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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. 36 22 to 30 September 2020

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IDMA Representation to DCG(I) *re.* Inclusion of 'Marketer' in D&C Rules – reg.

The Association has submitted the following representation on 23rd September 2020 to Dr V G Somani, Drugs Controller General of India, Central Drugs Standard Control Organisation, New Delhi (in response to Gazette Notification No.GSR 101(E) dated 11th February 2020) on the above subject:

"Greetings from Indian Drug manufacturers' Association.

We refer to the Gazetted Notification as above for defining "Marketer' under Drugs and Cosmetics Rules that places certain responsibilities for quality and regulatory compliance on the marketer for the products marketed by him. The Rule comes into force on the 1st day of March, 2021.

We had made a detailed submission on 24th July 2019 (copy enclosed for immediate reference)***** on the draft Notification amendment [GSR 447(E) dated 24th June 2019]. While IDMA had welcomed in principle the sharing of responsibilities for quality by the marketer, we had brought out the issues of:

a) lack of clarity related to responsibilities for quality and compliance with regulations; and

b) requirements being inconsistent with the law as a challenge for implementation of the Notification in it's draft form.

and had requested to keep the Notification in abeyance until the suggested changes were made. However, the draft Notification was finalized without considering our suggestions.

Some of our members have expressed a great concern about these issues and have shared their suggestions. We are reiterating these in a summary with a request to provide suitable explanation and necessary amendment to the Notification:

Rule 2

'(ea) "Marketer" *means* ***a person who as an agent or in any other capacity*** *adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution;'*

The term 'Agent or in any other capacity' in the definition of 'Marketer' have wider meaning and are not specific. Be sides, as explained below, Marketer not being a manufacturer or an agent gets an exemption under Section 19(3). The definition thus needs to be revised accordingly.

In fact, provisions under Section 19(3) of the Act provide safeguard to the person not being either a manufacturer or agent of the drug. Since the Section is not being amended, it would have conflicting implications for making marketers responsible for quality as well as other regulatory compliances. Any Rule contrary to the provisions under the Act or having overriding effect will not withstand judicial scrutiny.

84E. Responsibility of marketer of the drugs - Any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules."

As stated in our representation, the responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and has to be specified clearly, particularly in view of the fact that the outsourcing of products is done in two different manners - Loan License arrangement and P2P arrangement that has different set of responsibilities on the marketing company.

In the Loan License arrangement, where the technology/product know-how is provided by marketer, the Drugs and Cosmetics Rules, 1945 provide the responsibilities in the form of conditions for grant of a loan license.

In P-to-P arrangement, two P-to-P parties, one having manufacturing skills and capabilities and the other having

marketing skills and capabilities work synergistically using their respective skills and resources. Under this arrangement the marketer accepts the product developed and manufactured by the manufacturer under a drug license.

Under the marketing arrangement, it is practically not possible for a marketer to exercise a control on the manufacturing and testing of the drugs that is governed by the conditions of the license issued to the manufacturing company.

Further, the words “responsible for other regulatory compliance”, are vague, non-specific and wide in meaning. The expected regulatory compliances to be complied by the marketer needs to be provided in clear terms.

In fact, since the marketer is neither a manufacturer, nor a Loan Licensee, the provisions of Chapter VII governing conditions of manufacturing license would not apply to him. The applicable requirements for storage and distribution of drugs are specified in Part VI. Thus, providing for the responsibility of a marketer under Part VII would be out of place, context and scope of the part VII.

Further, Rule 84D requires that before marketing of the product the marketer should have an agreement with the manufacturer. However, here again the key contents of the agreement are not specified. The shared responsibilities for quality and regulatory compliance between the manufacturer and marketer have to be consistent with the legal requirements and hence have to be specified.

IDMA Suggestions:

Notwithstanding the above submission, the intent of making a marketing company responsible for quality, requires consideration of the following points:

a) Introduction of separate Part in the Drugs and Cosmetic Rules, since Part VII applies to license holders for manufacturing - Own License/Loan License and not to Marketers.

b) The definition of the term Marketer has to be modified to remove the words 'agent' or 'person in any other capacity’ since these words have wider meaning and are not specific. Marketer cannot be considered as an agent of the manufacturer since he works on a P-to-P Contract basis.

c) For the reasons explained in our response, the responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and has to be specified clearly.

d) For this purpose, the concept of Contract Giver (one who outsources the GMP service) and Contract Acceptor (one who manufactures products in accordance with applicable GMP requirements) provided in EU GMP, PIC/s Guideline will be beneficial. The requirements clearly divide the responsibilities between the Contract Giver and the Contract Acceptor.

e) In fact, an attempt has already been made on these lines in introducing this concept in the proposed draft amendment vide GSR 999(E) dated 05.10.2018 to Schedule M under Para 9, Production under loan licence or contract and contract analysis and other activities. IDMA has submitted a detailed response to this part that requires amendment to the Rules rather than Schedule M alone.

This Notification, if implemented without amendments suggested by us, may interrupt supply of medicines that would be against the interest of the patients, particularly in the current pandemic period. The disruption caused by the pandemic is predicted to last for at least 2 years and any interruption to the supply has to be prevented.

In conclusion, this amendment, in its current form, may not provide any additional benefit in terms of ensuring product quality but may act as an impediment in Government's thrust on 'Ease of doing business'. Until the suggested amendments are notified, the implementation of the Rules may be deferred. Thanking You”.

(*Not reproduced here. The said Representation was published in IDMA Bulletin Issue dated 7th August 2019 Page No. 5)

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IDMA Representation to DCGI for extension of validity of Form 10 Licence along with Form 41 Registration Certificate – reg.

The Association has made the following representation on 28th September 2020 to Dr V G Somani, Drugs Controller General of India, Ministry of Health and Family Welfare, New Delhi for clarification in Gazette Notification No. S.O.2450(E), dated 27th July 2020:

"Greetings from Indian Drug Manufacturers' Association.

We acknowledge with thanks receipt of Gazette Notification No. S.O.2450(E) dated 27 July 2020 by Government of India by which validity of Registration Certificate issued under Form 41 has been extended for 6 months. It is a timely decision particularly in view of the COVID-19 pandemic. The Notification also states that if an application has been made for a fresh Registration Certificate before the expiry of the existing certificate, "the existing Registration Certificate shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes". We are grateful to the Government for this gesture.

We request you to clarify whether Form 10 licence issued against Form 41 is also similarly valid. It will be a great favour if immediate clarification is issued by CDSCO or by Ministry of Health so that importers will not have to apply for fresh application to get Form 10 to avoid duplication of work.

We would appreciate an urgent clarification on this matter from your esteemed office. Thanking you".

S.O.2450(E), dated 27th July 2020 Gazette Notification extending the validity of Registration Certificate (Form 41) is reproduced below:

S.O.2450(E), dated 27th July, 2020

1. Whereas, an outbreak of COVID-19 pandemic is prevailing throughout India and worldwide;

And whereas, several Registration Certificates in Form-41 are in existence and their validity periods of three years are likely to expire shortly;

And whereas, pharmaceutical companies and their associations have requested for extension of the validity of Registration Certificate (Form-41) for six months in the wake of COVID-19 pandemic;

And whereas, the Central Government is of the considered view that supply of drugs may not get affected and the drugs must remain available to the public;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby directs that notwithstanding anything contained in rule 28A of the Drugs and Cosmetics Rules, 1945, for import of drugs for sale or distribution, if an existing Registration Certificate holder under the said rules, makes an application for a fresh Registration Certificate before the expiry of the existing certificate, the existing Registration Certificate shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes.

2. This order shall come into force on the date of its publication in the Official Gazette and shall remain valid for a period of six months.

F.No.X.11014/01/2020-DR

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

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IDMA Representation to FSSAI for Clarification of status of Methylcobalamin as Ingredient under FSS Regulations 2016 – reg.

The Association has submitted the following representation on 28th September 2020 to Mr Arun Singhal, IAS, Chief Executive Officer, Food Safety and Standards Authority of India (FSSAI), with copy to Ms Rita Teaotia, IAS, Chairperson, FSSAI, New Delhi for Clarification of status of Methylcobalamin as Ingredient under FSS Regulations 2016:

"Greetings from Indian Drug Manufacturers' Association.

We refer to the above mentioned subject and request your kind intervention to help dispel all prevailing confusions regarding Methylcobalamin usage as a standardized ingredient under the Schedule-I of the FSS Regulations, 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food products.

Schedule-I of the FSS Regulations as above lists the vitamins and minerals and their components. Table A is for vitamins and Table B for minerals. After the Table B is a footnote.

"Note - Suitable esters and salts of vitamins and salts and chelates of minerals may be used"

This matter was represented by us and there were deliberations and discussions held which resulted in the need for suitably changing the footnote under the Table B. Accordingly the FSSAI also issued a Circular dated: 29th December 2017 [F.No.Std/Nutra(DCGI)/ FSSAI/2017 (Pt.1)] which mentioned under Annexure I:

"(ii) after serial number B(15), in the note, for the words "Suitable esters and salts of vitamins and salts and chelates of mineral may be used", the following shall be substituted, namely;-

Suitable esters, derivatives and salts of vitamins and salts and chelates of minerals may be used."

The word 'derivative' especially is very necessary since it implies that all vitamin-derived ingredients can be included under the Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food products categories. The industry has believed in FSSAI's initiatives and consequently on release of the circular dated 29th December 2017 [F.No.Std/Nutra-(DCGI)/ FSSAI/2017.(Pt.1)], derivatives such as methylcobalamin, have been incorporated in marketed formulations by FBOs. In fact, methylcobalamin forms the backbone for consumer wellness as far as providing the benefits of vitamin B_{12}.

Cyanocobalamin has questionable efficacy following oral intake since it requires the Intrinsic Factor (IF) to facilitate absorption. The IF is saturated when up to 2 mcg of vitamin B_{12} is taken as cyanocobalamin. Thus, there is very limited scope to ensure adequate amounts of available vitamin B_{12} in blood with forms such as cyanocobalamin. "All of the B_{12} forms are reduced to the core cobalamin molecule inside the cytosol and then converted to the 2 active forms of B_{12}—MeCbl and AdCbl—irrespective of the form of B_{12} ingested."

Animals store bioavailable vitamin B_{12} compounds in their milk, eggs, muscles and organs, and especially in the liver. Adenosylcobalamin (AdCbl) is the predominant B_{12} form found in meats, at 68%, with the rest occurring as hydroxycobalamin (OHCbl) and methylcobalamin (MeCbl). MeCbl is the predominant form in milk and eggs.

*[Ref: Paul C & Brady DM. Comparative Bioavailability and Utilization of Particular Forms of B12 Supplements With Potential to Mitigate B12-related Genetic Polymorphisms. Integr Med (Encinitas) 2017; 16(1): 42-49 – copy enclosed]**

Thus, methylcobalamin is a safe and naturally occurring form of vitamin B_{12} and a derivative of cyanocobalamin.

Scientific Opinion of European Food Safety Authority:

The European Food Safety Authority (EFSA) has published a 'Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to food' titled *"Scientific Opinion on 5'-deoxyadenosylcobalamin and methylcobalamin as sources for Vitamin B12 added as a nutritional substance in food supplements"* which was adopted on 25 September 2008 (copy enclosed)**.** After a detailed study, the Panel has concluded that:

" … the use of 5'-deoxyadenosylcobalamin and methylcobalamin as a source of vitamin B12 in food supplements for the general population at the proposed uses and use levels *[below the Guidance value of 2000 µg/day defined by EVM (Expert Group on Vitamins & Minerals)]* ***is not of safety concern."***

FDCA Gujarat has issued a circular [Ref No.Food safety/Methylcobalamin/President/2019/I-56147-C-2 dated 11 June 2019] against use of methylcobalamin in food products. FSSAI has also issued another recent circular to Commissioners of Food Safety cautioning them about methylcobalamin being used in food products [File No.4(12)2016/Gujarat/Enf/FSSAI dated 31st October 2019]. In this context it is requested to expressly issue clarification that methylcobalamin is safe and can be used as a food product especially because:

- Cyanocobalamin is converted (90%) and utilized as methylcobalamin.
- Cyanocobalamin is synthetic whilst methylcobalamin is natural form of vitamin B_{12}.
- Cyanocobalamin cannot be absorbed in amounts more than 2 mcg since the IF is saturated thereafter; therefore it has necessarily to be administered as an injection if it is to be an effectively supplement to meet vitamin B_{12} requirements. Methylcobalamin in recommended, and already commonly incorporated in innumerable products, has proven efficacy as vitamin B_{12} supplement in amounts currently present in products.
- Methylcobalamin is safe and amounts upto 2,000 mcg per day as required, has been defined as Guidance value by EVM (Expert Group on Vitamins & Minerals).

Bearing in mind the above explanation, and the crucial need for methylcobalamin for consumer benefits with respect to vitamin B_{12} supplementation, we would request you to **issue Gazette Notification** stating:

1. Methylcobalamin and adenosylcobalamin are included under Schedule I (for Vitamins, Minerals and their components) of FSS Regulations, 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food products.
2. 'Suitable esters, derivatives, ***active moieties*** and salts of vitamins and salts and chelates of minerals may be used' as the modified statement below the above mentioned same Schedule I.

The word 'active moieties' was discussed during our meeting prior to accepting the change in footnote (Circular dated: 29th December 2017) but was by a typographic error omitted. Hence, including the same in the sentence mentioned above is imperative and would be requested.

47% of Indians need supplementation with vitamin B_{12} and hence it is essential stating that derivatives of vitamins are also to be considered as standardized under Schedule-I, AND all methylcobalamin-containing formulations need to be announced as IMMEDIATELY permissible under the various categories of FSSAI as may be applicable. Moreover, the Scientific Panel has already "approved methylcobalamin (vitamin B12) as a nutraceutical ingredient after risk assessment based on secondary data" as per communication by the erstwhile CEO Mr Pawan Agarwal to an FBO. ***(as below):***

PHARMABIZ.com
India's most comprehensive pharma portal

FSSAI yet to notify methylcobalamin as nutraceutical ingredient for neurological disorders despite scientific panel's nod

Shardul Nautiyal, Mumbai, **Wednesday, July 22, 2020, 08:00 Hrs [IST]**

Despite assurance regarding notifying methylcobalamin as nutraceutical ingredient based on Food Safety and Standards Authority of India (FSSAI)'s scientific panel nod in December 2019, industry has raised concern that FSSAI has not yet notified it.

Besides this, FSSAI has also not defined recommended dietary allowance (RDA) of vitamin B12 as there are four types of vitamin B12 namely methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin. The contention is that Indian Council of Medical Research (ICMR)'s scientific committee has recommended RDA value of 1 micro gram per day for vitamin B12 to FSSAI and FSSAI technical team has not been able to clearly define new RDA values based on scientific evidence.

"Correspondences by industry experts since June 2019 finally yielded the desired outcome from CDSCO, FSSAI and Gujarat state drug control department when FSSAI's Scientific Panel finally approved methylcobalamin (vitamin B12) as a nutraceutical ingredient after risk assessment based on secondary data," as per a letter shared from Pawan Agarwal, chief executive officer, FSSAI's office to pharma consultant Dr Sanjay Agrawal on December 18, 2019.

Also being forwarded two more press reports of the same as above. We urge you to review the Minutes of THE Meeting (held in first half of 2019) of the Scientific Panel pertaining to declaring 'methylcobalamin as a Nutraceutical' and immediately Gazette the said conclusion pertaining to this natural form of vitamin B_{12}.

Considering the contrary directives being sent by FSSAI that methylcobalamin is not to be considered as an approved ingredient in Schedule-I of the FSS Regulations, 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food products there is urgent necessity for your clarification. Only your quick resolve can prevent numerous consumers being denied the benefits of vitamin B_{12} being accrued through its natural, safe and effective form viz methylcobalamin.

We are confident of an early resolve of this uncertainty since there are a wide array of Health Supplements and Nutraceutical products that presently contain methylcobalamin and other derivatives and active moieties of vitamins listed in Schedule I.

Kindly issue Gazette of the following already decided and concluded findings of the Scientific Panel:

Include: Methylcobalamin *under* Schedule VI (List of ingredients as nutraceuticals) of FSS Regulations, 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food products.

'Suitable esters, derivatives, ***active moieties*** and salts of vitamins and salts and chelates of minerals may be used' *as the modified statement* below the Table B of Schedule I.

In the FAQs released in May 2020 pertaining to Question No.34, it has been explicitly mentioned and implied that derivatives are NOT allowed for nutrients in spite of your circular of 29th December 2017 [F.No.Std/Nutra(DCGI)/FSSAI/2017-(Pt .1)]. The various Press reports of the Scientific Panel have also accepted methylcobalamin as an approved ingredient under the category nutraceuticals. We request you to kindly please clarify this issue".

(*Enclosures not reproduced here)

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NPPA MATTERS

NPPA order for submission of data by manufacturers and re-fillers of medical oxygen - reg.

NPPA Notification dated 24th September 2020

To,

1. *All manufacturers and re-fillers of medical oxygen for compliance of direction given above.*
2. *All India Industrial Gases Manufacturers Association (AIIGMA) to circulate this order and ensure the compliance by their member companies.*

The Central Government has established a Central Control Room for monitoring the situation of Availability, Distribution and Demand of the medical oxygen. For this purpose availability of the precise information on situation of capacity, stocks, production and sales of the oxygen by all manufacturers and re-fillers is very important.

In exercise of powers conferred under para 29 (Maintenance of records and production thereof for inspection) of Drug Price Control Order (DPCO), 2013, the manufacturers and re-fillers of medical oxygen are hereby directed to submit the information to Control Room on e-mail: **oxygen-cr@gov.in** as per the attached format on daily basis till further order.

The information complete in all respect for the day may be given by the manufacturers/re-fillers to the Control Room on e-mail: **oxygen-cr@gov.in** by the end of the next day, without fail.

The DCGI, CDSCO will monitor that the information sought is provided by manufacturers and re-fillers, timely.

This issue with the approval of the Competent Authority.

F.No.12(41)/2020/Div.II/NPPA

S S Ojha, Joint Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

(Annexures not reproduced here. The same can be downloaded from NPPA website: www.nppaindia.nic.in OR contact IDMA Secretariat for having a soft copy of the same through email)

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CBIC notifies Administrative Instructions for recovery of Interest on Net Cash Tax Liability w.e.f. 01.07.2017 - reg.

CBIC Communication dated 18th September, 2020

To,
The Principal Chief Commissioners / Chief Commissioners / Principal Commissioners / Commissioners of Central Tax (All),
The Principal Director Generals / Director Generals (All).

1. Based on the recommendations of the 35th meeting of the GST Council held on 21st June, 2019, the provision of section 50 was amended vide section 100 of the Finance (No. 2) Act, 2019 to provide for charging interest on the net cash tax liability. The said amendment was to be made effective from a date to be notified by the Government. Accordingly, the said provision was made effective vide Notification No. 63/2020-Central Tax dated the 25th August, 2020, w.e.f. 01.09.2020.

2. The GST Council, in its 39th meeting, held on 14th March, 2020 recommended interest to be charged on the net cash tax liability w.e.f. 01.07.2017 and accordingly, recommended the amendment of section 50 of the CGST Act retrospectively w.e.f. 01.07.2017. The retrospective amendment in the GST laws would be carried out in due course through suitable legislation.

3. Post issuance of notification 63/2020 - Central Tax dated the 25th August, 2020, there were apprehensions raised by taxpayers that the said notification is issued contrary to the Council's recommendation to charge interest on net cash liability w.e.f. 01.07.2017. Consequently, a press release, dated 26.08.2020 was issued to clarify the position. Further, in order to implement the decision of the Council in its true spirit, and at the same time working within the present legal framework, it has been decided to address the issue through administrative arrangements, as under:

a. For the period 01.07.2017 to 31.08.2020, field formations in your jurisdiction may be instructed to recover interest only on the net cash tax liability (i.e. that portion of the tax that has been paid by debiting the electronic cash ledger or is payable through cash ledger); and

b. Wherever SCNs have been issued on gross tax payable, the same may be kept in Call Book till the retrospective amendment in section 50 of the CGST Act is carried out.

4. Difficulty, if any, in the implementation of these instructions may please be brought to the notice of the Board.

F. No. CBEC-20/01/08/2019-GST

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

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CBIC notifies New Exchange Rates w.e.f. 18th September 2020 - reg.

Notification No.88/2020-Customs (N.T.), dated 17th September, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.84/2020-Customs(N.T.), dated 3rd September, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, **shall, with effect from 18th September, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	54.75	52.45
2.	Bahraini Dinar	201.90	189.50
3.	Canadian Dollar	56.70	54.75
4.	Chinese Yuan	11.05	10.70
5.	Danish Kroner	11.85	11.45
6.	EURO	88.20	85.10
7.	Hong Kong Dollar	9.70	9.35
8.	Kuwaiti Dinar	249.15	233.80
9.	New Zealand Dollar	50.60	48.35
10.	Norwegian Kroner	8.25	7.95
11.	Pound Sterling	96.90	93.55
12.	Qatari Riyal	20.90	19.60
13.	Saudi Arabian Riyal	20.30	19.05
14.	Singapore Dollar	55.05	53.20
15.	South African Rand	4.65	4.35
16.	Swedish Kroner	8.45	8.20
17.	Swiss Franc	82.40	79.15
18.	Turkish Lira	10.15	9.55
19.	UAE Dirham	20.75	19.45
20.	US Dollar	74.60	72.90

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	71.50	68.85
2.	Korean Won	6.45	6.05

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

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

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DGFT extends implementation date of Track and Trace for Pharma Export Packs to 1st April 2021 – reg.

DGFT Public Notice No.16/2015-2020, dated 22nd September, 2020

1. In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.90A of Handbook of Procedure- 2015-20, as notified vide Public Notice No. 43/2015-20 dated 05.12.2017 read with Public Notice No. 52 / 2015-20 dated 05.01.2016, Public Notice No. 05/2015-20 dated 09.05.2018, Public Notice No. 43/2015 2020 dated 01.11.2018, Public Notice No. 16/2015-2020 dated 04.07.2019 and Public Notice No. 66/2015-2020 dated 30.03.2020 on laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations.

2. In Para 2.90 A (vi) and (vii) of Handbook of Procedure - 2015-20 (as amended vide Public Notice No. 66/2015-2020 dated 30.03.2020), "01.10.2020" may be substituted by **"01.04.2021".**

3. Effect of this Public Notice:

The date for implementation of Track and Trace system for export of drug formulations with respect to maintaining the Parent-Child relationship in packaging levels and its uploading on Central Portal has been extended upto 01.04.2021 for both SSI and non SSI manufactured drugs.

F.No. 01/91/180/648/AM 09/EC/E-21052

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

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Publication of Revised ANF-7A – reg.

DGFT Public Notice No.18/2015-2020, dated 23rd September, 2020

In exercise of powers conferred under Paragraph 1.03 of the Foreign Trade Policy 2015-2020, as amended from time to time, the Director General of Foreign Trade hereby notify the revised ANF-7A of Appendices & ANFs of Handbook of Procedure 2015-20 with immediate effect:

Effect of this Public Notice: NF-7A of Appendices & ANFs has been revised. **F. No. 01/92/180/19/AM-21/PC-VI**

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

ANF-7A

APPLICATION FOR CLAIM OF TED REFUND / DUTY DRAWBACK / BRAND RATE FIXATION

(Please tick whichever is applicable)

(Application shall be filed online once the software is ready)

1.	IEC No.	Branch Code:
2.	Applicant details: i. Name of the firm/company ii. Full address iii. Contact Number iv. E-mail address	

3.	Bank's details: i. Name of the Bank ii. Address of the Bank iii. IFSC code iv. Nature of account(SA/CA) v. A/c Number vi. Telephone / Fax No.	
4.	(a) Excise Authority details: i. Excise Registration No. ii. Address of the jurisdictional Central Excise Authority iii. Contact details of Excise Authority iv. Amount of excise duty paid during last year v. Product registered for manufacturing activities	
	(b) Jurisdictional Customs Authority details: i. Address of the jurisdictional Customs Authority ii. Contact details of Jurisdictional Customs Authority iii. Amount duty paid during last year iv. Product registered for manufacturing activities	
5.	Application for: i. Refund of Terminal Excise duty ii. Refund of Duty Drawback as per AIR iii. Fixation of brand rate for duty draw back	
6.	Application is made by: (i) Supplier of goods (ii) Recipient of goods	
7.	Supply details: i. Description of goods ii. Category of supplies under Para 7.02 of FTP	

8. If application is for refund on TED

Sl. No.	Inv. No.	Date of		Description of item(s) of supply	Quantity	Quantum of TED	Late cut, if any	Net claim
		Supply	Payment					

(Provision to be made to add multiple invoices)

9. If the application is for drawback as per AIR under drawback schedule:

Sl. No.	Invoice No.	Date of		Description of item(s)of supply	Tariff No.	FOR value	Net quantity of supplies	Draw back Rate
		Supply	Payment					

Value Cap (if any)	Amount of DBK	Late cut, if any	Net payable amount

(Provision to add multiple supply Invoices)

10.	If supply towards discharge of export obligation to Advance Authorisation Holder against Invalidation letter and drawback is claimed on inputs either imported or procured locally on payment of basic custom duty: Whether, in the application for Advance Authorisation for intermediate supply, it was declared that such inputs to be procured locally /imported on payment of basic custom duty?	Yes/No
11.	If answer to Col. No 10 is yes, Advance Authorization no. & date and File. no. under which it was issued.	
12.	Whether claim is made within the prescribed time	
13.	If not, rate of late cut as per Para 9.02 of HBP	
14.	If claim for refund of TED is made by supplier: Whether CENVAT credit has been availed by recipient?	
15.	If claim for refund of TED is made by recipient: Whether CENVAT credit has been availed by him?	
16.	If claim for duty drawback is made by supplier: Whether CENVAT credit has been availed by him on excisable inputs	
17.	If claim for duty drawback is made by recipient of goods: Whether CENVAT credit has been availed by supplier of goods on excisable inputs?	
18.	In case of claim made against supply under Para-7.02(a) & (c) whether authorization number and date figure in the supply invoices/ARE.	

19.	If the application is for fixation of brand rate: Drawback rate under AIR not available AIR is less than 4/5 of actual duty paid. (i) Claim is made for basic customs duty.	
20.	If answer to Col. 19 is yes, Whether: 1. Inputs/components were imported directly : 2. Imported inputs/component used from stock/ out sourced locally:	

21. DBK-I Statement

Sl. No.	Name of the materials/ Components	Quality/ Technical Characteristics	Whether imported/ indigenous	Unit	Gross Quantity required	Wastage Quantity	
						Irrecoverable	Recoverable
1	2	3	4	5	6	7	8

Sale Price of waste per unit of Qty	By Product/ co-product		Net wt. of the material	Remarks
	Qty.	Sale value per unit		
9	10	11	12	13

22. Statement of inputs/components used, either imported or imported materials procured locally **

S. No.	Description	Technical characteristics	S.No. in DBK-I statement	B/E /Invoice No & date under which imported/ procured	Name of the Customs House/Excise Authority	Unit	Qty. imported/ procured locally	Assessable value
1	2	3	4	5	6	7	8	9

Heading No. in Customs Tariff Act, 1975	Country from which imported / name of supplier	Name and full address of the supplier in case the foreign material/ Components obtained locally	Rate of Duty	Is assessment final	Total amount of duty paid (basic custom duty)	Remarks
10	11	12	13	14	15	16

** Only inputs which were imported/ procured and consumed during the period commencing 90 days prior to the date of supply(s) shall only be taken into account for such claim.

A separate work sheet as per DBK form II, and II(A) and certificates attached thereto duly certified by Chief Executive/production in-charge shall be submitted, as given in the **APPENDIX-7E**

23. Check List of documents to be attached duly scanned or submitted in the physical form at counter:

(1) (a) Copy of Invoices or a statement of invoices duly signed by the units receiving the excisable goods and attested by Central Excise Authorities, as per the procedure prescribed by CBEC in their circular 15/2008-Cus. dated 26.9.2008. To facilitate attestation by Central Excise Authorities, intimation regarding receipt of goods should be given to the said authorities within 48 hours of receipt of goods. Corresponding ER-1/ER-3 or a monthly statement confirming duty payment attested by excise Authorities or Invoices/statement of Invoices certified by Jurisdictional Central Excise Authority of recipient.

(b) In case of supply of non-excisable goods, copy of Tax invoices as prescribed under GST Rules or a statement of invoices duly signed by the units receiving the goods and attested by Jurisdictional Customs Authorities, as per the procedure prescribed by CBEC in their circular 15/2008-Cus. dated 26.9.2008. To facilitate attestation by Jurisdictional Customs Authorities, intimation regarding receipt of goods should be given to the said authorities within 48 hours of receipt of goods.

(2) In case supply of goods to EOU/EHTPI STPI BTP, procedure prescribed in Circular No-14/14/2017-GST dated 6th November, 2017 issued by GST Policy Wing, Central Board of Excise and Customs, Department of Revenue shall be followed, Accordingly, copy of Form A along with copy of Tax Invoice duly endorsed by recipient shall be considered as proof of deemed export supplies,

(3) Self certified copy of B/Es

(4) Proof of payment through e-BRC/Bank Certificate of Exports and Realisation as per **APPENDIX-2U** or Payment Certificate issued by Project Authority in **APPENDIX-7D** in original, as the case may be.

(5) PAC issued by the Project Authority in original as per **APPENDIX-7C** or File No. where the original has been submitted.

(6) Copy of contract if supplies were to Project Authority or supplier's copy of original ARO or recipient's copy of original Invalidation Letter (if supply against ARO/Invalidation Letter issued against AA/ DFIA/EPCG, as the case may be).

(7) Non-availment of CENVAT credit certificate as per **ANNEXURE-I**, by the recipient of finished goods (in case claim for TED).

(8) A certificate regarding non-availment of CENVAT credit on inputs used in the resultant product by the supplier of goods as per ANNEXURE-II (in case claim for drawback).

(9) Declaration/disclaimer certificate from supplier, in case claim is filed by recipient of goods and from recipient of goods, if claim is filed by supplier of goods, as per ANNEXURE-III

(10) Statement of supplies for Fixation of Drawback Rate as per **APPENDIX-7E**.

DECLARATION / UNDERTAKING

1. I/We hereby declare that the particulars and the statements made in this application are true and correct to the best of my/our knowledge and belief and nothing has been concealed or held there from. If found incorrect or false, it will render me / us liable for any penal action or other consequences as may be prescribed in law or otherwise warranted.
2. I/We undertake to abide by the provisions of F.T. (D&R) Act, the Rules and Orders framed there under, the FTP, HBP, SION and the ITC(HS) Classification of Export & Import Items.
3. I/we further declare that the claim made by me/us is not a matter of right and I/we shall immediately refund the amount of TED/drawback obtained by us in excess of any amount/rate which may be re-determined by concerned RA/DGFT/Government as a result of post verification/ Audit objection or otherwise.
4. None of the Proprietor/Partners(s)/Director(s)/Karta/Trustee of the firm/company has come under the adverse notice of DGFT or is in the caution list of RBI.
5. None of the Proprietor/Partners(s)/Director(s)/Karta/Trustee of the firm/company, as the case may be, is/are a Proprietor/Partner(s)/Director(s)/Karta/Trustee in any other firm/Company which has come under the adverse notice of DGFT or is in the caution list of RBI, to the bestof my knowledge.
6. I / We hereby declare that no export proceeds are outstanding beyond the prescribed period as laid down by RBI or such extended period for which AD/RBI permission has been obtained.
7. I/we further declare that the goods supplied are excisable goods but no CENVAT credit is availed/ available to the recipient of goods. (In case of items covered under schedule 4 of the central excise Act 1944).
8. I/we further declare that no CENVAT credit facility has been availed on inputs for which drawback claim is made.
9. I hereby certify that I am authorised to verify and sign this declaration as per Paragraph 9.06 of the FTP.

Signature of the Applicant

Name

Designation

Official Address

Telephone/Mobile No.

Residential Address

Email Address

Place

Date

ANNEXURE-I

DECLARATION FOR CLAIMING BENEFIT OF TERMINAL EXCISE DUTY (TED)

It is certified that no CENVAT credit under the Central Excise Rules has been availed by us, nor will be availed in future, on supply of these items as per the application.

Signature (Authorized Signatory):
Full Name:
Designation:
Name of the company:
Telephone Number:
E-mail Address:
Fax No.:

Note: To be given on the letter head of the recipient of goods.

ANNEXURE-II

DECLARATION FOR CLAIMING DEEMED EXPORT DRAWBACK

1. I, (Name & Designation) …..on behalf of M/s. ….. (Name and address of the supplier) hereby certify that we have supplied the following goods to M/s….. (Name and address of the recipient):

S.No.	Inv. No. & date	Description of goods	Unit	Qty.	Value

2. We are the manufacturer exporters/suppliers and are registered/not registered with Central Excise Authority and have not availed and will not avail CENVAT credit facility in respect of duty paid on inputs/components and/or tax paid on input services, in aforesaid supplies. We have also not availed and will not avail rebate on the duty paid on inputs/components used in aforesaid supplies and/or tax paid on input services.

3. We also certify that we have not been issued any Advance Authorization/Duty Free Import Authorization in respect of the aforesaid supply of goods and have not availed any benefit thereon.

4. The complete address of the Jurisdictional Assistant/Deputy Commissioner of the Central Excise Division is given as follows:

Yours faithfully,
Signature (Authorized Signatory)
Full Name
Designation
Name of the Company
Telephone Number
Address
Fax No.
E-mail address

Note : Declaration is to be given on letter head of the supplier. The Declaration furnished by the supplier to Office of the Development Commissioner or RA of DGFT should be in duplicate with complete address of the Jurisdictional Assistant/Deputy Commissioner of the Central Excise Division. The Development Commissioner/RA of DGFT would forward the second copy of this Declaration, duly stamped, to the addressed Assistant /Deputy Commissioner of the Central Excise Division for cross verification.

ANNEXURE-III

DISCLAIMER CERTIFICATE FOR NOT CLAIMING DEEMED EXPORT BENEFITS

We hereby declare that we have neither drawn nor will draw any benefit of deemed export on supply of goods as declared/to be declared in the application for claim of deemed export benefits and we have no objection if M/s…… (Name and address of the recipient/supplier, as the case may be) draws the deemed export benefits on such supply of goods as mentioned in the application.

(Either party will have to give disclaimer in favour of other for not claiming benefits of deemed export against supply of goods as declared in the Application for claim. The disclaimer is to be submitted on the letter head of the firm/company)

Yours faithfully,

Signature (Authorized Signatory)

Full Name

Designation

Name of the company

Telephone Number

E-mail

Address

Fax No.

ANNEXURE-IV

FORMAT OF CERTIFICATE TO BE ISSUED BY PUBLIC SECTOR OIL COMPANIES CERTIFYING AMOUNT OF TED PAID BY EOU / PROJECT ON PURCHASE OF HSD FROM THEIR DEPOTS:

I _____ (name of authorized signatory of PSU Oil Company) hereby declare that we (name of the Company) have supplies HSD to M/s. _____(Name of EOU/Project) from our depot at-------- _____as per details given below.

Description	Invoice No.	Invoice Date	Quantity	Value	Total Duty paid (with breakup of components)

Disclaimer Certificate:

We hereby certify that we are not claiming any deemed export benefits on the above supplies and we do not have any objection if (Name of EOU/Project) claims deemed export benefits.

Authorized Signatory (With full name and Designation)

● ● ●

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Impact of Covid-19 Pandemic and Lockdown of Economy

Lok Sabha Unstarred Question No.20

Shri Balubhau Alias Suresh Narayan Dhanorkar:

Shrimati Mala Roy:

Shri Benny Behanan:

Shri Asaduddin Owaisi:

Shri N K Premachandran:

Shri Kunwar Pushpendra Singh Chandel:

Shrimati Sangeeta Kumari Singh Deo:

Adv Adoor Prakash:

Dr Jayanta Kumar Roy:

Shri Syed Imtiaz Jaleel:

Shri K Navaskani:

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

(a): the details of financial crisis in the country due to lockdown and restrictions imposed due to Covid-19 indicating the fall in economy in last quarter along with the sectors affected due to lockdown and unlock process and the action taken in this regard;

(b): the details and status of stimulus package including *Atma Nirbhar Bharat* and *Pradhan Mantri Garib Kalyan Yojana* as announced and implemented by the Government for various sectors/individuals to overcome the economic slowdown, Sector-wise along with their utilization and the manner in which the Government is planning to raise funds for stimulus package;

(c): the details of assistance given to those who have lost their livelihood due to lockdown and the steps recently taken by the Government for the welfare of the workers of unorganized sector;

(d): whether the Government has analyzed the progress of programmes and schemes implemented as stimulus package and if so, the details thereof along with the future strategy likely to be adopted for reviving the economy of the country;

(e): whether the Government proposes to extend the period of moratorium and also to write off the interest of loans during the moratorium period considering the Covid-19 and there is any demand for restructuring of loans and if so, the details thereof along with the steps taken in this regard; and

(f): whether it has come to the notice of the Government that it is impossible to pay the interest even after the lifting the moratorium and if so, the action taken for protection from the penal actions of the banks and financial institutions?

Answered on 14th September 2020

A. (a): As per the Estimates of Gross Domestic Product for the First Quarter (Q1) of 2020-21 released by the National Statistical Office on 31st August 2020, the real GDP in India contracted by 23.9 percent during the first quarter of 2020-21 (as against a 5.2 percent growth in Q1 of 2019-20). On the demand side, private consumption spending fell by 26.7 percent and Investment demand also declined by 47.1 percent. On the supply side, the decline in Gross Value Added (GVA) was broad-based with fall of 50.3 percent seen in construction followed by services like trade, hotels, transport and communication, 2 manufacturing and mining. Agriculture emerged as the bright spot, growing at a healthy rate of 3.4 percent.

(b) to (d): The Government has announced a special economic and comprehensive package of Rs.20 lakh crores, equivalent to 10% of India's GDP to combat the impact of the COVID-19 pandemic in India. The details of the major components of the package along with the status are attached at Annexure. Under the *"Aatma Nirbhar Bharat Abhiyan",* an additional Rs.40,000 crore has been allocated for MGNREGS to help generate nearly 300 crore person days to address the need of work of returning migrant workers. Under Prime Minister Garib Kalyan Package (PMGKP), financial assistance has been extended to building & construction workers (BoCW). 31 State and UT Governments have announced cash benefits,

ranging from Rs.1000/- to Rs.6000/- to around 1.82 crore workers and total amount disbursed is Rs.4987.18 crore as on 7th September, 2020. Government of India launched a massive rural public works scheme *'Garib Kalyan Rojgar Abhiyaan'* on June 20, 2020 to empower and provide livelihood opportunities to the returnee migrant workers and rural citizens. 25 schemes of the Government have been brought together under this programme and villages across 116 districts in the six states viz Bihar, Uttar Pradesh, Madhya Pradesh, Rajasthan, Jharkhand, and Odisha through the Common Service Centres and Krishi Vigyan Kendras. A total of 26.34 crore person days have been generated and expenditure of an amount of Rs.22,761.15 crore has been incurred under the programme as on 8th September 2020. The implementation of the package is reviewed and monitored regularly.

(e) & (f): The Reserve Bank of India has announced certain regulatory measures wherein, in respect of all term loans (including agricultural term loans, retail and crop loans) outstanding as on March 1, 2020, all lending institutions regulated by the Reserve Bank were permitted to grant a moratorium of six months on payment of all instalments falling due between March 1, 2020 and August 31, 2020. Subsequently, the Reserve Bank of India has provided a framework to enable the lenders to implement a resolution plan in respect of eligible corporate exposures without change in ownership and personal loans. Under the Plan, lending institutions may, inter alia, grant moratorium upto two years. The Government has constituted an Expert Committee for making an overall assessment of the impact of waiving of interest and waiving of interest on interest on the COVID-19 related moratorium on the national economy and financial stability.

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

Annexure

Pradhan Mantri Garib Kalyan Package (As per Press Release dated 7th September, 2020):

Around 42 crore poor people have received financial assistance of Rs.68,820 crore so far, the details of which are as under:

- Rs.17,891 crore front loaded towards payment of the first instalment of PM-KISAN to 8.94 crore beneficiaries.
- Rs.10,325 crore credited to 20.65 crore (100%) women Jan Dhan account holders as first installment.
- Rs. 10,315 crore credited to 20.63 crore (100%) women Jan Dhan account holders with second installment.
- Rs.10,312 crore credited to 20.62 crore (100%) women Jan Dhan account holders with third instalment.
- Total Rs.2,814.5 crore disbursed to about 2.81 crore old age persons, widows and disabled persons, in two installments. Benefits transferred to all 2.81 crore beneficiaries in two installments.
- 1.82 crore Building & construction workers received financial support amounting to Rs.4,987.18 crore.
- Under *Pradhan Mantri Garib Kalyan Ann Yojana,* 37.52 LMT of food grains has been distributed, to 75.04 crore beneficiaries in April 2020, 37.46 LMT distributed to 74.92 crore beneficiaries in May 2020, and 36.62 LMT distributed to 73.24 crore beneficiaries in June 2020. Scheme was further extended for 5 months till November. Since then, 98.31 LMT food grains has been lifted by States/UTs so far. In July 2020, 36.09 LMT food grains has been distributed to 72.18 crore beneficiaries, in August 2020, 30.22 LMT distributed to 60.44 crore beneficiaries, and in September 2020, 1.92 LMT distributed to 3.84 crore beneficiaries as on 7th September, 2020. A total of 5.43 LMT pulses has also been distributed to 18.8 crore beneficiaries between April – June 2020. 4.6 LMT Chana has been dispatched so far. In July 1.03 LMT Chana has been distributed to 10.3 crore beneficiary households, in August 23, 258 MT distributed to 2.3 crore beneficiary households. As on 7th September, 2020, 1475 MT of Chana distributed to 0.15 crore beneficiary households in September, 86 MT distributed to 0.008 crore beneficiary households for October, and 40 MT distributed so far to 0.004 crore beneficiary households for November.
- During the distribution period up to August, total 2.67 LMT of food grains was distributed to 5.32 crore, migrants. This works out to an average of about 2.66 crore beneficiaries per month, which is nearly 95% of the estimated number of migrants. Total quantity of Chana distributed is 16,417 MT to 1.64 crore migrant households, which is 82 Lakh households on an average per month.
- Total 8.52 crore *Pradhan Mantri Ujjwala Yojana* (PMUY) cylinders have been booked and already,

delivered for April and May 2020 under this Scheme so far. 3.27 crore PMUY free cylinders delivered to beneficiaries for June 2020, 1.05 crore for July 2020, 0.89 crore for August 2020, and 0.15 crore for September 2020.

- 36.05 Lakh members of EPFO has taken benefit of online withdrawal of non-refundable advance from, EPFO account amounting to Rs.9,543 crore. 24% EPF contribution transferred to 0.43 crore employees amounting to Rs.2476 crore. Benefits for March were given to 34.19 lakh employees amounting to Rs.514.6 crore, for April given to 32.87 lakh employees amounting to Rs.500.8 crore, for May given to 32.68 lakh employees amounting to Rs.482.6 crore, for June given to 32.21 lakh employees amounting to Rs.491.5 crore, for July given to 30.01 lakh employees amounting to Rs.461.9 crore, and for August given to 1.77 lakh employees amounting to Rs.24.74 crore.
- MNREGA: Increased rate has been notified w.e.f 01.04.2020. In the current financial year, 195.21 crore person's man-days of work generated. Further, Rs.59,618 crore released to states to liquidate pending dues of both wage and material.
- Under District Mineral Fund (DMF), States have been asked to spend 30% of the funds, which amounts to Rs.3,787 crore and that Rs.343.66 crore has been spent so far.

Progress of *Aatma Nirbhar Bharat Package* – Progress so far pertaining to Ministry of Finance and Ministry of Corporate Affairs:

- *Rs.3 lakh crore Collateral-free Automatic Loans for Businesses, including MSMEs and Rs.45,000 crore Partial Credit Guarantee Scheme 2.0 for NBFCs*;
- As per press release dated 3rd September 2020, an amount of Rs.1.58 lakh crore has been sanctioned as on 31.8.2020 under the 100% Emergency Credit Line Guarantee Scheme (ECLGS), out of which more than Rs.1.11 lakh crore has been disbursed in 24 lakh accounts. Under Partial Credit Guarantee Scheme 2.0, Bonds/CPs of Rs. 25,055.5 crore have been approved for purchase by Public Sector Banks so far, out of which Rs.13,318.5 crore amounting to more than 53% of the portfolio pertains to Bonds/CPs rated below AA-, a crucial intervention for lower rated Bonds/CPs.
- **Rs 30,000 crore Special Liquidity Scheme for NBFCs/HFCs/MFIs:**

  As per press release dated 24th July 2020, five proposals involving an amount of Rs.3090 crore have been sanctioned as on 23rd July. Further, 35 more applications have been received seeking financing upto Rs.13776 crore, which are under process.
- For local MSMEs, Department of Expenditure amended present Rule 161 (iv) of General Financial Rules (GFR), 2017 and GFR Rules relating to Global Tenders. Now, no Global Tender Enquiry (GTE) shall be invited for tenders upto Rs.200 crore, unless prior approval is obtained from Cabinet Secretariat.

Relief to Contractors:

All central agencies like Railways, Ministry of Road Transport and Highways and CPWD will give extension of up to 6 months for completion of contractual obligations, including in respect of EPC and concession agreements. On the invocation of Force Majeure Clause (FMC), contract period may be extended for a period not less than three months and not more than six months without imposition of any cost or penalty on the contractor/concessionaire. Instructions were also issued to return the value of performance security to the contractor/suppliers proportional to the supplies made/ contract work completed to the total contract value. The same is being implemented by various Departments/ Ministries.

Rs.30,000 crore Additional Emergency Working Capital Funding for farmers through NABARD:

New front loaded special refinance facility of Rs.30,000 crore was sanctioned by NABARD during COVID-19 to RRBs & Cooperative Banks to benefit 3 crore farmers, consisting mostly small and marginal farmers in meeting their credit needs for post-harvest and kharif sowing requirements. Rs.24,876.87 crore out of Rs.30,000 crore has been disbursed as on 06.07.2020, out of this special facility. Support to State Governments Borrowing limits of States has been increased from 3% to 5%, for 2020-21 in view of the unprecedented situation, which will give States extra resources of Rs.4.28 lakh crore. Additional borrowing of 2 percent of projected GSDP will be given to the States in 2020-21 subject to implementation of specific State Level Reforms.

Rs.50,000 crore liquidity through TDS/TCS rate reduction:

TDS rates for specified payments to residents and specified TCS rates were reduced by 25% for transactions made from 14th May, 2020 to 31st March, 2021.

Other Direct Tax Measures:

- The Central Board of Direct Taxes (CBDT) has issued refunds worth Rs.71,229 crore in more than 21.24 lakh cases upto 11th July, 2020, to help taxpayers with liquidity in Covid-19 pandemic days, since the Government's decision of 8th April, 2020 to issue pending income tax refunds at the earliest, as stated in press release dated July 17, 2020. Income tax refunds amounting to Rs.24,603 crore have been issued in 19.79 lakh cases to taxpayers and corporate tax refunds amounting to Rs.46,626 crore in 1.45 lakh cases have been issued to taxpayers during Covid days.
- The Department also issued Notification dated 24.06.2020, the due date for income-tax return for FY 2019-20 (Assessment Year 2020-21) has been extended from 31st July, 2020 (for individuals etc) and 31st October, 2020 (for companies etc) to 30th November, 2020. Further, the due date for furnishing of tax audit report has also been extended from existing 30th September, 2020 to 31st October, 2020.
- The Department of Revenue has extended the time barring date for assessments getting barred by limitation on 30th September, 2020 to 31st March, 2021. Payment without additional amount under the "*Vivad se Vishwas*" Scheme will be extended to 31st December, 2020 and the legislative amendments for the same in the Vivad Se Vishwas Act, 2020 (VsV Act) shall be moved in due course to time. Further, through the Notifications, compliance dates mentioned under the VsV Act falling during period 20th March, 2020 to 30th December, 2020 have been extended to 31st December, 2020.

Enhancement of Ease of Doing business through IBC related measures:

- Ministry of Corporate Affairs has raised the threshold of default under Section 4 of the IBC, 2016 to Rs.1 crore (from the existing threshold of Rs.1 lakh) i.e. "in exercise of powers conferred under Section 4 of Insolvency & Bankruptcy Code, 2016 (31 of 2016), the Central Government hereby specified Rs.1 crore as the minimum amount of default for the purposes of the said section" vide Notification dated 24.06.2020.
- Ministry of Corporate Affairs is finalising a special insolvency resolution under section 240A of the Code, to provide relief to the MSMEs and the same would be notified soon.
- Insolvency and Bankruptcy Code (Amendment) Ordinance, 2020 has been promulgated on 5th June, 2020 thereby provided for insertion of Section 10A in the Insolvency and Bankruptcy Code 2016 to temporarily suspend initiation of Corporate Insolvency Resolution Process (CIRP) under Section 7, 9 & 10 of the Code for a period of six months or such further period, not exceeding one year from such date.

Ban on Freebies to Doctors by Pharmaceutical Companies

Lok Sabha Unstarred Question No: 2134

P Velusamy:

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

(a): whether the Government has banned doling out freebies, cruise tickets, paid vacations and sponsorships for educational conferences and seminars to doctors by Pharmaceutical companies from January 1, 2014, if so, the details thereof;

(b): whether the Government is aware that Mumbai branch of the Income Tax Appellate Tribunal has disallowed an allowance of Rs.76.55 lakhs paid by a leading Pharma company, if so, the details thereof;

(c): the steps taken by the Government to prevent such kind of unethical practices followed by the Pharma companies hitherto; and

(d): whether the Government is having any proposal to bring out specific comprehensive law in this regard, if so, the details thereof?

Answered on 14th September 2020

A. (a) The Department of Pharmaceuticals has informed that the Government had prepared and announced in year 2014 a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for stopping unethical practices employed by Pharma Companies for promoting sales of their medical products, on

12th December, 2014. It was sent to all the Pharma associations for voluntary implementation with effect from 01.01.2015.

Further, as per clause 6.8.1 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, a Registered Medical Practitioner is not allowed to receive gifts, travel facilities, hospitality and cash/monetary grants.

(b): No.

(c): The Department of Pharmaceuticals has informed that the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) is voluntary in nature and under UCPMP, there is no provision for Department of Pharmaceuticals to directly deal with complaints received regarding unethical practices. As per UCPMP, any complaint received against a Pharmaceutical company is dealt by an Ethical Committee for Pharma Marketing Practices (ECPMP) constituted in the Pharmaceutical associations.

(d) No.

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

In Rajya Sabha

Uniform Code for Pharmaceutical Marketing Practices (UCPMP)

Rajya Sabha Unstarred Question No. 702

Shri Jyotiraditya M Scindia:

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

(a): whether Government had decided to make a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) mandatory;

(b): if so, the present status of the UCPMP;

(c): whether the implementation of voluntary code has not shown any results and unethical practices have increased and;

(d): if so, the corrective steps that Government proposes to take in this regard?

Answered on 18th September 2020

A. (a): No Sir.

(b): In view of reply to (a) above, the question does not arise.

(c) & (d): The Uniform Code for Pharmaceutical Marketing Practices (UCPMP) is voluntary in nature and under UCPMP, there is no provision for Department of Pharmaceuticals to directly deal with complaints received regarding unethical practices. As per UCPMP, any complaint received against a Pharmaceutical company is to be handled by an Ethical Committee for Pharma Marketing Practices (ECPMP) that is to be constituted in each of the Pharmaceutical associations. Department has been following up with the Pharma associations to implement the code effectively. In this regard, this department has also taken multiple meetings with the Pharmaceuticals associations and most of the associations have put UCPMP on their websites and constituted the Committees for handling complaints regarding breach of UCPMP.

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

Draft Environmental Impact Assessment (EIA) Notification, 2020

Rajya Sabha Unstarred Question No.76

Smt Shanta Chhetri:

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

(a): Whether the Draft Environmental Impact Assessment (EIA) Notification, 2020 legitimises ex-post facto environmental clearances and encourages industries with no prior clearance to commence operations and eventually get regularized by paying a penalty amount (Clause 22);

(b): Whether draft EIA Notification allows only project proponents and Government authorities to officially report cognisance of violations (Clause 22 (1)) and non compliance of conditions (Clause 23 (1)), curbing the rights of any other concerned or affected person; and

(c): If so, the details thereof; if not, the reasons therefor?

Answered on 14th September 2020

A. (a) to (c): No Sir. The draft EIA Notification 2020 does not provide for ex-post facto clearance to cases that have commenced operations without prior environmental clearance. Clause 22 (14) of the draft EIA Notification 2020 clearly specifies that the project

proponent is liable for action under Section 19 of the Environment Protection Act 1986 for the violations committed by it. In addition, the draft Notification also lays down additional liability on the project proponent for causing damage to the environment through assessment of environment damage caused, remedial plans and community augmentation plan (reference clause 22(5) of the draft Notification). The Environment Clearance shall be granted only prospectively as also held by the Hon'ble Supreme Court in the case of Common Cause V/s Union of India. The draft EIA Notification 2020 is based on the following guiding principles:

(1): Various court decisions have directed the Government to consider violation cases on merit and it has held that closure is not an option.

(2): All entities, not complying with environmental regulations, be brought under regulatory ambit in an expedient manner;

(3): Establish a process for appraisal of violation cases so as to prescribe requisite environmental safeguards;

(4): Process should deter future violations.

(5): 'Principles of Proportionality' and 'Polluters Pays' principles as enunciated by Hon'ble Courts has been followed.

The draft EIA Notification 2020 does not curb the right of any concern or affected person to report cases of violation. Clauses 22 (1) and 23 (1) of the Draft EIA Notification, 2020 mention that the cognizance of violation or non-compliance shall be made on the basis of (a) *Suo-moto* application of project proponent, (b) Report by any Government authority, (c) Violation/Non-compliance found during the appraisal by appraisal committee or while during processing of applications by any Regulatory Authority. The public, NGOs and other affected persons can approach any of the Government authorities, who after preliminary verifications, can refer the matter to the Ministry or respective States for taking action in the matter.

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

Steps for revival of MSME sector due to COVID-19 Pandemic

Rajya Sabha Unstarred Question No.121

Shri Kanakamedala Ravindra Kumar:

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

(a): whether Government is aware of the fact that due to announcement of nation-wide lockdown in the country w.e.f. 25th March, 2020 the Micro, Small and Medium Enterprises (MSME) sector was severely affected across the country particularly in the State of Andhra Pradesh;

(b): if so, the details thereof;

(c): whether Government has initiated any steps to help/revive the MSME sectors which were severely affected due to nation-wide lockdown;

(d): if so, the details thereof; and

(e): if not, the reason therefor?

Answered on 14th September 2020

A. (a) & (b): Yes Sir. Various sectors including MSME Sector has been affected temporarily by nation-wide lockdown in the country including Andhra Pradesh.

(c) to (e): The Ministry of MSME implements various schemes and programmes for 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), Interest Subvention Scheme for Incremental Credit to MSMEs, 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). 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. Some of them are:

(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 18,723 grievances have been redressed upto 09.09.2020. RBI has also announced several measures to Reduce Financial Stress of MSMEs.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Support to MSMEs in light of COVID-19 Pandemic

Rajya Sabha Unstarred Question No.130

Shri Binoy Viswam:

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

(a): whether Government has conducted a research on the impact of COVID-19 on the Micro, Small and Medium Enterprises (MSMEs) sector the country, if so, the details thereof;

(b): the total number of jobs lost in the MSME sector due to the COVID-19 Pandemic;

(c): whether Government plans to extends the moratorium given by RBI to enterprises in MSME sector on repayment of loans; and

(d): the number of MSMEs which have availed loans under the emergency provisions announced by Government as part of the '*Atmanirbhar'package*?

Answered on 14th September 2020

A. (a) & (b): No formal research has been conducted on the impact of COVID-19 on the MSME sector and on the total number of jobs lost in the MSME sector. However, the Ministry held a number of consultations with various MSME/Industry Associations of the country. During the deliberations, certain problems were highlighted by stakeholders. This included need for easy finance, more liquidity, moratorium on loans, etc.

(c): As per RBI's Covid-19 Regulatory Package dated March 27, 2020, RBI had permitted moratorium of three months on payment of all installments/ interest falling due between March 1, 2020 and May 31, 2020. RBI, again, on May 22, 2020 had extended moratorium on repayment of loans/ interest for another 3 months till August 31, 2020 along with Asset Classification standstill during this period. (Total 6 months moratorium starting from March 1, 2020). In addition, RBI vide its Notification dated August 6, 2020 on restructuring of advances related to MSME sector, has extended the one-time restructuring window upto March 31, 2021 for the existing loans to MSMEs upto Rs.25 crore, classified as 'standard' as on 01.03.2020 without a downgrade in the asset classification.

Further, as per RBI's Notification dated August 6, 2020 on Resolution Framework for COVID-19-related stress, in respect of eligible corporate exposures exceeding Rs.25 crore, the Resolution framework permits lenders to allow moratorium up to two years, as per their Board approved policy, depending on the merits of the case.

(d): 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 crore disbursed to 25,01,216 borrowers under the Emergency Credit Line Guarantee Scheme (ECLGS) as on September 9, 2020.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

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T cells take the lead in controlling SARS-CoV-2 and reducing COVID-19 disease severity

Ever since SARS-CoV-2 first appeared, researchers have been trying to understand whether sometimes the immune system does more harm than good during the acute phase of COVID-19. The latest study by researchers at La Jolla Institute for Immunology clearly argues in favor of the immune system. Their work, published in the September 16, 2020, online issue of Cell, confirms that a multi-layered, virus-specific immune response is important for controlling the virus during the acute phase of the infection and reducing COVID-19 disease severity, with the bulk of the evidence pointing to a much bigger role for T cells than antibodies. A weak or uncoordinated immune response, on the other hand, predicts a poor disease outcome. The findings suggest that vaccine candidates should aim to elicit a broad immune response that include antibodies, helper and killer T cells to ensure protective immunity.

"Our observations could also explain why older COVID-19 patients are much more vulnerable to the disease," says senior author Shane Crotty, Ph.D., who co-led the study with Alessandro Sette, Dr Biol.Sci., both Professors in LJI's Center for Infectious Disease and Vaccine Research. "With increasing age, the reservoir of T cells that can be activated against a specific virus declines and the body's immune response becomes less coordinated, which looks to be one factor making older people drastically more susceptible to severe or fatal COVID-19."

Adds Sette, "What we didn't see was any evidence that T cells contribute to a cytokine storm, which is more likely mediated by the innate immune system." When SARS-CoV-2 (or any other virus) infiltrates the body, the innate immune system is first on the scene and launches a broad and unspecific attack against the intruder. It releases waves of signaling molecules that incite inflammation and alert the immune system's precision forces to the presence of a pathogen.

Within days, the so-called adaptive immune system tools up and moves with pinpoint precision against the virus, intercepting viral particles and killing infected cells. The adaptive immune system consists of three branches: antibodies; helper T cells (Th), which assist B cell to make protective antibodies; and killer T cells (CTL), which seek out virus-infected cells and eliminate them.

For their latest study, the researchers collected blood samples from 50 COVID-19 patients and analyzed all three branches of the adaptive immune system - SARS-CoV-2 specific antibodies, helper and killer T cells - in great detail. "It was particularly important to us to capture the whole range of disease manifestation from mild to critically ill so we could identify differentiating immunological factors," says co-first author and infectious disease specialist Sydney Ramirez, M.D., Ph.D., who spearheaded the sample collection.

What the team found was that similar to their previous study all fully recovered individuals had measurable antibody, helper and killer T cell responses, while the adaptive immune response in acute COVID-19 patients varied more widely with some lacking neutralizing antibodies, others helper or killer T cells or any combination thereof.

"When we looked at a combination of all of our data across all 111 measured parameters we found that in general, people who mounted a broader and well-coordinated adaptive response tended to do better. A strong SARS-CoV-2 specific T cell response, in particular, was predictive of milder disease," says co-first author and postdoctoral research Carolyn Moderbacher, Ph.D. "Individuals whose immune response was less coordinated tended to have poorer outcomes."

The effect was magnified when the researchers broke down the dataset by age. "People over the age of 65 were much more likely to have poor T cell responses, and a poorly coordinated immune response, and thus have much more severe or fatal COVID-19," says Crotty. "Thus, part of the massive susceptibility of the elderly to COVID-19 appears to be a weak adaptive immune response, which may be because of fewer naïve T cells in the elderly."

Naïve T cells are inexperienced T cells that have not met their viral match yet and are waiting to be called up. As we age, the immune system's supply of deployable naïve T cells dwindles and fewer cells are available to be activated to respond to a new virus. "This could either lead to a delayed adaptive immune response that is unable to control a virus until it is too late to limit disease severity or the magnitude of the response is insufficient," says Moderbacher.

In line with what other research teams had found before, antibodies don't seem to play an important role in controlling acute COVID-19. Instead, T cells and helper T cells in particular are associated with protective immune responses. "This was perplexing to many people," says Crotty, "but controlling a primary infection is not the same as vaccine-induced immunity, where the adaptive immune system is ready to pounce at time zero."

If a vaccination is successful, vaccine-induced antibodies are ready to intercept the virus when it shows up at the doorstep. In contrast, in a normal infection the virus gets a head start because the immune system has never seen anything like it. By the time the adaptive immune system is ready to go during a primary infection, the virus has already replicated inside cells and antibodies can't get to it. "Thus, these findings indicate it is plausible T cells are more important in natural SARS-CoV-2 infection, and antibodies more important in a COVID-19 vaccine," says Crotty, "although it is also plausible that T cell responses against this virus are important in both cases."

Source: La Jolla Institute for Immunology, Science Daily, 16.09.2020 (Excerpts)

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Kochi-based Company to start Phase 2b trials of COVID drug next week

PNB Vesper Life's Chief Executive P N Balaram is upbeat the company's experimental drug PNB-001 will be effective in treating symptoms of Covid-19. The Kochi-based Pharma Company is set to begin Clinical Trials on patients suffering from the disease next-week.

Balaram said the company received approval from the Drug Controller General of India (DCGI) on Friday, 18.09.2020 to conduct phase 2b Clinical Trial of their proprietary drug PNB-001 (GPP-Baladol). He said the molecule is capable of treating fever, body pain and lung infection - conditions normally associated with Covid-19.

According to Balaram, the company had proposed testing the drug on two sets of people - one group that would consume only PNB's proprietary drug and another that would consume it along with other drugs to treat these other conditions. However, the Government declined permission for it and, hence, the Clinical Trials will be done on patients who will also be consuming other drugs for their other conditions and symptoms.

"This is the first chemical entity in the phase 2 chemical trial in the world," he said. "If it works, it will be a miracle molecule. We think it will give a much better effect than dexamethasone or any other steroids. This is also a very safe molecule because just a 100mg capsule is required to get the effect on patients. We are planning to complete the whole phase-II Clinical Trial within 60 days as the Government is speeding up the approval process and recruiting patients may not be a big problem," he said. The study will be conducted on 40 Covid-19 patients at Pune's BMJ Medical College who are moderate patients on oxygen support.

Source: The Economic Times, 20.09.2020 (Excerpts)

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NATIONAL NEWS

Indian Pharma sector set to emerge stronger due to higher Exports

The Growth in exports will be around 11-12 percent, says a CRISIL Report

Higher exports are likely to help the Indian Pharma sector to garner upto eight to nine percent growth this fiscal. It is expected that the Rs. 2.8 lakh crore Indian Pharmaceutical Sector is set to emerge stronger due to higher exports despite the COVID-19 pandemic this fiscal. A report by CRISIL says that the Indian Pharma Sector is well-diversified with exports and domestic formulations accounting for almost equal share. The report points out that this fiscal, the growth in exports will be around 11-12 percent when compared to 10 percent during the last fiscal. The report observes that the operating profitability for around 350 Pharmaceutical companies rated by CRISIL representing 70 percent of the sector revenue, would soften by 100-150 bps but remain healthy at 19 percent despite higher input prices for drug manufacturing. Credit profiles of Pharma companies will continue to be supported by healthy balance sheets. Interestingly the export pie is divided into regulated markets such as the US and Europe (45 percent), Rest of World (ROW) markets (35 percent) and bulk drugs (20 percent). It is expected that exports growth will remain strong at 10 and above in each of the segments in the current fiscal.

The growth in the regulated markets will be supported by steady increase in new product launches from compliant plants that will lower pricing pressure on existing generics, and a visible easing in scrutiny by the United States Food and Drug Administration (US FDA) in recent months. "India accounted for almost half the Abbreviated New Drug Application Approvals provided by the US FDA since fiscal 2019. This strong pipeline, coupled with lower import alerts and warning letters in recent months, should ensure a steady pace of new launches, which will help sustain export momentum to regulated markets," remarked Isha Chaudhary, Director, CRISIL Research.

At the same time exports to ROW markets, too, are expected to rebound to 10 percent compared with 7 percent this fiscal that will be driven by opportunities in under penetrated generic markets such as Africa and Latin America. Also, bulk drug exports are expected to benefit from moves worldwide to reduce dependence on China. Experts at CRISIL on a query from THE WEEK on the increase in raw material prices by China and that impacting Indian Pharma players said that although there has been an increase in raw material prices from China, Pharma players are able to pass on the rise in prices.

Also diversification of supply chain from China and dual sourcing strategy (China plus India) has opened new opportunities for players, supporting revenue and margin growth. Some bulk drug players have also allocated their capacities and resources to more profitable products. Export demand for both formulation and bulk drugs is strong owing to COVID-19. The PLI (Performance-Linked Incentive) scheme, announced recently by the Government to boost domestic bulk drug manufacturing, aims at reducing import dependence. However, it will come to fruition only in the medium to long term.

"Higher exports should offset some of the reduction in domestic formulation sales because of pandemic led disruptions, especially in the acute therapies segment. At the same time, lower footfalls in hospitals and fewer field visits by medical representatives have affected prescription based sales in acute therapies, as evident from the steep moderation in the first quarter sales of anti-infectives and gastro-intestinal drugs. On the other hand, a steady demand for chronic therapies pertaining to lifestyle diseases should help keep domestic formulation sales growth at around 5 to 6 percent," said Tanvi Shah, Associate Director, CRISIL Ratings.

It is expected that despite the slight moderation in business performance, credit profiles of domestic companies would remain largely steady, benefiting from healthy balance sheets and liquidity. Equity infusions from private equity funds have also helped improve credit metrics in recent times. Experts at CRISIL expect an increase in Capital and Research and Development spending, as well as efficient working capital management will enable Indian Pharma companies to manage transition through the current challenging times. However there are challenges as a few large Indian pharmaceutical companies are facing antitrust suits in the US and any unanticipated litigation costs or adverse developments such as increased US FDA scrutiny impacting new product launches will be monitorables.

Source: Abhinav Singh, The Week, 24.09.2020

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Incentives not enough, Bulk Drug industry seeks level playing field to make India *'Atma Nirbhar'*

The PLI package announced in July for 53 bulk drugs offers financial incentives to domestic manufacturers Even as the Narendra Modi Government hopes to see a tremendous response for its Production Linked Incentive (PLI) scheme for Greenfield bulk drug manufacturing projects, the domestic Pharmaceutical industry fears that the incentives alone may not be enough to ward off Chinese imports that turned manufacturing of several key bulk drugs unviable in the first place.

"The scheme seems to be encouraging and there is a possibility that people will come forward with a positive state of mind. But, apprehensions remain. First of all, there is a very strong chance that China may dump these products at a much lesser price once India starts production. Unless countered with very quick anti-dumping measures, it may turn the production of such items unsustainable for Indian industry. There is a need for a written assurance from the Government that quick action by way of anti-dumping investigations and anti-dumping duty will be taken in such cases" says B R Sikri, Chairman of Federation of Pharma Entrepreneurs (FoPE).

He said concerns have been flagged and the Government is seriously considering the industry proposal to provide additional protection. The PLI package announced in July for 53 bulk drugs (raw materials for medicine production)

offers financial incentives to domestic manufacturers based on sales for 41 specific products (which cover all 53 bulk drugs that are heavily import-dependent) in a graded manner for six years.

The Government will select two to four companies for each product, depending on the bids manufacturers offer. The deadline to apply is November end. Sikri also said the industry is doubtful if the entire quantum of incentive announced by the Government will be available to the manufacturer due to conditionalities attached to the scheme. "Though the Government is saying there is a 10 percent incentive for chemical synthesis products and 20 percent incentive for fermentation-based products, the actual incentive for at least some products may be 4 percent or less," Sikri said.

"For instance, the current market rate of Meropenem, one of the products in the list, is Rs.68,000 per kg. The scheme stipulates that the industry sets up a unit of 10-tonne annual capacity to avail concessions under the scheme. Theoretically, if I produce and sell 10 tonnes of Meropenem, my turnover is going to be Rs.68 crore annually. Hence, according to the scheme, I am eligible for 10 percent of the turnover or Rs.6.8 crores as an incentive," Sikri said.

He added that it's where it hurts. "The fine print of the PLI scheme puts a limit for incentive, which is either Rs.2.5 crore or 10 percent of the turnover, whichever is less. There are many products where the issue is similar. It erodes the attractiveness of the scheme," he adds. The industry is also worried that the sale price (based on which the cost calculation happens) remain frozen upwards once you quote a price at the time of applying for the scheme. "Tomorrow, if the price goes down, the Government will give less incentive, but if it goes up, the incentive will continue to be decided based on the declared price," he said.

This is also a problem as the cost of inputs remains dynamic, he added. "How can I factor in the changes in chemical prices, other inputs, power tariffs, manpower cost, and economic circumstances of the future while quoting the price? In short, there are impractical and unrealistic demands too. The overall enthusiasm will receive a big boost if the Government looks at such operational issues," Sikri said.

According to FOPE Chairman, the existing manufacturers have the capacity and technology to produce some of these products on the list immediately. "All that the Government needs to do is put a condition that whatever such companies are manufacturing today, that should not be discontinued. A declaration that the company is producing so and so products...so and so capacity...and it will continue. Any additional capacity within the existing infrastructure, used for the production of the items in the PLI list, should be incentivised.

Among the chemical synthesis products, 60 to 70 percent products can be manufactured from tomorrow if that happens," he said. Sikri points out the members of apex industry associations like IDMA (Indian Drug Manufacturers' Association) and BDMA (Bulk Drug Manufacturers' Association) have informed that they are willing to start production.

However, it is not viable today because they can't match the costing of Chinese imports. "The PLI scheme, no doubt, is a timely decision and *Atma Nirbhar Bharat* scheme will give a chance to our industry to shine. The overall industry seems to be happy, it's just that if the Government can give incentives for existing manufacturers, India's self-reliance in bulk drugs will improve tomorrow itself," he adds.

Source: Business Today, 26.09.2020

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India's World Bank Executive Director named New Pharma Secretary

IAS Officer S Aparna, who was serving as the World Bank's Executive Director from India, has been appointed as next Secretary, Pharmaceuticals, under the Ministry of Chemicals and Fertilisers, and will take over after the retirement of incumbent Dr P D Vaghela, an official statement said on Friday, 18.09.2020. Dr Vaghela's superannuation date is September 30.

A 1988-batch IAS officer of the Gujarat cadre, Aparna was appointed an Executive Director to the World Bank, representing the constituency of India, Bangladesh, Bhutan, and Sri Lanka in August 2017, and her three-year stint ended this year.

Aparna, 56, has held several top positions in Gujarat, including Principal Secretary, Economic Affairs, and Surat Municipal Commissioner, while she has also served as Joint Secretary, Urban Development at the Centre.

Source: IANS.Ommcom News, 19.09.2020

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DCGI's new Guidelines for Covid-19 vaccine: At least 50 percent efficacy in Phase 3 Trials

On the lines of the World Health Organization (WHO) and the US Food and Drug Administration (US FDA), the Drugs Controller General of India (DCGI) has issued a new set of Guidelines for Covid-19 vaccine candidates, focussing on safety, immunogenicity and efficacy parameters.

The Drugs Controller General of India (DCGI) has issued a new set of Guidelines, focusing on safety, immunogenicity and efficacy parameters for Pharma giants who are developing COVID-19 vaccines. The DCGI has said that a COVID-19 vaccine candidate should have at least 50 percent of efficacy in the Phase-III Clinical Trial for it to be widely deployed and adequate data informing the potential risk of vaccine-associated Enhanced Respiratory Disease (ERD) needs to be generated.

The comprehensive draft regulator Guideline for the development of a vaccine with special consideration for the COVID-19 vaccine provides Guidance to the vaccine developers to ensure that — vaccines are well characterised and manufactured consistently. The Guidance reads that considering the urgent need for a safe and effective vaccine for prevention of COVID-19, clinical development programs of the COVID-19 vaccine may proceed through an adaptive and seamless approach including data to inform the potential risk of vaccine-associated ERD will be needed.

The document has highlighted that the use of COVID-19 preventive vaccines in pregnancy and in women of childbearing potential is an important consideration for vaccination programs. "There are three things for a vaccine – (i) the safety, (ii) immunogenicity, and (iii) the efficacy. Even, WHO says that if we can get more than 50 percent efficacy that is an accepted vaccine. For respiratory viruses, we never get 100 percent efficacy. We are aiming for 100 percent efficacy but may get 50-100 percent," Dr Balram Bhargava, ICMR, Director-General said on Tuesday, 22.09.2020 while responding to a query on the efficacy of COVID-19 vaccine.

Dr Bhargava answered in view of the draft Guidelines published by the Central Drugs Standard Control Organisation (CDSCO) for the development of a vaccine with special consideration for the COVID-19 vaccine. The draft Guidelines further say that the Pharma companies for a statistical final analysis plan finalised before closing the trial database and unblinking treatment assignments (if these were blinded). "This should include any planned interim analyses, which should be adequately addressed in terms of purpose, timing, and any statistical adjustments required."

If a trial fails to meet the predefined criteria for superiority and/or non-inferiority with respect to any of the antigenic components, the possible reasons for the result and the clinical implications it should be carefully considered before proceeding with clinical development or licensure, noted the Guidance. Safety assessments throughout clinical development and all pregnancies in study participants for which the date of conception is prior to vaccination or within 30 days after vaccination should be followed for pregnancy outcomes, including pregnancy loss, stillbirth, and congenital anomalies, it said.

COVID-19 vaccine trials should periodically monitor for unfavorable imbalances between vaccine and control groups in COVID-19 disease outcomes, in particular for cases of moderate to severe COVID-19 that may be a signal for vaccine-associated ERD. Studies should include pre-specified criteria for halting based on signals of potential vaccine-associated ERD. It has also recommended the Pharmaceutical companies to use an independent Data Safety Monitoring Board (DSMB) for vaccine-associated ERD and other safety signal monitoring, especially during later-stage development.

Source: ANI, newsx.com, 23.09.2020

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Indian Pharma needs regulatory surveillance system for disposal of unused & date expired drugs: Dr Jagashetty

Indian Pharma needs a regulatory surveillance in place to monitor the disposal of unused and date expired drugs. Currently, in the absence of any rules under the Drugs & Cosmetics Rules, disposal is guided by the Biomedical Waste Management Rules under State Pollution Control Board (SPCB) norms, said Dr B R Jagashetty,

former National Adviser (Drugs Control) to Union Health Ministry.

It is high time the D&C Act includes a schedule or a dedicated guidance for proper disposal of unused and date expired drugs. Rule 65(17) of D&C Rules only states about not to sell such drugs and to keep aside with proper labeling till its disposal, but does not provide any procedure for disposal of such drugs. However, it follows the norms prescribed under Biological Waste Management Rules, he added.

The D&C Act Schedule P provides the life period of certain drugs and Rule 96 calls to mention the date of expiry on its label as per said schedule. If it is not found under Schedule P, then the date of expiry on the label of drug shall not exceed 60 months from the date of manufacture, provided this period may be extended by the Central Licensing Authority if satisfactory evidence is produced by the manufacturer, said Dr Jagashetty.

This procedure for disposal of date expired drugs needs to be issued by the CDSCO either as a separate schedule to D&C Rules or in the form of Guidelines. Going by the profusion of formulations marketed in India, there is a need for a separate schedule to be included in the D&C Act or dedicated Guidelines. To this end, it is learnt that various sub-committees were formed under DCC which have submitted their recommendations however, the decision is pending, Dr Jagashetty told.

The current practice by Pharma companies to dispose date expired and unused medicines include returning to manufacturer, landfill, and waste immobilization: encapsulation/inertization, flushing it down the sewer and incineration. Despite precautions associated with these methods, these methods are not that effective, he noted.

What we need is a surveillance system to monitor the disposal of such drugs. This is when the Government brought in the Track and Trace system to ensure transparency of drug dispatch from manufacturers to chemists and its disposal of such unused and date expired drugs. It will also prevent entry of spurious drugs into the market as the entire inventory will be monitored. The manufacturers should keep track of the drugs including those of disposal across the supply chain from the distributor to the pharmacy retail. In the absence of guidance, disposal of expiry dated drugs is a problem, he said.

Source: Nandita Vijay, Pharmabiz, 21.09.2020

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Ayurveda offers myriad approaches to pandemics and all infectious diseases: Dr Ram Manohar

While modern medicine is struggling to come up with a solution for epidemics like COVID-19, Ayurveda offers myriad approaches to pandemics and all infectious diseases. The classical clinical narrations specified in Ayurveda need to be repurposed with the Guidance of learned Ayurveda Practitioners for the medical management of COVID-19.

There is no particular drug for curing COVID in Ayurveda, but there are preventive and curative measures for any kind of such pandemic and it has to be applied accordingly, said Dr Ram Manohar, Director of Research, School of Ayurveda at the Amrita University in Kerala.

"There is no simple solution prescribed in Ayurveda to cure COVID-19 or any viral disease, but there is a comprehensive approach to treat infectious diseases and they have to be applied after repurposing them with the Guidance of modern Ayurveda Practitioners," he commented.

Participating in an online international seminar on Ayurveda organized by a German team of Ayurveda Practitioners from Frankfurt, Dr Ram Manohar said the traditional system of Ayurveda is well-equipped with its classical formulations by which even 98% of all infectious diseases are getting cured. If the good clinical care protocols specified in Ayurveda are applied in conditions of diseases, even the present pandemic can be cured without waiting for research for medicines for Coronavirus disease. Ayurveda has no magical vaccine to stop viral infection at once, but the formulations specified there can cure even any deadly viral disease, he claimed.

Apart from medicines, the traditional system encourages sleep and exercise as other tools to fight against diseases and to develop immunity in humans. For this, each person of the modern day has to correct his lifestyle and physical activities. Ayurveda cannot recommend one medicine for COVID-19, but a clinical understanding based on traditional knowledge in the Indian system is necessary to find new medicines for viral diseases like COVID and to contain the spread of the pandemic. It is the collective responsibility of all concerned to address infectious diseases. He said even the developed countries which have accessed good healthcare have now been affected by the epidemic.

According to Dr Manohar, the future healthcare system will be a healthcare of self-responsibility rather than a system that envisages health for all. He said 'Rasayanas' prescribed in Ayurveda helps to boost immunity in people of all ages. In the international webinar, quoting *Charakasamhita*, the Ayurveda Research Director said pandemic like COVID-19 is the effect of affliction of vayu (air), jala (water), desa (land) and kaala (time). With the influence of these factors one disease can affect a large number of people simultaneously. As per *Charakasamhita* there is a reason to consider modern day epidemics like SARS, MERS, Swine Flu, Ebola and COVID-19 as '*Janapadodhvamsaka*' disease. Janapadodhva? saka refers to epidemic among large number of people happening simultaneously.

"Charaka says that available medicines will not work on the epidemic. Medicines have to be specially prepared with high potency by anticipating epidemics. Cleansing therapies and immune stimulating medicines should also be administered in addition to the available medicines," said Dr Manohar who is part of the German Ayurveda academy for the last 20 years.

Source: Peethaambaran Kunnathoor, Pharmabiz, 21.09.2020

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Haryana showcases readiness to bid for Bulk Drugs and Medical Device Parks at PHDCCI webinar

The Haryana State Industrial and Infrastructure Development Corporation (HSIIDC) is ready to bid for the central Government announced bulk drug and medical device parks. It has acquired 1000-acre land in Panipat for a proposed bulk drug park and is in the process of acquiring more land. The state Government is also proposing to set up a medical devices park in Karnal.

In the recently held webinar organised by the PHD Chamber of Commerce and Industry (PHDCCI) on "The Future of Pharma Industry", the authority informed that the proposed bulk drug park will be designed and equipped keeping all the industry requirements for ease of doing business. Anurag Aggarwal, MD, HSIIDC said that Haryana is ideal for setting up the Pharma parks due to its strategic advantage as Haryana surrounds Delhi from three sides providing access to nearly 11 percent of the domestic market.

It has excellent road and air connectivity because 15 national highways are present in Haryana with four of them passing through the Delhi-NCR region and has international airports in its vicinity, at Delhi and Chandigarh. However, he also raised concerns that the evaluation criteria of the bulk drug parks seem to be favouring the coastline states. He said that the state has slipped from its ranking of ease of doing business and will be losing the three points for coastal preference in the selection criteria.

He stated, "We do not understand why the coast has been given the advantage in the detailed Guidelines of Bulk Drug Parks when only 11 states in the country have a coastline." He said that during the Britishers' time the ports used to play an important role in the movement of goods but now the situation is not the same. And it is something that cannot even be created. He said that the state is looking forward to a fair evaluation in the selection criteria.

N K Ahuja, Haryana State Drug Controller highlighted the Pharma Policy of Haryana, which has been drafted in consultation with all stakeholders. He added that the regulatory policy of Haryana acts as a friend, philosopher and guide and its focus is to handhold and encourage entrepreneurs in the State. Presenting the industry's expectations, B R Sikri, Vice President, Bulk Drugs Manufacturers Association of India stressed that transparency, ease of doing business, location of all concerned offices in the park, single window system and deemed approval, competitive land cost etc., will go a long way in the success of proposed parks in Haryana.

Mohit Jain, Chairman, Haryana State Chapter PHDCCI, appreciated the Haryana Government's move to boost the Pharmaceutical sector in the State by launching a dedicated Haryana Pharmaceutical Policy 2019. A K Singh, Principal Secretary, Industries and Commerce, Government of Haryana also informed that there is a big scope for the Pharma industry in Haryana as the State has an attractive industrial policy, titled Enterprise Promotion Policy.

He said that the policy will now lay stress on employment too. He said that for designing the bulk drug park in Panipat it has entered into an MoU with NIPER Mohali for setting up a research unit. It is also aiming to sign 10 more MoUs with the industry for research collaborations. Responding to the query on the coastline, Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Government of India said that the Bulk Drug Parks scheme is on a challenge mode and the marks to the coastline states is not only considered only from a dumping purpose but also from the fact that

huge capital is required for effluent treatment plants and compete with China when it is playing the game of volume.

To make Indian industry competitive, the Government of India is giving preference to high scale and high-quality manufacturing. He also informed that Pharma is one of the 'champion sectors' identified by the Government of India to provide hand-holding to investors for improving manufacturing capabilities in the country. He said that the Production Linked Incentive (PLI) schemes for promoting domestic manufacturing of KSMs, DIs, APIs and Medical Devices will go a long way in boosting domestic manufacturing.

Informing that for the PLI scheme, the Government is receiving a good response, he mentioned that it has received a suggestion from the industry to increase the investment criteria of one of the product categories for which the minimum investment criteria was set at Rs.4000 crores. The participants at the webinar also raised queries like; will anti-dumping duty be put on China on all government announced PLI scheme products to safeguard the industry, would the units in the bulk drugs parks be exempted from Environment Clearance etc.

Source: Usha Sharma, Express Pharma, 22.09.2020

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Hyderabad soon to emerge as leading API Hub of India as more firms seek land to set up their API units in Pharma City

With many Pharmaceutical companies in the field of Active Pharmaceutical Ingredient manufacturing seeking land for setting their bases in the newly developing Pharma City region, very soon Hyderabad is going to become the leading API manufacturing Hub of India. With the central Government granting the national investment manufacturing zone status to Hyderabad Pharma City, the Telangana Government is now going ahead with its plans to allot land to as many as 150 Pharmaceutical companies in the first phase.

Earlier, out of the total earmarked extent of over 19,000 acres of Pharma City land, the Telangana State Industries and Infrastructure Corporation (TSIIC) has already taken over 8,500 acres and developed roads, drains, common effluent plants, established power lines and other necessary infrastructure needed for the Pharmaceutical companies.

According to officials from the industries department of Telangana, as many as 350 firms have approached the Government seeking land in the Pharma City. Of them, the officials have decided to allot land to 150 firms in the first phase. "We are about to complete the first phase of Pharma City project in the next few days. Already a couple of API manufacturing, research and formulation based Pharma companies have been allotted lands and work for setting up of their units is in the process. The TSIIC has also completed more than 95 percent of works under the first phase and very soon by end of this year we are planning to operationalise the first phase of the Pharma City," informed Jayesh Ranjan, Principal Secretary, Industries.

Recently, the Saptagir Labs, an API manufacturing company based in Hyderabad, had also expressed its intention to set up its unit in the Pharma City project and had even revealed that it had applied to the state Government for the allotment of the land. As already Saptagir Labs has invested Rs.75 crore in its WHO GMP certified Pharmaceutical plant located at Chegunta in Medhcal. The firm is now planning to accomplish its dream of becoming a US FDA certified firm by setting up its most advanced API manufacturing unit at Pharma City.

"We have already submitted an application to the industries department for allotment of land in Pharma City. We are targeting to achieve a manufacturing capacity of 500 kiloliter in the coming 2-3 years and planning to set out a strong footage as a leading API exporter from Hyderabad," informed Shilpa Reddy, Promoter and Managing Director of Saptagir Labs.

Source: A Raju, Pharmabiz, 19.09.2020

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SCTIMST signs MoU with Tynor Orthotics for joint R&D in orthotics and rehabilitation devices

The Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) has signed a Memorandum of Understanding (MoU) with Tynor Orthotics Private Limited to set up an orthotics and rehabilitation Research & Development (R&D) vertical to promote indigenous device development in this sector.

The main objective of this Institute-Industry collaboration is to develop a cluster of orthoses for catering to clinical conditions such as osteoarthritis and diabetic foot ulcer. The project is planned for 1 year with

Tynor contributing Rs.27 lakhs to the programme, said the statement.

"R&D ties up with an Indian industry right from the start and after a detailed study of the Indian market is the way to go forward to ensure development of high-quality affordable technologies for India and to strengthen our medical devices industry, reduce the country's import dependence for such devices and ensure commercial success of our products. Our research team is enthused to work with an industry leader in this segment and will do their best to get the desired results of this partnership in a year or two," said Dr Asha Kishore, Director, SCTIMST.

Global diabetic foot ulcers and pressure ulcer market is expected to reach US$ 5,265 million by 2025 with a CAGR of 6.6% from 2019-2025 which is quite alarming. Similarly, the global knee braces market is growing due to the rising prevalence of osteoarthritis, increasing number of orthopedic knee surgeries, and growing number of sports injuries in athletics.

The global knee braces market size was estimated at US$ 1.5 billion in 2018 and is expected to witness a CAGR of 4.3%. The growing burden of osteoarthritis, the increase in target population, and the technology of cost effective and easy to wear braces are the major growth propellers for the market, said the release.

"SCTIMST has done considerable amount of R&D work in biomedical devices over the last 30 or more years and has established itself as a pioneer in this field. This collaboration with an Industry leader for co-development of ortho rehab devices in the country is a commendable step and is fully aligned with the Prime Minister's Vision of *Aatmanirbhar Bharat*", said Dr V K Saraswat, NITI Aayog Member, noted missile scientist and the President of SCTIMST.

Source: Pharmabiz, 21.09.2020

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Punjab Government receives encouraging response from Pharma industry for Bathinda Bulk Drug Park

The Punjab Government led by Finance Minister Manpreet Singh Badal, held strategic discussions with industry captains and academic leaders during a virtual stakeholder consultation session for upcoming Bulk Drug Park in Bathinda in Punjab. The webinar saw participation from more than 50 eminent Pharma industries from across India (including Punjab) and USA.

These included Dr Reddy's, Divis Labs, IOL Chemicals, Sun Pharma, Nectar Lifesciences, Anupam Rasayan, Sequent Scientific, Ami Lifesciences, Saurav Chemicals etc. The session was also attended by other stakeholders such as UNIDO, NCL, CSIR, Pharma EXCIL amongst others. The session started with an introduction of Government of India's "Promotion of Bulk Drug Parks" Scheme by Joint Secretary, Department of Pharmaceuticals, Government of India, Mr Navdeep Rinwa.

The high-level interaction included engagement with senior officers of Invest Punjab and Housing & Urban Development. Apart from sharing a brief overview of the advantages of Punjab as a preferred investment destination especially for incoming Pharma units, the main emphasis was on apprising the participants on the upcoming Bulk Drugs Park at Bhatinda spread over an area of approx 1300 acres.

The webinar served as a platform for Punjab Government to understand the requirements of the Pharma units in India and to take industry feedback on the State Government's bulk drugs park proposal. The progressive reforms and initiatives taken by the Punjab Government for creating an investor-friendly ecosystem in the State and for taking an innovative approach towards the conceptualization of a Pharma Park was appreciated by the participants.

Meanwhile, the State Chief Secretary Vini Mahajan outlined the close relationship that industries within Punjab share with the Government which in turn promotes collaboration and excellence. The Finance Minister assured the participating leaders from industry and other organizations of the serious intent of the State Government to encourage the growth of the emerging Pharma sector in Punjab through offering plug and play infrastructure at competitive rates and facilitating collaborations for strengthening backward and forward integration for the industry.

This was a unique engagement between Punjab and leaders of Pharma industry to showcase Punjab's position as the preferred Pharma destination within India.

Source: Punjab New Express, 23.09.2020

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Industry approaches Centre to urgently notify methylcobalamin for neurological disorders

The pharmaceutical industry has recently led a delegation to Union Minister of Chemicals and Fertilizers D V Sadananda Gowda to urgently notify methylcobalamin for neurological disorders as regulatory action cannot be taken against those who are manufacturing methylcobalamin based formulations without scientifically defined efficacious Recommended Dietary Allowance (RDA) value due to delay in notification.

Once notified, approved RDA value can be defined in a scientific way based on evidence. The issue, however, has been festering due to missing exact information on Tolerable Upper Limit (TUL) of vitamin B12 or methylcobalamin for neurological disorders and immunity booster from the public domain.

The pending notification which is being sought for is also based on former Food Safety and Standards Authority of India (FSSAI) CEO Pawan Agrawal's confirmation that methylcobalamin has been approved by its scientific committee in December 2019. Mail correspondences shared on the issue have been reviewed by Pharmabiz.

Drug and nutraceutical industry players have voiced concern that methylcobalamin RDA value has been approved by Central Drugs Standard Control Organisation (CDSCO) uptill 2000 mcg but FSSAI is approving only 1 mcg which is of no use. Drugs Controller General of India (DCGI) recommended 2,000 mcg of methylcobalamin even in injectable form and brands are available as patients take methylcobalamin based on the medical condition. However, on January 7, 2020, FSSAI issued a Notification regarding RDA of vitamin B12 which is specified as 1 mcg without mentioning type of vitamin B12 like methylcobalamin, adenosylcobalamin, hydroxycobalamin and cyanocobalamin.

"No adverse effect has been associated with excess methylcobalamin intake from food or supplements in healthy individuals. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption but industry is yet to see the much awaited Notification on the same," informed Anshu Yadav who led the delegation to the Government further adding that we are pursuing the issue of banning methylcobalamin by FSSAI for more than a year without a logical conclusion. On the contrary, FSSAI has allowed usage of cyanocobalamin which has cyanide content within but banned methylcobalamin which is a superior form of vitamin B12.

"Until and unless FSSAI does not inform the industry that methylcobalamin is approved, there is no value of prescribing RDA value for the same. Surprisingly the mails which we have received from FSSAI methylcobalamin and cyanocobalamin both have the same RDA value to manufacture. Please be advised we are talking about per serving usage value which the manufacturer can refer to and not the RDA value for a healthy person," Pharma consultant Dr Sanjay Agrawal argued.

Methylcobalamin is an essential nutrient and is required to treat vitamin B12 deficiency, in people with pernicious anemia, diabetes and other conditions as well. It is important for the brain, nerves and for the production of Red Blood Cells (RBCs). Methylcobalamin as a supplement is very essential specifically for Indians where the majority of the population is vegetarian as naturally it is present in non-vegetarian products. When a supplement is taken for prophylactic cause it must at least be of the therapeutic dose.

Source: Shardul Nautiyal, Pharmabiz, 18.09.2020

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Union Minister Gowda lauds contribution of Indian Pharma Industry amid COVID-19 crisis

Union Minister for Chemical and Fertilizers D V Sadananda Gowda has lauded the contribution of the Indian Pharma industry during the testing time of COVID expressing confidence that the Indian Pharma industry will be among the first one to develop and supply low-cost vaccines for this pandemic. Gowda was addressing a Webinar organized by Invest India Pharma Bureau and Department of Pharmaceuticals on #EIF2020 Medical Devices and Pharmaceutical Sector Edition - unraveling the investment potential, GoI initiatives, infrastructure & emerging opportunities in the sector through video conferencing recently.

Union Minister also stressed that the Indian Pharma and medical devices industry was able to rise to the occasion. He added, "It is a matter of great pride for me and millions of Indians that from being a net importer, India has become the second-largest producer of PPE Kits

in the world with daily production capacity surpassing more than 5 lakh per day. Similarly in the case of ventilators, within a very short span of time, indigenous production capacity has increased to 3 lakh per annum. In addition, India did not face any scarcity of medicines, prices of medicines remained stable throughout. This was achieved due to active cooperation among various Departments and agencies of the Central Government, State Governments, and private sector, Shri Gowda said.

Stressing on the need of development of indigenous capacity in Medical devices Gowda said, "it is very important as it has a crucial role to play in improving accessibility and affordability of healthcare especially with respect to the availability of precision devices for screening and diagnosis, advanced surgical equipment needed for treatment, and devices for monitoring of health indicators, among others."

He further said under the leadership of Prime Minister Shri Narendra Modi, the Department of Pharmaceuticals has taken several measures to create an enabling environment for the development of domestic capacity in the Pharma and medical device sector and has decided to support the development of three bulk drug parks and four medical devices parks across the country in coordination with State Governments and private sector. The objective is to make India self-reliant in the production of 53 critical APIs or Key Starting Materials (KSMs), and in the production of medical devices, for which India is crucially dependent upon imports.

Gowda said that he is very much sure that these parks will be able to attract significant investment as well as the latest technology. Within a period of 2-3 years, due to business-friendly policies of the Union Government under the leadership of Shri Narendra Modi, the Pharma sector will become *atmanirbhar*, not only in sense of meeting domestic requirements but also for fulfilling global demand of low cost - high-quality medicines and medical devices. It is expected that these schemes of the Union Government for the development of bulk drug & medical device park will attract cumulative investment of Rs.78000 crore and can generate about 2.5 lakh employment.

Source: Ruchika, Medical Dialogues, 20.09.2020

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Can't directly deal with complaints of Unethical Practices: Department of Pharmaceuticals

The Department of Pharmaceuticals (DoP) has admitted in Parliament that under the Uniform Code of ethical Marketing Promotion (UCPMP), there is no provision for it to directly deal with complaints received regarding unethical practices by Pharma companies. Yet, a big exercise is underway to make Pharma associations submit quarterly reports to drug price regulator.

"As per UCPMP, any complaint received against a Pharmaceutical company is to be handled by an Ethical Committee for Pharma Marketing Practices, that is, to be constituted in each of the Pharmaceutical associations," it said in response to a question in the Parliament on September 18. "DoP has been following up with Pharma associations to implement the code effectively. This department has also taken multiple meetings with associations, most of whom have put UCPMP on their websites and constituted committees for handling complaints regarding breach of UCPMP. The Government also held a meeting on September 4, asking Pharma companies and associations to submit a quarterly report on implementation of Uniform Code of Ethical Marketing Promotion. DoP also asked Pharma associations to submit compliance report and form committees to look into action taken on the complaints.

Pharma lobby groups and associations have been asked to make sure companies adhere to marketing norms during their conferences, despite the clear failure to self-regulate by Pharma companies. Malini Aisola, co-convenor, All India Drugs Action Network (AIDAN) said the meetings by the Government are eyewash. "It is sheer absurdity that the Government is trying to monitor a self-regulatory mechanism of the industry that it has no tools to enforce.

The DoP Secretary has admitted that under the code, only associations can take action against companies. To make matters worse, NPPA, the agency that had been tasked by DoP to oversee UCPMP implementation, has conceded it is neither mandated nor authorised to monitor Pharma Marketing Practices. This is just days after it instructed associations and companies to submit quarterly reports to its office." Earlier DoP had even said it had received grievances that Pharma companies "arrange hotels, accommodations, local sight-seeing" in conferences conducted by the doctors. UCPMP has been voluntarily adopted by Pharma companies since 2015.

However, concerns over the influence of offering gifts to medical professionals by Pharmaceutical companies have surged from time to time. The meeting was attended by the Secretary DoP, other officials in DoP, NPPA Chairperson along with members of the associations including Indian Pharmaceutical Assocaition (IPA)-that represent the top Pharma companies, Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers' Association (IDMA), among others. "We have been pressing for a legal instrument to replace the voluntary code and submitted evidence of unethical practices. Yet, DoP has not held a single consultation with civil society in the last two years. The whole process is an eyewash," Aisola added.

Source: Teena Thacker, The Economic Times, 24.09.2020

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INTERNATIONAL NEWS

Russia to supply Avifavir drug to 17 nations for Coronavirus Treatment

AP Avifavir and other favipiravir-based drugs produced in Russia, as well as Remdesivir developed in the US are currently the leading drugs against Covid. (Representational image)

The Russian Direct Investment Fund (RDIF), Russia's sovereign wealth fund, and ChemRar Group have agreed to supply Avifavir, the world's first registered Favipiravir-based drug against Coronavirus and Russia's first drug approved for the treatment of COVID-19, to 17 countries. Avifavir and other Favipiravir-based drugs produced in Russia, as well as Remdesivir developed in the US are currently the leading drugs against COVID-19 registered globally.

Avifavir will be delivered to Argentina, Bulgaria, Brazil, Chile, Colombia, Ecuador, El Salvador, Honduras, Kuwait, Panama, Paraguay, Saudi Arabia, Serbia, Slovakia, South Africa, UAE and Uruguay. The drug has already been delivered to Belarus, Bolivia, Kazakhstan, Kyrgyzstan, Turkmenistan and Uzbekistan. On May 29, 2020, Avifavir received a registration certificate from Russia's Ministry of Health based on thorough and transparent clinical data and became the first Favipiravir based drug in the world approved for the treatment of COVID-19.

Approximately five months after the Clinical Trials of Avifavir in Russia, the efficacy of Favipiravir against the novel Coronavirus infection was confirmed by Japan's Fujifilm. On September 23, 2020, the company announced that according to the results of its Phase III Clinical Trial, the administration of its Favipiravir-based drug Avigan to 156 patients demonstrated shorter time to resolution as compared with the placebo group.

The efficacy of Avifavir has been demonstrated in Clinical Trials which significantly exceed in scale those conducted by other Russian manufacturers of Favipiravir. These trials have been conducted in full compliance with international standards and the requirements of regulatory authorities around the world. Since April, 408 patients with confirmed Coronavirus have participated in the studies at 35 medical centers across Russia. In October the number of patients will increase to 460.

Since June 2020, more than 60,000 packages of Avifavir have been delivered to clinics in 74 Russian regions. Since the start of Avifavir supplies, clinical monitoring has been carried out based on data from the register of patients with Coronavirus of the Ministry of Health of Russia. Data on the use of Avifavir has been collected, with further analysis as well as scientific and medical assessment conducted.

According to the results of the observational post-registration Clinical Trial of 940 patients, those taking Avifavir demonstrated elimination of the virus at an earlier stage in 30% of the cases and the level of oxygen saturation was restored to normal twice as quickly compared with standard therapy (within two days versus four days). According to the results of the research, the drug is well tolerated, with no new adverse events identified.

Avifavir is now the leading Russian anti-COVID drug in terms of exports. In particular, the start of deliveries to Bolivia and other countries in Latin America was announced on September 21 as part of the agreement to deliver 150,000 packs. Avifavir has also been approved by regulators in Europe, Middle East and Asia. Kirill Dmitriev, CEO of the Russian Direct Investment Fund, said, "When we registered the first anti-Coronavirus drug in the world based on Favipiravir there was a lot of skepticism as people were wondering how we could register it when Japan had not registered it yet.

Now five months after our Clinical Trials we see that Japan has confirmed the clinical efficacy of Favipiravir. Avifavir has been tested in more than 1,300 patients including 408 patients in Clinical Trials and 940 patients during the observational post registration Clinical Trial."

"We have now conducted the largest Clinical Trial of a favipiravir-based drug against Coronavirus in the world and can confirm its high efficacy. Since June, more than 60,000 packages of Avifavir have been delivered to clinics in 74 Russian regions and more than 15 countries have confirmed their interest in the drug. Based on our extensive Clinical Trials and the research in Japan confirming Favipiravir's efficacy against Coronavirus we believe that Avifavir and other favipiravir-based products will be the leading antiviral medicines against COVID-19 in the world. In addition to proven efficacy and safety Avifavir is also three to four times cheaper than Remdesivir."

RDIF is Russia's sovereign wealth fund established in 2011 to make equity co-investments, primarily in Russia, alongside reputable international financial and strategic investors. RDIF acts as a catalyst for direct investment in the Russian economy. RDIF's management company is based in Moscow. Currently, RDIF has experience of the successful joint implementation of more than 80 projects with foreign partners totalling more than RUB1.9 tn and covering 95% of the regions of the Russian Federation.

RDIF portfolio companies employ more than 800,000 people and generate revenues which equate to more than 6% of Russia's GDP. RDIF has established joint strategic partnerships with leading international co-investors from more than 18 countries that total more than $40 bn. ChemRar Group unites R&D service and investment companies in the field of innovative Pharmaceuticals for the development and commercialization of innovative medicines, diagnostics, preventive care and new treatments of life-threatening diseases in Russia and abroad.

Source: Dipanjan Roy Chaudhury, The Economic Times, 24.09.2020

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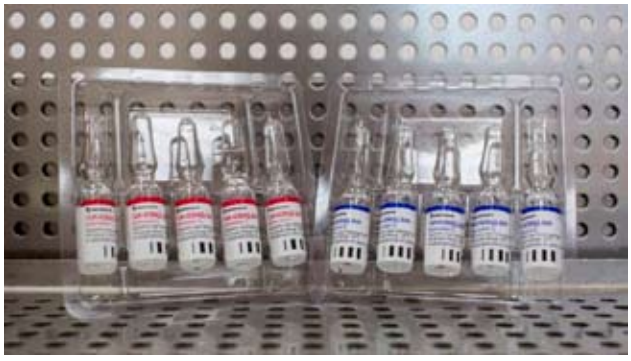
FEATURE

Why Vaccines are a better bet against Coronavirus than Drugs

In humanity's millennia-long struggle against viruses, prevention with vaccines has been far more successful than treatment with drugs

Michelle Cortez



Ampoules containing components of the Covid vaccine 'Gam-COVID-Vac', also known as Sputnik V, developed by the Gamaleya National Research Center for Epidemiology and Microbiology and theRussian Direct Investment Fund (RDIF) | Andrey Rudakov | Bloomberg

A Global push is on to develop a vaccine to slow the spread of Covid-19, and experts hope several will be ready in 2021. Yet even with one, the Coronavirus is likely to remain with us for years, demanding long efforts to find a cure for those who still fall sick.

In humanity's millennia-long struggle against viruses, prevention with vaccines has been far more successful than treatment with drugs. In fact, modern medicine has come up with a true cure for only one viral infection. For many serious infections, the best approaches are a cocktail of drugs that throw speed bumps in front of the infection. It's a lackluster medical armory, belied by the seeming simplicity of our viral foes. "They can't live by themselves, they aren't independent, they can't process food, take in oxygen, reproduce themselves without the master support system of being the parasite inside a living cell," said Paula Cannon, a Professor at the University of Southern California's Keck School of Medicine. So why do viruses give humans so much trouble? Outside of the body, a vigorous hand-washing is enough to kill many. Inside, the immune system's long memory is enough to make short work of most.

It's when we run into a new virus that the problems start. The Coronavirus, SARS-CoV-2, is the latest in a procession of new infectious diseases that have surprised the world in recent years. The best hope against it is a

vaccine, which can stop infections before they take hold. A vaccine is, essentially, a shortcut to immunity. But if we don't have immunity and get sick, things get more complicated. Because viruses can't survive on their own, they hijack our cells to multiply. That parasitic dependence makes them hard to treat with most traditional drugs. A virus is so interwoven with its host that it's difficult to hurt one without hurting the other.

SARS-CoV-2 infects the airways and lungs — the very things we need to breathe. That leaves an unappealing choice, according to Cannon. "I can kill the virus, but I would have to kill you to do it." Some vaccines, such as for measles, have created enough herd immunity that the virus can no longer take hold and spread in the population. In the best case, as with small pox, the shots have driven the disease out of the human host population and into extinction. Treating an active infection is another matter. There's a Pharmaceutical cure for only one virus: Hepatitis C. Because of the "kill the virus, kill the host" problem, the best bet is often to slow the virus down enough that the body's own defenses can do their job. "When we can't kill a virus, the best thing we can do is stop them from replicating," said Raed Dweik, Chair of the Cleveland Clinic's Respiratory Institute in Ohio. "All we can do is shorten the period of infection, not cure. Even when the infection is over, the patient is more recovered than cured."

Remdesivir, the only drug in wide use that targets SARS-CoV-2 itself, works by messing with the virus's ability to replicate. It causes errors when the virus tries to copy itself. It was also a product of luck: the drug was originally developed as a treatment for Ebola, but it wasn't terribly effective and the waning outbreak in Africa made it difficult for its manufacturer, Gilead Sciences Inc., to study. Clinical trials have shown that Remdesivir can help hospitalized Covid-19 patients recover more quickly. But it's not a cure, and it's unlikely there will be one any time soon. "It will take years to have potent and specific drugs that can stop Coronavirus in it stracks," Cannon said. "The vast majority of drug candidates fail."

In the future, patients will likely get a cocktail of therapies that attack the virus and others that help keep them stable. Currently, Remdesivir is part of a cocoon of care that includes the only other cleared therapy, the steroid *dexamethasone*, as well as standard fare like fluids, plus aggressive approaches when needed including putting patients on ventilators. Other medicines are layered on top: blood thinners and experimental approaches to calm a potentially overactive immune system. As new approaches reach the market, they'll be added to the mix. But for most people, any viral treatment will have to outperform an already formidable and existing approach: the human immune system.

The best defence:

It's not a coincidence that many infections last for about two weeks, Cannon said. That's how long it takes for the immune system to kick into gear. "Our immune system is the world's best drug maker," she said. "Whether you had measles as a 5-year-old or Covid as a 50-year-old, our immune system comprises this vast library of potential antiviral approaches that offer protection." Antibodies, the infection-fighting proteins produced to ward off foreign invaders, are biological drugs we make ourselves, Cannon said. The body has the ability to make millions and millions of them, activating just the right one when it binds to a virus – then mass producing it over a period of about 14 days. "This is when the immune system gets the upper hand," Cannon said. "There are so many antibodies in the blood, coating the virus. They do a good job of neutralizing the virus. Eventually, the antibodies win the day." Those antibodies never fully recede to their initial low levels. Instead, they remain in reserve and on patrol for years, in case the threat returns. If that happens, the response doesn't take 14 days.

"If you get that same virus, the infection doesn't take off because the antibodies kick in,"Canon said. "You don't even get sick. That's why, with the vast majority of viruses, you get them once and you are immune in the future." It's this process that vaccines mimic. The man-made immunizations offer up a piece of the virus to the immune system, providing just enough for the body to activate against a potential threat without actually making the person sick. The immune system is thus alerted and able to prevent infection, rather than having to fight one off. It's also the approach behind another wave of therapies in development for more severe Covid-19 patients. Drug makers have figured out how to grow antibodies that mimic the natural ones the body produces, and experimental medicines based on them are coming from Regeneron Pharmaceuticals Inc., Roche Holding AG and Eli Lilly & Co.

But those therapies are likely to be reserved for the sickest, hospitalized patients. And those types of therapies tend to be expensive — thousands of dollars for a single course. Gilead's hepatitis C drug, for example, cost $84,000 after it was approved for US sale in 2013. Biotechnology drugs like the ones under development for Covid-19 likewise tend to cost tens of thousands of dollars per course. Vaccines, on the other hand, tend to be cheap— and keep people out of more expensive care.

"Because we can't treat them very well, the critical thing is always prevention," the Cleveland Clinic's Dweik said. "Once you get infected, there is very little we can do other than support you through it or perhaps shorten it a bit. That's why finding a vaccine is so important."

Drugmaker incentives:

There are hundreds of viruses that cause respiratory infections and are generally lumped together under the "common cold" banner. Several are Coronaviruses. The reasons we don't have treatments for them is because each is so individualized and drug development is so expensive, often topping $1 billion per therapeutic. Each treatment would have to be crafted for a specific pathogen, following a tailor-made path so narrow that it would be almost impossible. Already, thousands have failed. And a cold? It typically goes away on its own. The broader economics have historically worked against medicines for viral infections, leaving a gap in the type of innovation that has happened with other, more profitable conditions like cancer and heart disease. The most recent viral outbreaks, including SARS and MERS, both novel Coronaviruses, as well as Zika, all ebbed before new treatments gained a foothold.

"Think about it from the perspective of a Pharmaceutical company," said James Cutrell, Director of the infectious diseases fellowship program at the University of Texas Southwestern Medical Center in Dallas. "Infection typically is an acute illness that you are going to treat for a short period of time. If it's a rare infection, there may not be that many people who take it. When these other viruses initially came out there was a lot of interest in developing treatments, but once they died off there wasn't enough for clinical trials." The economic incentives for drug makers changed with the Covid-19 pandemic, which is so widespread and so disruptive that a vaccine is seen as a societal necessity. The US Government, under its Operation Warp Speed program, has struck deals worth about $10 billion with drugmakers to develop and manufacture multiple vaccines. The shots they come up with, and their successors, could end up being used for years around the globe. It's also certainly not the last new virus the world will encounter. "The science tells us that this virus isn't unique, it's one of many that are circulating in animals that may spread to us," Dweik said. "There is no reason to think this won't happen again.".

Source: Bloomberg/theprint.in,14.09.2020 (Excerpts)

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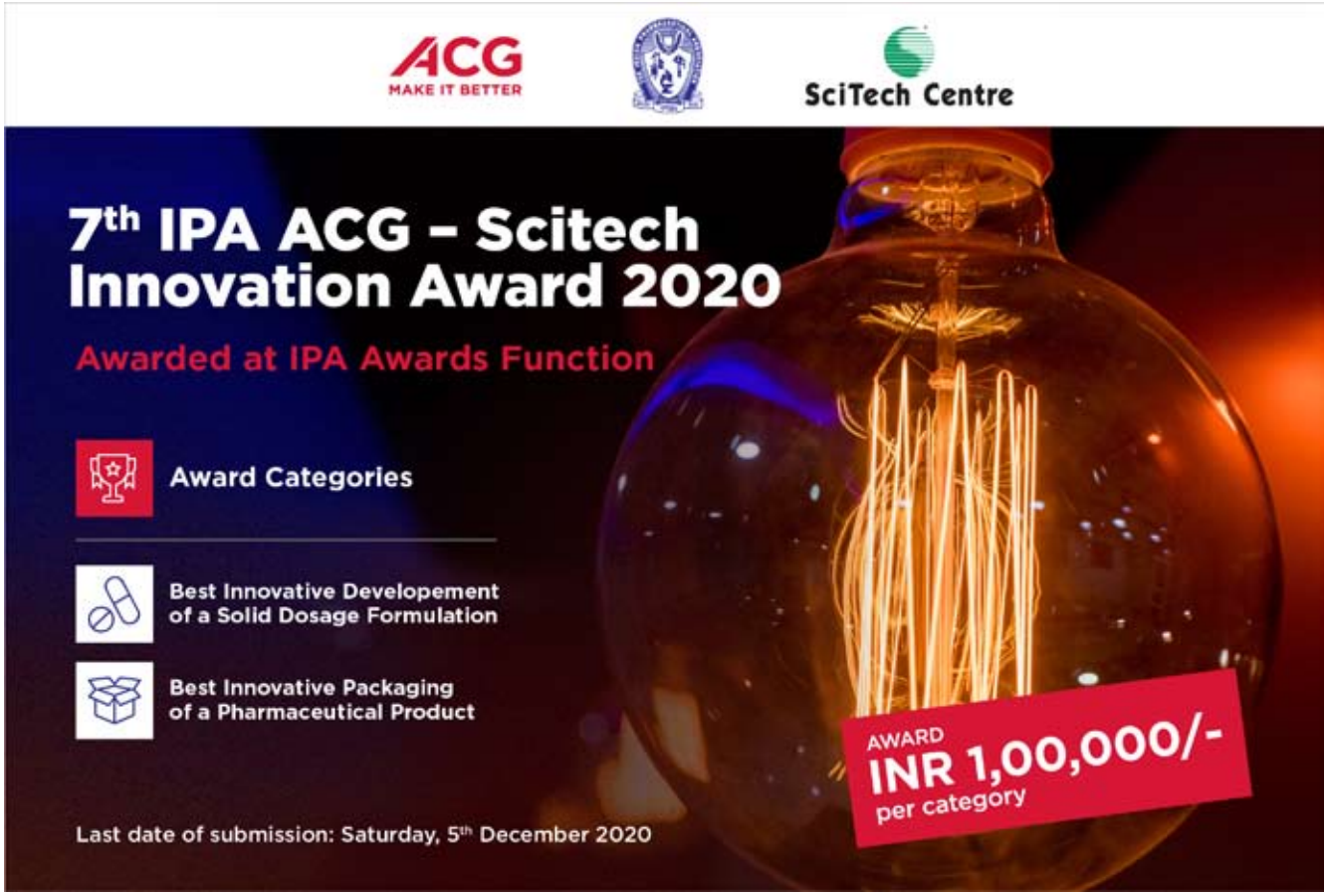

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