert panel and then they can proceed for the phase 3 trial," the official added.

On October 13, ANI had reported that Dr Reddy's Laboratories re-applied fresh protocol to DCGI in order to seek its approval for conducting phase 2 and 3 Clinical Trials of the Russian Covid-19 vaccine. It may be noted that on October 5, the Subject Expert Committee (SEC) had done a thorough evaluation of the previous application submitted by Dr Reddy's lab. Thereafter, the SEC had directed the Pharma company to apply with a revised protocol along with more information.

The Indian drug maker has joined hands with the Russian Direct Investment Fund (RDIF) to conduct Clinical Trials of the Sputnik V vaccine as well as its distribution. As per the RDIF, it will supply 100 million doses of its potential Covid-19 vaccine to India drug company Dr Reddy's Lab. Last month, Kirill Dmitriev, CEO, RDIF informed that Russia is in close dialogue with the Indian Government and drug manufacturers of India regarding localisation of production of its Sputnik V vaccine in India.

Also, a prestigious medical journal *The Lancet* had published the results of Clinical Trials of Phase I-II of the Russian vaccine demonstrating its safety and efficacy. On August 11, the Sputnik V vaccine candidate developed jointly by RDIF and the Gamaleya National Research Center of Epidemiology and Microbiology was registered by the Ministry of Health of Russia and became the world's first registered vaccine against Covid-19. According to Russian researchers, Sputnik V is a human adenoviral vector vaccine that fights against Coronavirus disease.

Source: ANI, ET-Health World, 23.10.2020

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Addition of 41 new AMCs during lockdown helped Clinicians Practice Evidence-Based Medicines to tackle COVID-19: Dr Y K Gupta

Addition of 41 new ADR Monitoring Centres (AMCs) under PvPI during lockdown period immensely helped healthcare professionals to practice evidence-based medicines to tackle COVID-19, according to Dr Y K Gupta, National Scientific Coordinator, Pharmacovigilance Programme of India (PvPI).

With the setting up of new 41 Adverse Drug Reaction (ADR) Monitoring Centres (AMCs), currently the total count of 311 AMCs also provided a base to take regulatory decisions on the basis of the safety profile of drugs during the challenging times in COVID-19 pandemic, he further added. PvPI has been expeditiously analyzing safety profile of medicines used for prophylaxis and the treatment of COVID-19 infection and recommendations in terms of Package Insert Leaflet (PIL) update and drug safety alerts are regularly shared with Central Drugs Standards Control Organization (CDSCO).

It has also been learnt that online training activities for all stakeholders have already been initiated and the task force at PvPI is also arranging online trainings and workshops for Market Authorization Holders (MAHs), NABH accredited hospitals and other stakeholders to ensure capacity building in Pharmacovigilance. Dr Gupta further added, "PvPI took prominent actions for reporting of ADRs on account of emergency use of different medicines in prophylaxis and treatment of COVID-19 infection. PvPI tools such as Toll free Helpline number - 1800-180-3024 and android mobile app 'ADR PvPI' made available for all stakeholders to report the safety issues of medicines."

The Ghaziabad-based Indian Pharmacopoeia Commission (IPC) which is the national co-ordinating centre (NCC) for PvPI had earlier chalked out its plan to increase AMCs from the current 270 AMCs to 300 AMCs by the end of the financial year in March 2020. CDSCO under the Union Health Ministry had initiated a nation-wide PvPI in July 2010.

According to Dr Jai Prakash, Secretary-cum-Scientific Director, IPC, Ghaziabad, "AMC Personnel, industry stakeholders and multidisciplinary experts will continue providing credible data to rely upon and to boost the public confidence in the safety of medicines. PvPI took lead in responding to the emerging challenges of medicine safety during the COVID-19 pandemic and rolled out the newly devised suspected ADR reporting form for the drugs used in the treatment and prophylaxis of COVID-19 infection."

IPC has also formally started functioning as WHO collaborative centre for PV since 2017 to support World Health Organization (WHO) member countries in establishing pharmacovigilance programme (PV). IPC-PV division has been assigned the status of WHO collaborating centre which will help promote medicine safety not only in India and globally but will also provide Guidelines and support in policy decision making process of WHO.

IPC has also been assigned to update information on ADRs that is being reported in India from across all its centres through Vigiflow software to the Uppsala Monitoring Centre (UMC) in Sweden, which is WHO's collaborating centre for international drug monitoring. This will help PvPI to share WHO responsibility on expanding the scope of PV for the global population and effective integration of PV with national health programmes globally and in India.

Source: Shardul Nautiyal, Pharmabiz, 22.10.2020

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JSS Hospital, Mysuru to conduct Phase II and III Trials on Russian COVID-19 vaccine Sputnik

JSS Hospital, Mysuru, a WHO approved vaccine site and armed with experience of such related human studies, is all set to conduct the Russian COVID-19 vaccine Sputnik trials. The hospital was approached by Dr Reddy's to carry out the Phase II and III human studies.

The hospital with 1,800 beds is already getting ready to start the Serum Institute of India's Clinical Trials for phase 2 and 3 of its vaccine candidate Novavax. All the paper work is ready for both Sputnik and Novavax vaccines. The latter is expected to commence any time now, Dr B Suresh, Pro-Chancellor, JSS Academy of Higher Education and Research, which manages the JSS Hospital, told.

For us, Sputnik vaccine is an extension of the ongoing vaccine human studies. We have gathered sufficient experience in conducting such trials and have the efficient systems and the medical expertise to complete and submit the study data, he added. It was only last week that Hyderabad based Dr Reddy's Laboratories and Russian Direct Investment Fund (RDIF), Russia's sovereign wealth fund, received approval from the Drug Control General of India (DCGI) to conduct late-stage Clinical Trials for Sputnik vaccine in India. The multi-center and randomized controlled study, will include safety and immunogenicity studies.

The Sputnik vaccine was developed by Gamaleya National Research Institute of Epidemiology and Microbiology. Last month, Dr Reddy's and RDIF entered into a partnership to conduct Clinical Trials of Sputnik vaccine and its distribution in India. As part of the partnership, RDIF will be supplying 100 million doses of the Sputnik vaccine to Dr Reddy's upon regulatory approval in the country.

Both Dr Reddy's and RDIF had in the beginning planned to conduct only a phase 3 trial of the vaccine. However, the Subject Expert Committee (SEC) of the Central Drugs Standards Control Organization (CDSCO) asked the Hyderabad-based Pharma major to carry out a systematic phase 2 and 3 Clinical Trials in India, instead of just a phase 3 study. This was because the safety and immunogenicity data in overseas phase I/II studies was small and there was no data available on Indian subjects.

Dr Suresh said the authorities of Dr Reddy's Laboratories have approached the hospital to conduct the II and III phase study with Sputnik vaccine. This is even as the Clinical Trials on Covishield of the Oxford AstraZeneca vaccine is already in progress. "The subject enrolment for COVID-19 vaccine Covishield was not easy as only those familiar with the system volunteered.

This is unlike BA/BE studies for a known drug which needs to be developed into a formulation, where subjects

come forward. The COVID-19 vaccine trial is an entirely new drug so people are given complete information on its impact and an agreement of confidentiality is recorded on their consent. However there have been no challenges during this particular study", said Dr Suresh.

Source: Nandita Vijay, Pharmabiz, 22.10.2020

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This startup is helping Pharma Companies go digital to promote drugs, including Remdesivir

A large Indian drug maker which had launched anti-viral drug Remdesivir for COVID-19 treatment, is in a dilemma over how to pitch the brand to doctors. The company is competing with five other brands. Fielding sales representatives on ground to meet the doctors and hospitals was quite risky during COVID. That's when it reached out to Delhi-based digital marketing technology startup, Doceree, to roll out the launch campaign digitally.

It isn't this company alone. Another leading Indian Pharmaceutical company has decided to stop deploying sales representatives to promote an old legacy brand, and go completely digital. They relied on Doceree to promote the brand. The brand reinforcement campaign they launched on the Doceree platform was a success, as the sales of the brand grew, compared to last year.

Launched in March, Doceree says it is already working with seven top 10 big Pharmaceutical companies to roll out their brand promotion campaigns. Doceree says that the cost for a campaign on its platform was just a fraction of what companies would have originally spent.

COVID accelerates digital marketing:

The COVID-19 outbreak has accelerated the adoption of digital marketing by pharmaceutical brands as the traditional approach of reaching out to doctors via sales representatives don't work due to safety reasons. "Companies want continuous engagement with doctors. They don't want to lose touch with them. Also, Pharma companies found that the brand doesn't have any relationship with doctors, and it is the sales reps who have that," said Harshit Jain, Founder & CEO, Doceree. Jain, a Doctor-cum-Marketing-Specialist, founded Doceree along with Daleep Manhas, who was Country Head at McCann Health India.

But there are challenges. While the traditional approach of advertising through sales representatives is highly targeted, it isn't the same with digital campaigns. Digital campaigns have limitations in assessing whether the ad reached the intended doctors and there is no visibility on the campaign progress. "Pharma marketers went to independent platforms like Lybrate or DocPlexus to run some form of campaign. They are still very platform-centric. They don't know which doctors they are targeting," Jain said. "We are aggregating all professional platforms all over the internet, so that brands can now target specific doctors instead of platforms," he added.

How does it work?

Doceree uses a proprietary identity resolution technology called ESPYIAN, which helps create a database of verified and authentic medical and healthcare professionals. To get that information, the company partners with over 100 professional platforms such as journals, telemedicine platforms, large specialty doctors networks and media outlets for advertisements. Some of the names include Medscape, Radiopaedia, ResearchGate, DocPlexus, DoctorForMe, MediNexus, GoDoctr, MediMetry, Cureus and Medical Joyworks. "For instance, we partner with a platform like (knowledge-sharing platform) DocPlexus. DocPlexus collects the data from physicians. The information is shared in an encrypted form, as per data compliance regulations. Only when the person is identified as a physician, we display Pharma brands. In return, DocPlexus makes some money for every ad displayed," Jain said.

Jain said there isn't big competition in this space, as even the likes of Google don't allow advertising of Pharmaceutical drugs, leaving a gap for them to leverage. "Google is present across all categories, except pharmaceutical drugs, because this category requires customisation. All other categories behave in a similar manner. This category has a lot of regulations and customization," Jain said. "We understand Pharma is a regulated category, and the regulation suggests that any communication for a prescription drug should only be visible to verified healthcare practitioners," he added.

Doceree charges Pharma companies through subscription fees. The packages cost anywhere between Rs.5 lakh to Rs.11 lakh annually. Jain says Doceree provides full transparency. "If companies have spent Rs.5,000, how many doctors did they reach out, how many times, how many clicks they got in real time? The marketers have a real-time dashboard. They can see what's happening and

can take action. If some campaign is not doing well, they can abort the campaign, tweak their campaign and make it alive again," Jain said.

Skyrocketing growth:

As of last month, Doceree has 72 brands, and 300 campaigns on its platform. Jain said Doceree has been growing month-on-month by 100 percent, and hired 25 people in the last three months to support its growth momentum. Doceree is seeing 30 million impressions per month. Jain says there is still a huge room for growth. "About 25 percent total revenues of the brand are invested in marketing. Out of that, only 3-5 percent is invested in digital. A consumer brand spends about 50 percent of their advertising budget on digital," he said.

Jain added that the company is planning to raise about $10 million in Series-A round. The startup, in March, had raised seed capital of $1.25 million. "We are in active conversation with large fund houses," he said. The funds will be utilised to launch Doceree Services in Japan. The company is currently present in India and the US.

Source: Viswanath Pilla, Money Control, 21.10.2020

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True Masterpiece - Assam Artist makes Durga Idol from 30,000 expired Capsules and Syringes

- *Pandals with themes are a common trend in Durga Puja.*
- *This year, while many used the COVID theme, an artist who hails from Dhubri, Assam, used medical waste to make an idol of the Goddess.*
- *Sanjib Basak took 2 months to make a Maa Durga idol and he did with more than 30,000 expired capsules and syringes.*

Pandals with themes are a common trend in Durga Puja. This year, while many used the COVID theme, an artist who hails from Dhubri, Assam, used medical waste to make an idol of the Goddess.

Sanjib Basak took 2 months to make a Maa Durga idol and he did with more than 30,000 expired capsules and syringes.

Basak works with the Disaster Management Department in Dhubri, saw medical stores getting rid of their expired medicines stocks.

"Often, shopkeepers give expired medicines back to the company. But, this time, because of the lockdown, they could not do so. Hence, there was a lot of waste stock," he said while talking to Indian Express.

This prompted him to use those expired medicines and syringes and make an idol.

Source: Somak Adhikari, www.indiatimes.com, 22.10.2020

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Why the Pharma industry needs monitoring tech for its cold storage products

Adapting to industry 4.0, especially in light of the demands of a global pandemic, means that pharmaceutical and other life-science industries are more aware than ever of the importance of wireless and cloud computing technology and the benefits that they provide.

Adopting new processes in the Pharmaceutical industry can be slow; there are lives at stake, not just profits, should the cons outweigh the pros. But the most obvious benefit of cloud-based technology is increased efficiency, as well as the reduction in operating costs associated with streamlined processes. While for many cyber security may be their first concern, IT teams work diligently to protect processes and keep data safe, with the added benefit of enabling reliable supply chain visibility.

Cloud computing is used for various tasks across the pharmaceutical industry, from streamlining global Clinical Trial data analysis to monitoring patient preferences. One such area that requires the efficiency and visibility that cloud-based solutions provide is temperature and inventory monitoring of pharmaceutical products.

Web-based, automated tracking and recording of temperature and inventory data ensures that products are safely stored and kept in stock, as well as companies being protected from theft and counterfeiting with products being tracked at every step. Eithicheck's Matos Plus Cloud models and Matos Wireless Monitoring solutions are such examples of technology being developed to meet this demand from the pharmaceutical industry.

The Matos Plus Cloud solution builds on the benefits of the Matos Plus Eco series – a European - manufactured range of purpose-built medical and vaccination refrigerators, freezers and thermostatic chambers that offer fast cool-down, a PID microprocessor controller with LCD display, auto-diagnostics, automatic defrost capabilities, fan control for reliable temperature maintenance, and door open alarms.

In addition to this list of benefits, the cloud range features a patented web monitoring and fridge rescue system that alerts users in the event of a fridge component failure and bypasses the fridge's systems to automatically maintain temperature until an engineer can see to the issue. So far, this solution has saved hundreds of thousands of pounds' worth of products around the world.

With security always in mind, each client has secure website access, with alerts sent to designated users regarding temperature and door status (which is constantly monitored) or power loss. The monitoring unit has a UPS backup, which will store data for up to 36 hours if a power or connectivity loss event occurs.

No complicated software is involved; the solution is easy to use and web-based. Matos Monitoring is an automatic temperature monitoring system, which enables direct access to fridge temperatures and data from anywhere at any time utilizing dedicated secure servers. Colour-coded indicators for temperature history and fridge status make the process easy at a glance, in addition to immediate SMS or email alerts, automatic and custom reports, as well as double backup and RAID systems that secure data for upwards of ten years.

Ethicheck also introduced its Wireless Monitoring Kit, which can be easily and quickly retrofitted to any refrigerator, freezer, cool-room or airspace. Once installed inside the unit that users wish to monitor, the sensor wirelessly transmits data to a base station that is connected online via an Ethernet cable.

The data is then uploaded to the Matos Monitoring Azure Server to grant users access to full temperature records, automatic reporting and alert services. With the industry becoming increasingly global and the demand for remote access greater than ever before, secure web-based and cloud-stored data is the solution the Pharmaceutic industry needs.

Source: Pharmaceutical Technology, 21.10.2020 (Excerpts)

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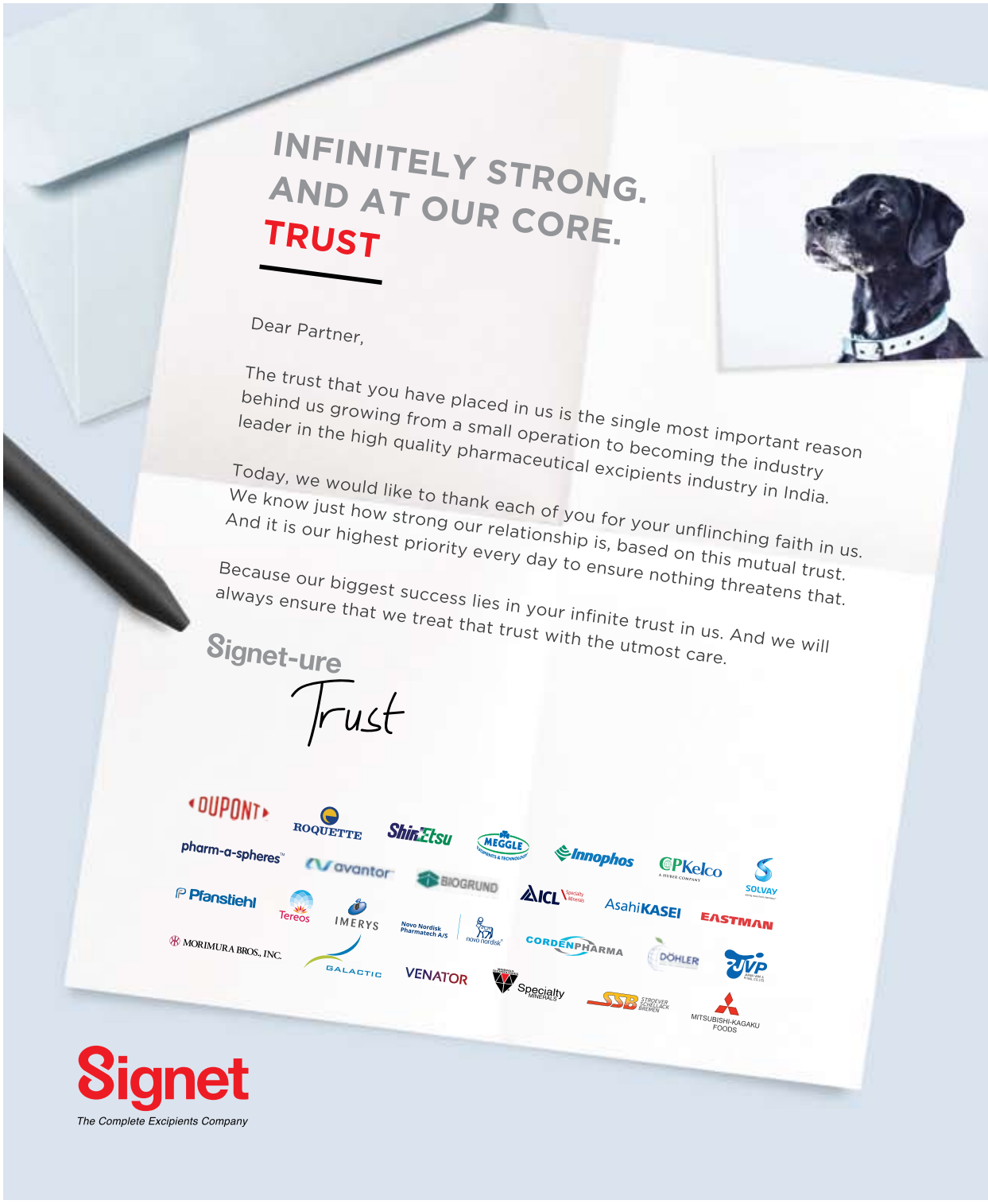
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