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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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IDMA BULLETIN

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IDMA Representation to Chairman, CBIC to reconsider Classification of Aerosol Therapy Apparatus

The Association has made the following representation on 27th August 2020 to Shri M Ajit Kumar, IRS, Chairman, Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi on the above subject: Copy of the said representation was also submitted with separate covering letter dated 28th August 2020 to Dr P D Vaghela, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

"Greetings from Indian Drug Manufacturers' Association.

IDMA believes in facilitating timely and effective representations to the Government authorities for quick resolutions of issues and provide necessary support in connection with all problems of the Pharmaceutical Industry.

IDMA has received several representations/concerns from the Pharmaceutical Industry raising major issues over some departmental circular from the Office of the Commissioner of Customs Audit addressed to all Chief Commissioners of Customs wherein the said office has erroneously considered classification of all the hand spray pumps under one generic category being used for lotion, soap, and scent dispenser under CTH 9616.

However it seems that it has escaped attention of the department to the fact that there are also other category of apparatus/appliances, like aerosol type hand sprays which are used for application of therapeutic agents (medicines) in a treatment of disease. These kinds of sprays cannot be classified under CTH 9616. Such kind of spray pumps/aerosols/apparatus which are used for delivering any therapy (medicine) should be classified under CTH 9019.

In order to help you understand better, a comparative table has been prepared to show the difference between the two classifications, which would make it clear without doubt that items falling under each of them are totally different, and have a completely different end use, based on the 'Item Description' defined in the Customs Act:

The description of the items of the each chapter thus makes it clear without doubt that the spray pumps

Sr. No	Details of classification under CTH 9019	Details of classification under CTH 9616
1.	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus.	Scent sprays and similar toilet sprays, and mounts and heads therefor; powder-puffs and pads for the application of cosmetics or toilet preparations.
2.	This heading covers Aerosol Therapy apparatus under 9019.20.	This heading covers Scent, brilliantine and toilet spray, Mounts of toilet spray, Head pieces of toilet spray, Powder puffs and pads.
3.	The description of Aerosol Therapy' makes it clear that: These apparatuses/spray pumps are being used as hand sprays/aerosols for application therapeutic agents/medicines in Pharmaceutical (Drug) Products for a treatment of a disease, they fall under the category of 'Drugs' as per the Drug and Cosmetic Act. These apparatus are used in Pharmaceutical Products and not in Toiletry, scents, soaps or cosmetics.	The description makes it clear that: Spray heads covered in this head are used for scents, toiletry, soaps and cosmetics and not for any Pharmaceutical Product/medicine. None of the sprays are used for applying any therapeutic agent for a treatment of a disease. Spray pump under this head don't have any measurement of the quantity delivered upon each use.

	These Pharmaceutical (Drug) products contain therapeutic agent (i.e. API) which are used in therapy for treatment of many diseases. These spray pumps/Aerosols used in pharmaceutical products deliver a specific quantity of the drug, unlike other spray pumps which are classified under CTH 9616, which do not have any measurement of the quantity, when being used. Products in which these apparatus/Aerosol sprays are used, being medicines, require a valid drug license.	Products in which the spray heads are used, being cosmetics and soaps, require a valid cosmetic license.

used in the pharmaceutical products, should be rightfully classified under CTH 9019 as Aerosol Therapy Apparatus (including hand sprays) instead of CTH 9616. A copy of classification under CTH 9616 and CTH 9019 is enclosed herewith as ***'Annexure-1'****.*

The error in the said classification as explained above has adversely affected the Pharmaceutical Industry and IDMA believes that there is a need to re-consider the classification since the said classification from CTH 9019 to CTH 9616 has been done incorrectly resulting into increased financial burden on the companies who have to pay higher Basic Customs Duty (BCD) due to the said misclassification which in turn makes life-saving drugs expensive for the needy patients.

Many Pharmaceutical companies import spray pumps for pharmaceutical and therapeutic use for their product and considering the same IDMA is compelled to raise the industry concerns with your good offices.

The pharmaceutical products with specified measured dosage categorized under CTH 9019 are different from other commercial cosmetic products categorized under CTH 9616. The significant facts of the same are reproduced herein below:

1. All the Pharmaceutical Products with spray pumps require a valid drug license unlike the pumps used in any toiletry, essence, soap etc which require a cosmetic license.

2. All Pharmaceutical Products have an Active Pharmaceutical Ingredient (API) which has a therapeutic activity on the human body unlike soaps and toiletries (which don't have any therapeutic agent).

3. Additionally, all pharmaceutical products have to be taken in the right dose, at the right time, in the right way and in the right frequency. Taking this into account, the pharmaceutical products with specified dosage is designed in a manner to administer specific ***dosage of medicine*** to get desirable therapeutic result and minimal adverse side effects. Thus, the spray pumps used in pharmaceutical products are totally different from that of the spray pumps used in cosmetics and other toilet preparations.

4. As a matter of fact, if the medicines are not administered properly, it might result into over dose or under dose which could create unfavorable and life-threatening conditions for the patients.

5. The aforesaid submission gets a statutory backing from perusal of First Schedule (**General Principles and Practices for Clinical Trial**) of New Drug and Clinical Trial Rules, 2019 (NDCT) where importance of dosage and its impact have been clearly mentioned at every phases of human trials (Phase-I, Phase-II, Phase-III and Phase-IV). A copy of the said First Schedule is enclosed as **'Annexure-2'*.**

6. Besides, there are several pharmaceutical products in different critical therapeutic categories which administers precise volume of the formulation as required under the respective therapy to cure an ailment in the right manner. Few of critical therapeutic categories are enlisted as below:

Therapeutic Category:	Ailment	Types of Molecules administered
Analgesics/Anti-inflammatory	Used for acute musculoskeletal pain	Diclofenac Aceclofenac Ibuprofen
Bronchodilators	Used to treat asthama including asthama attacks and Chronic Obstructive Pulmonary Disease (COPD)	Salbutamol Salmeterol Ipratropium Bromide
Nasal Decongestants	Used to treat nasal congestions	Oxymetazoline Xylomatazoline Sodium Chloride
Corticosteroids	To lower inflammation in the body and to reduce immune system activity	Fluticasol Mometasone Budesonide

7. Due to the said misclassification from CTH 9019 (Basic Custom Duty 7.5% + SWS 10% + HC 5% + IGST 12%) to CTH 9616 (Basic Custom Duty 20% + SWS 10% + IGST 12%) pharmaceutical companies pay higher basic customs duty which in turn will make drugs more expensive and unaffordable for the needy Indian patients.

8. *It is pertinent to note that many of the pharmaceutical products mentioned above are lifesaving in nature, and hence increasing the price of such products makes them more expensive and unaffordable to the common citizen of India, and overall lowering the health of Indian population.*

APPEAL:

(i) To correctly classify the spray pumps used in pharmaceutical products as Aerosol therapy Apparatus and classify the same under CTH 9019 instead of CTH 9616.

(ii) To withdraw such circular/directions/instructions made in the subject matter so as to ensure that critical pharmaceutical product (therapeutic agent) is made available to the needy patients at an affordable price. Thanking you and assuring you of our best attention all the times."

*{*Annexures 1 & 2 not reproduced here)*

● ● ●

GST and Income Tax Updates

Advisories by Mr B G Barve, Chairman, Excise & Taxation Committee, IDMA

Interest on delayed payment of GST

Amendment in CGST Section 50 comes into force from 01-09-2020

Notification No. 63/2020-Central Tax, dated 25-08-2020

The Central Government has appointed 01-09-2020 prescribing that interest in case of delayed furnishing of Section 39 return (e.g. GSTR-3B), shall be levied on that portion of tax that is paid by debiting the electronic cash ledger, i.e., after excluding input tax credit (ITC).

The new proviso however excludes situation when such return is furnished after commencement of any proceedings under Section 73 or Section 74.

It may be noted that the GST Council in its 39th meeting held on 14-03-2020 had recommended that interest for delay in payment of GST is to be charged on the net cash tax liability with effect from 01-07-2017, and that the law should be amended retrospectively.

Later CBIC has issued Press release stating that the notification has been issued prospectively due to certain technical limitations. It has been assured that no recoveries shall be made for the past period as decided by the GST Council.

Registration

Amendments in Aadhar based authentication process

Notification No. 62/2020-Central Tax, dated 20-08-2020

The Ministry of Finance has amended the CGST Rules, 2017 to revise the procedure for Aadhar based authentication process for registration under GST.

According to the newly substituted sub-rule (4A) of Rule 8, if any person opts to undergo authentication of Aadhar number, the date of submission of application will be the date of authentication of the Aadhar number or 15 days from submission of application in Part B of Form GST REG-01, whichever is earlier.

In case a person fails to undergo such authentication or does not opt for it, notice in Form GST REG-03 may be issued within 21 days from the date of submission of the application.

Further, amendment has been made in Rule 9(4) to substitute the word "shall" by the word "may" in respect of rejection of registration application.

Rule 9(5) has also been amended to revise few timelines in respect of deemed approval of application for grant of registration.

E-Invoice System

61/2020-Central Tax dated 30.07.2020

Registered person whose aggregate turnover in a financial year exceeds 500 crore rupees, shall prepare e-invoice w.e.f. 1st October 2020.

We hereby advise to get ready for implementation of E Invoice template in SAP or Accounting platform.

Other Highlights

Webinar on 19th August 2020	IDMA organised Webinar in association with Laxmikumaran and Sridharan on "GST , Customs and Income Tax implications on the Pharmaceutical Industry" wherin 627 persons registered and 397 persons participated.
41st GST Council Meeting on 27th August 2020 Council deliberated on issue of compensating states for revenue shortfall.	GST Council deliberated on 2-options to meet the compensation gap of Rs. 2.35 lacs crores i.e. (i) impact due to COVID-19 worked out at Rs. 97000 crores could be given to states with reasonable rate of interest in consultation with RBI (ii) entire Gap can be met by borrowing facilitated by RBI. States have asked to put options in detailed note and give them 7 working days after which they will come back.
Delhi HC dismisses PIL seeking- (i) classification of masks and sanitizers as "Essential Commodity" and (ii) reduction of GST rate from 18% on alcohol based sanitizers to either 5% or 12%.	A writ petition seeking direction to suspend imposition of GST on hand sanitizers and face masks in the wake of the Novel Coronavirus Pandemic was dismissed by SC. Goa AAR in the case of Springfields (India) Distilleries ruled that Hand Sanitizers falls under Heading 3808, taxable at 18%.....

INCOME TAX

The Finance Act 2020 has introduced a new Section 206C(1H) to curb and track usage of unaccounted money.

This is effective from 01.10.2020.

New sub-section (1H) under Section 206C prescribes that if a seller (being a person, whose turnover in the previous financial year exceeds 10 Crores) makes sale of "goods" whose value, either individually or in aggregate exceeds 50 Lakhs, the seller shall collect tax at source at 0.1% on the value of sale consideration exceeding 50 Lakhs from the buyer.

The person responsible for collecting tax shall deposit the TCS amount within 7 days from the last day of the month in which the tax was collected.

Every tax collector shall submit quarterly TCS return i.e., Form 27EQ in respect of the tax collected by him in a particular quarter.

The section states that tax shall be collected on the consideration value exceeding 50 Lakhs only, which means that there is an exemption limit of up to 50 Lakhs (individually or in aggregate on sales during any financial year). Export of goods is not covered under TCS on sale of goods

Income Tax Notification Updates

Particulars	Due Date	Circular dated 24th April, 2020 Further Extended	Applicability
Reporting under clause 30C and clause 44 of Form 3CD (Tax Audit Report)	31-03-2020	31-03-2021	Clause 30C (impermissible avoidance arrangement) not applicable to BCL. Clause 44 (GST Break-up of total expenditure of entities) is applicable to BCL & will duly comply with the requirements as & when applicable.

- As on 25-08-2020, ITR 1, 2, 3, 4 & 5 for AY 2020-21 are available for e-Filing. Other ITRs will be available shortly.
- One-time ***relaxation for e-Verification of Income Tax returns*** filed (but not e-verified) which have remained incomplete due to non-submission of ITR-V form forverification for ***AY 2015-16, 2016-17, 2017-18, 2018-19 and 2019-20 has been re-enabled upto 30-September-2020 .***

  Also the time frame for ***issuing intimation*** has been relaxed and directs that such returns shall be processed by ***31.12.2020 .***
- **Allowance of freebies to doctors by *pharmaceutical companies & the healthcare sector*** as opined by (ITAT MUM) in case of MEDLEY PHARMACEUTICALS LTD V/S CIT dated 22/07/2020.

  The ***disallowance*** under the ***Explanation to 37(1) of "freebies" to doctors*** by relying on CBDT Circular No. 5 dated 01.08.2012 & the IMC (Professional Conduct, Etiquettes & Ethics) Regulation, 2002 is not justified. The ***code of conduct prescribed by the Medical Council*** is applicable only to medical practitioners/ doctors registered with the MCI and ***does not apply to pharmaceutical companies & the healthcare sector*** in any manner. The CBDT has no power to extend the scope of the MCI regulation to pharmaceutical companies without any enabling provision either under the Income tax Act or the Indian Medical Regulations
- **Highlights of "Transparent Taxation - Honouring the Honest:**
  - Hon'ble PM has launched "Transparent Taxation - Honouring the Honest that will have ***faceless assessments & taxpayer charter*** applicable from ***14th August, 2020*** and ***faceless appeal*** applicable from ***25th September, 2020.***
  - ***No physical interface*** between taxpayers and I-T Dept.
  - Scrutiny, notice, and survey are currently handled by the IT officer of your own city. But now, it will be handled by technology. **Scrutiny will be randomised**.

    For example, a Mumbai officer may survey tax related cases of someone in Guwahati.
  - **Computer to randomly decide who gets to handle tax cases**. This system will eliminate the need of building relationships with taxpayer and tax offices.
  - More transparency in official communication through the newly ***introduced Document Identification Number*** (DIN) wherein every communication of the Department would carry a computer generated unique DIN.

    Similarly, to increase the ease of compliance for taxpayers, the I-T Department has moved forward with the ***pre-filling of income tax returns*** to make compliance more convenient for individual taxpayers.
- CBDT notifies ***new Form 26AS (Annual Information Statement)*** effective from ***01st June, 2020*** *(CBDT vide* ***Notification No. 30/2020*** *dated May 28, 2020)*
  - Form 26AS will now be a ***complete profile*** of the taxpayer;
  - This form will also have ***mobile no, email I'd and Aadhar*** no. of the taxpayer;
  - This will be a live 26AS, as this will be ***updated regularly within 3 months*** from the end of the month in which such information is received;
  - Information relating to ***tax deducted or collected at source;***

- Information relating to ***specified financial transaction (SFT)***;
- Information relating to ***payment of taxes;***
- Information relating to ***demand and refund;***
- Information relating to ***pending proceedings*** and ***completed proceedings*** which may include assessment, reassessment under section 148, 153A & 153C revision, appeal
- Further an enabling provision has been notified empowering the CBDT to ***authorise Director General Income tax (Systems) or any other officer to upload in this form***, information received from any other officer, authority under any law. Thus any adverse action initiated or taken or found or order passed under any other law such as custom, GST, Benami Law etc. including information about turnover, import, export, etc. will also be inserted in the form 26AS;
- This form 26AS will also provide information ***received by Tax Department from any other country under the treaty /exchange*** of information about ***income or assets*** of the taxpayer ***located outside India***.

➢ **Changes in ITR-6 form for AY 2020-21*(utility not yet available for e-filing)***

Sr. No.	Changes in ITR-6 [Field Name]	Description	BCL Action
1	**Option for section 115BAA /115BAB**	A new option is added in the 'Filing Status' section with regard to exercising of option under section 115BAA/115BAB of the Act Option needs to be exercised in Form 10- IC/10-ID.	BCL has opted for Section 115BAA of the Act and will select the appropriate option
4	**Schedule 112A inserted to report individual scrip wise details**	From sale of equity share in a company or unit of equity oriented fund or unit of a business trust on which STT is paid under section 112A' is inserted to ***report individual scrip wise details on long term shares*** which was earlier exempt from tax and eligible for grandfathering. Earlier, this was introduced in the later version e-filing utility for AY 2019-20, but made optional.	BCL will report individual scrip wise details on sale of long term equity oriented fund
5	**115AD(1)(b)(iii)** **proviso inserted to report individual scrip wise details for Non- resident**	For ***NON-RESIDENTS*** - From sale of equity share in a company or unit of equity oriented fund or unit of a business trust on which STT is paid under section 112A' is inserted.	Not Applicable
6	**Schedule VI-A Deductions under Chapter VI-A:** **Investment/deposit/ payments between 01.04.2020 to 30.06.2020**	If the taxpayer has made any investment/ deposit/ payments between 01.04.2020 to 30.06.2020, then he has to fill Schedule DI.	BCL will report the requisite details
7	Schedule DI - Details of Investment	A new '**Schedule DI - Details of Investment'** is added to report investment/expenditure made between 01.04.2020 to 30.06.2020 to commensurates with the time extension granted by Taxation and Other Laws (Relaxation of certain provisions) Ordinance, 2020 for the purpose of claiming deduction for AY 2020-21 for investments, etc made under chapter VI-A till 30.06.2020.	BCL will report the required details

❖ **FOR INDIVIDUAL**

Surcharge on TDS and advance tax in case of Individual as per Finance Act 2020:

1. ***10%*** of Income tax where total income exceeds Rs.50 lakh upto 1crore (***including dividend***, STCG u/s 111A & LTCG u/s112A)
2. ***15%*** of Income tax where total income exceeds Rs.1 crore upto Rs. 2 crore (***including dividend***, STCG u/s 111A & LTCG u/s112A)
3. ***25%*** of Income tax where total income exceeds Rs.2 crore upto 5Crore (***excluding dividend***, STCG u/s 111A & LTCG u/s112A)
4. ***37%*** of Income tax where total income exceeds Rs.5 crore (***excluding dividend***, STCG u/s 111A & LTCG u/s112A)
5. ***15%*** of income tax where the ***aggregate of dividend***, ***STCG u/s 111A & LTCG u/s112A exceeds Rs. 2 crores***

Note*: *Enhanced Surcharge rate for HNI *(25% or 37%) is* ***not applicable*** *in case of* ***dividend****, STCG u/s 111A & LTCG u/s112A and the surcharge on the same shall* ***not exceed 15%***

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GST MATTERS

CBIC extends the due date for filing FORM GSTR-4 for Financial Year 2019-20 up to 31st October, 2020 - reg.

Notification No.64/2020-Central Tax, dated 31st August, 2020

In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Government, on the recommendations of the Council, hereby makes the following further amendment in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.21/2019-Central Tax, dated the 23rd April, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.322(E), dated the 23rd April, 2019, namely:–

In the said notification, in the third paragraph, in the first proviso, for the figures, letters and words "31st day of August, 2020", the figures, letters and words **"31st day of October, 2020"** shall be substituted.

F.No.CBEC-20/06/07/2019-GST

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

Note: *The Principal Notification No.21/2019-Central Tax, dated the 23rd April, 2019, published in the Gazette of India, Extraordinary, vide number G.S.R.322(E), dated the 23rd April, 2019 and last amended by Notification No.59/2020-Central Tax, dated the 13th July, 2020, published in the Gazette of India, Extraordinary, vide Number G.S.R.443(E), dated the 13th July, 2020.*

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Ceiling/Cap on MEIS benefits available to exporters on exports made from 01.09.2020 to 31.12.2020 – not available from 01.01.2021

DGFT Notification No.30/2015-2020, dated 1st September, 2020

1. In exercise of the powers conferred by Section 5 of the Foreign Trade (Development and Regulation) Act, 1992 read with Para 1.02 of the Foreign Trade Policy, 2015-20 and the enabling para 3.13 of the FTP, the Central Government hereby makes the following amendments in the Foreign Trade Policy 2015-20 with immediate effect:

2. Two new paragraphs, 3.04A and 3.04B are inserted in the Foreign Trade Policy as below:

"3.04 A

The total reward which may be granted to an IEC holder under the Merchandise Exports from India Scheme (MEIS) shall not exceed Rs.2 Crore per IEC on exports made in the period 01.09.2020 to 31.12.2020 [period based on Let Export Order (LEO) date of shipping bill(s)]. Any IEC holder who has not made any export with LEO date during the period 01.09.2019 to 31.08.2020 or any new IEC obtained on or after 01.09.2020 would not be eligible for submitting any claim for benefits under MEIS for exports made with effect from 01.09.2020. The aforesaid ceiling may be subject to further downward revision to ensure that the total claim under the Scheme for the period (01.09.2020 to 31.12.2020) does not exceed the allocation prescribed by the Government, which is Rs.5,000 Cr.

3.04 B

Benefits under MEIS shall not be available for exports made with effect from **01.01.2021."**

Effect of this Notification: A limit on total reward under MEIS has been imposed so that for exports made in the period 01.09.2020 to 31.12.2020 the total reward which can be claimed by an IEC holder does not exceed the ceiling of Rs.2 Cr. Further, it has also been notified that any IEC holder who has not made any exports for a period of one year preceding 01.09.2020 or any new IECs obtained on or after the date of publication of this Notification would not be eligible for submitting any claim under MEIS. In addition, it has been notified that MEIS Scheme is withdrawn with effect from 01.01.2021. The aforesaid ceiling will be subject to further downward revision to ensure that the total claim under MEIS for the period (01.09.2020 to 31.12.2020) does not exceed the prescribed allocation by the Government, which is Rs.5,000 Cr.

F.No.01/61/180/288/AM20/PC-3.(Part-1)

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

● ● ●

Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013 amended - reg.

NDPS Gazette Notification No.G.S.R.536(E), dated 26th August, 2020

In exercise of the powers conferred by section 9A of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance, Department of Revenue number G.S.R.191 (E), dated the 26th March, 2013, namely:-

1. (1) This order may be called the **Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Amendment Order, 2020.**

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

2. In the Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013, in the Schedule,-

(a) in Schedule A, after serial number 5 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:-

"6. 4-Anilino-N-phenethylpiperidine (ANPP)

7. N-Phenethyl-4-piperidone (NPP)";

(b) in Schedule B, after serial number 19 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:-

"20. 3,4-MDP-2-P methyl glycidate (PMK glycidate) (all stereoisomers)

21. 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) (all stereoisomers)

22. *alpha*-phenylacetoacetamide (APAA) (including its optical isomers)

23. methyl alpha-phenylacetoacetate (MAPA) (including its optical isomers)";

(c) in Schedule C, after serial number 19 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely:-

"20. 3,4-MDP-2-P methyl glycidate (PMK glycidate) (all stereoisomers)

21. 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) (all stereoisomers)

22. *alpha*-phenylacetoacetamide (APAA) (including its optical isomers)

23. methyl alpha-phenylacetoacetate (MAPA) (including its optical isomers)".

F.No.N/11012/3/2010-NC-II-Part-1

Ritvik Pandey,
Joint Secretary,
Department of Revenue,
Ministry of Finance,
New Delhi.

Note: *The Principal Notification was published in the Gazette of India, vide number G.S.R.91(E), dated the 26th March, 2013 and subsequently amended vide Number G.S.R.186(E), dated the 27th February, 2018 and Number G.S.R.779(E), dated the 14th October, 2019.*

● ● ●

Cipla Limited, permitted to import morphine, codeine, thebaine and their salts for use in manufacture of products to be exported notified - reg.

NDPS Gazette Notification No. S.O.2895(E), dated 26th August, 2020

1. In exercise of the powers conferred by the proviso to rule 54 of the Narcotic Drugs and Psychotropic Substances Rules, 1985, the Central Government hereby notifies that M/s. Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadma Marg, Lower Parel, Mumbai-400013, is permitted to import morphine, codeine, thebaine and their salts for use in manufacture of products to be exported, after following the procedure specified in rule 55 of the said rules and subject to such conditions as may be specified in the import certificate issued in Form No.4A annexed to the aforesaid rules.

2. This notification shall remain in force from the date of its publication in the Official Gazette till the **31st day of December, 2022.**

F.No.N/11012/1/2013-NC-II

Ritvik Pandey, Joint Secretary, Department of Revenue, Ministry of Finance, New Delhi.

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CBIC notifies New Exchange Rates w.e.f. 21st August 2020 - reg.

Notification No.80/2020-Customs (N.T.), dated 20th August, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.69/2020-Customs(N.T.), dated 6th August, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 21st August, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods. .

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	55.15	52.80
2.	Bahraini Dinar	205.40	192.85
3.	Canadian Dollar	57.80	55.75
4.	Chinese Yuan	11.00	10.70
5.	Danish Kroner	12.15	11.70
6.	EURO	90.50	87.30
7.	Hong Kong Dollar	9.85	9.50
8.	Kuwaiti Dinar	253.70	238.05
9.	New Zealand Dollar	50.60	48.30
10.	Norwegian Kroner	8.55	8.25
11.	Pound Sterling	100.00	96.65
12.	Qatari Riyal	21.20	19.80
13.	Saudi Arabian Riyal	20.65	19.40
14.	Singapore Dollar	55.75	53.85
15.	South African Rand	4.50	4.20
16.	Swedish Kroner	8.75	8.45
17.	Swiss Franc	83.65	80.45
18.	Turkish Lira	10.60	9.95
19.	UAE Dirham	21.10	19.80
20.	US Dollar	75.90	74.15

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	72.10	69.45
2.	Korean Won	6.55	6.15

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

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

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Geographical Indications of Goods (Registration and Protection) (Amendment) Rules, 2020 - reg.

DPIIT Notification No.G.S.R.528(E), dated 26th August, 2020

Whereas the draft rules, further to amend the Geographical Indications of Goods (Registration and Protection) Rules, 2002 were published as required under sub-section (3) of by Section 87 of the Geographical Indications of Goods (Registration and Protection) Act, 1999 (48 of 1999), *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.645(E) dated the 12th September, 2019 in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), for inviting objections and suggestions from all persons likely to be affected, 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 12th September, 2019;

And whereas, no objections and suggestions received from the public in respect of the said draft rules; Now, therefore, in exercise of the powers conferred by section 87 of the Geographical Indications of Goods (Registration and Protection) Act, 1999 (48 of 1999), the Central Government hereby makes the following rules further to amend Geographical Indications of Goods (Registration and Protection) Rules, 2002, namely:-

1. Short title and commencement:

(1) These rules may be called the **Geographical Indications of Goods (Registration and Protection) (Amendment) Rules, 2020.**

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

2. In the Geographical Indications of Goods (Registration and Protection) Rules, 2002 (hereinafter referred as the "said rules"), for Rule 56 following Rule shall be substituted, namely:-

"56. Authorised User;

(1) An application for registration of authorized user under section 17 may be made to the Registrar in Form GI-3 accompanied by a statement of case as to how the applicant claims to be the producer of the registered geographical indication.

(2) A copy of application made under sub-rule (1) shall be forwarded to the registered proprietor of geographical indication and intimate the same to the Registrar."

3. In the said rules, in rule 59 for sub-rule (1), the following sub-rule shall be substituted, namely:-

(2) "Where no notice of opposition is filed to an application advertised or re-advertised in the Journal within the period specified under sub-clause (e) of sub-section (3) of Section 17 or where an opposition is filed and it is dismissed, the Registrar shall enter the authorised user in Part B of the register and shall issue a registration certificate with the seal of Geographical Indication Registry".

4. In the said rules in rule 59, in sub-rule (2), clauses (f) and (g) shall be omitted.

5. In the said rules, in rule 59, in sub-rule (3), the words:-

"An unmounted representation of the geographical indication exactly as shown in the form of application for registration thereof at the time of registration shall accompany such request." shall be omitted.

6. In the said rules, in the FIRST SCHEDULE-,

a) for the entry 3A, the following entry shall be substituted, namely:-

"

3A	On application for the registration of an authorised user of a registered geographical indication under section 17, Rule 56(1)	10	GI-3

"

b) the entry 3B shall be omitted;

c) for the entry 3C, the following entry shall be substituted, namely:-

"

3B	For renewal of an authorised user (sub-section (2) of section 18 sub-rule(1) of rule 60)	10	GI-3

"

7. In the said rules, in the SECOND SCHEDULE-,

a) the following Form number,:

"

GI-3	Section 18(5), rule 59	Request for issuance of a registration certificate as an authorised user.	3B

"

shall be omitted;

b) for the Form number

"

GI-3	Section 18(2), rule 60(1)	For renewal of an authorised user	3C

"

the following form number shall be substituted, namely:-

"

GI-3	Section 18(2), rule 60(1)	For renewal of an authorised user	3C

"

8. In the said rules, for Form GI 3, the following form shall be substituted, namely:-

Geographical Indications of Goods (Registration & Protection) Act, 1999
Geographical Indications of Goods (Registration & Protection) Rules, 2002
Form GI 3A
Application for the Registration of an Authorized User [Section 17 (1), Rule 56 (1)] Fee: Rs.10 [See entry No.3A of the First Schedule]

(1) Name of the Applicant (proposed Authorized user: _____

(2) Address of the applicant: _____

(3) Address of service (if different from Above): _____

(4) Registered Geographical Indication for which application is made:

_____

(5) Email id: _____

(6) Phone/mobile number :_____

Declaration:

(1) I hereby declare that I have enclosed the statement of case and evidence of due service of copy of my application to the registered proprietor (Name of registered proprietor) for_____, registered as a Geographical Indication.

(2) I also declare that all the above information is true and correct to the best of my knowledge and belief.

(3) I undertake that if any of the information is found incorrect or false, my application may be rejected and if already accepted, my registration may be revoked and my name removed from Part B of the register.

Date:

Place: SIGNATURE

Geographical Indications of Goods (Registration & Protection) Act, 1999
Geographical Indications of Goods (Registration & Protection) Rules, 2002
Form GI 3B
Application for Renewal of Registration of an Authorized User [Section 18 (2), Rule 60 (1)] Fee: Rs.10 [See entry No.3B of the First Schedule]

(1) Name of the Applicant (Authorised User): _____

(2) Address of the Applicant: _____

(3) Address of service (if different from above): _____

(4) Registered Geographical Indication for which application is made:

_____

(5) Email id: _____

(6) Phone/mobile number : _____

DECLARTION:

I acknowledge that my registration as an authorised user will be valid after renewal for a period of 10 years, or for such period as the geographical indication continues to be registered, whichever is lesser.

Date:

Place: SIGNATURE

F.No.P-24027/4/2018-IPR-IV(Pt-1)

Ravinder, Joint Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, New Delhi.

Note: *The Principal Rules were published in the Gazette of India; Extraordinary, Part II, Section 3, Sub-section (i) vide Notification Number G.S.R.176(E), dated 08th day of March 2002.*

● ● ●

A new Platform for controlled delivery of key nanoscale drugs and more

In work that could have a major impact on several industries — from pharmaceuticals to cosmetics and even food — MIT engineers have developed a novel platform for the controlled delivery of certain important drugs, nutrients, and other substances to human cells.

The researchers believe that their simple approach, which creates small capsules containing thousands of nanosized droplets loaded with a drug or other active ingredient, will be easy to transition from the lab to industry.

The active ingredients in many consumer products intended for use in or on the human body do not easily dissolve in water. As a result, they are hard for the body to absorb, and it is difficult to control their delivery to cells.

In the pharmaceutical industry alone, "40 percent of currently marketed drugs and 90 percent of drugs in development are hydrophobic wherein [their] low water solubility greatly limits their bioavailability and absorption efficiency," the MIT team writes in a paper on the work in the August 28 issue of the journal Advanced Science.

Nanoemulsions to the Rescue:

Those drugs and other hydrophobic active ingredients do, however, dissolve in oil. Hence the growing interest in nanoemulsions, the nanoscale equivalent of an oil-and-vinegar salad dressing that consists of miniscule droplets of oil dispersed in water. Dissolved in each oil droplet is the active ingredient of interest.

Among other advantages, the ingredient-loaded droplets can easily pass through cell walls. Each droplet is so small that between 1,000 to 5,000 could fit across the width of a human hair. (Their macroscale counterparts are too big to get through.) Once the droplets are inside the cell, their payload can exert an effect. The droplets are also exceptionally stable, resulting in a long shelf life, and can carry a large amount of active ingredient for their size.

But there's a problem: How do you encapsulate a nanoemulsion into a dosage form like a pill? The technologies for doing so are still nascent.

In one of the most promising approaches, the nanoemulsion is encapsulated in a 3D network of a polymer gel to form small beads. Currently, however, when ingested those beads release their payload — the ingredient-loaded oil droplets — all at once. There is no control over the process.

The MIT team solved this by adding a shell, or capsule, around large individual droplets of nanoemulsion, each containing thousands of nano oil droplets. That shell not only protects the nano droplets inside from harmful physiological conditions in the body, but also could be used to mask the often unpalatable taste of the active ingredients they contain.

The result is a "pill" about 5 millimeters in diameter with a biodegradable shell that in turn can be "tuned" to release its contents at specific times. This is done by changing the thickness of the shell. To date they have successfully tested the system with both ibuprofen and Vitamin E.

"Our new delivery platform can be applied to a broad range of nanoemulsions, which themselves contain active ingredients ranging from drugs to nutraceuticals and sunscreens. Having this new control over how you deliver them opens up many new avenues in terms of future applications," says Patrick Doyle, the Robert T. Haslam Professor of Chemical Engineering and senior author of the paper.

His colleagues on the work are Liang-Hsun Chen, a graduate student in chemical engineering and first author of the paper, and Li-Chiun Cheng SM '18, PhD '20, who received his PhD in chemical engineering earlier this year and is now at LiquiGlide.

Many Advantages:

The MIT platform has a number of advantages in addition to its simplicity and scalability to industry. For example, the shell itself "is derived from the cell walls of brown algae, so it's very natural and biocompatible with human bodies," says Chen.

Further, the process for making the nanoemulsion containing its payload is economical because the simple stirring involved requires little energy. The process is also "really gentle, which protects the [active] molecule of interest, like a drug," says Doyle. "Harsher techniques can damage them." The team also demonstrated the ability to turn the liquid nanoemulsion inside each shell into a solid

core, which could allow a variety of other applications. They did so by adding a material that when activated by ultraviolet light cross-links the nano oil droplets together.

For Chen, the most exciting part of the work was preparing the capsules and then "watching them burst to release their contents at the target times I engineered them for." Doyle notes that from a pedagogical point of view, the work "combined all of the core elements of chemical engineering, from fluid dynamics to reaction engineering and mass transfer. And to me it's pretty cool to have them all in one project."

[This work was supported by the Singapore National Research Foundation, the U.S. National Science Foundation, and the Think Global Education Trust (Taiwan).]

Source: scienceblog.com, 31.08.2020

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NPPA soon to roll out online system for clearing applications filed under various provisions of DPCO-2013 towards ease of doing business

The National Pharmaceutical Pricing Authority (NPPA) is planning to develop an online system for disposing and monitoring of applications filed under various provisions of DPCO-2013 towards ease of doing business.

Development and implementation of an ecosystem for timely disposal and monitoring of various applications filed under various provisions of DPCO, 2013 from Pharma companies with NPPA is under process. This includes submission of Form-I for application for the pricing of new drugs. NPPA has stipulated that the applicant companies need to submit the application with all requisite documents via email at **pricing-nppa@gov.in.**

It has also stipulated Pharma companies to Form-I related to revised prices for scheduled formulations, Form-II related to quarterly return in respect of production/ import and sale of NLEM Drugs and Form-V related to Price List. Pharma companies should submit these forms on Integrated Pharmaceutical Database Management System (IPDMS) within the prescribed timelines. Besides this, the application for the discontinuation of the production of scheduled formulation with all requisite documents should be sent via email at **monitoring-nppa@gov.in.**

Applications for special price for packaging under paragraph 11(3) of DPCO 2013 can be submitted at **pricing-nppa@gov.in.** As per NPPA recommendations, NPPA authority meeting would be preferably held every month. If due to certain circumstances the same could not be held in a particular month, the authority meeting would be held in subsequent months as per requirement. Meeting of the multidisciplinary committee of experts would be held prior to the authority meeting

All Indian Pharma manufacturer associations should upload the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) on their website including the detailed procedure mentioned in paragraph 10 of the UCPMP regarding lodging of complaints. A quarterly report mentioning details of the complaint received and the decision taken thereon should be submitted by the concerned association to NPPA within 30 days of the end of the quarter via email to **monitoring-nppa@gov.in.**

NPPA has also stipulated timelines for disposal of applications in different categories like in Form-I which is related to new drug prices and the given timeline is within 60 days. Form-II is used for the revised prices of scheduled formulations and the stipulated timeline to file is within 15 days from the date of Notification. Form III is applied for the purpose of quarterly returns in respect of production/import and sale of NLEM drugs and the set timeline for the manufacturer is within 15 days from the date of the end of quarter.

Form-IV and Form-V are applied for the discontinuation of production of scheduled formulations and Price List. Manufacturers need to file within 60 and 15 days from the date of Notification respectively. For further assistance, the NPPA has also created a helpdesk to deal with problems related to any documentary or technical issue while applicants are submitting their applications. It has also created email IDs and phone numbers for each category.

Queries related to Form-I can be addressed to email ID **pricing-nppa@gov.in** (011-2334 5175), and Form-I1, Form-II, Form-IV and Form-V to be mailed at **monitoring-nppa@gov.in** (011-23345177). For technical IT/IPDMS related issues, applicants can be reached at **nppa@nic.in** and Phone Number - 011-2336 0265.

Source: Shardul Nautiyal, Pharmabiz, 31.08.2020

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Commerce Ministry's decision to discontinue MEIS benefits causes financial hardships to MSME Pharma exporters

The Union Commerce Ministry's decision to discontinue the Merchandise Export from India Scheme (MEIS) from July 23, 2020 is causing immense financial hardships to the MSME Pharma exporters in the country. Though the Government had earlier announced that exporters will get incentives under the MEIS till December 31, 2020, the Government's rather sudden decision to stop the MEIS benefits since last month, due to shortage of funds, is causing financial hardships to the MSME Pharma exporters.

The Commerce Ministry has shut down the online system for exporters to apply for tax benefits under the

MEIS scheme from July 23, 2020 due to shortage of funds. The Government is facing a fiscal constraint post COVID-19 and the limited resources need to be appropriately used, said Government sources.

Now, the MSME Pharma exporters have been hit by the double whammy of financial distress since COVID-19 induced lockdown and stoppage of MEIS benefits. The Directorate General of Foreign Trade (DGFT) in a trade notice in April 2020 said, "Benefits under MEIS for any item/tariff line/HS Code currently listed will be available only up to December 31, this year".

It said that Remission of Duties and Taxes on Exported Products (RoDTEP) scheme was approved by the cabinet to replace the ongoing MEIS from January 1, 2021.

Under the RoDTEP scheme, a mechanism would be created for reimbursement of taxes/duties/levies, at the central, state and local level, which are currently not being refunded under any other mechanism, but which are incurred in the process of manufacturing and distribution of exported products. RoDTEP is a combination of the current MEIS scheme and Rebate of State and Central Taxes and Levies (RoSCTL) scheme.

Earlier the Department of Revenue has asked the Department of Commerce to examine the coverage of MEIS tariff lines and rates to reduce the incentive level to Rs.9,000 crore this year.

According to an Office Memorandum of DGFT, the Department of Revenue had in May stated that it may not be feasible to exceed allocation beyond Rs. 9,000 crore for FY 2020-21 (up to December 2020). Rewards under the scheme are payable as percentage of realised free-on-board value and MEIS duty credit scrip can be transferred or used for payment of a number of duties including the basic customs duty.

Said Nipun Jain, Chairman of Small and Medium Pharma Manufacturers Association (SMPMA), "In the current COVID-19 scenario, where MSME Pharma exporters are facing challenges, they need to be supported by the Government by providing a better operating and financial atmosphere. The continuation of MEIS scheme is very important in improving sentiments of MSME exporters."

Source: Laxmi Yadav, Pharmabiz, 31.08.2020

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Governmment modifies CSR Rules to allow Pharma & Medtech firms to contribute to COVID-19 R&D under CSR obligations

In a bid to expedite Research and Development activities to find a cure for COVID-19 pandemic, the Central Government has amended the Companies (Corporate Social Responsibility Policy) Rules, 2014 to allow pharmaceutical and medical device companies to support COVID-19 R&D, collaboratively, in publicly funded institutions.

The Ministry of Corporate Affairs has inserted a provision in Companies (Corporate Social Responsibility Policy) Rules, 2014 through amendment that would allow pharmaceutical, vaccine and medical device firms engaged in R&D activities of new vaccine, drugs and medical devices in their normal course of business to claim CSR benefits for undertaking R&D activity of new vaccine, drugs and medical devices related to COVID-19 for financial years 2020-21, 2021-22 and 2022-23.

The companies are required to carry out R&D in collaboration with any of the institutes or organisations mentioned in item (ix) of Schedule VII to the Act. The item (ix) of Schedule VII includes public funded Universities, Indian Institute of Technology (IITs), National Laboratories and Autonomous Bodies (established under the auspices of Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), Department of Atomic Energy (DAE), Defence Research and Development Organisation (DRDO), Department of Biotechnology (DBT), Department of Science and Technology (DST), Ministry of Electronics and Information Technology.

The companies need to disclose details of such activity separately in the annual report on CSR included in the Board's report. The amendment temporarily removed a provision that would have excluded "activities undertaken in pursuance of its (the company's) normal course of business" from being considered as CSR activities. However, the Ministry has also amended Schedule VII to substitute it with incubators or Research and Development projects in the field of Science, Technology, Engineering and Medicine that are funded by the central or state Government, a public sector undertaking or any Government Agency.

It means contributions to R&D projects in the field of Science, Technology, Engineering and Medicine, funded by the central or state Governments or any public sector entity

would also be counted under CSR. The decision was taken in line with the Prime Minister's directive to encourage New Drug Discoveries for COVID-19, said K Vijay Raghavan, Principal Scientific Adviser to the Government of India.

CSR rules were modified last year to support research in publicly funded institutions and incubators. CSR can support organisations working in areas outside companies' 'normal course of business'. So, a Pharma company could not fund Pharma R&D, he said. The Companies Act requires firms with a net worth of Rs. 500 crore or more, or turnover of Rs.1,000 crore or more, or net profit of Rs.5 crore or more in the immediately preceding financial year, to mandatorily spend 2% of average net profit of the preceding three years on CSR. Money earmarked for spending on CSR activities in a year is about Rs.15,000 crore.

The activities under Schedule VII of CSR include eradicating extreme hunger, poverty, promotion of education, promoting gender equality and women's empowerment as well as reducing child mortality, improving maternal health and combating diseases. Ensuring environmental sustainability and prompting employment enhancing vocational skills are other activities approved under CSR.

Source: Pharmabiz, 27.08.2020

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AMMOI seeks PM's intervention to take strict action against publishing and spreading misleading information against Ayurveda

The Ayurveda Medicine Manufacturers Organisation of India (AMMOI) has urged Prime Minister Narendra Modi to take strong action against publishing and spreading misleading and slanderous information against Ayurveda system of medicine through social media.

"Recently it has been brought to our notice a definition appearing in Wikipedia, a popular site used by all, searching information on various subjects. On the other site, on Ayurveda they have given the definition which is nothing but blasphemy," stated AMMOI General Secretary Dr D Ramanathan in his letter to the PM.

According to AMMOI, Wikipedia defines Ayurveda as 'Ayurveda is an alternative medicine system with historical roots in the Indian subcontinent. Indian Medical Association (IMA) characterizes the practice of medicine by ayurevdic practitioners as quackery. The study of Ayurveda is pseudoscientific while the practice can be classified as protoscience or unscientific'.

Whereas Kampo system of medicine, traditional Japanese herbal medicines used in Japan for more than 1,500 years and Chinese system of medicine based on Compendium of Materia Medicine and Huangdi Neijing with more than 3,500 years of Chinese medical practice that includes various forms of herbal medicine, acupuncture, cupping therapy, gua sha, massage (tui na) and dietary therapy, Ayurvda system of medicine has been in practice for more than 5,000 years and WHO has also recognized, it is an alternative medicine system, Dr Ramanathan in his letter to PM said.

Having said the above, it is pertinent to note that as per Indian Medical Council Ethics Committee it is not allowed to criticize or belittle another branch of medicine without solid scientific proof to support the same. As you know, Ayurveda is a medical system practiced in India for more than 5,000 years and this industry has adopted scientific methods in their operations keeping in tune with major trends in the medical field. Major Ayurveda manufacturers have adopted latest GMP standards in their manufacturing process and have done ISO certification for their units. More than 300 university-recognized Ayurveda colleges across the country, well equipped with latest laboratory equipments, are producing more than 5,000 qualified Ayurveda doctors every year who study for more than 5 years with an approved syllabus by Government appointed Expert Committee of highly qualified personnel with Doctorates in their selected subject.

Hence, it is very saddening to note that the entire system is put under a cloud by the IMA and our system is termed as 'quackery', Dr Ramanathan rued. Government of India and various state Governments have recently taken up promotion of Ayurveda in a big way during these times of COVID-19 as Ayurveda is recognized as system of medicines which gives more importance to the preventive way of treatment.

In the letter, AMMOI sough the intervention of the PM to take this matter with the Ethics Committee of Indian Medical Council to ensure that such slanderous remarks are not made from responsible quarters. It also sought the PM's intervention to take up this matter with Wikipedia to remove such statements from their sites immediately.

Source: Neethikrishna, Pharmabiz, 31.08.2020

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GST is complicated and there is confusion over its interpretation: IDMA

The Indian Drug Manufacturers' Association (IDMA) contends that GST is complicated and there is confusion over its interpretation. The tax, according to the Association, has taken the industry on a roller coaster ride and its adherence continues to be a challenge.

A deliberation on 'GST, Customs, and Income Tax--- Implications on the Pharma Industry', organized by IDMA along with Lakshmikumaran & Sridharan (L&S) Attorneys who was the knowledge partners for the event, provided the perspective of interplay of these taxes on various activities of the Pharma industry.

The discussion examined the impact of levies on R&D activities, including domestic and cross-border arrangements, contract manufacturing and contract development, co-marketing and other distribution models like limited risk model, profit share, promotional expenses and treatment of samples and expired stocks. V Lakshmikumaran, Managing Director, Lakshmikumaran & Sridharan Attorneys stated that GST is good but not simple and is like two sides of a coin. One is the law and the other is its compliance. Jigar Shah, Partner, L&S Ahmedabad, stated that a majority of Pharma products attract GST at 12% and 5% whereas major inputs and services suffer GST at 18%. Thus, there is an inverted duty structure. Refund provisions allow reimbursement of excess credit. But credit on input services and capital goods is not considered for refund.

In this regard Shah noted, "Recently, the Gujarat HC held that provision which denied refund of input services as ultra vires. Thus, major relief on this aspect can be expected." India Pharma is not just engaged in domestic research and manufacuture but also has overseas arrangements.

Delving on R&D, Shah told that not every research undertaken for a fixed price can be regarded as contract research. One has to understand who undertakes the functions of Development, Enhancement, Maintenance, Protection and Exploitation (DEMPE) of the research and its outcome. If DEMPE functions are significantly carried by the research centre in India, then, it would have to be remunerated at a much higher margin than a cost plus 20% markup that a regular research activity entails. The CBDT issued an order based on the recommendation of the 'Rangachary report on Taxation of Development Centres' and BEPS Action Plan 8-10 of OECD defining a research centre and the manner of remunerating its functions.

In contract manufacturing, where related parties transact, issue of transfer price is important. The method adopted for determining transfer price between the contract manufacturer and the principal manufacturer would have to be determined on a case-to-case basis.

On promotional expenses for Pharma companies, Shah said there was a controversy around the business promotion expenditure post the CBDT circular based on Indian Medical Council Professional Conduct Ethics Regulations. The circular bars expenditure incurred by Pharma companies on providing gifts, travel facility, monetary grant or similar freebees to doctors. This is based on the presumption that the IMC regulation applies to Pharma companies. However, there is a conflicting interpretation of this circular by Courts and Tribunals. A detailed and reasoned judgment on the question is the need of the hour. Further, income tax concessions on free gifts as promotional items will not be available, he said.

Free Trade Agreement (FTA) too has led to an adverse situation for domestic manufacturing industry. Government has taken some steps to curb misuse of FTAs by amending relevant provisions in the Customs Act, said Shah.

Source: Nandita Vijay, Pharmabiz, 27.08.2020

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Pharma MSMEs urge DoP to expedite implementation of PTUA Scheme by appointing lead banker

The Small and Medium Pharmaceutical Companies have urged the Department of Pharmaceuticals (DoP) to expedite implementation of Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) by appointing a lead banker so that they can avail interest subsidy of 6% to upgrade infrastructure and technology to globally accepted standards. The DoP, which was supposed to launch the scheme in February this year through a public sector financial institution to be selected after open competitive bidding, is yet to finalise the banker.

The aim of the scheme is to help Pharma MSMEs improve technology and infrastructure to migrate from Schedule M to World Health Organisation Good Manufacturing Practice (WHO-GMP) standards, subject to achieving export targets. For this, the DoP has offered

a 6% interest subvention on loan up to Rs.8-10 crore for three years. It has earmarked Rs.300 crore for disbursal as interest subsidy for 2020-2022.

Small and Medium Pharma Manufacturers Association (SMPMA) in a representation to DoP appealed it to speed up efforts to appoint a lead banker to implement the PTUAS scheme. The SMPMA made the representation to DoP ahead of the second meeting of the Forum of Pharma Associations. Convened by DoP recently, the second meeting of the Forum of Pharma Associations was attended by several Pharma associations including IPA, OPPI, CIPI, BDMA and FOPE.

As per the Guidelines, the scheme will be implemented only through a Public Sector Financial Institution (PSFI) as implementing agency. Only machinery and electronic management systems required to help a Schedule M plant attain WHO-GMP compliance will be considered for financial assistance under the PTUAS scheme.

The lender must ensure that the beneficiary company obtains WHO-GMP certification within two years from the date of first disbursement of the loan. They should also achieve incremental export revenue in excess of the sanctioned loan amount within 36 months of the last draw of the loan, failing which the assistance will be converted into a normal loan by the financial institution. Interest subvention against sanctioned loan by any scheduled commercial bank/financial institution, both in public and private sector, will be provided to medium enterprises of proven track record.

Said Nipun Jain, Chairman of SMPMA, "The PTUAS scheme is meant to strengthen the presence of Pharma MSMEs in domestic as well as global markets given the globalised nature of the pharmaceutical industry. The scheme will also promote continuous technological upgradation and trigger healthy competition among the Pharma SMEs towards improving quality of drugs by availing soft loan assistance. We have urged DoP to make speedy efforts to implement the scheme by appointing a lead banker."

Source: Laxmi Yadav, Pharmabiz, 26.08.2020

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ICMR to develop new portal to disseminate information on COVID-19 vaccine development

In order to provide information and updates relating to the COVID-19 vaccine, Indian Council of Medical Research (ICMR) is in the process of developing a vaccine portal which will provide information related to the COVID-19 vaccine development in India and abroad. This will complement Electronic Vaccine Intelligence Network (eVIN) meant to strengthen immunization supply chain systems across the country. eVIN is being implemented under National Health Mission (NHM) by Union Health Ministry to provide real-time information on vaccine stocks and flows and storage temperatures across all cold chain points in the country. This robust system has been used with the requisite customization during the COVID–19 pandemic for ensuring continuation of the essential immunization services and protecting children and pregnant mothers against vaccine preventable diseases.

Updates and information on vaccine development would also be made available in regional languages in addition to English to make sure every citizen is able to access the information. The portal is likely to be functional by next week. The portal would be made operational in phases. In the first phase, the portal will provide all information related to COVID-19 vaccine in India and abroad. Over a period of time, information about all other vaccines used to prevent various other ailments will be put on the portal.

eVIN combines state-of-the-art technology, a strong IT infrastructure and trained human resource to enable real time monitoring of stock and storage temperature of the vaccines kept in multiple locations across the country. eVIN has reached 32 States and Union Territories (UTs) and will soon be rolled-out in the remaining States and UTs of Andaman & Nicobar Islands, Chandigarh, Ladakh and Sikkim. At present, 23,507 cold chain points across 585 districts of 22 States and 2 UTs routinely use the eVIN technology for efficient vaccine logistics management.

Over 41,420 vaccine cold chain handlers have been introduced to digital record-keeping by training them on eVIN. Nearly 23,900 electronic temperature loggers have been installed on vaccine cold chain equipment for accurate temperature review of vaccines in storage. eVIN has helped create a big data architecture that generates actionable analytics encouraging data-driven decision-making and consumption based planning that helps in maintaining optimum stocks of vaccines leading to cost savings.

Vaccine availability at all times has increased to 99% in most health centers. An activity rate of more than 99% reflects high adoption of the technology across all

health centers where eVIN is currently operational. While instances of stock-outs have reduced by 80%, the time taken to replenish stocks has also decreased by more than half, on an average. This has ensured that every child who reaches the immunization session site is immunized, and not turned back due to unavailability of vaccines.

To support the Government of India's efforts to combat COVID-19, eVIN India is helping the State/UT Governments monitor the supply chain of COVID response material. Since April 2020, eight States (Tripura, Nagaland, Manipur, Meghalaya, Arunachal Pradesh, Haryana, Punjab and Maharashtra) are using the eVIN application with 100% adherence rate to track State specific COVID-19 material supplies, ensure availability and raise alerts in case of shortage of 81 essential drugs and equipment.

Source: Shardul Nautiyal, Pharmabiz, 25.08.2020

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Commerce Ministry's new Turant scheme eases Customs Procedures for Pharma companies

The Union Ministry of Commerce has brought in a major transformation on the ease of doing business in the customs department by launching Turant, a contactless scheme, which has led to faster clearances by the Central Board of Indirect Taxes and Customs by maximizing use of technology for companies.

Pharma industry views it is as a major transformation as it has done away with the usual interface with the customs officers and has brought in the required consistency in reviewing the global trading protocols. It brings down the transaction costs and eliminates the practice of port shopping for favourable assessments. Further, it gives a boost to the country's competitiveness in the world market. Indian Customs Electronic Data Interchange System (ICES) now operational at 245 major customs locations handles almost all of India's imports and export goods.

According to Sunil Attavar, President, Karnataka Drugs and Pharmaceutical Manufacturers Association, this is a good policy change and now it is all online and based on risk assessment. So far, the industry has not faced any glitches except when there are network connectivity issues and the server is down when companies have some delays. However these are minor and will surely improve. All in all it is definitely a positive move for the sector.

The ambit of the programme covers automated clearance of bills of entry, digitization of customs documents, paperless clearance, faceless assessment and creation of the Turant Suvidha Kendra. The first phase of this contactless programme took off in Bengaluru and Chennai and the second phase from Mumbai and Delhi. The Government hopes to achieve all-India target by January 2021.

The COVID-19 lockdown which posed challenges in the area of exports, led the Government to come up with this scheme, which was implemented from July 6, 2020. The scheme eliminates cumbersome procedures brings in transparency. Paperless processes which came into effect from June 22, mandated only digital copy of shipping bill bearing final Letter of Export Order to be provided to the exporter. An E-Gate Pass PDF copy of the shipping bill will be communicated to the customs brokers and exporter via email.

Stating that the Turant Customs programme is a significant change into India's international trade landscape, Jatish N Sheth, Director, Srushti Pharmaceuticals and Steering Committee member KDPMA noted that the scheme was the next best thing to happen after the Merchandise Exports from India Scheme (MEIS) under Foreign Trade Policy of India which went digital and was introduced two decades ago.

While Srushti Pharmaceuticals will be using the Turant scheme next week, he said that duty drawback introduced by the Government in October 2019 also brought in a similar ease of doing business. The only thing is that from now on submissions by the Pharma companies who import materials need to complete and error free. There is also no choice for the customs department but to instantly give the clearance as per the system. Therefore this is a good move, noted Sheth.

Source: Nandita Vijay, Pharmabiz, 25.08.2020

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ICMR calls for research proposals on leishmaniasi to encourage interdisciplinary, innovative, close to practice research

To encourage interdisciplinary, innovative, close to practice research in the field of leishmaniasis (VL or *kala-azar*), the Indian Council of Medical Research (ICMR) has called for research proposal from eligible institutions

like medical colleges, universities, educational and research institutes and NGOs. The focus areas of the ICMR task force initiative are comprehensive epidemiological studies (indigenous/imported) in visceral leishmaniasis and cutaneous leishmaniasis and to characterize parasite variants and establish phylogenetic origin and genetic relatedness of the parasite species/subspecies.

It also focuses on tools or biomarkers to detect active disease (antigen-based/nucleic acid based diagnostic) that can be used at peripheral health facility to discriminate between post-treatment cure versus relapse; to predict the progression in an asymptomatic carrier to active VL and to measure parasite load as test of cure to monitor the efficacy of new drugs.

Another area of these proposals include burden studies (active case finding) on post *kala azar* dermal leishmaniasis (PKDL) load in community and the prevalent forms (macular, maculo-nodular or nodular) in different VL epidemiological settings. Studies to document failure/ resistance and relapse rates after miltefosine treatment and new drug treatment regimen (oral, mono or combination) to lower the relapse rates.

It also includes Bionomics of P. argentipes effect of climatic factors including rainfall and temperature on sandfly density in different settings. Impact of IRS as a vector control measure and on disease; Monitoring of insecticide resistance, mechanisms and rate of resistance in vectors and Xenomonitoring of P. argentipes as a routine surveillance tool with an appropriate rapid response for vector control.

Visceral leishmaniasis (VL or *kala-azar*) is a deadly tropical disease caused by the protozoan parasite genus leishmania. VL is endemic in >80 countries, however, 90 percent of the global cases are reported in six countries: Brazil, Ethiopia, India, Somalia, South Sudan, and Sudan. In India, VL is widely prevalent in the 54 districts of four endemic states of India namely Bihar, Jharkhand, Uttar Pradesh and West Bengal. Full project submission ends on September 15, 2020.

Source: Neethikrishna, Pharmabiz, 25.08.2020

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Governmnment likely to announce short term incentive scheme, excipient makers may get benefit

The Department of Pharmaceuticals (DoP) is in the process of formulating a short term incentive scheme for the industry. It is likely that the government will announce the proposed scheme shortly. The proposed initiative comes on the wake of appeals by industry stakeholders who appreciated the Production Linked Incentive (PLI) scheme but also requested a short term incentive scheme which can remain active until PLI scheme starts yielding results.

Seemingly, the government has heeded these requests and given consent to formulate a short term incentive scheme which will help the industry to reduce its dependency on other countries.

In the recently held virtual technical session organised by the PHD Chamber of Commerce, Dr Eswara Reddy, Joint Drug Controller General of India informed that based on the industry's recommendations, consideration might be given to existing facilities which have the capabilities as well as capacity to manufacture listed APIs, DIs and KSMs in the PLI scheme. The government is looking at formulating an alternate scheme for a short term period. DoP officials are in the process of formulating the scheme guidelines which is likely to be announced shortly.

He also added that authorities are also looking into identifying excipients which can also be part of the proposed scheme. The objective is that the production of those excipients can also be started on an immediate basis.

Yogin Mazumdar, Chairman of Bulk Drug Committee, IDMA commented, "We have suggested to the government to take into consideration about free capacities of nearly 30 per cent with many existing units which cannot be utilised under the present PLI scheme. It seems that the government is considering those recommendations and working on formulating a separate incentive scheme for the existing units. This time the government has not involved industry stakeholders in formulating the guidelines and they are doing it by themselves internally. But, earlier it comes, it will be better for the industry. Though we will need to study the fine print of the proposed guidelines once it is out."

He also added, "We are hopeful the proposed scheme will be worthwhile in nullifying the Chinese competition. Because, with the spare capacities which are available with the "brownfield" units, it would give immediate results towards reducing our dependence over Chinese."

According to an industry observer in the chemical synthesis category, out of 27 products, 20-21 products can be manufactured by the industry on an immediate

basis, provided the government takes a prompt decision in implementing the proposed suggestion of announcing a short term incentive scheme. He mentioned that there are 20-25 manufacturers who have shown interest in the scheme and pointed out that manufacturing of nearly 75 per cent of products in the chemical synthesis category can be started soon as they have the capability and capacity, however, they were not willing to carry out the production due to intense investment criteria.

Source: Usha Sharma, expresspharma.in, 27.08.2020

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Need to boost local API production for India to become self-reliant in coming years: Unichem

Drug firm Unichem Laboratories has called for measures to step up local production of raw materials to produce drugs in order to reduce the country's dependence on imports, especially from China. Sharing information with shareholders in company's annual report for 2019-20, the drug firm said the ongoing corona virus pandemic calls for concentrated efforts to build upon capacities for Active Pharmaceutical Ingredients (APIs) in the country.

"Our country is heavily dependent on China for import of most of its APIs. India needs a healthy and financially strong ecosystem to boost manufacture of APIs to remain self-reliant in the years to come," Unichem Laboratories Chairman and Managing Director Prakash A Mody said.

The present health crisis calls for proactive measures to step up economies of scale in production of intermediates and other key materials, with focus on research and development for APIs, he added.

With growing diseases and complications, a need has arisen to expedite drug discovery. The procrastination syndrome surely calls for prompt treatment, Mody noted. "Over-dependence of the Indian pharmaceutical industry on imported APIs exposes it to raw material supply disruptions and pricing volatility," Mody said.

While the government is working on developing bulk drug manufacturing parks to boost local production and reduce dependence on imports, the company, at its end, is focusing on efficiency and backward integration by ramping up its capacities in APIs and intermediates, he added.

The company is looking to use these APIs for captive consumption, which will give it an edge in the global generics market, Mody said. The drug firm's strategic investments in two pharma companies engaged in research and development, marketing and distribution of APIs will help meet the demand of exports for incremental growth, he noted.

Unichem offers a broad portfolio of APIs across various therapeutic areas. It has three manufacturing facilities to cater to the segment. The Mumbai-based firm also has a sizable presence in finished drug formulation segment. The global API market is projected to reach USD 268 billion by 2026 from USD 182 billion in 2019, growing at a CAGR of 6 percent.

Source: PTI, ET-HealthWorld, 09.08.2020 (Excerpts)

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Industry again seeks clarity from FSSAI on ICMR stipulated values of RDA for methylcobalamin as prophylactic use in neurological disorders

Industry has once again sought clarity from the Food Safety and Standard Authority of India (FSSAI) on Indian Council of Medical Research (ICMR) stipulated values of recommended dietary allowances (RDA) for methylcobalamin as prophylactic use in neurological disorders. Industry's recent correspondences with the FSSAI in spite of being addressed in a holistic manner have turned into a blame game between FSSAI and ICMR.

According to industry sources, taking an entirely U-turn, the national food safety regulator has instead directed the industry to refer the issue to the ICMR in blatant denial of laid down protocols and ethics. This is leading to confusion and hence detrimental to the public interest, industry experts have rued.

Industry after almost more than a year is still perplexed with FSSAI clarification regarding RDA values on methylcobalamin (Vitamin B12). Pharmaceutical experts Anshu Yadav and Dr Sanjay Agrawal on behalf of the industry have been questioning the rationality of RDA value of ICMR for almost a year but have not got the desired response from the FSSAI till date.

A recent letter addressed to Yadav and Dr Agarwal, from the newly appointed FSSAI CEO Arun Singhal has stated, "With reference to your email regarding request for revising RDA of methylcobalamin from 1 micro gram (mcg) to 500 micro gram, it is pertinent to mention that ICMR is the nodal institute established for setting up of RDA for different essential nutrients for Indians. Further, please

note that Section 22 of FSS Act, 2006 mentions foods for special dietary uses or functional foods or nutraceuticals or health supplements shall contain minerals or vitamins or proteins or metals or their compounds or amino acids in amounts not exceeding the RDA for Indians. As the regulations are bound to follow provisions mentioned under Act, the same has been enshrined into the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016."

"Any Food Business Operator (FBO) who wants to manufacture, import, market or sell the aforementioned products shall comply with the provisions of these regulations. In view of the above, you may approach ICMR for revision of RDA of Vitamin B12. Upon revision of the RDAs by ICMR, the same shall be incorporated into the regulations," the letter from FSSAI CEO Arun Singhal further stated.

Industry led by Anshu Yadav is planning make a representation on the matter with the Union Ministry of Chemicals and Fertilizers as their correspondences and pleas to notify FSSAI scientific panel approval on methylcobalamin in December last year and the FSSAI improper communication on the issue later in June 2020 with reference to a letter from FSSAI has not been addressed with due diligence and rationality. "This is to bring to the notice of the general public that former CEO FSSAI Pawan Agrawal on the other hand has been very cooperative and had last year sounded to all the concerned to take up the matter in a holistic manner by notifying methylcobalamin first to offer some semblance and clarity on the issue," Dr Agarwal pinpointed.

On January 7, 2020, FSSAI had issued a Notification regarding RDA of Vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin.

Drugs Controller General of India (DCGI) has recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available since long as patients take methylcobalamin based on the requirement. "The issue has been festering due to missing exact information on Tolerable Upper Limit (TUL) of vitamin B12 or methylcobalamin from the public domain. No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption," according to Anshu Yadav. Nutraceutical industry had received a letter in December 2019 from FSSAI about methylcobalamin approved RDA value for neurological disorders but industry is yet to see the much awaited Notification on the same, industry experts argue.

Source: Shardul Nautiyal, Pharmabiz, 27.08.2020

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Mankind Pharma ties up with South Korean co for clinical trials of COVID-19 drug

Mankind Pharma on Tuesday said it has collaborated with South Korean firm Daewoong Pharmaceutical Co for conducting phase-I clinical trial of a novel formulation of Niclosamide for the treatment of COVID-19 patients in India. The trial is designed towards addressing the need for an investigation on this new formulation based on encouraging preclinical evidence for the treatment of COVID-19, Mankind Pharma said in a statement.

"We are excited to collaborate with Daewoong Pharmaceutical Co Ltd to bring novel formulation of Niclosamide (DWRX2003) for the treatment of COVID-19 patients in India. "We believe that the product would provide for a safe and effective alternative to patients suffering from this disease," Mankind Pharma COO Arjun Juneja said. Pharma Manufacturing systems are highly variable with each system having different levels of interdependence and variability. These factors increase the unpredictability of the system making it increasingly difficult to predict the behavior.

Both the companies have received approval from the Drugs Controller General of India (DCGI) to conduct phase-1 clinical trials. Daewoong Pharmaceutical CEO Sengho Jeon said, "Through development of candidates for COVID-19 treatments such as Nicosamide, which Daewoong Pharmaceutical is currently developing, we expect to provide innovative treatment option for patients suffering from COVID-19." Mankind Pharma is one of the best partners to accelerate the clinical development and supply of DWRX2003 for India, he added.

Source: PTI, ET-HealthWorld, 04.09.2020

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When will we have COVID Vaccine?

Drugmakers made big promises for a quick turnaround on Coronavirus Vaccines. The moment of truth for the front-runners is coming as soon as this month.

The first results showing whether a vaccine can stop people from getting the virus could come by mid-September from AstraZeneca Plc, according to Airfinity Ltd., an analytics company that tracks drug trials. The drugmaker has pledged as many as 30 million doses to the UK by the end of the month.

Two other contenders -- the US's Moderna Inc and the US German partnership of Pfizer Inc and BioNTech SE -- may also have initial data before a key Food and Drug Administration meeting on virus vaccines scheduled for October 22, Airfinity said. A fourth, China's Sinovac Biotech Ltd., could have preliminary results shortly after the meeting.

These early results will be far from the full picture. They're what's known as interim readouts -- snapshots taken before a study is complete, with only a fraction of the data. The World Health Organization on Monday, 31.08.2020 cautioned against approving a vaccine before its full risks and benefits are clear. But with the virus resurgent in Europe and continuing to spread in India and the Americas, the initial numbers will be an important early indicator.

The first results should be enough to "give us a very good idea of where we're heading," Airfinity Chief Executive Officer Rasmus Bech Hansen said. "They are moving faster than one could have anticipated."

Airfinity's projections are based on publicly available data on trial enrollment and design, together with infection rates in places where patients are enrolled.

Each of these experimental vaccines has already shown promise in smaller trials designed to flag any serious safety concerns and show whether candidates can spur some response from the immune system. Early safety data is key; unlike drugs, vaccines are typically given to relatively healthy people and shouldn't create severe risks.

The real proving ground, though, is a study big enough to show with a high degree of certainty whether a vaccine candidate can work in the real world. This requires tens of thousands of participants, compared to the few hundred people who took the vaccines in early-stage trials.

Drugmakers would usually wait for final results before requesting regulatory approval, and the trio of front-runners are on track to get that full data by the end of the year, Airfinity says. In the US, that might not be fast enough. Overwhelmingly positive interim results could lead to studies being stopped early and the vaccines being rushed to the public, Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, told the Los Angeles Times earlier this week.

Political pressure will be high to approve a vaccine if even the initial snapshot of data from these trials is promising. President Donald Trump has said a vaccine is possible by the November 3 election and accused the FDA of trying to slow the approval process. Commissioner Stephen Hahn said last week he's open to clearing a vaccine under an emergency use authorization, which is based on more limited data. Russia and China, meanwhile, have each cleared experimental vaccines for limited use before testing was complete.

Pfizer has said it's on track to have enough data for an authorization as early as October. Based on how quickly and where it's currently recruiting people for its 30,000-person trial, it will probably be the first U.S. drugmaker with interim data -- by October 15 -- but won't have full results until November 17, Airfinity projects. A Pfizer spokeswoman declined to comment on how many virus cases it will need to see in order to get results in the trial.

Companies testing vaccines in the US, where the virus has spread more quickly than in Europe for the past several months, may have an advantage in potential volunteers and infections. AstraZeneca said it expects results later this year, depending on the rate of infection in the communities where it's running trials. J&J said it still plans to start its late-stage trial this month, with first batches of vaccine available for potential emergency use in early 2021, pending the study results. Sinovac declined to comment. Moderna declined to comment on the time-frame for its data readouts.

The drugmakers have already made deals to supply hundreds of millions of doses to governments around the world. The WHO has said any vaccine should be shown to be effective in at least half the people who get it to gain clearance. It will be important to follow participants in the trials long enough to see whether serious side effects emerge, WHO Chief Scientist Soumya Swaminathan said on

Monday, 31.08.2020. A premature approval would make it hard to continue studying the vaccine in randomized trials, she said. The agency counts 176 Covid-19 vaccines in development, of which 33 have entered human trials.

"What's going to be really important, I think, is to make decisions based on science," Swaminathan said, warning that an "inadequately studied" vaccine could present either safety problems or "low efficacy, thereby not doing the job of bringing an end to this pandemic."

Source: livemint.com, 03.09.2020

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Pharmaceuticals, CROs have hard time doing clinical trials amid prolonged pandemic

Amid the protracted Covid-19 pandemic, pharmaceutical and Contract Research Organization (CRO) companies are experiencing difficulties in conducting clinical trials to develop new drugs other than coronavirus-related medicines, industry sources said.

Local pharmaceuticals and CROs said it is not easy to comply with such toughened rules in clinical trials involving many subjects, and it is also difficult to halt the clinical trials due to their initial schedules.

"To make a patient participate in a clinical trial, medical workers have to explain trial procedures and methods and obtain consent from the patient," a company official said asking to remain anonymous. "In the case of infectious diseases such as Covid-19, contacts between clinical researchers and patients are not easy even at hospitals."

Adding to such problems, the ministry's new rule will likely prolong the trial period, which, in turn, will delay the commercialization process, he added. "As many clinical sites have banned outsiders, it has become impossible to predict the clinical schedule while the results of the trial must be handed over only after a Clinical Research Associate (CRA) staff monitors the data, an official at a local CRO said. "However, as our CRA staff cannot visit the clinical centers and monitor the result, the process itself cannot move forward."

Stressing these clinical trials must be conducted according to timelines, she said it is difficult even to establish a plan because few know how long the Covid-19 crisis will last. Officials at pharmaceutical and CROs said that Korea, too, has to adopt a non-contact clinical trial method to continue trials as an integral part of launching new drugs.

Major regulatory agencies, such as the U.S. Food and Drug Administration, the European Medicines Agency, and the U.K. Drug and Health Management Product Regulatory Authority, are actively recommending virtual trials, or non-face-to-face remote clinical trials, as a method to prevent the spread of Covid-19 in their guidelines.

The companies also maintained that some parts of the data collecting process should be revised to collect such data off-site. However, other industry officials said that it would be difficult to conduct non-contract clinical trials here due to patient privacy concerns.

The Korean regulations only allow patients information to be accessed inside hospitals, making it essential for CRA staff to visit hospitals and check the data. In response to such needs, the food and drug safety ministry said it is considering changing part of the regulations. "We are examining the introduction of a non-face-to-face system in the process of new drug development, clinical trials, and approval review," said Kim Young-ok, Director of the ministry's Drug Safety Division.

Source: KBR, m.koreabiomed.com, 04.09.2020

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Let data – not politics – guide development of Covid-19 drugs, vaccines, biotech execs urge

A group of biotechnology leaders is urging biopharmaceutical companies in an open letter to ensure that the Food and Drug Administration remain independent and that development of new medicines for Covid-19 be free of political influence, while also pointing to the importance of clinical trial diversity and judicious disclosure of data.

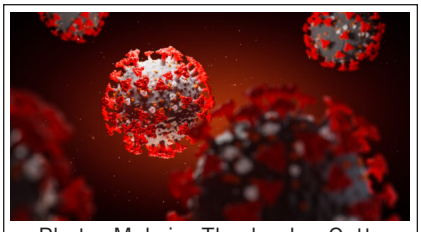

Photo: Maksim Tkachenko, Getty Images

The letter, published Thursday, 03.09.2020 was signed by Biotechnology Innovation Organization Chairman Jeremy Levin, CEO of Ovid Therapeutics; BIO CEO Michelle McMurry-Heath; Paul Hastings, CEO of Nkarta Therapeutics; Ted Love, CEO of Global Blood Therapeutics; Ron Cohen, CEO of Acorda Therapeutics; Rachel King,

CEO of GlycoMimetics; John Maraganore, CEO of Alnylam Pharmaceuticals; and Richard Pops, CEO of Alkermes. All of the biotech CEO signatories are current or former members of BIO's Board.

"These new products will need to be manufactured in large quantities and distributed rapidly to all segments of our society," the letter read. "Physicians, public health officials, patients and healthy citizens will need to be educated as to their safety, efficacy, and risk/benefit. Their widespread adoption will be based on trust in the integrity of the scientific and public health principles governing their development and approval."

The signatories urged biopharma companies to ensure that clinical trials were conducted according to best practices to ensure credibility of their data and ethical participation of diverse study populations, while the resulting data should be disclosed at "well-respected" scientific meetings or in peer-reviewed journals.

Data should not be disseminated via press release alone, and data released to the press should be "clear and include accurate descriptions of key data points" while stating that the full data will be submitted for peer review.

Regarding the FDA, they wrote that the agency should maintain its independence as the "gold-standard" international regulatory body and be free from external influence, in order to provide assurance to the public. And political considerations should be set aside by both parties.

Moreover, use of products should be driven by data, they wrote, noting that different subpopulations would react differently to medicines. They singled out vaccines in particular when they wrote, "The public should be assured that only rigorously considered data will dictate the subsequent use of any product."

While not referring to them explicitly, the letter's list of principles coincides with a number of growing concerns surrounding the development of drugs and especially vaccines against Covid-19, as well as criticism that the FDA has fallen under the political influence of the Trump administration in its decisions.

One of the earliest announcements of data from Moderna, which in May announced early data for its vaccine against SARS-CoV-2, mRNA-1273. However, while shares of the company rallied on the news, many observers pointed out that the data were far too early to draw conclusions.

Last month, experts writing in The New England Journal of Medicine stated that the Phase III clinical trials testing Gilead Sciences' antiviral drug remdesivir were insufficiently diverse, not reflecting the disproportionate morbidity and death caused by Covid-19 in Black, Latino and Native American populations in the U.S. More recently, fears have mounted that the FDA has been issuing some emergency use authorizations – particularly the one granted for convalescent plasma – under political pressure, and that it may fast-track a vaccine against the SARS-CoV-2 virus under similar pressure.

Source: Alaric DeArment, www.medcitynews.com, 04.09.2020

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FEATURE

COVID-19 and heart health: The big impact that is 100% avoidable

Dr Rachna Kataria, MD, Montefiore Medical Center

As the Coronavirus pandemic approached the New York metro region in March, doctors who specialize in heart disease already knew enough about COVID-19 to be very concerned about their patients. People with heart conditions are among the group hit hardest by the infection, and we continue to study the specific links between COVID-19 and cardiovascular disease. While we're certain the virus interacts with the heart in a number of ways, there's at least one needless impact of the pandemic on people with heart disease that is 100% avoidable. Here's what you need to know.

One impact of COVID-19 every heart patient can avoid:

During the 10 weeks beginning March 15, 2020, when COVID-19 was officially declared a health emergency, the arrival of heart patients in emergency rooms declined dramatically. We knew that heart attacks and strokes don't stop during a pandemic, so it came as no surprise when we learned that approximately 5,000 more people than normal had died from heart disease in New York State during that time period. There are many things that may have contributed to this increase during the height of the surge in New York, including fear of contracting the virus at the hospital or of creating an additional burden on the health care system. During a time when elective procedures were postponed and many clinics closed to keep people safe, not knowing when, whom and how to call for help likely caused a tragic delay in seeking necessary care. After an additional eight weeks, many people still hesitate to seek treatment for health emergencies. This is a completely avoidable impact of the pandemic that continues to risk the health of heart patients as the pandemic recedes in our region.

An emergency is still an emergency:

Heart disease remains the number one killer in the United States, taking a life every 37 seconds. If you have cardiac symptoms that are not normal for your baseline condition, it's essential that you seek help. If you feel something acute (chest pain or discomfort; pain in other parts of the upper body such as jaw, arms, neck, back or stomach; shortness of breath; or other signs like a cold sweat, nausea or light-headedness) call 911 or get to the emergency room without delay. The Montefiore Einstein Center for Heart and Vascular Care has been taking care of patients continuously, right through the worst of the pandemic, and we have effective measures in place to protect both patients and staff members from COVID-19, at the hospital and every facility in the health system. Do not delay necessary care for a health emergency today out of fear of COVID-19, which you may never have.

How COVID-19 affects the heart:

We're learning more about COVID-19's effect on the human body every day, but we observed from the start that patients with heart disease tend to have worse outcomes than those with healthy cardiovascular systems. We continue to study how this virus contributes to cardiac injury, and we've learned a great deal already. COVID-19, with its ability to cause a systemic inflammatory response, can create significantly increased strain on the heart as it works overtime to cope. The virus causes chronic hypoxia as it infects the lungs, depriving the body of necessary oxygen — including the heart.

Emerging evidence suggests that the virus may affect the heart muscle directly or by way of myocarditis or inflammation of the heart muscle. There is also evidence that COVID-19 causes blood clots in the heart vessels, leading to heart attacks.

Finally, we've seen stress cardiomyopathy. Commonly known as Takotsubo or "broken heart syndrome," this is when the heart breaks under stress, and COVID-19 can cause this if the patient has underlying conditions and/or Comorbidities like diabetes, high blood pressure and obesity. Although we know that patients with pre-existing heart conditions generally fare more poorly, we are still learning how Coronavirus and cardiac injuries are linked.

Self-care is still some of the best care:

If you are currently under the care of a doctor for heart disease, this is a good time to check in and review your ongoing care. Telemedicine or doctor video visits are a perfect way to clear up questions about any new symptoms that may have emerged or concerns about medications you're taking. It's important to remember that though COVID-19 infection is still possible for any of us, maintaining the following heart healthy behaviors give you the best chance of staying healthy or recovering well if you do contract the virus.

- **Do not skip medications.**

  Many patients struggled to refill prescriptions during the height of the pandemic, and this can be dangerous even without COVID-19. Help is always available by contacting your doctor or pharmacist. There is always a way to get you the medications you need. And please don't let concerns about medications interacting poorly with the virus stand in the way. Your doctor is the best source of information about this, so don't skip or discontinue any prescribed medicine without having a conversation with him or her first. And it is just as important to ask your doctor before trying any medication or treatment you may be hearing or reading about to avoid or treat COVID-19. Some of these substances can be particularly dangerous to a person with heart disease.

- **Manage stress levels**:

  We know that stress can be bad for anyone, but particularly for people with heart disease. 2020 has been a difficult year, and being stuck at home can contribute a lot of anxiety. Figuring out what your stressors are and avoiding them, like turning off the news or limiting your time on social media, can be helpful. Exercise is also very beneficial, but with gyms closed it's been hard for many people to keep moving. Walking outside is a good alternative, as long as you maintain that all important social-distancing and wear a mask as recommended. There are also many apps available to help you exercise and manage stress, including mindfulness and at-home exercise programs. If you are still feeling extremely stressed and anxious, a telemedicine app like MontefioreFirst can connect you with the psychological support you need from a professional.

- **Mind your diet**:

  Under all circumstances, we tell our heart patients to avoid fried foods, too much salt, red meats and excessive alcohol intake. We can do a lot for you in the hospital, but I always tell my patients that my role as a heart specialist is just 20%. The other 80% is up to the them. We need to trust each other to do what it takes to make the plan work. This feeling of ownership helps most people feel empowered to do what needs to be done to build the heart healthy habits that can protect and restore their lives for years to come.

(Members of the editorial and news staff of the USA TODAY Network were not involved in the creation of this content).

*(*Dr Rachna Kataria is the daughter of Mr Vasudev Kataria, Hon Treasurer, IDMA and Director, Vindas Chemical Industries Pvt Ltd.)*

Source: www.lohud.com, 19.08.2020 (Excerpts)

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Fate of unused Medicines and its Impact on our Health

Sacheen Gandhi, Social Talks

Medicines are an integral part of health care system. Each and every day millions of people are taking the medicine for numerous purposes. But after recovery from the condition people no longer needed them. Therefore often we have gathered all those expired, unused or unwanted medicines in our home and trash it eventually.

A survey was conducted by Drug Disposal Awareness Programme (DDAP) team, Delhi on 'methods of disposing these medicines by common people'. The answer was very simple as what many of us do is throwing them into dustbin. Have you ever thought that after throwing them into dustbin what is next? From dustbin it goes to dump yard.

From the yard it may be goes for burning in open air and pollute the air, some may be eroded in soil and reach to plants/animals; some of it gets mixed with rain or water stream and reach to fishes and other water animals and humans. So by any of the mechanisms the waste of those medicines again revert back to us in a more harmful form. Several Pharmaceuticals have been found in goat, cow, and human milk. The bio-accumulation of

Pharmaceutical products in aquatic animals, plants, and animals significantly affects the human life in turn.

As medicines are mostly chemical and once it expires it usually becomes a toxic agent. Therefore United States Food & Drug Administration initiated 'drug take back programme' to prevent the entry of these medication into environment. But in India drug take back programme is not well developed. People are used to dispose medicines by common methods such as burning, flushing into toilet and throwing somewhere or into waste-basket which results in serious environmental and health hazards.

Major consequences of improper disposal:

1. Development of drug resistance problems: If medicines enter into our body unknowingly and without any purpose for some time then body produce resistance against that drug. Drug resistance is the reduction of effectiveness of a medication to cure a disease or condition. This specially happens with antimicrobial drugs or antibiotics.

2. Cytotoxicity: Medicines for cancer are cytotoxic that means kills the healthy cells along with cancerous cells. Due to improper disposal these drugs may get into our water or food directly or indirectly through plant and other animal resources and can cause cancer, infertility, mental retardation or other sever health issues. Therefore improper disposal is one of the major causes of cancer.

3. Genotoxicity: It describes the property of chemical agents that damages the gene within a cell and cause mutations, which may lead to cancer or other hazards and can be carried it next generations.

4. Death: Globally about 700,000 people die of resistant infections every year because available antimicrobial drugs have become less effective at killing the resistant pathogens.

5. Accidental poisoning and drug abuse.

Solution for safe disposal:

World Health Organization has mentioned several Guidelines for safety disposal like proper land filling, flushing into sink or toilet, high temperature incineration and others. But all these practices are mainly for industries and not feasible for common public. Therefore Sacheen Gandhi has launched an easy and effective solution that can be used by common public. The idea is to incorporate those discarded medicines with cement or ceramic and convert them into solid brick or other structures like flower pot for gardening. After solidifying the medicines with cement it become very hard and non breakable therefore chances to mix in water or air is negligible. With this simple trick people can safely dump the medicines easily in home instead of throwing them into dustbin. There is a quote "If mindset changes, everything on the outside will change along with it".

Along with Drugs disposal campaign we are also working for Mask & Gloves disposal. Making people aware about used masks and gloves disposal during this Corona Pendamic.

Courtesy: Mr Sacheen Gandhi, Chief Patron - DDAP - Drug Disposal Awareness Program.

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