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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 Issue No. 47 15 to 21 December 2020

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IDMA Suggestions to DGFT on Foreign Trade Policy

The Association has submitted the following suggestions on 14th December 2020 to Shri Amit Yadav, IAS, Director General of Foreign Trade, Office of Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry, New Delhi for the Foreign Trade Policy:

"Greetings from Indian Drug Manufacturers' Association.

At the outset we thank you for the kind opportunity given to IDMA to interact with Hon'ble Minister of Commerce and Industry Shri Piyush Goyal on 7th December, 2020 in the Web meeting on Foreign Trade Policy.

Dr Viranchi Shah, Senior Vice President, IDMA had attended the meeting with the Hon'ble Minister of Commerce and Industry.

We are attaching herewith suggestions made for your kind consideration. Thanking you with warm regards".

Sr	Topic	Status as per current FTP	Issues	Request/Suggestions
1	MEIS	Being phased out from 31st December 2020, and RODTEP being introduced. Though RODTEP is not an incentive but a reimbursement only.	RODTEP roll out is still unclear for Pharmaceutical Products, and the time gap between phasing out of MEIS and introduction of RODTEP can have negative impact on pharma exports.	1. Until the RODTEP is rolled out, the MEIS may please be extended and fund please be allocated accordingly.
2	Currency for Realization of Export Proceeds	FTP Para 4.21, sub para (iii) requires that the payment be received from FCA Account.	In case of pharmaceutical intermediate imported by a API manufacturer located in DTA under advance authorization, and the relevant API is sold to SEZ unit, since the invoice is in INR, SEZ unit has to pay to DTA in INR and cannot pay through FCA. Thereby, the DTA importer cannot close obligations under the advance authorization of the intermediate so imported and this leads to litigations.	2. We pray that Para 4.21, Sub para (iii) be removed and Sub para (iv) be amended to read as "Export to SEZ units/Developers/ Co- developers can also be taken into account for the discharge of export obligations"
3	Advance Authorization – Pre-import & Physical Export condition	Subsequent to migration to GST, Pre-import and Physical Export condition was introduced through Notification No 79/2017 dated 13.10.2017. Due to	Though it was accepted that Pre-import and Physical exports condition needed to be removed, the Notifications do not address the period from 13.10.2017 and 10.01.2020.	1. It is prayed that the New FTP should not include the clauses for Pre-import and Physical Export conditions for Advance Authorization

		difficulties faced, the same was removed through DGFT Notification No.53/2015-2020 dated 10.01.2019 and Customs Notification No 01/2019 dated 10.01.2019	Advance authorization before and after this period are however covered. This has led to litigations specific to the period of 13.10.2017 and 10.01.2019.	2. It is also prayed that DGFT Notification No.53/2015-2020 and Customs Notification No 01/2019 both dated 10.01.2019 may be amended to give effect for the period 13.10.2017 onwards.
4	Mutual Recognition Agreements – Non-Tariff Trade Barrier	Many Bilateral and Multilateral agreements are signed under the leadership of CIM for promotion of trade	Good Manufacturing Practi ces (GMP) certificate is mandatory for registration of pharmaceuticals for the purpose of imports by almost all countries. These certificates are issued as per the World Health Organization's scheme (WHO GMP Scheme for Products moving into international trade) as per international agreement. However, many countries do not recognise the GMPs issued by Indian Authorities, under the WHO GMP scheme and create a non-tariff barrier for the entry of Indian medicines. This slows down the entry of Indian medicines in such markets.	1. It is suggested that while signing Free Trade Agreements, India may also add Mutual Recognition of Good Manufacturing Practices (GMP) issued by Indian Authorities as per the WHO-GMP Inspection Scheme for products moving into international trade, as a certificate for plant compliance to Good Manufacturing Practices.
5	Interest Subvention	Current FTP provides 3% interest subvention for MSME exporters.	-	1. The Interest Subvention scheme may please be continued under the new FTP, and the interest subvention rate may please be revised upwards to 5%.
6	Promotion of exports	Scheme for promotion Incremental Exports is available in some products but not in Pharma.	-	1. Pharmaceuticals may please be included in the Scheme for promotion Incremental Exports under the new FTP.

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NEED FOR REGULATORY AFFAIRS PERSONNEL DEVELOPMENT

Dr D B Anantha Narayana

Dear Reader,

Scientists seldom try to read regulations, let alone understand or interpret them. Most pharmacy students would have studied a subject called Forensic Pharmacy and read the almost bible like book by late Prof B M Mittal with the same title. Late Mr. Katti Shettar, the then Drugs Controller of Karnataka taught me this subject. He used to bring printed cartons, labels, literature while teaching Drugs and Cosmetics Act and Rules in 1970-71. He used to tell me "what kind of research scientist would you become if you don't know regulations?"

Pharmaceuticals are highly regulated worldwide with great clarity on scientific and technical information and data on the drug, premises, equipment, process and personnel involved in the manufacture and the total supply chain till it reaches the patients are regulated. A fairly large amount of documentation is required before any drug is approved for marketing and even imported to a country. It is a known fact that elaborate guidelines and documentation are demanded, inspection and audit of all stages are carried out in this process. This led to development of a new category of scientists whose main expertise was understanding the regulatory requirements and preparing adequate documentation with detail and accuracy. Such personnel got the title of Regulatory Affairs Scientists (RAS).

RAS became the bridge between the R&D department, manufacturing, quality assurance wings and the business heads. Primarily RAS had to deliver timely obtaining approvals from regulators to support marketing and business needs. Delays meant financial and business loss. These experts with skills of reading the law, regulations, guidelines, are responsible to translate them to implementable processes and procedures, specifications along with data on validations through well planned testing and appropriate documentation. Many Indian pharmaceutical firms suffered to receive deficiency notes from global regulators. Inadequate documentation were primary reasons while quality produced was never a question.

Health care is moving from an illness centric to a wellness centric approach. In addition to medicines, foods, medical foods, supplements and nutraceuticals and dermatologicals are expanding the health care routes. This has led to need for understanding regulations related to foods, food additives, labelling, advertisements, nutrition and health benefits, claims that can be made and those claims that are not permitted. Unlike drugs where

Dr Anantha Narayana, is the Chief Scientific Officer, AYURVIDYE TRUST, Bangalore. He Championed the Notifications of Supplements and Nutraceuticals Regulations, FSSAI, 2016 Updated in 2017 and Phytopharmaceuticals as Drugs under Drugs & Cosmetics Act & rules, 2016. He is a recipient of Indian Drugs award for Contribution to IDMA and Indian Drugs and is a recipient of Eminent Pharmacist's Award of IPA, 2007. Currently is an expert member, amongst others contributing significantly to (1) Member-Expert committee – Non-Specified Foods & Food Ingredients – FSSAI, (2) Chairman-Expert Committee – Advertisement & Claims – FSSAI, (3) Chairman-Scientific Panel – Nutraceuticals of FSSAI. (4) Chairman – Phytopharmaceuticals & Herbal products of Indian Pharmacopeia Commission (5) Member-Steering Committee of NMPB, Ministry of Ayush.

He continues to guide youngsters in research and also guides many startup firms in the area of Supplements/Nutraceuticals, Foods, Herbals and Cosmetics.

the claims are approved while issuing the marketing authorization, in the foods and supplements area health claims are not permitted automatically. The 'risk reduction and health benefits claims' have to go through a separate regulatory approval process.

The expanding health care in India and greater consumer appeal has opened the area of Ayurveda based products and herbal remedies. Products made with botanicals can be fitted into Ayurvedic Medicines category on one side and phytopharmaceuticals as drugs a category on the other with clear regulations in place.

Hence the role of RAS is expanding from medicines to foods to supplements/nutraceuticals, to Ayurvedic medicines and phytopharmaceuticals depending on the business objectives of the firms. Reduced number of NCEs, reduced generic drug introduction possibilities, difficulties and demands to introduce new Fixed Dose Combinations, many pharma companies are looking at other categories of health care products.

In this scenario employment opportunities for RAS is increasing. However, trained and qualified RAS are not available. Most RAS are not treated on par with other scientists and some of them feel they are doing a clerical job which is not true.

More than ever, innovative research, Intellectual Property Rights (IPR) practice and protection of IPR and the consequent need for detecting patentability or non-infringing operations are calling for alertness and attention of the Regulatory Affairs Scientists. Working around solutions and serendipitous inventive opportunities from deviation analysis can be achieved by RAS only through basic understanding of IPR regulations and practices. As such IPR is also forming an essential aspect and integral part of RAS training.

It may be appropriate for pharmaceutical education institutions and universities to initiate appropriate courses to convert a scientist to a regulatory affairs scientist. A six months to one year course to begin with may be adequate for a postgraduate in pharmacy, food science or Ayurveda to become fully functional RAS. Professional associations can also conduct such regulatory affairs courses on a part time basis or online courses with a specified number of contact hours in a R&D or factory.

(With inputs from Editor-in-Chief, Indian Drugs)

Courtesy: Indian Drugs, Guest Editorial, Vol. 57 (09) September 2020

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NPPA MATTERS

Availability of Enoxaparin Injection in State of Chhattisgarh - reg.

NPPA Notification dated 8th December, 2020

To
The Managing Director/CEO,
*All Manufacturers of Drugs Enoxaparin as per list**
(For immediate compliance).

1. The undersigned is directed to invite a reference to email dated 08.12.2020 received from MoHFW regarding the hampered availability of Enoxaparin Injection for management of COVID-19, in the State of Chhattisgarh.

2. In view of above, the Manufacturers of Enoxaparin Injection are directed to make available adequate stocks in the trade channels of state of Chhattisgarh under intimation to this office on immediate basis.

F.No.37001/2020/Div.III/NPPA-(part)

Manjesh Porwal, Deputy Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

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Faceless Assessment – CBIC Clarifications on the Issues raised by Stakeholders

Circular No.55/2020-Customs, dated 17th December, 2020

To,

All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),

All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,

All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),

All Principal Commissioners/Commissioners of Customs & Central tax,

All Principal Director Generals/Director Generals under CBIC.

1. Kind reference is invited to Board's earlier Circulars and Instruction on the subject of Faceless Assessment.

2. After a series of consultations with various stakeholders, such as the NACs, trade and industry associations, it is felt that there is a need to further enhance the efficiency of the process involved in Faceless Assessment. With a view to achieve this objective, certain key areas, which require immediate attention, have been identified and the following instructions/guidelines are being hereby issued so as to smoothen the process of Faceless Assessment by the field formations.

a) Re-assessment in accordance with the Principles of Natural Justice: Despite several Board instructions on the issue, it has been observed that many a times the importers are not being afforded an opportunity of being heard before re-assessment of the goods. Such a practice is not in conformity with the provisions of law and needs to be accordingly discontinued, forthwith. It is emphasised that the process of reassessment must be in accordance with the provisions of Sub Sections (4) and (5) of Section 17 of Customs Act, 1962. In order to lend clarity and streamline this process, the procedure to be adopted by the FAGs for carrying out re-assessment, wherever required, is delineated as follows:

i. During verification of the assessment, if there are reasons to believe that the self-assessment is not done correctly, or additional details are required to complete the verification, necessary clarifications should be sought from the importer/Customs Broker through the query module of ICES.

ii. While raising the query, all the aspects of additional information required for finalisation should be covered and clearly worded. Also, as far as possible, multiple queries need to be avoided and all the information may be solicited in one-go and not in a piece-meal manner. Further, in the event that the officer concerned is required to raise a second (or more) query/ies on the same Bill of Entry, approval shall be taken from the respective Additional Commissioner/Joint Commissioner, with full justification thereof. Needless to say, this approval should be given only as an exception and not as a matter of routine. Pr. Commissioners/Commissioners across the NACs may ensure that minimal queries are raised by the concerned FAGs and may devise their own mechanism to regularly monitor the same, in a manner that needless and repeated queries, which have the effect of delaying assessments, are avoided.

iii. Based on the reply to the query, the FAG may either accept the self-assessment or proceed to re-assess the Bill of Entry.

iv. While re-assessing the Bill of Entry, it must be ensured that the importer is given an opportunity to justify the self-assessment either in writing or in person through Video Conferencing. The importer, can, if he so desires, waive off this requirement in writing. No re-assessment, which would lead to change in classification, valuation and/or applicability of notification etc, should be carried out, unless an opportunity is provided to the importer for presenting his/her viewpoint.

v. Where the assessing officer re-assesses the Bill of Entry and where the importer does not accept the change in assessment in writing, through the query module in ICES, the proper officer shall mandatorily issue a speaking order without delay and in accordance with Sub-Section (5) of Section 17 of Customs Act, 1962.

b) Complete description of imported goods: It has been brought to the notice of the Board that one main reason for the raising of a query is that in many instances, the importers do not give complete description of the imported goods, while filing the Bill of Entry. This constrains the assessing officer and delays the process of verification of the assessment by the FAG. Therefore, it is important that the importers/Customs Brokers are advised to give the complete description of the imported goods while filing the Bill of Entry, in the first instance. In this context, the attention of the importers/Customs Brokers may be drawn to the following fields that are available in the electronic Bill of Entry format:

i. **Generic Description**: The description in generic text relevant to text provided in the duty exemption notification that is claimed/Anti-Dumping (ADD)/IGST levy, as applicable.

ii. **Specific Description**: The description specific to the product and as given in the invoice, trade name or specific product details to be provided (Brand name or model details may be avoided-same needs to be provided separately).

iii. **Model and Brand Name**: Model details and Brand Name may be provided and if the imported goods are unbranded, the text "UNBRANDED" may be used.

iv. **Supplier and Manufacturer Details**: In cases where duty applicability is based on manufacturers such as Anti-Dumping Duty (ADD), Safeguard Duty (SD) etc, the details of manufacturer may be provided. In case of products attracting ADD, these details would be required to be mandatorily provided.

v. **Item Qualifiers**: Some imported items may have specific distinguishing characteristics or have industry specific names (e.g. scientific names, IUPAC names etc.). These item names or qualifiers may be declared, as applicable. The illustrative list of such item qualifiers are at Annexure A. DG Systems, CBIC would shortly issue a detailed advisory for guidance of the trade, in this regard.

vi. **Previous Bills of Entry**: The Bill(s) of Entry details of previous import may be mentioned, if available.

c) Document codes for regular documents to be uploaded in e-Sanchit: Another reason why FAG officers are compelled to raise queries is that importers/Customs Brokers are not uploading all the required supporting documents to justify their claim of a duty exemption notification or fulfilment of a CCR requirement etc along with the Bills of Entry. It appears that this is happening, as in the past, the importers/Customs Brokers were habituated to produce these documents directly to the assessing officers. As these documents are essential for carrying out verification of self-assessment by the FAG and their non-submission at the stage of filing the Bill of Entry delays the verification/assessment process, Board has decided that w.e.f. **15.01.2021**, these supporting documents shall be mandatorily required to be uploaded in e-Sanchit by the importers/Customs Brokers, in such situations. The illustrative list of the required documents along with their document code and description is at Annexure B. DG Systems, CBIC would shortly issue a detailed advisory for guidance of the trade, in this regard.

d) Enhancement in the monetary limit for assessment by the Appraising Officers: As of the present, all Bills of Entry with an assessable value of up to Rupees 1 lakh are assessed only by the Appraising Officers. All Bills of Entry beyond the above threshold, are necessarily subjected to a two-step scrutiny, first by the Appraising Officer and then by the Deputy/Asst Commissioner of Customs. In order to expedite the assessment process, it has been decided that an enhancement in these long standing prescribed monetary limits would speed-up the assessment process. Accordingly, the Board has decided to enhance the monetary limit of assessment of Bills of Entry by the Appraising Officers. All Bills of

Entry with an assessable value of up to Rupees 5 lakh shall be accordingly finally assessed only by the Appraising Officers, w.e.f. **21.12.2020.** However, the re-assessments of Bills of Entry would continue to be done with the approval of the Assistant/Deputy Commissioner, as is the present practice. In order to assess the impact of this change, the Board has also decided that 10% of the Bills of Entry that are now entrusted to the Appraising Officers would be subjected to transactional PCA. A fortnightly report on the outcome of the transactional PCA would be submitted to Joint Secretary (Customs), CBIC with first report being due on 05.01.2021. The Pr Commissioners/Commissioners concerned would also monitor the outcome of this change and immediately inform the Board, if any correction is required.

e) Assessments in respect of Liquid Bulk Cargo: The Board has also received representations in respect of delays in the assessment of liquid bulk cargo. One common refrain of the trade here is the unnecessary resort to the First Check System of assessment, in such cases. With respect to import of *'liquid bulk cargo',* it is stated that the assessments are to be carried out on a provisional basis. This is primarily on account of the ascertainment of actual imported quantity which is done subsequently. Also, at times, there may be a doubt with respect to the composition, product specification etc. Both these aspects do not warrant a First Check system of assessment. The respective Co-Convenors of the NACs assessing such consignments are advised to ensure that all such consignments are subjected to the Second Check system of assessment, with duty being assessed on a provisional basis. Moreover, the concerned officers in the FAGs and the respective NAC Commissioners may be suitably sensitised to follow Board's Circulars No.34/2016–Cus, dated 26.07.2016 and No.38/2016-Cus, dated 22.08.2016, while carrying out such assessments. Board has also observed that suitable templates in the form of Public Notices, issued by major Custom Houses are available in the public domain, so as to serve as a ready reckoner and guidance tool for the Assessing Officers, for assessment of liquid bulk cargo. The same may be incorporated as standard practice by the concerned NACs, with a view to remove any ambiguity in the process to be followed.

3. Any difficulties faced or doubts arising in the implementation of this Circular may please be brought to the notice of Board.

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

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

Annexure A

Info Type CD	Infor QFR CD	Info QFR Desc
CHR	SQC	Statistical Unit Quantity Code for Customs
CHR	SEX	Sex
CHR	BRD	Breed
CHR	CLR	Colour
CHR	PLV	Plant Variety
CHR	STT	Storage Temperature
CHR	STC	Storage Condition
CTG	GRA	Grade of the Product
CTG	PLC	plant Category
CTG	PLP	Plant Parts
CTG	DRC	Drug Related Category
CTG	FSP	Foods & Supplement Proprietry Status
IDT	PAS	Animal Passport Number
IDT	ECI	Electronic Component Identification Number
IDT	GTI	Global Trade Item Number
IDT	VIN	Vehicle Identification Number
IDT	MIC	Microchips numbers inserted into animals for identifification purposes

IDT	CAS	Chemical Abstract Service registration number.
ORC	COO	Country of Origin
ORC	ORG	Origin Criteria
ORC	ACM	Accumulation
ORC	WP	Wholly Obtained or Produced
ORC	VA	Value Added
ORC	PS	Product Specific Rules
PNM	PET	Pet Name
PNM	SCI	Scientific Name
PNM	COM	Common Name
PNM	CON	Trade or Commercial Name
PNM	MOD	Name of the model
PNM	IUP	Name as per the IUPAC Nomenclature
PNM	PHA	Name as contained in a Pharmacopeia
PNM	INN	International Non-proprietary Name
PNM	PCN	Plant Commodity Name
PNM	LSP	Name of the Livestock product
PNM	SIU	SIMS Unique Reference Number

Annexure B-1

(Documents already made mandatory as per Circular No.42/2019-Customs dated 29.11.2019, Notification No.81/2020-Customs-N.T. dated 21.08.2020 read with ICES Advisory No.34/2020 dated 17.09.2020)

S. No.	Document Code	Name of the Document
I.	**INVOICE (One of the two) – for every invoice**	
1.	380000	Invoice
2.	331000	Invoice cum Packing List
II.	**TRANSPORT CONTRACT (One of the below) – for every Bill of Lading / Airway Bill in the IGM**	
3.	704000	Master Bill of Lading
4.	714000	House Bill of Lading
5.	705000	Bill of Lading
6.	703000	House waybill
7.	709000	Tanker Bill of Lading
8.	710000	Sea Way Bill (Non Negotiable)
9.	711000	Inland Waterway Bill of Lading
10.	740000	Air waybill
11.	741000	Master air waybill
12.	700000	Way Bill (Non Negotiable)
III.	**Country of Origin Certificates ONLY when exemption notification(s) is/are claimed.**	
13.	861001	COO-CEPA(Singapore)- Country of Origin Certificate as per the Comprehensive Economic Cooperation Agreement between the Republic of India and Republic of Singapore, Rules,2005. Vide Notfn. no. 59/2005-Cus(N.T.) dated 20.07.2005
14.	861002	COO-PTA(Chile)- Country of Origin Certificate as per the Preferential Trading Agreement Between the Republic of India and the Republic of Chile,Rules 2007. vide Notfn No. 84/2007-Cus(N.T.) dated 17.08.2007

15.	861003	COO-FTA(Srilanka)- Country of Origin Certificate as per the Free Trade Agreement between the Democratic Socialistic Republic of Sri Lanka and the Republic of India Rules, 2000. vide Notfn No. 19/2000 Cus(N.T.) dated 01.03.2000
16.	861004	COO-PTA(Malaysia)- Country of Origin Certificate as per the Preferential Trade Agreement between the Government of Republic of India and Malaysia, Rules, 2011. vide Notfn No. 43/2011-Cus(N.T.) dated 01.07.2011
17.	861005	COO-PTA(Korea)- Country of Origin Certificate as per the Preferential Trade Agreement between Government of India and the Republic of Korea, Rules 2009. vide Notification no. 187/2009-Cus(N.T.) dated 31.12.2009
18.	861006	COO- PTA(ASEAN)- Country of Origin Certificate as per the Preferential Trade Agreement between the Governments of Member States of the Association of Southeast Asian Nations (ASEAN) and the Republic of India,Rules,2009 videNotfn. No.189/2009-Cus(N.T.) dated 31.12.19
19.	861007	COO-SAFTA- Country of Origin Certificate as per the Agreement on South Asian Free Trade Area (SAFTA). Vide Notfn. No. 75/2006(N.T.) dated 30.06.2006.
20.	861008	COO-PTA(Mercosur)- Country of Origin Certificate as per the Preferential Trade Agreement between the Government of MERCOSUR Member states and Republic of India, Rules, 2009. Vide Notfn. No. 56/2009-Cus(N.T.) dated 30.05.2009
21.	861009	COO-PTA(Afghanistan)- Country of Origin Certificate as per the Preferential Trade Agreement between the Transitional Islamic State of Afghanistan and Republic of India, Rules, 2003. Vide Notification no. 33/2003-Cus(N.T.) dated 13.05.2003.
22.	861010	COO-APTA- Country of Origin Certificate as per the ASIA- Pacific Trade Agreement (Formerly known as Bangkok Agreement) rules, 2006. Vide Notfn. No. 94/2006-Cus(N.T.) dated 31.08.2006.
23.	861011	COO- PTA(SAARC)- Country of Origin Certificate as per the Agreement on SAARC Preferential Trading Agreement,Rules,1995. Vide Notfn. No. 73/1995 dated 07.12.1995.
24.	861012	COO-PTA(Thailand)- Country of Origin Certificate as per the Preferential Tariff Concessions for Trade between India and Thailand. Vide Notfn. No.101/2004-Cus(N.T.) dated 31.08.2004.
25.	861013	COO-PTA(LDC)- Country of Origin Certificate as per the Duty free Tariff Preference Scheme for Least Developed Countries, Rules, 2015. Vide Notfn. No. 29/2015-Cus(N.T.) dated 10.03.2015.
26.	861014	COO-GSP- Country of Origin Certificate as per the Agreement on Global System of Trade Preferences among Developing Countries, Rules, 1989. vide Notfn No. 281/89-Cus(N.T.) dated 18.12.1989.
27.	861015	COO-CEPA(Japan)- Country of Origin Certificate as per the Comprehensive Economic Partnership Agreement between the Republic of India and Japan, Rules, 2011. Vide Notfn. No. 55/2011-Cus(N.T.) dated 01.08.2011.

Annexure B-2
(Documents mandatory ONLY when benefit of relevant notification is claimed)

S.No.	Document Code	Name of Document	Document Description
1.	002TE1	MTCTE Certificate	MTCTE Certificate issued by TECI to certify that the product conforms to the Essential Requirement under Mandatory Testing and Certification of Telecom Equipment.
2.	101IR1	Certificate of Registration	Certificate of Registration issued by DSIR of availing import duty benefit
3.	101RB1	Registration-cum-Membership Certificate (RCMC)	Registration-Cum-Membership Certificate [RCMC] is issued by Rubber Board for availing benefits under Foreign Trade Policy and of customs duty exemption

4.	101SG1	Registration cum Membership Certificate	Registration cum Membership certificate issued by SPORTS for availing benefits under Foreign Trade Policy and for customs duty exemption
5.	101TO2	Registration-Cum-Membership Certificate [RCMC]	Registration-Cum-Membership Certificate [RCMC] is issued by Tobacco Board for availing benefits under Foreign Trade Policy and of customs duty exemption
6.	101WW1	Registration-Cum-Membership Certificate	Registration-Cum-Membership Certificate issued by WWEPC for availing benefits under Foreign Trade Policy and for customs duty exemption
7.	911AE1	Import Certificate	Import Certificate issued by AEPC for availing import duty benefit
8.	911DA1	Air Operator Permit (Scheduled)	Air Operator Permit (Scheduled) is issued by DGCA for operating a scheduled flights service. This is also a pre-requisite for allowing import of Aircraft
9.	911DA2	Air Operator Permit (Non-Scheduled)	Air Operator Permit (Non-Scheduled) is issued by DGCA for operating a non-scheduled flights service. This is also a pre-requisite for allowing import of Aircraft
10.	911DA3	No Objection for Import/Procurement of Aircraft/Helicopter for Operating Air Transport Services	No Objection for Import/Procurement of Aircraft/Helicopter for Operating Air Transport Services issued by DGCA
11.	911DH2	NOC (Block Add)	NOC(Block Add) is issued by DGHC to use the goods imported by availing import duty exemption for utilizing in a particular block of area, however, he wants to utilize the goods in another block area also.
12.	911EP1	Duty Free Import Certificate	Duty Free Import Certificate issued by EPCH for availing import duty benefit
13.	911FT0	DGFT Licenses/Scrips	All Licenses/Scrips issued by DGFT under various export promotion schemes like DEEC, EPCG, MEIS etc.
14.	911IB1	Grant of exemption from Custom duty on the films/video tapes/DVD AND publicity material	Grant of exemption from Custom duty on the films/video tapes/DVD AND publicity material to be entered in India for different Film Festivals.
15.	911IB2	Grant of exemption from Custom duty under General Exemption on temporary import of filming equipment	Grant of exemption from Custom duty on temporary import of filming equipment for the shooting of any feature film/T.V serial in India.
16.	911IB3	Eligibility Certificates to the owners of registered publications for the import of Newsprint under	Eligibility Certificates to the owners of registered publications for the import of Newsprint under Exim Code 4801 on Actual User Condition as per the Foreign Trade Policy of the Ministry of Commerce and Industry
17.	911LE2	Certificate for Import Clearance of Textile and Textile Articles	Import certificate is issued by council of Leather Exports for availing custom duty exemptions on imports
18.	911ME1	Concessional Customs Duty Certificate(CCDC) for import of mould, tools or dies	Concessional Customs Duty Certificate(CCDC) for import of mould, tools or dies issued by MEITY
19.	911ME2	Concessional Customs duty certificatefor import of raw materials	Concessional Customs duty certificate or import of raw materials issued by MEITY

20.	911ME3	Concessional Excise duty Certificate	Concessional excise duty certificate issued by MEITY
21.	911MN1	Concessional Custom Duty Certificate for Solar project	Concessional Custom Duty Certificate for Solar project issued by MNRE
22.	911MN2	Concessional Custom Duty Certificate for Wind farm Project	Concessional Custom Duty Certificate for Wind farm Project issued by MNRE
23.	911MN3	Concessional Custom Duty Certificate for Municipal Corporation- Urban and Industrial Waste	Concessional Custom Duty Certificate for Municipal Corporation-Urban and Industrial Waste issued by MNRE
24.	911SG1	Import Certificate	Import Certificate issued by SPORTS for availing custom duty exemptions on imports
25.	911SG2	Export Performance Certificate	Export Performance certificate is issued by SPORTS for availing custom duty exemptions on imports
26.	911TB1	CC for Tea Import by TB	CC for Tea Import by TB issued by Tea Board

Annexure B-3

(Documents mandatory as per restrictions/prohibitions -Specific only to certain Tariff items)

S.No.	Document Code	Document Name	Document Description
1.	002TE1	MTCTE Certificate	MTCTE Certificate issued by TECI to certify that the product conforms to the Essential Requirement under Mandatory Testing and Certification of Telecom Equipment.
2.	0380AQ	Vaccination certificate	Official document proving immunisation against certain diseases.
3.	101002	RCMC	Registration Cum Membership Certificate issued by an Export Promotion Council
4.	101BN1	Registration of import contract for	Registration of import contract for import of poppy seeds issued by CBN
		import of poppy seeds into India	
5.	101CI3	Certificate of Registration for Import	Certificate of Registration for Import issued by CIB&RC
6.	101CI4	Certificate of Registration for Indigenous Manufacturer	Certificate of Registration for Indigenous Manufacturer issued by CIB&RC
7.	101CP1	Registration Certificate	Registration Certificate issued by CPCB
8.	101CT1	Registration cum Membership Certificate	Registration cum Membership certificate issued by TEXPROCIL for availing benefits under Foreign Trade Policy and for customs duty exemption
9.	101LM1	Certificate of Registration of Importer of Weights and Measures	Certificate of Registration of Importer of Weights and Measures issued by Legal Metrology Division, Department of Consumer Affairs.

10.	101PI1	Registration cum Membership Certificate	Registration-Cum-Membership Certificate (RCMC) is Project EPCI by Tobacco Board for availing benefits under Foreign Trade Policy and of customs duty exemption
11.	101PP1	Registration cum Membership Certificate	Registration cum Membership certificate issued by PEPC for availing benefits under Foreign Trade Policy and for customs duty exemption
12.	101RN1	Certificate of Registration	Certificate of Registration issued by RNI for registering the publisher/Owner.
13.	101SF1	QC Registration	QC Registration issued by SHEFXCIL
14.	101SF2	Registration for Gum Karaya	Registration for Gum Karaya issued by SHEFEXCIL
15.	101SF3	R & QC for SHELLAC products	R & QC for SHELLAC
16.	101SR1	Registration cum Membership Certificate	Registration cum Membership certificate issued by Synthetic and Rayon Textile Export Promotion Council for availing benefits under Foreign Trade Policy and for customs duty exemption
17.	101TO2	Registration-Cum-Membership Certificate [RCMC]	Registration-Cum-Membership Certificate [RCMC] is issued by Tobacco Board for availing benefits under Foreign Trade Policy and of customs duty exemption
18.	101TS1	Registration cum Membership Certificate	Registration cum Membership certificate issued by Telecom Equipment and services Export Promotion Council for availing benefits under Foreign Trade Policy and for customs duty exemption
19.	651002	Extended Producer Responsibility Authorisation	Import Authorisation for Import of Goods notified by CPCB
20.	626000	Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) Certificate	A certificate used in the trade of endangered species in accordance with the CITES convention.
21.	626WC2	CITES Comparable Document forDalbergia sissoo	CITES Comparable Document for Dalbergia sissoo issued by WCCB
22.	626WC3	Captive Bred/ artificially propagated Certificate	Captive Bred/ artificially propagated Certificate is issued by WCCB for those species which fall under appendix 1 of CITES and have been captively bred or artificially propagated
23.	911001	FSSAI Import License	
24.	911AB1	No objection Certificate for Procurement of Radiation Source	No Objection Certificate for Procurement of Radiation Source issued by AERB
25.	911BN1	Import Certificate for import of Psychotropic Substance	Import Certificate for import of Psychotropic Substance issued by CBN
26.	911BN2	Import Certificate for import of Narcotic Drugs	Import Certificate for import of Narcotic Drugs issued by CBN

27.	911BN3	No objection Certificate for Import of Precursor Chemical (Controlled Substance)	No objection Certificate for Import of Precursor Chemical (Controlled Substance) issued by CBN
28.	911BN4	Certicate of official approval for import of opium, etc under Rule 54 of NDPS Rules 1985	Certificate of official approval for import of opium, etc under Rule 54 of NDPS Rules 1985 issued by CBN
29.	911CI1	Import Permit for Research Test and Trial	Import Permit for Research Test and Trial issued by CIB&RC
30.	911CI2	Import permit for Biocide	Import permit for Biocide issued by CIB&RC
31.	911CI3	Import Permit for Non-Insecticidal use	Import Permit for Non-Insecticidal use issued by CIB&RC
32.	911CT1	Import Certificate	Import certificate is issued by TEXPROCIL for availing custom duty exemptions on imports
33.	911DE1	Import Licence	Licence for import is issued by Department of Atomic Energy for import of prescribed substance as per Atomic energy Act, 1962 and Rules thereunder
34.	911DF1	Permit for Import of Livestock Products	Permit for Import of Livestock Products issued by DADF
35.	911EP1	Duty Free Import Certificate	Duty Free Import Certificate issued by EPCH for availing import duty benefit
36.	911LE1	Import Certificate	Import Certificate issued by CLE
37.	911PE1	Licence Form LE - 8(Licence to Import explosives)	Licence Form LE -8(Licence to Import explsovies) issued by PESO
38.	911PE2	License to Import Ammonium Nitrate (licence Form P-5)	License to Import Ammonium Nitrate (licence Form P-5) issued by PESO
39.	911RB1	No Objection Certificate (NOC) for import of Natural Rubber	No Objection Certificate (NOC) for import of Natural Rubber issued by Rubber Board
40.	911RN1	Self declaration certificate for Import	Self Declaration Certificate is submitted by the Publisher/Owner of the newspaper and authenticated by RNI before importing the newsprint.
41.	911SR1	Import Certificate	Import certificate is issued by Synthetic and Rayon Textile Export Promotion Council for availing custom duty exemptions on imports
42.	911SR2	Export Certificate	Export certificate is issued by Synthetic and Rayon Textile Export Promotion Council for availing custom duty exemptions on imports
43.	911SR3	Turnover Certificate	Turnover certificate is issued by Synthetic and Rayon Textile Export Promotion Council for availing custom duty exemptions on imports
44.	911TB1	CC for Tea Import by TB	CC for Tea Import by TB issued by Tea Baord

Annexure B-4
(Documents which are optional and are required on case to case to basis)

S.No.	Document Code	Document Name	Document Description
1.	001000	Certificate of analysis	Certificate providing the values of an analysis.
2.	001002	Lab analysis Report	Certificate providing the values of an analysis of a sample by a laboratory.
3.	001003	Blood Analysis Report	Certificate providing the values of an analysis of a sample of blood.
4.	002000	Certificate of conformity	Certificate certifying the conformity to predefined definitions.
5.	003000	Certificate of quality	Certificate certifying the quality of goods, services etc.
6.	003001	Product Approval	A Certificate signifying the quality approval of a food product.
7.	0030DC	Batch Release Certificate	A Certificate confirming the release of a production batch after due testing and quality controls.
8.	004000	Test report	Report providing the results of a test session.
9.	004001	Test Certificate	A Certificate providing the results of a test session.
10.	004TC1	Test Report	Test Report issued by Textiles Committee
11.	005000	Price/sales catalogue	A document/message to enable the transmission of information regarding pricing and catalogue details for goods and services offered by a seller to a buyer.
12.	006000	Product specification report	Report providing specification values of products.
13.	006001	Technical Writeup/ Literature	A report providing technical specifications of products
14.	022CO1	Self-Declaration on Customs Cases	Document/message providing declaration on the status of cases booked under Chapter XVI of the Customs Act.
15.	0530HZ	Safety and hazard data sheet	Document or message to supply advice on a dangerous or hazardous material to industrial customers so as to enable them to take measures to protect their employees and the environment from any potential harmful effects from these material.
16.	105000	Purchase order	Document/message issued within an enterprise to initiate the purchase of articles, materials or services required for the production or manufacture of goods to be offered for sale or otherwise supplied to customers.
17.	101CE1	Registration cum Membership Certificate	Registration cum Membership Certificate issued by CEPC for availing benefits under Foreign Trade Policy and for customs duty exemption
18.	101HE1	Registration cum Membership Certificate	Registration cum Membership Certificate issued by HEPC for availing benefits under Foreign Trade Policy and for customs duty exemption
19.	101IS1	Registration cum Membership Certificate	Registration cum Membership certificate issued by SILK for availing benefits under Foreign Trade Policy and for customs duty exemption
20.	101PD1	Registration cum Membership Certificate	Registration cum Membership Certificate issued by PDEPC for availing benefits under Foreign Trade Policy and for customs duty exemption

21.	2670PQ	Fumigation certificate	Certificate attesting that fumigation has been performed.
22.	271000	Packing list	Document/message specifying the distribution of goods in individual packages (in trade environment the despatch advice message is used for the packing list).
23.	315000	Contract	Document/message evidencing an agreement between the seller and the buyer for the supply of goods or services; its effects are equivalent to those of order followed by an acknowledgement of order.
24.	315HS1	High Sea Sale Agreement	Agreement of the sale of goods on the high seas.
25.	325000	Proforma invoice	Document/message serving as a preliminary invoice, containing - on the whole - the same information as then final invoice, but not actually claiming payment.
26.	380HS1	High Sea Sale Invoice	Document/message claiming payment of goods and services and supplied under an HSS contract.
27.	430000	Banker's guarantee	Document/message in which a bank undertakes to pay out a limited amount of money to a designated party, on conditions stated therein (other than those laid down in the Uniform Customs Practice).
28.	465000	Documentary credit	Document/message in which a bank states that it has issued a documentary credit under which the beneficiary is to obtain payment, acceptance or negotiation on compliance with certain terms and conditions and against presentation of stipulated document.
29.	520000	Insurance certificate	Document/message issued to the insured certifying that insurance has been effected and that a policy has been issued.
30.	648000	Certificate of compliance with standards of the World Organization for Animal Health (OIE)	A certification that the products have been treated in a way consistent with the standards set by the World Organization for Animal Health (OIE).
31.	708000	Empty container bill	Bill of lading indicating an empty container.
32.	713000	Mate's receipt	Document/message issued by a ship's officer to acknowledge that a specified consignment has been received on board a vessel, and the apparent condition of the goods; enabling the carrier to issue a Bill of lading.
33.	720000	Rail consignment note (generic term)	Transport document constituting a contract for the carriage of goods between the sender and the carrier (the railway). For international rail traffic, this document must conform to the model prescribed by the international conventions concerning car
34.	730000	Road consignment note	Transport document/message which evidences a contract between a carrier and a sender for the carriage of goods by road (generic term).
35.	780000	Freight Invoice	Document/message issued by a transport operator specifiying freight costs and charges incurred for a transport operation and stating conditions of payment.
36.	788000	Container manifest (unit packing list)	Document/message specifying the contents of particular freight containers or other transport units, prepared by the party responsible for their loading into the container or unit.

37.	811WC1	Pre-Convention Certificate	Pre-Convention Certificate is issued by WCCB if a specimen is procured before its being listed on CITES
38.	8510FS	Phytosanitary certificate	A message/document consistent with the model for certificates of the IPPC, attesting that a consignment meets phytosanitary import requirements.
39.	852000	Sanitary certificate	Document/message issued by the competent authority in the exporting country evidencing that alimentary and animal products, including dead animals, are fit for human consumption, and giving details, when relevant, of controls undertaken.
40.	856000	Inspection certificate	Document/message issued by a competent body evidencing that the goods described therein have been inspected in accordance with national or international standards, in conformity with legislation in the country in which the inspection is required
41.	856001	Pre-Shipment Inspection Certificate	A Certificate issued prior to the goods being shipped after inspection by a competent body evidencing that the goods described therein have been inspected in accordance with national or international standards
42.	911000	Import licence	Document/message issued by the competent body in accordance with import regulations in force, by which authorization is granted to a named party to import either a limited quantity of designated articles or an unlimited quantity of such articles dur
43.	911DH3	NOC (Rollover)	NOC(Rollover) is issued by DGHC to the importer who had imported the goods for utilizing in a contract however, he has been awarded new contract and wants to utilize the goods in new contract in the same area
44.	911DH4	NOC (Transfer)	NOC(xfer) is issued by DGHC to the importer who availed import duty benefit at the time of import of goods.However instead of reexporting the goods back he prefers to xfer the goods back to another person holding contract/sub-contract for exploration
45.	911DH5	NOC (Lost in Hole)	NOC(Lost in Hole) is issued by DGHC to the importers for the goods imported by him availing customs duty benefit, however, the goods can not be re-exported as the goods are lost in hole during exploration and are beyond retrival.
46.	911HE1	Import Certificate	Import Certificate is issued by HEPC for availing custom duty exemptions on imports
47.	XXX0FS	Rejection Certificate	Certificate issued by the country of import where an export consignment was rejected.

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Verification of the Preferential Certificates of Origin in terms of CAROTAR Rules 2020 – reg.

Instruction No.20/2020-Customs, dated 17th December, 2020

To
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Prev.);
All Principal Chief Commissioner/Chief Commissioner of GST;
All Principal Chief Commissioner/Chief Commissioner of Customs & GST;
All Directors General under CBIC.

1. Reference is drawn to Board's letter dated 13.11.2020 vide file of even number (copy enclosed)*, wherein it was advised to ensure judicious application of CAROTAR 2020, without causing disruption to the supply chain. It was also advised to review the function of customs ports under your charge

to ensure that unnecessary delays and arbitrary practices are not being resorted to during custom clearance of goods.

2. On review of the verification requests in terms of rule 6 of CAROTAR 2020, being received by the FTA Cell in the Board, it is observed that significant number of such requests have to be returned on account of being deficient, thus leading to delay in verification process and adversely impacting trade facilitation.

2.1 Common grounds on which the requests are being returned to field formations are:

(i) the scanned documents are found to be illegible;

(ii) the certificates are being scanned and sent without requisite covering letter to indicate nature of request or approval of jurisdictional Principal Commissioner or Commissioner; or

(iii) bulk COOs are sent rather that representative COOs, as required in terms of Para 4(i) of Board's circular 38/2020-Cus, dated 21.08.2020

3. It is also observed that some requests do not appear to merit verification, but continue to be referred to the Board for same. Some illustrative examples of such grounds for verification are:

(i) non-availability of name of issuing authority, even in cases where same is not mandated as per that specific trade agreement;

(ii) non-availability of specimen seal and signatures for cases where same has already been communicated by the Board.

4. Attention is also drawn to para 4 (iv) of Circular 38/2020-Cus, dated 21.08.2020, wherein it has been advised to ensure that verification requests should be communicated immediately to the Board in case requests are in terms of rule 6(1)(a) or 6(1)(c) of CROTAR 2020; and within 10 days from the date of receipt of requisite information and documents from the importer in case the request is being considered in terms of rule 6(1)(b). It has however been observed that matters are being referred to the Board after significant time lapse.

4.1 Attention is also drawn to para 7.1 of the aforementioned Circular, wherein it has been advised to email all verification related correspondence to Board on ftaroo-cbic@gov.in, to help reduce time taken in communication. It is however observed that many field formations continue to dispatch only physical documents without using the email mode, leading to unwarranted delays in processing of the matter.

5. It is directed that, where a reference for verification is made to the Board in terms of rule 6 of CAROTAR, 2020, same should be complete, and follow the established Standard Operating Procedures, prescribed format and timelines. All proposals for verification should be duly vetted to ensure valid grounds for verification.

6. Further, representation from trade are still being received about difficulties being faced on account of multiple queries or importers being asked to directly seek clarifications from the issuing authorities of the exporting country. Accordingly, officers under your charge may also be sensitised to ensure that enquiry on origin of imported goods is initiated only where there are sufficient grounds to suspect origin of a good, or where same has been identified as a risk by the Risk Management System. They should be suitably supervised to ensure that unnecessary queries are not raised on account of goods origin, as also advised at para 2.2 of Circular No.45/2020-Customs, dated 12.10.2020.

7. Any difficulties faced or doubts arising in the implementation of these instructions or CAROTAR, 2020 may please be brought to the notice of Board.

F.NO.15021/18/2020(ICD)

Mandeep Sangha,
Joint Commissioner (Customs),
International Customs Division,
Central Board of Indirect Taxes & Customs, (CBIC),
Department of Revenue,
Ministry of Finance,
New Delhi.

(*Not reproduced here)

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Impact of Covid-19 on MSME Sector

Lok Sabha Unstarred Question No: 1966

Shri Rahul Ramesh Shewale:

Shri N K Premachandran:

Shri Santokh Singh Chaudhary:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether the Government has made any assessment of the impact of Covid-19 pandemic on MSME sector so far and if so, the details and outcome thereof and if not, the reasons therefor;

(b): the number of MSMEs which have become sick/been closed during the period of nation wide lockdown due to said pandemic, State/UT-wise and the details of contribution of MSME sector in enhancing unemployment due to the same;

(c): the financial package announced by the Government for MSME sector for its revival along with number of MSMEs revived from such package so far, State/UT-wise;

(d): whether banks are not implementing stimulus package in its true spirit and if so, the details thereof and the steps taken thereon;

(e): whether the Government proposes to introduce an effective monitoring system for implementation of the scheme and if so, the details thereof; and

(f): whether loans to MSMEs have contracted year-on-year in July and August, 2020 and if so, the details thereof along with the reasons therefor and the steps taken by the Government to revive MSMEs and generate employment?

Answered on 22nd September 2020

A. (a): Various sectors including MSME Sector have been affected temporarily by nation-wide lockdown/ Covid-19 Pandemic in the country.

(b): Under Framework for Revival and Rehabilitation of Micro, Small and Medium Enterprises, the number of Accounts referred to the Committee and Accounts resolved by the committee are:

S No.	For the half year	Total MSME	
		Accounts referred to the Committee during the half year	Accounts resolved by the Committee during the half year
1	October 2016- March 2017	1,00,803	1,37,282
2	April 2017- September 2017	87,062	95,107
3	October 2017-March 2018	1,30,208	1,30,473
4	April 2018-September 2018	1,50,165	1,23,227
5	November 2018-March 2019	1,42,275	1,46,519
6	April 2019-September 2019	1,72,949	1,50,613
7.	October 2019-March 2020	3,39,728	3,24,621

Source: RBI
Note: Number of cases resolved by the committees is more than the cases referred due to some pending cases with the committees at the beginning of the half year which have been resolved during the period.

(c) & (d): Recently, Post COVID-19, Government has taken a number of initiatives under Aatma Nirbhar Bharat Abhiyan to support the MSME Sector in the country especially in Covid-19 pandemic which include:

(i) : Rs 20,000 crore Subordinate Debt for MSMEs.

(ii): Rs.3 lakh crores Collateral free Automatic Loans for business, including MSMEs.

(iii): Rs.50,000 crore equity infusion through MSME Fund of Funds.

(iv): New revised criteria for classification of MSMEs.

(v): New Registration of MSMEs through ''Udyam Registration'' for Ease of Doing Business.

(vi): No global tenders for procurement up to Rs. 200 crores, this will help MSME.

An online Portal "Champions" has been launched on 01.06.2020 by Hon'ble Prime Minister. This covers many aspects of e-governance including grievance redressal and handholding of MSMEs. Through the portal, total 19,593 grievances have been redressed upto 17.09.2020.

As per data reported by Member Lending Institutions (MLIs), an amount of Rs. 1,63,103 crore has been sanctioned to 42,01,060 borrowers and an amount of Rs. 1,17,885 core disbursed to 25,01,216 borrowers under the Emergency Credit Line Guarantee Scheme (ECLGS) as on September 9, 2020.

(e): Ministry of MSME has already implemented SAMADHAAN Portal for empowering micro and

small entrepreneurs across the country to directly register their cases relating to delayed payments and SAMBANDH Portal for monitoring the implementation of Public Procurement Policy for micro and small enterprises in the country.

(f): Growth/decline in credit outstanding to MSMEs by Scheduled Commercial Banks for the quarter ended June 2020 vis-à-vis March 2020 is given below:

	Credit Outstanding to MSMEs in Rs. Crores		
Bank Group Category	March 2020	June 2020*	Growth/ Decline over the previous quarter
Public Sector Banks	893314.83	838708.28	-6.11%
Private Sector Banks (including Small Finance Banks)	646988.27	659074.25	1.87%
Foreign Banks	73279.06	65458.95	-10.67%
Total	1613582.166	1563241.49	-3.12%

*June 2020 data is provisional
Source: RBI

The Ministry of Micro Small and Medium Enterprises (MSME) implements various schemes and programmes for the growth and development of MSME Sector in the country. These schemes and programmes include Prime Minister's Employment Generation Programme (PMEGP), Scheme of Fund for Regeneration of Traditional Industries (SFURTI), A Scheme for Promoting Innovation, Rural Industry & Entrepreneurship (ASPIRE), Credit Guarantee Scheme for Micro and Small Enterprises, Micro and Small Enterprises Cluster Development Programme (MSE-CDP), Credit Linked Capital Subsidy and Technology Upgradation Scheme (CLCS-TUS).

Minister of State in the Ministry of Micro, Small and Medium Enterprises (Shri Pratap Chandra Sarangi)

Ease of Doing Business Initiative for MSMEs

Lok Sabha Unstarred Question No: 2033

Shri Shantanu Thakur:

Shri Parbatbhai Savabhai Patel:

Shrimati Gitaben Vajesingbhai Rathva:

Shri Naranbhai Bhikhabhai Kachhadiya:

Shri Jaswantsinh Sumanbhai Bhabhor:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): the steps taken/being taken by the Government to create favorable conditions to propel and boost Micro, Small and Medium Enterprises (MSMEs) sector under Ease of Doing Business;

(b): the success achieved so far in this regard during the last two years;

(c): whether the Government has formulated any model law to regulate the functioning of MSMEs in the country and if so, the details thereof;

(d): whether all the States across the country including Gujarat and West Bengal have adopted/are implementing the said law and if so, the details thereof; and

(e): if not, the steps taken/being taken by the Government in this regard?

Answered on 22nd September 2020

A. (a) & (b): The Government of India has taken several initiatives to promote Ease of Doing Business; some of them are given below:

(i): Udyam Registration (UR) Portal to provide fully online, paperless and transparent MSME registration process. No documents or proof are required to be uploaded for registering an MSME. Only Aadhaar Number/PAN is enough for registration. PAN and GST linked details on investment and turnover of enterprises are taken automatically from Government data bases.

(ii): Digital Payments to pass on the benefits of the schemes of Ministry of MSME through digital payment gateway.

(iii): MSME SAMBANDH Portal- to help in monitoring the implementation of Public Procurement Policy for micro and small enterprises.

(iv): MSME SAMADHAAN Portal for empowering Micro and Small Entrepreneurs across the country to register their cases relating to delayed payments.

(v): MSME SAMPARK Portal-A digital platform, wherein jobseekers (pass out trainees / students of 18 MSME Technology Centers) and recruiters get connected.

(vi): Champions Portal for speedy redressal of grievances (online).

(vii): Returns under 8 Labour laws and 10 Union regulations to be filed once in a year.

(viii): Returns to be accepted through self-certification and only 10 percent MSME units to be inspected.

(ix): For minor violations under the Companies Act, entrepreneurs no longer have to approach court but can correct them through simple procedures.

(c) to (e): The Micro, Small and Medium Enterprise Development (MSMED) Act, 2006 has been already enacted. This Act is promotional and developmental in nature and applicable to all the States and Union Territories of India.

Minister of State in the Ministry of Micro, Small and Medium Enterprises (Shri Pratap Chandra Sarangi)

Penalty on Polluters

Lok Sabha Unstarred Question No: 2106

Shrimati Geetha Viswanath Vanga:

Shri Kotha Prabhakar Reddy:

Q. Will the Minister of **ENVIRONMENT, FORESTS AND CLIMATE CHANGE** be pleased to state;

(a): whether the new/amended Environment Impact Assessment (EIA), 2020, is likely to impose heavy penalty on polluters, in case of violations;

(b): if so, the details thereof, State-wise; and

(c): the amount of penalty collected/utilized for environmental violations, State-wise during the last three years?

Answered on 22nd September 2020

A. (a): The draft EIA notification 2020, follows the Principles of 'Polluter Pays' and 'Principle of proportionality' as enunciated by the Hon'ble Supreme Court in Indian Council for Enviro-Legal Action Versus Union of India (the Bichhri village industrial pollution case) (1996 [3] SCC 212); and Alembic Pharmaceuticals Ltd. Versus Rohit Prajapati & Ors., (2020 SCC Online SC 347), respectively, for dealing with violation cases, and bringing defaulters into the environmental regime with requisite action, penalty, remediation and monitoring. Besides penalty prescribed in the section 15 of the Environment (Protection) Act, 1986, the draft EIA Notification 2020 proposes imposition of late filing fee, damage cost, remediation cost etc., based on 'Polluter pays' principle.

(b) and (c): The draft EIA Notification 2020 is currently in the draft stage and accordingly the provisions envisaged in the draft Notification are not yet implemented.

Minister of State In the Ministry of Environment, Forest and Climate Change (Shri Babul Supriyo)

Biological Diversity Act

Lok Sabha Unstarred Question No:2114

Shri Uday Pratap Singh:

Q. Will the Minister of **ENVIRONMENT, FORESTS AND CLIMATE CHANGE** be pleased to state;

(a): the provisions made by the Government under Biological Diversity Act, 2002;

(b): the efforts being made under the said provisions to conserve forests and wildlife in Madhya Pradesh;

(c): whether any action has been taken/any changes have been made in the rules to control forest crimes in Madhya Pradesh; and

(d): if so, the details thereof?

Answered on 23rd September 2020

A. (a): The Biological Diversity Act was enacted in 2002 by the Union Government for the conservation, sustainable utilization and equitable use of its components and fair and equitable sharing of benefits arising out of utilization of genetic resources. The Act has 12 Chapters and 65 sections.

Chapter I of the Act pertains to the title and definitions.Chapter II deals with regulation of access to biological diversity in India. Chapter III pertains to the establishment and functioning of the National Biodiversity Authority (NBA). Chapter IV deals with the functions and powers of the NBA. Chapter V deals with activities that require approval of NBA. Chapter VI covers the establishment and functions of the State Biodiversity Boards (SBB). While Chapter VII deals with the Finance, accounts and Audit of NBA. Chapter VIII deals with the Finance, accounts and Audit of SBBs. Chapter IX deals with the duties of the Central and State Governments to conserve country's biodiversity. Chapter X pertains to the establishment of Biodiversity Management Committees (BMCs) in every local body. Chapter XI deals with the Local Biodiversity Fund. Chapter XII covers the penal provisions for violations of the act and their adjudication.

(b): Madhya Pradesh has established a State Biodiversity Board which is functioning as per the provisions of the Biological Diversity Act and the Madhya Pradesh Biological Diversity Rules, 2004 to govern the biological diversity of the State. As per the information shared by State Government of Madhya Pradesh, following efforts are being made for the protection of forest wealth and wildlife in Madhya Pradesh:

(i). Thirteen Rare, Endangered and Threatened (RET) flora and fauna have been notified in Madhya Pradesh under Section 23 of Biological Diversity Act, 2002 by Ministry of Environment, Forest and Climate Chang's notification No. 1329 dated 07.06.2010;

(ii). Two Biodiversity Heritage Sites, one at Patalkot in Chhindwara District and another at Naro Hills in Satna District were notified under Section 37 of Biological Diversity Act, 2002;

(iii). As per Section 41 of Biological Diversity Act, 2002, 23,557 Biodiversity Management Committees have been constituted in local bodies of the State to manage the Biodiversity of the State as per the existing legal framework.

(iv). As per Rules, 23 (12) of Biological Diversity Rules, 2004, 23,557 People Biodiversity Registers (PBRs) have been documented.

(c) and (d): As per the information received from State Government of Madhya Pradesh, the actions/ change in rules made to check forest crimes taking place in Madhya Pradesh are:

A. In exercise of the powers conferred by the sub-rule (4) of Rule 17 of the Madhya Pradesh State Biodiversity Rules, 2004, the State Government has declared:

i. Chief Conservator of Forests (Territorial), Field Director, Tiger Reserves and Regional Chief General Manager, Madhya Pradesh Rajya Van Vikas Nigam Limited as Ex-Officio Joint Member Secretary of Madhya Pradesh State Biodiversity Board;

ii. Conservator of Forests/Divisional Forest Officer/ Deputy Director, Tiger Reserve and Divisional Manager, Madhya Pradesh Rajya Van Vikas Nigam Limited as Ex-Officio Assistant, Member Secretary of Madhya Pradesh State Biodiversity Board;

B. The Ex-Officio Assistant, Member Secretary of Madhya Pradesh State Biodiversity Board has been delegated the power to issue grant of approval to traders, utilizing the bioresources for commercial purposes under Section 7 of the Biological Diversity Act, 2002.

Minister of State in the Ministry of Environment, Forest And Climate Change (Shri Babul Supriyo)

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DGFT MATTERS

Amendment in Para 2.60 of Handbook of Procedure, 2015-2020 - reg.

DGFT Public Notice No. 32/2015-2020, dated 16th December, 2020

1. In exercise of powers conferred under Paragraph 1.03 of Foreign Trade Policy, 2015 2020 read with Paragraph 2.04 of Foreign Trade Policy, 2015-2020, the Director General of Foreign Trade hereby replaces the existing Para 2.60 of the Handbook of Procedure (2015-20) on Procedure for Import under the Tariff Rate Quota Scheme. The revised para is as follows:

'***Para 2.60: Procedure for Import under the Tariff Rate Quota Scheme***'

Imports under the Tariff Rate Quota Scheme is governed as per the Customs Notification No.28/2020-Customs dated 23.06.2020 of Department of Revenue, Ministry of Finance, Government of India as amended from time to time.

2. Effect of the Public Notice: Paragraph 2.60 of Handbook of Procedure, 2015-2020 is replaced to update the latest Customs Notification governing imports under Tariff Rate Quota Scheme.

F.No. 01/93/180/49/AM-17/PC-2(B)/E-1729

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

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Groundbreaking Technology could change the way we vaccinate, use medicine

It's groundbreaking and could change the way we administer drugs or use medicine in General

As we're all focused on the current rollout of the COVID-19 vaccine, a technology known as thin-film freezing is getting a lot of attention. It's groundbreaking and could change the way we administer drugs or use medicine in general. You've probably heard about the need to keep the COVID-19 vaccine cold. It has to be so cold, in fact, that the shipment and transport are challenging.

Well, what if that vaccine could be turned into powder? "What we've most recently been working on is the elimination of cold chain by storing as a powder, a dry powder where the drug is much more stable than if it was stored as a liquid or as a frozen liquid," said co-inventor Dr Robert Williams.

Williams said it would eliminate the need for extreme cold storage and transport. The technology isn't new. He got a research grant and came up with it about 15 years ago. Williams, who is also a Pharmacy Professor at the University of Texas in Austin, said they were working on the technology and its multiple uses when the pandemic hit. And all of a sudden, they got a lot of attention.

"We have published over 70 papers on the technology and using it for different products - it's quite a mature process," Williams said. "We developed it because with other vaccines, the majority of the vaccine cost is in wastage because of this cold chain issue, so we published several key papers where we showed our thin-film freezing technology would protect vaccines - and you wouldn't need cold chain storage."

Glenn Mattes, President, and CEO of TFF Pharmaceuticals added that the powders can be converted to topical preparations and they are currently working with the US Army to take some of the preparations and would then administer them directly through the eye. TFF is launching thin-film freezing into development through the FDA process.

"I use the term ubiquitous because it is and disruptive because it is," Mattes said. He added that they've explored their technology in the cannabinoid realm. But, as for the COVID vaccine, they're aiming for a second-generation usage.

"To truly eradicate the pandemic, you have to have a global response," Mattes said. "The companies we've been speaking to certainly recognize the broad utilization of the technology but the application to the developing world, rural area, remote areas, where you can take a powder and inhale it or take the powder and reconstitute it has tremendous potential." Experts say it is only just the beginning as they launch their technology into a new world recognize the broad utilization of the technology but the application to the developing world, rural area, remote areas, where you can take a powder and inhale it or take the powder and reconstitute it has tremendous potential." Experts say it is only just the beginning as they launch their technology into a new world.

Source: Stephanie Stone, thedenverchannel.com, 15.12.2020

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Oral drug blocks SARS-CoV-2 Transmission, Researchers Find

Treatment of SARS-CoV-2 infection with a new antiviral drug, MK-4482/EIDD-2801 or Molnupiravir, completely suppresses virus transmission within 24 hours, researchers in the Institute for Biomedical Sciences at Georgia State University have discovered.

The group led by Dr Richard Plemper, Distinguished University Professor at Georgia State, originally discovered that the drug is potent against influenza viruses. "This is the first demonstration of an orally available drug to rapidly block SARS-CoV-2 transmission," said Plemper. "MK-4482/EIDD-2801 could be game-changing." Interrupting widespread community transmission of SARS-CoV-2 until mass vaccination is available is

paramount to managing COVID-19 and mitigating the catastrophic consequences of the pandemic. Because the drug can be taken by mouth, treatment can be started early for a potentially three-fold benefit: inhibit patients' progress to severe disease, shorten the infectious phase to ease the emotional and socio-economic toll of prolonged patient isolation and rapidly silence local outbreaks.

"We noted early on that MK-4482/EIDD-2801 has broad-spectrum activity against respiratory RNA viruses and that treating infected animals by mouth with the drug lowers the amount of shed viral particles by several orders of magnitude, dramatically reducing transmission," said Plemper. "These properties made MK-4482/EIDD/2801 a powerful candidate for pharmacologic control of COVID-19."

In the study published in Nature Microbiology, Plemper's team repurposed MK-4482/EIDD-2801 against SARS-CoV-2 and used a ferret model to test the effect of the drug on halting virus spread. "We believe ferrets are a relevant transmission model because they readily spread SARS-CoV-2, but mostly do not develop severe disease, which closely resembles SARS-CoV-2 spread in young adults," said Dr Robert Cox, a postdoctoral fellow in the Plemper group and a co-lead author of the study.

The researchers infected ferrets with SARS-CoV-2 and initiated treatment with MK-4482/EIDD-2801 when the animals started to shed virus from the nose. "When we co-housed those infected and then treated source animals with untreated contact ferrets in the same cage, none of the contacts became infected," said Josef Wolf, a doctoral student in the Plemper lab and co-lead author of the study. By comparison, all contacts of source ferrets that had received placebo became infected.

If these ferret-based data translate to humans, COVID-19 patients treated with the drug could become non-infectious within 24 hours after the beginning of treatment. MK-4482/EIDD-2801 is in advanced phase II/III Clinical Trials against SARS-CoV-2 infection.

{(Co-authors of the study include R.M. Cox, J.D. Wolf and R.K. Plemper at Georgia State). (The study was funded by public health service grants from the National Institutes of Health/National Institute of Allergy and Infectious Diseases to Georgia State). (Materials provided by Georgia State University. Note: Content may be edited for style and length)}.

Source: Georgia State University, Science Daily, 04.12.2020 (Excerpts)

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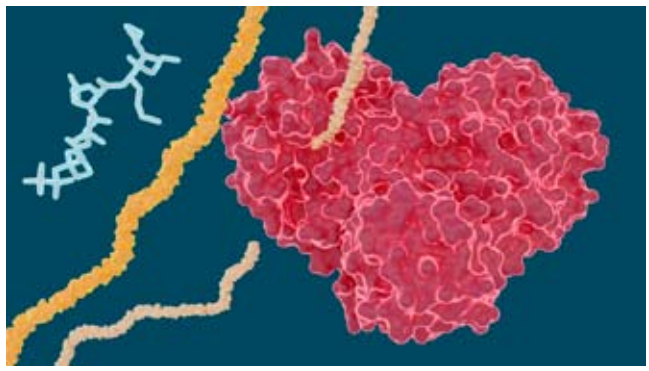
Potential of Hepatitis-C Drugs to treat COVID-19 by stopping the virus from spreading



The heart-shaped SARS-CoV-2 main protease enables the virus to reproduce by cutting long chains of proteins that activate the replication process. Experiments show existing drugs used to treat Hepatitis-C may have potential to treat COVID-19 by stopping the "heart" of the virus. Credit: Michelle Lehman, Jill Hemman/ORNL, US Dept of Energy.

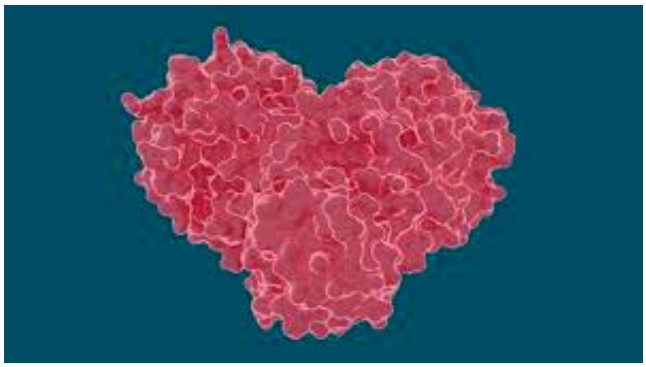
Experiments led by researchers at the Department of Energy's Oak Ridge National Laboratory have determined that several hepatitis C drugs can inhibit the SARS-CoV-2 main protease, a crucial protein enzyme that enables the novel Coronavirus to reproduce.

Inhibiting, or blocking, this protease from functioning is vital to stopping the virus from spreading in patients with COVID-19. The study, published in the journal *Structure*, is part of efforts to quickly develop pharmaceutical treatments for COVID-19 by repurposing existing drugs known to effectively treat other viral diseases.

"Currently, there are no inhibitors approved by the Food and Drug Administration that target the SARS-CoV-2 main protease," said ORNL lead author Daniel Kneller. "What we found is that Hepatitis-C drugs bind to and inhibit the Coronavirus protease. This is an important first step in determining whether these drugs should be considered as potential repurposing candidates to treat COVID-19."

The SARS-CoV-2 Coronavirus spreads by expressing long chains of polyproteins that must be cut by the main protease to become functional proteins, making the protease an important drug target for researchers and drug developers. In the study, the team looked at several well-known drug molecules for potential repurposing efforts including leupeptin, a naturally occurring protease

inhibitor, and three FDA-approved Hepatitis-C protease inhibitors: telaprevir, narlaprevir, and boceprevir.



The heart-shaped SARS-CoV-2 main protease enables the virus to reproduce by cutting long chains of proteins that activate the replication process. Experiments show existing drugs used to treat Hepatitis-C may have potential to treat COVID-19 by stopping the "heart" of the virus. Credit: Michelle Lehman, Jill Hemman/ORNL, US Dept of Energy

The team performed room temperature X-ray measurements to build a three-dimensional map that revealed how the atoms were arranged and where chemical bonds formed between the protease and the drug inhibitor molecules. The experiments yielded promising results for certain hepatitis C drugs in their ability to bind and inhibit the SARS-CoV-2 main protease — particularly boceprevir and narlaprevir. Leupeptin exhibited a low binding affinity and was ruled out as a viable candidate.

To better understand how well or how tightly the inhibitors bind to the protease, they used *in vitro* enzyme kinetics, a technique that enables researchers to study the protease and the inhibitor in a test tube to measure the inhibitor's binding affinity, or compatibility, with the protease. The higher the binding affinity, the more effective the inhibitor is at blocking the protease from functioning.

"What we're doing is laying the molecular foundation for these potential drug repurposing inhibitors by revealing their mode of action," said ORNL corresponding author Andrey Kovalevsky. "We show on a molecular level how they bind, where they bind, and what they're doing to the enzyme shape. And, with *in vitro* kinetics, we also know how well they bind. Each piece of information gets us one step closer to realizing how to stop the virus." The study also sheds light on a peculiar behavior of the protease's ability to change or adapt its shape according to the size and structure of the inhibitor molecule it binds to. Pockets within the protease where a drug molecule would attach are highly malleable, or flexible, and can either open or close to an extent depending on the size of the drug molecules. Before the paper was published, the researchers made their data publicly available to inform and assist the scientific and medical communities. More research, including Clinical Trials, is necessary to validate the drugs' efficacy and safety as a COVID-19 treatment.

"The research suggests that Hepatitis-C inhibitors are worth thinking about as potential repurposing candidates. Immediately releasing our data allows the scientific community to start looking at the interactions between these inhibitors and the protease," said ORNL corresponding author Leighton Coates. "You can't design a drug without knowing how it works on a molecular level, and the data we're providing is exactly what developers need to design stronger, more tightly binding drugs for more effective treatments." The X-ray measurements and synthesis of the protease samples used in the experiments were performed with support from the Center for Structural and Molecular Biology using facilities located at the Spallation Neutron Source.

The research team plans to conduct neutron scattering experiments to locate the hydrogen atom positions and the network of chemical bonds between the protease and the inhibitor molecules.

(Reference: "Malleability of the SARS-CoV-2 3CL Mpro Active-Site Cavity Facilitates Binding of Clinical Antivirals" by Daniel W. Kneller, Stephanie Galanie, Gwyndalyn Phillips, Hugh M. O'Neill, Leighton Coates and Andrey Kovalevsky, 23 October 2020, Structure. DOI: 10.1016/j.str.2020.10.007. The paper's co-authors also include Stephanie Galanie, Gwyndalyn Phillips and Hugh M. O' Neill. COVID-19 research at ORNL is supported in part by the DOE Office of Science through the National Virtual Biotechnology Laboratory, a consortium of DOE national laboratories focused on response to COVID-19, with funding provided by the Coronavirus CARES Act.) (SNS is a DOE office of Science user facility).

Source: Oak Ridge National Laboratory, SciTechDaily, 05.12.2020

FSSAI overhauls labelling, display norms; makes display of expiry date mandatory

Packaged food companies will need to mandatorily display use by or expiry date instead of "best before date", present nutritional information on the principal display panel in bigger font sizes and ensure that name of the food and vegetarian and non-vegetarian classification symbol is on the front of the pack with effect from January 1, 2022.

The Food Safety and Standards Authority of India (FSSAI), which has notified the new labelling and display regulations, has for the first time also defined the age of children for the food industry as below 18 years.

Labelling norms have also been set for the e-Commerce Food Business Operators and the restaurant industry. However, the earlier proposed key provisions of colour-coded labels to classify food products that are high in fat, salt and sugar and front-of-the-pack labelling are still under the process of being finalised, sources said.

Industry concerns:

Though FSSAI has finalised these regulations after a long-drawn consultation process, the industry has raised concerns regarding the definition of children as below 18 years in line with the Juvenile Justice Act. "There is no logic behind defining children's age in line with the Juvenile Justice Act for the food industry. Companies will need to re-haul their entire marketing strategies if this gets implemented," a Senior Industry Executive said.

Industry bodies have also raised concerns about the bigger size (height) for numerals and alphabets as prescribed in the norms for the "principal display panel" and said it is not practically feasible to accommodate such big sizes on the label.

Companies will need to redesign their packaging and use higher amount of packaging material to meet the new norms," another Senior Industry Executive pointed out. "Date of manufacture or packaging" and "Expiry/Use by" shall be declared on the label. However, "Best before" may also be used as optional or additional information," the regulations stated.

Industry players have raised concerns about this provision too stating that it will not be feasible to display expiry date like the Pharmaceutical Industry instead of the current norm of "best before date". "When a food product is sold through e-Commerce or any other direct selling means, the mandatory requirements of the label as given in these regulations shall be provided to the consumer through appropriate means before sale except 'batch number/ lot number, best before, use by date, expiry date, date of manufacturing/packing," the regulations added.

Caloric values:

Restaurants and cafes, having central license or outlets at 10 or more locations will need to mention the caloric values against food items on menu cards, boards or booklets.

"Additionally, reference information on calorie requirements shall also be displayed clearly and prominently as "An average active adult requires 2,000 kcal energy per day, however, calorie needs may vary", it added. These provisions will also be applicable on e-Commerce Food Business Operators. The regulations also have put certain labelling prohibitions for categories such as edible oils and packaged drinking water. For instance: Packaged water companies cannot make claims concerning medicinal (preventative, alleviative or curative) effects on the labels.

Source: Meenakshi Verma Ambwani, The Hindu Business Line, 15.12.2020

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VCBC Haryana asks Government to ban aceclofenac for veterinary use in the wake of its misuse leading to vulture mortality

The Vulture Conservation Breeding Centre (VCBC), Haryana has recommended to the Union Health Ministry to ban Non-Steroidal Anti-Inflammatory Drug (NSAID) aceclofenac for veterinary use in the wake of its misuse leading to vulture mortality. Aceclofenac is a NSAID given to cattle to treat pain and inflammation and its irrational use and misuse for veterinary use has become rampant in many parts of India.

Earlier, Government of India had prohibited 'Diclofenac and its formulations for animal use' vide Notification No.G.S.R.499(E) dated July 4, 2008 and permitted 'Diclofenac injection for human use shall be in single unit dose pack only' vide Notification No.G.S.R.558(E) dated

July 17, 2015. The VCBC Haryana had earlier played an important role in confirming that diclofenac, a NSAID, given to cattle to treat pain and inflammation, was the main cause of vulture mortality and population crash in vultures.

Anti-inflammatory painkillers like aceclofenac are also called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), or sometimes just 'anti-inflammatories'. Aceclofenac is also prescribed for people with painful rheumatic conditions such as osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. The VCBC is a joint project of the Haryana Forest Department and the Bombay Natural History Society (BNHS). It is a collaborative initiative to save the three species of vultures, the White-backed, Long-billed and Slender-billed, from looming extinction.

It has been recommended that banning aceclofenac will also be contributing towards Prime Minister's flagship programme *"Swatchha Bharat Abhiyaan".* Drugs Consultative Committee (DCC) under the Union Health Ministry after detailed deliberations has also recommended for making provisions in the drug rules for prohibition of aceclofenac for veterinary use to save vultures.

As per scientific studies, there is evidence for the toxicity to vultures of six other than diclofenac, namely aceclofenac, carprofen, flunixin, ketoprofen, nimesulide and phenylbutazone. NSAID is a drug class that reduces pain, decreases fever, prevents blood clots, and in higher doses, decreases inflammation. In view of the same, the VCBC has requested the appropriate action in this matter for prohibition of aceclofenac for veterinary use for saving vultures.

DCC has been apprised that, Principal Scientist and Deputy Director, BNHS, VCBC, Panchkula, Haryana has given a research note on 'Metabolism of aceclofenac in cattle to vulture killing diclofenac'. DCC has also been apprised that in its 56th meeting last year deliberated the matter and recommended SDC, Haryana to write a letter to Principal Scientist and Deputy Director, BNHS, VCBC to provide detailed supporting scientific data in this regard for further action. Accordingly, upon request said research paper has been received and kept for review of the committee.

SDC, Haryana has apprised DCC on how the aceclofenac and diclofenac are posing problems for the survival of vultures leading to the environmental issue due to the dead forest animals, since vultures are scavengers and thus protect the environment from dead animals. Regulatory experts have also since long been recommending NSAIDs like meloxicam as safer alternatives to diclofenac as illegal sale and misuse of human diclofenac for veterinary use has also become rampant in many parts of India. Non-toxic drugs like meloxicam which is a safer alternative to diclofenac has been recommended as it has been tested and shown to be safe for vultures.

Witnessing its rampant misuse, the VCBC had earlier undertaken a major exercise of extracting diclofenac from the tissue samples of vulture carcasses which were collected from different parts of the country and its presence was estimated in collaboration with Aberdeen University, UK. It was found that 75% of the vulture carcasses collected from various parts of the country had "Visceral Gout". This happens when there is kidney failure and the uric acid crystals get deposited on the visceral organs. It was established that all the vultures which had died of visceral gout had diclofenac residues in their tissues.

Source: Shardul Nautiyal, Pharmabiz, 11.12.2020

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NPPA asks Companies to ensure adequate stock of enoxaparin injection in Chhattisgarh for management of COVID-19

In the wake of hampered availability of enoxaparin injection for management of COVID-19 in the State of Chhattisgarh, the National Pharmaceutical Pricing Authority (NPPA) has directed manufacturers and urged the Drugs Controller General of India (DCGI) to make available adequate stocks of enoxaparin injection in the trade channels of state of Chhattisgarh under intimation to the NPPA office on immediate basis.

NPPA had earlier directed all manufacturers to ensure production and stock of 138,710 vials of methyl prednisolone, 30,15,442 vials (40 mg) of heparin (enoxaparin) and 14,07,206 vials (60 mg) up to July 31, 2020 and also 33 lakh tablet (6 mg) of dexamethasone uptil August 15, 2020 for COVID-19 disease management. It had also directed State Drug Controllers (SDCs) to issue instructions to all the concerned manufacturers to ensure availability and production of these medicines.

This directive is with reference to Union Health Ministry's letters dated, March 18, 2020, June 24, 2020, June 27, 2020 and June 29, 2020 regarding requirement and availability of drugs across the country as part of the clinical treatment protocol of COVID-19. Director General

of Health Services (DGHS) has also informed requirement for the same to the NPPA.

Heparin is an anticoagulant (blood thinner) that prevents the formation of blood clots. It is used to treat and prevent blood clots caused by certain medical conditions or medical procedures. It is also used before surgery to reduce the risk of blood clots.

The National Drug Pricing Regulator has also through a letter stated to immediately intimate details regarding production or sale of drugs during the last 2 years, stock lying with the company as on date, production schedule for next six months, details of suppliers from whom sourcing API for the drugs is done and problems if any being faced in such sourcing, details of procurement orders placed by state Governments and other additional details.

In order to ensure adequate stocks and ensure supply across the country, NPPA had recently revised the prices of blood thinner drug heparin upwards by 50 percent until December, 2020 for its consistent availability in view of the increase in API costs from China in COVID-19 scenario. Price revision was based on a Union Health Ministry committee report which states that there has been a 211 percent increase in the price of heparin's API as of today when compared to the base year of September 2018.

Upward price revision was also attributed to the fact that heparin is among the essential drugs listed by the Union Health Ministry that need to be manufactured taking into consideration its commercial viability for its consistent availability in the country. Heparin injection in dosage form and strength of 1,000 IU/ml which used to cost Rs.15.31/ml and heparin injection in dosage form and strength of 5,000 IU/ml which used to cost Rs.37.99/ml will now cost Rs.24.39 per 1 ml in dosage and strength of 1,000 IU/ml and Rs.60.54 in dosage and strength of 5,000 IU/ml 1 ml respectively, as per the NPPA order.

Source: Shardul Nautiyal, Pharmabiz, 11.12.2020

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Health Ministry soon to exempt BA/BE studies for drugs manufactured solely for export purpose

Based on the recommendations made by the industry and Union Commerce Ministry, Union Health Ministry may soon exempt bioavailability (BA)/bioequivalence (BE) studies for drugs manufactured solely for export purpose. BA/BE studies are needed by regulations to guarantee remedial proportionality between a pharmaceutically comparable test item and a reference item.

The recommendations come close on the heels of representations made by the Union Commerce Ministry and Pharma industry which suggested exemption of BA/BE studies data for the drugs manufactured for export purpose as the manufacturers comply with the regulations of the importing countries. Some countries may not require BA/BE study, while some others may require BA/BE study of specific design as per their BA/BE Guidelines. Therefore, it would be appropriate to provide exemption of the BA/BE study for manufacture of drugs solely meant for export, it was recommended.

Based on the recommendations, Drugs Technical Advisory Board (DTAB) deliberated the proposal and further recommended for amendment of Rule 74, 74B, 76, 78, 78A and 84 of the Drugs and Cosmetics (D&C) Rules, 1945 to provide exemption of BA/BE studies for the drugs manufactured solely for export purpose. The D&C Rules, 1945 were amended vide G.S.R.327(E) dated April 3, 2017, providing that the applicant shall submit the result of BE study, along with the application for grant of a licence of oral dosage form of drugs specified under Category II and Category IV of the biopharmaceutical classification system.

As per Rule 84 of the D&C Rules, the provisions shall apply to the manufacture of drugs for sale notwithstanding that such drugs are manufactured for sale outside India. However, for export of any drug to any country, the manufacturer is required to meet the requirements of the importing country.

Source: Shardul Nautiyal, Pharmabiz, 10.12.2020

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Centre introduces Co-WIN Mobile App for COVID-19 vaccine delivery

The Central Government has introduced a new digital platform called Co-WIN for COVID-19 vaccine delivery. There will be a new mobile app as well with the same name that will allow people to register for the vaccine. The platform will be used for recording vaccine data and will form a database of healthcare workers too. All COVID-19 related data necessary for the delivery of the vaccine is presently being uploaded on the Co-WIN platform.

"Co-WIN digital platform includes a free downloadable mobile application which can help record vaccine data. One

can register themselves on it if they want the vaccine. There are five modules in Co-WIN app -- administrator module, registration module, vaccination module, beneficiary acknowledgement module and report module," said Health Secretary Rajesh Bhushan.

The Health Secretary also briefed in detail about the Government's preparation for COVID vaccination drive. Some vaccine candidates which are in different stages of trial may get licensed in the next few weeks. The Government will be vaccinating priority groups in the first two phases: frontline workers including all healthcare professionals in the first stage and emergency workers in the second stage. While the data of these people are already being compiled by the state Governments, from the third stage onwards where people with co-morbidity will be given vaccines, self-registration will be introduced. And that will happen through the Co-WIN app.

The App will have separate modules for Administrator, Registration, Vaccination, Beneficiary Acknowledgment and reports. Once people start to register for the app, the platform will upload bulk data on co-morbidity provided by local authorities. The CO-WIN app is yet to be available for smart-phone users and it is expected that it will be publicly available soon. The different modules of the platform cater to the entire process of COVID-19 vaccination starting from registration to verification.

"Every single India who needs to be vaccinated will be vaccinated, which roughly includes one crore healthcare workers, two crore frontline workers, and 27 crores of prioritized age groups," Bhushan further stated.

Source: Pharmabiz, 10.12.2020

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BE signs exclusive License Agreement for COVID-19 vaccine with US based OSIF

The Hyderabad-based Biological E and US-based Ohio State Innovation Foundation (OSIF) have signed an exclusive agreement for sharing the necessary technology to develop a COVID-19 vaccine in the coming days. As part of the agreement, the OSIF has licensed novel live attenuation measles virus vectored vaccine candidate against SARS-Cov-2, which were developed by the Ohio State University College of Veterinary Medicine (OSUCVM). In continuation to this, the Hyderabad based vaccine maker BE will be responsible for the evaluation and further development, including commercialization of the vaccine. "Biological E is a global vaccine maker and we are excited to further evaluate and develop a new vaccine through the platform of OSUCVM," informed Mahima Datla, Managing Director and CEO of BE.

According to Dr Patrick Green, Associate Dean for Research and Graduate Studies, Ohio State University College of Veterinary Medicine, the translation process of the research work done by the university to that of to a global vaccine manufacturing company like BE is a very critical process and an important step, because now the scientists at the BE will be analyzing and evaluate the research process and practically develop a new vaccine that is safe, effective and long lasting. It is learnt that the Ohio college research team chose the approach to utilize the SARS-COV-2 spike protein as a target protein for SARS-COV-2 vaccine candidate, which will generate a series of attenuated recombinant measles viruses (rMeVs) expressing SARS-COV-2 antigens.

Later a World Health Organization approved cell line for vaccine production process is followed, where in all resultant rMeVs, which are the basis for the vaccine candidates, will grow to high virus titer in Vero cells. The *Viro* cells were also shown to express the recombinant S antigens, a critical step in developing a SARS-COV-2 vaccine. As already the rMeVs based SARS-COV-2 vaccine candidates have already proceed through proof-of concept trials in multiple animal bodies, it has demonstrated successful production of SARS-Cov-2 antibodies.

Source: Pharmabiz, 10.12.2020

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CSIR-CFTRI inks MoU with Clevergene to sequence SARS-CoV-2 genome

As part of various initiatives towards mitigating COVID-19, CSIR Central Food Technological Research Institute (CFTRI) has signed a MoU recently with Clevergene, a Bengaluru-based company for sequencing of the SARS-CoV-2 genome. This is part of the various initiatives to mitigate the deadly virus. It is expected that the study would provide insights into virus genome changes (mutations), evolution, epidemiology, and provide an understanding of the spatial and temporal information on infection dynamics of the SARS-CoV-2. Further, under the MoU, the development of novel diagnostics and vaccines for COVID-19 are envisaged.

The Mysuru-based CSIR-CFTRI has also established a COVID Testing Centre in Mysuru, and on an average, more than 1,000 samples are tested in a day. Further, the Institute is also working on the development of novel dipstick and aptamer-based diagnostics in collaboration with private parties. It is also an ISO 9001:2008 and ISO 14001:2004 Organization and ISO 17025:2005 (NABL) Accredited Laboratory. Clevergene is a tech company offering genomics services for contract research and genetic diagnostics. The MoU was exchanged recently between Dr B Manohar, Chief Scientist and Adviser (M&A), and Tony Jose, Co-Founder, and CEO, Clevergene. Dr Prakash M Halami, Chief Scientist and Nodal Officer, and Dr P V Ravindra, In-charge Coordinator, CFTRI-COVID Testing Laboratory, were present.

Source: Pharmabiz, 09.12.2020

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Indian Pharma SMEs upbeat on hiring Professionals across senior, mid and entry levels

Indian Pharma's Small and Medium Enterprises (SMEs) have indicated a positive sentiment to hire professionals across domains. This follows the anticipated second wave of the COVID-19 pandemic in the country which is expected to create a higher demand for drugs and medical devices.

These two sectors are in the essential services category and not susceptible to crisis. Moreover, Pharma and Healthcare even though they were affected during the pandemic proved to be resilient compared to some of the other sectors that took a beating. We do continue to see consistent progress resulting in the need to scout for professional talent, Rituparna Chakraborty, Co-Founder & Executive Vice President, TeamLease Services, told.

There is an intent to hire talent not just at senior levels but also to ramp up mid and junior-level talent. But the biggest growth in hiring intent has been in the entry level, she added. It is definitely a better situation when it comes to augmenting workforce across cadres compared to the early days of the national COVID-19 lockdown when it was more about survival of the business for Pharma and Healthcare. In fact, our observation is based on the intent to hire because it was difficult even for organizations to give any outlook on hiring. The two sectors have shown a confidence in hiring compared to other sectors in the county, she said.

In its Employment Outlook Report, TeamLease has observed the Pharma and Healthcare sectors intent to hire by small business has improved by 6% and 7% points from April-September 2020 respectively. While the large business continues to lead in the overall intent to hire, it is the SMEs that recorded a significant growth from October.

While India Inc is on a gradual recovery path, though it is yet to reach the pre-COVID levels, the economy is rebounding and there is cautious optimism reflecting in the hiring scenario as well. Most of the sectors intend to ramp up their hiring. While signs are encouraging, still too early to predict how Q4 shall pan out given traditionally it is a tepid hiring quarter, said Chakraborty.

The overall demand from the drug manufacturing and healthcare companies indicate blue collar worker requirement will be in excess of 30 percent, sales around 20%, information technology being 18%, marketing is 16% and engineering around 13%.

Source: Nandita Vijay, Pharmabiz, 09.12.2020

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Covid-19: Serum Institute of India to get India nod soon after UK Approval

Serum Institute of India (SII) may get emergency use approval for Covishield in India soon after the UK's drug regulator MHRA gives a nod to the vaccine, which officials expect to be before Christmas. The Medicines and Healthcare Products Regulatory Agency (MHRA) is currently evaluating data including which dosing regimen is best to use for the Covid vaccine developed by UK's Oxford and AstraZeneca. Regulatory sources said the MHRA approval is

expected before Christmas and India may give a go-ahead soon after that. "The regulatory approval in the UK is crucial to strengthen SII's application seeking emergency use authorization in India because the proposal here refers to trials being conducted in the UK and Brazil. Moreover, the vaccine is yet to be approved in any country.

It is a sensitive matter and only once we are sure of the safety, efficacy and immunogenicity of the vaccine, we can grant an approval," an official said. Also, the MHRA's evaluation of data is likely to bring more clarity on dosage of the vaccine — which has shown efficacy of 62% when two full doses were given to trial participants, but 90% for a smaller sub-group given a half dose and then a full dose.

During an Inter-Ministerial Meeting on vaccination of South Asia organised by the World Bank, Health Minister Harsh Vardhan said, "It is expected that the vaccine will be available in the coming few weeks and vaccination process will kick-start in India as soon as it is approved by the regulatory agency concerned."

Source: The Times of India,12.12.2020

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DCGI denies EUA to Covid vaccines shots of Bharat Biotech, Serum

'Expert panels seeks more data on efficiency, safety'

In a setback to two major Pharma companies in the race for the vaccine for Coronavirus, the Drug Controller General of India (DCGI) has not granted the Emergency Use Authorization permission (EAU) to city-based Bharat Biotech and the Serum Institute of India (SII) for their respective vaccines, Covaxin and Covisheild.

The data submitted by both companies was found to be "insufficient" by the Central Drugs Standard Control Organisation (CDSCO) of the DCGI in terms of data on the trials of Indian patients, according to sources. The panel sought additional data on the safety and efficacy of their proposed shots. Due to lack of data on Indian patients, the CDSCO subject expert committee, which met on Wednesday, 09.12.2020 found that the "data submitted of phase 1 and phase 2 trials was not sufficient".

The DCGI said that Covid-19 vaccine candidates should have "at least 50 per cent efficacy in phase III clinical trials" for it to be widely deployed. The DCGI rules of 2019 state that there must be at least 3,000 patients on whom the vaccine has to be tested before approval.

Dr Kiran M, senior anaesthesiologist, Government Hospital, Nizamabad, said, "Phase III trials are still not complete. They are currently ongoing. Without data of these trials, the EUA cannot be given. There is no concept of EUA in India. This is for the first time vaccines are being taken up under this given the emergency of the pandemic. For this reason, scientists and drug controllers are very cautious."

According to sources aware of the proceedings, "the data submitted by a company to CDSCO in order to get a EUA pertained to data of overseas patients by a company for phase III human Clinical Trials". In case of another company, recruitment of all 26,000 volunteers is still not complete, sources said.

Given these lapses it will take time for the EUA to be given to these companies. Experts argue that vaccine development takes time and evaluation of data requires time. Dr Sanjay Reddy, senior pharmacist, said, "The data generation will be based on the dosage regime, time after doses and adverse effects, if any. These phases have to be completed. Till it is completed, it will not be known where this vaccine can be administered to people safely."

Experts believe that the waiting period for EUA will take at least another month, if not ore. There are three committees which have to evaluate the request from these two companies, including the vaccine subject expert committee, the technical panel and the apex committee. The first committee, SEC, has asked for more data from the companies, which means that the wait for the vaccine from these two firms reaching people has gotten much longer.

The application by the Indian arm of US pharmaceutical firm Pfizer was not taken up for deliberation on Wednesday, 09.12.2020 as the company sought more time for making a presentation before the committee, they said. The recommendations by the SEC have been approved by the DCGI," an official source was quoted by PTI to have said. Bharat Biotech applied to DCGI for EUA on December 7 for Covaxin, developed indigenously by the firm in collaboration with the Indian Council of Medical Research, while Pune-based Serum Institute sought a nod for its Oxford vaccine, Covishield, on December 6.

Source: Kaniza Garari, The Asian Age, 10.12.2020

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Rajasthan to emerge as most viable industrial location for Pharma sector in a couple of years: Vinod Kalani

Rajasthan is prepared to emerge as the most viable industrial location for Pharmaceutical formulations, medical devices and neutraceuticals in India in a couple of years. The Pharma sector in Rajasthan will emerge stronger after the COVID pandemic and the state will become a growth engine for the entire Pharmaceutical sector in the country. The disruptive effect of the COVID-19 has not much impacted the pharma sector in Rajasthan, according to Vinod Kalani, President of the Rajasthan Pharmaceutical Manufacturers Association (RPMA).

Expressing hope for a better industrial atmosphere for growth in Pharmaceutical production sector, Kalani said, "Pharmaceutical manufacturing in Rajasthan is in an upward growth and several new units are being set up by investing more on technology. The state Government is supporting the industry with all sources to develop the Pharma sector.

The focus areas are formulations, bulk drugs, medical devices, neutraceuticals and Ayush medicines. In a telephonic interaction with Pharmabiz, Kalani said there are eight major players and 90 SME units who concentrate on formulations and APIs. He said the pharmaceutical exports from Rajasthan garner foreign exchange earnings of Rs.3,000 crore annually. Twenty Pharma companies from Jaipur and Jodhpur export their products to other countries.

The advantage of the Rajasthan Pharma industry is its proximity to the national capital and it foresees a bright future. According to Kalani, compared to Pharma industries in Maharashtra and Gujarat the number of manufacturing units in Rajasthan is limited, but there is big scope for growth in the national level.

He said the regulatory changes that happened in the last 15 years in the Pharma sector have brought good results in the pharmaceutical sector in Rajasthan as most of the units were upgraded to GMP status without closing down the plants. However, there are several challenges faced by the industry now and they are related to skilled personnel and current global standards.

RPMA is giving training to the workforce in the units with the support of the department of pharmaceuticals, industry department and NGOs. Like everywhere else, the COVID pandemic has been a big source of worry for the Pharmaceutical industry in Rajasthan in the current year and the manufacturing segment was hit hard by the pandemic.

However, the manufacturing units could come up gradually though the production has been down by 30% initially. The President of the RPMA said the support of the Government and the Drugs Control Administration was a big thrust on the Pharma sector to survive the situation to move the industry smoothly now.

Responding to queries from Pharmabiz, Kalani said his association has given several proposals to the Government for the development and growth of the state Pharmaceutical industry. Now the Government has come forward with some attracting projects and some of them are setting up an API park and a medical devices park in Jodhpur. Further, one Pharma cluster is in the pipeline. All these projects are supported by the Central schemes.

Source: Peethaambaran Kunnathoor, Pharmabiz, 15.12.2020

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Industry sees relevance of US FDA norms on DDT as COVID-19 drug & vaccine research and approvals gather pace

Pharma industry finds US FDA norms on Drug Development Tools (DDT) to be pertinent as research on COVID-19 drug development picks up pace. DDTs can be used to support regulatory applications, including Investigational New Drug applications (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs). In its latest guidance titled 'Qualification Process for Drug Development Tools', US FDA has provided methods to aid drug development and regulatory review.

Prema Desai, a Pharma Consultant, noted that DDT can be used to supplement a study of the population with individuals exhibiting certain characteristics which may help to shorten the duration of the Clinical Trial. This gains relevance as regulators are looking to fast track drug and vaccine approvals during COVID-19.

Noting that this US FDA Notification provided high level Guidance on the use of drug development tools for new therapies: Biomarkers, Animal Models and Clinical Outcome Assessment, Dr Gopal Dasika, global head, R&D, Biocon Biologics said that it provides a three step process:- Letter of Intent, Qualification Package and Full Qualification Package with associated timelines. "While

it is intended to enable both individual drug development companies and consortia/academic labs to leverage qualified drug development tools for the specified context of use with the goal of reducing the overall development and regulatory timelines, it remains to be seen how the industry will come together to collaborate and share information for realizing the potential benefit," added Dr Dasika.

The use of reliable DDTs can significantly facilitate the development of new, safe, and effective drugs. Qualified DDTs allow integration of innovative technology and new science areas as knowledge of disease and pathogenesis advances. It could be applied to obtain approval of any drug. FDA expects the content in DDT submissions to provide supporting evidence demonstrating the reliability and accuracy of the proposed DDT, stated the regulatory note.

According to Section 507(e)(3) of the FD&C Act Clinical Outcome Assessment is a measurement of a patient's symptoms, and his over all mental state, or the effects of a disease or condition on how it functions. Here the Clinical Outcome Assessment is used to determine whether a drug has demonstrated a clinical benefit. Further FDA has decided that animal models evaluated under the Animal Model Qualification Programme (AMQP) aids drug development and regulatory review.

Here FDA has accepted the description of the model's appropriate use in regulatory applications, including the definition of the parameters of the disease that will be used as measures of quality control and quality assurance when the model is used. In addition the regulatory authority noted that the Cures Act contains transparency provisions that includes information in the qualification submission. The Act codified a statutory process for DDT qualification has added transparency provisions that helps to promote an understanding of how to develop drug development tools.

Source: Nandita Vijay, Pharmabiz, 15.12.2020

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Health Ministry outlines action plan to ensure Schedule H & H1 drugs are not sold without prescription to tackle AMR

Taking strong view of the fact that antimicrobial resistance (AMR) is increasingly becoming a serious threat to public health, the Union Health Ministry has outlined an action plan towards strong implementation of the provisions of the Drugs And Cosmetics (D&C) Rules, 1945 to ensure that no drugs including antibiotics in Schedule H and H1 category are sold at retail pharmacies without prescription of a Registered Medical Practitioner (RMP).

Concerns have been raised regarding the sale of prescription drugs at retail pharmacies across the country without prescription of RMP. Besides this, in recent decades, widespread and rampant use of antibiotics, especially in low and middle income countries have led to the phenomenon of AMR. The action plan envisages strengthening and enforcing regulations to minimise the substandard, spurious, falsely labelled and falsified antimicrobials, strengthen legislation to regulate prescription and dispensing of antimicrobials and identify additional regulatory interventions or support needed to effectively implement Schedule H1 and X restrictions.

The plan is also meant to ensure prescription sale of antibiotics and their use under supervision; regulate bulk selling, importation and labelling for specific use. Union Health Ministry in consultation with various stakeholders had developed and released National Action Plan on AMR (NAP-AMR) earlier which talks about interventions planned which consider harmonized approach across various sectors to address use of and resistance to antimicrobial agents in human health.

Modern medicine is incomplete without antibiotics which are being used across the globe in the treatment of deep-rooted infections, complex surgeries and even common ailments. "New drugs take time for development, testing and approval before they are available to patients and bacteria keep on evolving. If we do not instill behaviour change, we will continue to stimulate bacteria to develop resistance against the new antibiotics of the future," according to an industry expert.

Source: Shardul Nautiyal, Pharmabiz, 14.12.2020

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Health Ministry approves Allura red colour for Pharmaceutical preparations

The Union Health Ministry has considered industry recommendation to approve Allura red colour for Pharmaceutical preparations for better identification for drug usage compliance and patient convenience. The same has been permitted in regulated markets including USA, UK, Canada, Australia and Singapore. According to industry sources, since it is meant for identification purposes and

is being approved in regulated markets, it would be the right step from the export perspective also as India supplies medicines to over 250 countries in the world.

Allura Red AC is a coal tar colour which is a red azo dye compound derivative of naphthalene. This term coal tar is an older nomenclature for synthetic chemical that started out with coal tar as the precursor. The colour FD&C Red 40 is a synthetic chemical and is also referred to as coal tar colours. This colour is, however, not included in the list of approved colours as prescribed in rule 127 of the D&C Rules, 1945. The same has been considered for approval based on Drugs Technical Advisory Board (DTAB) deliberations and recommendations for amending the Rule 127 of the Drugs and Cosmetics (D&C) Rules, 1945 to include FD&C Red # 40 Aluminum Lake (E I29) Allura red colour.

Representation on the same has been received from the industry that currently conjugated estrogen tablets USP are being manufactured by them in a white tablet format using Opadry white as the colouring agent. Now, the manufacturers want to change the colour coat of conjugated estrogen tablets USP from white to maroon coat utilizing colour pigment FD & C Red # 40 Aluminum Lake (E129) Allura red. The Opadry Maroon colour coat contains HPMC 2910/ Hypromellose [6cP], titanium dioxide, FD&C Red # 40 Aluminum Lake (EI29) (Allura red) PEG 400/Macrogol and FD&C Blue #2 Aluminum Lake (EI32).

However, the same is approved and used for many years by major regulatory authorities across the world as permitted colour for Pharmaceutical preparations and food products. Further, the Food Safety and Standards Authority of India (FSSAI) has also approved FD&C Red # 40 Aluminum Lake (E I29) (Allura red) as colorant in food products in India.

Source: Shardul Nautiyal, Pharmabiz, 14.12.2020

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COVID-19 vaccines are big business and spell big bucks for big pharma companies

India with its huge population and flourishing pharma industry is poised to both import and export vaccines

Even after 67 million COVID cases and 1.5 million deaths, there seems to be no end to the pandemic in sight. But the year is about to end on high promise, with at least four vaccines set to hit the market. Vaccines are normally administered to children between 0 to 10 years. There are some like the Pneumococcal and Flu Vaccine, which are given to adults seasonally. However, the difference with COVID-19, is that virtually the entire world is a potential market to protect the present global population of 7.8 billion.

Medical experts say that to achieve 'Herd Immunity', at least 70 percent of the population needs to be covered, which means around 5.5 billion people. Most potential vaccines require two doses. This adds up to 11 billion doses. This huge demand automatically offers tremendous scope for Vaccine makers and big Pharma.

They have been quick to realise and in India, Dr Reddy's, Bharat Biotech, Hetero, Aurobindo, Zydus Cadila and Strides Pharma have moved in to get a slice of the big pie through global and domestic collaborations. Bill Gates, the Microsoft Founder and Bill & Melinda Gates Foundation has repeatedly stated that India will be the key player producing more than half the world's requirement with its strength in drugs and vaccines.

In addition to the manufacture of vaccines, an entire ancillary industry to make vials, syringes, packaging, boxes, cold storage, transportation etc will witness a big surge, points out Dr Rao Vadlamudi, Pharma Veteran and President of the Commonwealth Pharmacist Association.

The two mRNA based vaccines developed by PfizerBioNTech and Moderna Inc are expected to be priced in the range of $20 to $50 per dose. The OxfordAstraZeneca- Serum Institute of India (SII), has indicated a price of Rs.1000/- per two doses in India. The makers of Sputnik V, RDIF of Russia has announced $10 per shot for international market. The prices will differ in countries and also will be lower for a global vaccine alliance that is expected to help nearly 100 low income nations.

Countries with politically strong leadership and regulatory frameworks like the US, UK & some EU nations have taken the lead in pushing for vaccines and fast tracking the process. Not far behind are Russia, China, India and Brazil. At one point, the race was so intense and inward looking that the WHO cautioned against vaccine nationalism.

Source: M Somasekhar, National Herald, 14.12.2020

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Next four to six months could be worst of Coronavirus pandemic: Bill Gates

Microsoft co-founder and the co-chair of the Bill and Melinda Gates Foundation, has warned that the next four to six months could be the worst of the Coronavirus pandemic (Bill Gages: Photo Credit - AP)

"Sadly, the next four to six months could be the worst of the pandemic. The IHME (Institute for Health Metrics and Evaluation) forecast shows over 200,000 additional deaths. If we would follow the rules, in terms of wearing masks and not mixing, we could avoid a large percentage of those deaths," Gates said. "I thought the US would do a better job handling it," said Gates, who in 2015 had warned the world of such a pandemic.

"Overall, when I did the forecasts in 2015, I talked about the deaths potentially being higher. So, this virus could be more fatal than it is. We didn't get the worst-case. But the thing that has surprised me is that the economic impact in the US and around the world has been much greater than the forecasts that I made five years ago," he said. Earlier in October Gates had said that life will only be back to normal once the second generation of Covid-19 vaccine becomes available.

The COVID-19 has so far killed more than 290,000 people in the US. Gates said that his Foundation has been funding a lot of the research for the vaccines. "We're very agile. We're a partner in a thing called CEPI, which is the second biggest funder after the US Government," he said. "So, in diagnostics, therapy and vaccines, we know where the science is, we know how the pieces need to come together in an urgent way. And so our expertise in infectious disease, which normally only relates to developing countries, applied to the entire world for this crisis," he added.

The US need to help all of humanity, Gates said when asked of the Executive Order signed by President Donald Trump which prioritizes distribution of the vaccine to Americans before it goes to people in other countries. "We want the world economy to be going. We want to minimize the deaths. And, you know, the basic technology is a German company. And so blocking international sharing and cooperation has been disruptive and a mistake during this entire pandemic," he said. "So, we need to ramp up the capacity of all the vaccines.

There will be some additional ones approved in the months ahead that are easier to scale up the manufacturing. But the US has benefited from other countries' work care, and we shouldn't be entirely selfish in how we go forward," he added. Responding to a question, Gates said that he will take the vaccine publicly as the former US President, Bill Clinton, George Bush and Barack Obama, have said to increase the confidence of the people in the vaccine.

"I will do the same. When it's my turn -- I'm not going to budge, but when my turn comes up, I will visibly take the vaccine, because I think that it's a benefit to all people to not be transmitted," he said. Gates said that access to the vaccine should be based on medical need, not wealth at all. "After all, this epidemic has been awful in the way that it's exacerbated inequities.

It's been worse for Hispanics, worse for blacks, worse for low-income service workers, multi-generational households, a number of things that mean that, in terms of picking who gets the vaccine, we better be using equity to drive all those decisions," he said. Despite the availability of the vaccine, Gates said that the next four to six months really call on Americans to do their best. "Because we can see that this will end, and you don't want somebody you love to be the last to die of Coronavirus," he said.

"Certainly, mask-wearing has essentially no downside. They're not expensive. Bars and restaurants in most of the country will be closed as we go into this wave. And I think, sadly, that's appropriate. To date, more than 72 million people have been infected with the Coronavirus Worldwide, with over 1.61 million fatalities, according to Johns Hopkins University. *(With inputs from agencies)*

Source: wionnewsweb@gmail.com, 14.12.2020 (Excerpts)

Bangladesh inks vaccine contract with Indian Pharma

Health Minister says shots expected to arrive in January

Bangladesh on Sunday (13.12.2020) signed a procurement contract with Serum Institute of India, which is producing doses of Oxford-AstraZeneca's COVID-19 vaccine, an official said. Bangladesh will get five million shots each month after the vaccine is approved for mass use, Bangladesh Health and Family Welfare Minister Zahid Maleque said at the official ceremony held in the capital Dhaka. Doses are expected to first arrive in January, he added. On November 5, the Health Ministry inked an MoU with Beximco Pharmaceuticals of Bangladesh and Serum Institute of India to purchase 30 million doses of the vaccine. It will be available for 15 million people as two shots are needed per person.

A study published in the Lancet medical journal has confirmed that the Oxford-AstraZeneca vaccine works in an average 70% of cases, with efficacy of 62% for those given two full doses, and of 90% in those given a half then a full dose. Bangladesh has also signed with the UN's COVAX Facility to receive millions of doses. The South Asian country of 162 million people has so far registered 490,533 infections and 7,052 related deaths.

Source: S M Najmus Sakib, Asia-Pacific, AA, 14.12.2020 (Excerpts)

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China vs India: the fight for Pharma Supremacy

Meera Navlakha

India's position as a Pharma powerhouse is well established, but a galvanized China has set its sights on overtaking rivals

As the world races to develop and distribute a vaccine to combat Coronavirus, there is a parallel contest gathering momentum between India and China's Pharmaceutical markets. The Pharma industries in both countries are perceived to be competing for a position at the head of the global market. While India retains its position as a world leader in generic medicine production, China has increased its investment in Research and Development, signalling an interest in overtaking competitors.

India, recognised as a Pharmaceutical powerhouse, is facing a threat. In *Made in China 2025*, China's industrial policy aiming to make the country dominant in global high-tech manufacturing, biomedicine is a key strategic goal. A laser-sharp focus on expanding their burgeoning Pharma market is providing China with a distinct edge in drug development compared with India.

China's growth driver: emphasising innovation:

In 2016, China's Pharmaceutical Market was worth $123 billion, but this figure is projected to surge to $573 billion by 2022. McKinsey & Company hails China's Biopharma industry as only second behind the United States in global numbers. Its imminent transformation will arise from the investment and support being put into innovation.

"China is investing heavily in R&D and they know this is the first step to achievement in this industry," says Dr Kamal Rashid, founding Director of the US Center for Biopharmaceutical Education and Training. "Investment in the workforce is also essential. To produce a good product that will receive approval, you need both manpower and facilities. There is a need for a good workforce to make innovation a reality. This is something China is getting into more aggressively."

The Chinese Government has created a support system to incubate new firms, allowing them to leap from old technologies into creating biologics. Key players in their domestic market include Sinopharm Group and Shanghai Pharmaceuticals, but multinationals such as AstraZeneca, Pfizer, and Novartis make up a substantial component of the ecosystem. In China, the latter contribute to global Pharma revenues at an average of 8 percent.

Indian Pharma continues focus on generics:

A dearth in the creation of biologics sets India a few steps behind China's vision for their Pharma market. Yet India continues to be hailed as the largest provider of generics globally. "India is referred to as the Pharmacy of the world and with good reason," says Nithya Balasubramanian, Director at investment management firm Bernstein.

At present, generic drugs manufactured in India account for 20 percent of the global consumption of generics, in addition to 40 percent of prescriptions dispensed in the United States, which is safely positioned as the largest Pharma market. In 2019, Indian Pharma was worth $38.8 billion, contributing significantly to the country's economic growth. "While the US market has been in the driver's seat dictating valuations, the Indian domestic market remains the ever-reliable vertical for most Indian generics and is slowly gaining prominence," says Balasubramanian.

While their growth will continue in the supply of generics, innovation has been given far less attention in India compared to China. Balasubramanian notes that most recent product launches in India have been "incrementally innovative". India's Market Growth will stem, instead, from the "commercial muscle of Indian generics", she says.

According to the Indian Pharmaceutical Alliance (IPA), there are several challenges to the exponential growth Indian pharma could achieve. For one, an environment

conducive to long-term investment decisions in the pharmaceutical industry has yet to be established. Other key challenges include lack of innovation, less access to skilled workers and stricter Guidelines in quality compliance in international markets. The IPA reports there are about 29 skilled workers available for every 10,000 people in India, in comparison to China, where there would be about 41.

A noticeable dependence in India on external markets, including China, for intermediates and Active Pharmaceutical Ingredients is an additional factor. However, analysts believe India will persevere and show growth in this sector. "We remain optimistic about the growth prospects for the industry in the next four to five years and believe they will continue to be the largest contributor to profitability for Indian generic manufacturers," says Balasubramanian.

All eyes remain on the Chinese as they climb the global market rankings, foreshadowing a possible change of leadership in new technology and life science.

Pharmaceutical power on a global scale:

This clash of global pharmaceutical titans is ongoing. However, it begs the question of whether this race will result in the potential cutting of corners in manufacturing and approval processes, ultimately lowering standards?

"We can't play with human health, so cutting corners would be the last thing to do," says Rashid. "In the United States, the Federal Government heavily regulates innovative drugs. In other countries, regulation may not be as stringent and this will need to be discussed."

The impact of the next Pharmaceutical powerhouse may extend far beyond healthcare markets, spilling over into global influence and soft political power. China's Pharmaceutical companies appear to be playing a very different game to India's and this strategy is likely to clinch the position of Pharmaceutical Supremacy.

(Written by Meera Navlakha - Politics, culture and technology journalist, with bylines in the New York Times, the Independent, and VICE)

Source: Raconteur, 10.12.2020 (Excerpts)

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ATTENTION MEMBERS

Invitation to participate in 'IDMA MARGI MEMORIAL BEST PATENT AWARDS 2019-20'

As you will be aware, the **IDMA Margi Memorial Best Patent Awards** recognize the **'Best Patent of the Year'**, both national and international. We request you to kindly send us details of your **patent/s granted in the last 12 months period (01.04.2019 to 31.03.2020)**. An Expert Panel will examine and evaluate the applications received and recommend their selection for the Award. A copy of the Patent granted should also be enclosed to enable the Panel to evaluate the Patent for the Award.

Applications should be forwarded in a closed and sealed envelope marked **'IDMA Margi Memorial Best Patent Awards 2019-20'** along with an ENTRY FEE of ₹10,000/- + GST @18% (Total ₹11,800/-) per Member Company immediately to reach us **latest by 07th January 2021.**

For the convenience of the panelists, soft copies of the application along with relevant supporting patent documents may also be sent separately.

Applications for the Award will need to comply with certain criteria as enumerated in the Guidelines (Do's and Don'ts) for IDMA Margi Memorial Best Patent Awards 2019-20 (as mentioned below). Kindly peruse the same before applying for the Award.

The winners will be notified by email after the Expert Panel finalizes selection of Award Winners. The Awards will be presented at the **IDMA 59th Annual Day Celebrations to be organized by end of February 2021 at Online Web.**

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

The Expert Panel, constituted to scrutinise the Applications, has set the following **DOs and DON'Ts** for consideration for Awards as below:

DOs:

1. Applications must include Patents granted only during the financial year 2019-20 (1st April 2019 to 31st March 2020) for evaluation.
2. A Member-Company can apply for more than one Patent. Multiple Patents can be listed in a single application.
3. The Application is to be submitted both as Soft Copy as well as Hard Copies with Summary of the Patents. However, details of Patents may please be sent preferably only in Soft copy.
4. All Family Patents belonging to same invention will be considered as one patent. Country-wise validations for EU or ARIPO patents will not be considered as independent patents. Divisional patents granted with similar inventions will be considered along with parent patent.
5. Different inventions having same title with common priority document will be identified and considered as One Patent.
6. Group companies (including Research Centres) applying independently may indicate if they wish to be considered together or separately. If patent is granted to other than the applicant, the documents justifying the inclusion of such patents (group status) need to be attached.
7. Applications for Awards for Patents granted to individuals will be considered with documentary support of rights transferred to the Applicant (Member Company)
8. Applicants are requested to self-certify the authenticity of information submitted to minimise the review and verification work by IDMA.
9. The Application must be forwarded under a covering letter/or by email duly signed by an authorised signatory along with name, designation and contact details.
10. The covering letter should carry a declaration that *"We have read 'The Guidelines and Criteria for Evaluation of Patents submitted for IDMA Margi Memorial Patent Awards 2019-20 and abide by the same"*.

DON'Ts:

1. Please do not apply for Patents granted earlier than 1st April 2019 or after 31st March 2020. It will not be considered for this year's Awards.
2. Please do not apply for a pending patent. It will not be considered and will be disqualified.
3. Please do not apply for Patents which are already withdrawn, abandoned, not maintained or revoked will obviously not be considered.
4. An Application of a patent of the same family (of an invention which has already qualified for award in earlier years), even if granted in another country in the relevant year will not be considered.
5. If the data submitted is found to be not correct or factual, the applications will be disqualified.

(Note: The Decision of the Expert Panel will be Final).

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The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
Because our biggest success lies in your infinite trust in us. And we will always ensure that we treat that trust with the utmost care.
Signet-ure
Trust
DUPONT
ROQUETTE
ShinEtsu
MEGGLE
Innophos
avantor
pharm-a-spheres
Nouryon
BIOGRUND
ICL
AsahiKASEI
EASTMAN
Pfanstiehl
Tereos
IMERYS
CORDENPHARMA
DOHLER
JVP
MORIMURA BROS., INC.
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VENATOR
Specialty
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The Complete Excipients Company

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