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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 51 **Issue No. 48** **22 to 30 December 2020**

Address by Shri Arun Singhal, CEO, FSSAI at the National Executive Committee Meeting of IDMA held on Friday, 18th December, 2020 *(via VC on Zoom)* on FSSAI Activities & Initiatives: A Report

Mr Daara B Patel

Mr Mahesh H Doshi

Dr R K Sanghavi

Mr George Patani

Mr Arun Singhal

Mr Arun Singhal, CEO of FSSAI, graciously consented to address the members on accepting the invite by IDMA. His talk was with special relevance for the Food Business Operators (FBOs) in matters pertaining the nutraceutical vertical of healthcare. Mr Mahesh H Doshi, National President extended a warm welcome and Mr Daara Patel, Secretary General, IDMA elaborated on Mr Singhal's achievements and experiences. Following the initial pleasantries, Mr Singhal mentioned that India's Nutraceutical Market of Rs.30-35k crores at present is expected to double to Rs.60-65k crores in the next 10 years.

Mr Arun Singhal emphasized the role being played by Food Safety Standards Authority of India (FSSAI) in releasing a number of regulations for ensuring safer consumption of articles of food, including supplements and nutraceuticals. He stated that over 700 standardized ingredients have been listed under the various schedules specified under the regulations for nutraceuticals. The same being an ongoing process and in 2020 near 50 standardized ingredients more are being added under the various respective schedules.

In another first, FSSAI has collaborated with AYUSH to moot a new entity that will be known as *AYURAHAR* for approval of home-made recipe of traditional healthy Indian food items. Also the FSSAI has jointly with CDSCO resolved the stalemate pertaining to the jurisdiction under which the mere vitamins and minerals supplements

fall under. Anything product with quantities of vitamins/ minerals up to specified RDA amounts is to be considered Health Supplement and under FSSAI; all others having exceeding RDA quantities will be drugs and need to be certified by the DCG(I).

Indians averagely spend Rs.15-20 per month on nutraceuticals whilst in US it is 500 times the amount. Hence, the FSSAI is on a mission to facilitate the proliferation of the nutraceutical vertical of healthcare. The availability of ample of variants of immunity boosters and modulators to counter the COVID-19 crises exemplifies stimulus for nutraceuticals.

Dr Arun Singhal was extremely forthcoming by inviting questions to clarify any issue/s from IDMA's Nutraceutical Committee. Dr R K Sanghavi, Chairman of the Nutraceutical Committee requested clarifications on certain pressing concerns of the FBOs:

Footnote below Table-B of Schedule-I:

The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Amendment Regulations, 2020 (Draft Guidelines) on 29th October 2020. Following with deliberations held, FSSAI has agreed to modify the footnote stating as (instead of above):

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

However, Dr R K Sanghavi suggested that FSSAI to consider modifying the footnote as:

"Suitable esters, derivatives, active moieties, pro-vitamins and salts of vitamins and salts and chelates of minerals may be used."

When Dr Sanghavi stressed upon the need for having additional words such as 'active moieties' or else an important vitamin such as benfotiamine may not be able to have a place in the composition of products, Mr Singhal suggested that a separate suitable representation be forwarded to FSSAI for its immediate consideration.

Inclusion of Vitamin Derivatives and other Pro-Vitamins Additionally under the Table-B of Schedule-VI:

Dr Sanghavi requested that FSSAI consider separate listing, in addition to footnote modification, of various vitamin derivatives, etc like methylcobalamin, L-methylfolate, benfotiamine and others under the Table-B of Nutraceutical Schedule-VI. Since there is already a precedence of mentioning some other vitamins under this list additionally, Mr Arun Singhal also requested that the suitable list of vitamins required to be mentioned separate as per above also be forwarded to the FSSAI.

- CONSIDERATION OF REPLACING RDA WITH TUL UNDER THE FSS ACT (FSSA) FOR ALL PRODUCTS UNDER THE FSS Regulations 2016 for Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food.

Dr R K Sanghavi drew attention of the CEO that the FSSAI in its 2020 amendment has accepted to adopt TUL (Tolerable Upper Limits) as criteria for capping quantities of vitamins and minerals that are incorporated in the FSDU (Food for Special Dietary Use) products. He suggested that the same should be generalized and also be applicable for Health Supplement, Nutraceuticals and FSMP (Food for Special Medical Purpose) categories as well.

Mr Arun Singhal opined that TUL implying 'toxic' quantities the amounts of vitamins and minerals are allowable only as 50% of TUL and that also for FSDU. Also since we consume in usual food items various nutrients, the added load could have potential adverse outcome the Scientific Panel has accordingly taken the decision as such. When Dr Sanghavi clarified that TUL implies Tolerable and not Toxic upper limits Mr Singhal requested that a suitable representation in detail be made to FSSAI for the consideration of its Scientific Panel.

Dr R K Sanghavi asked the members of IDMA for any other clarifications and in absence of any more queries thanked Mr Arun Singhal for his suitably addressing the various issues that were put forth.

Mr George Patani, General Secretary, IDMA proposed a vote of thanks and assured Mr Arun Singhal that IDMA intends to work in close cooperation with the FSSAI to resolve all clarifications and provide the needed and deserving thrust to the nutraceutical vertical of healthcare.

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CBIC amends Central Goods and Services Tax Rules, 2017 (Fourteenth Amendment of 2020) - reg.

GST-Central Tax Notification No.94/2020, dated 22nd December, 2020

(Central Tax)

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

1. Short title and commencement;

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

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

2. In the Central Goods and Services Tax Rules, 2017 (hereinafter referred to as the said rules), in rule 8, for sub-rule (4A), with effect from a date to be notified, the following sub-rule shall be substituted, namely:-

"(4A) Every application made under rule (4) shall be followed by—

(a) biometric-based Aadhaar authentication and taking photograph, unless exempted under sub-section (6D) of section 25, if he has opted for authentication of Aadhaar number; or

(b) taking biometric information, photograph and verification of such other KYC documents, as notified, unless the applicant is exempted under sub-section (6D) of section 25, if he has opted not to get Aadhaar authentication done,

of the applicant where the applicant is an individual or of such individuals in relation to the applicant as notified under sub-section (6C) of section 25 where the applicant is not an individual, along with the verification of the original copy of the documents uploaded with the application in **FORM GST REG-01** at one of the Facilitation Centres notified by the Commissioner for the purpose of this sub-rule and the application shall be deemed to be complete only after completion of the process laid down under this sub-rule.".

3. In the said rules, in rule 9,-

(a) in sub-rule (1),-

(i) after the words "applicant within a period of", for the word "three", the word "seven" shall be substituted;

(ii) for the proviso, the following proviso shall be substituted, namely:-

"Provided that where-

(a) a person, other than a person notified under sub-section (6D) of section 25, fails to undergo authentication of Aadhaar number as specified in sub-rule (4A) of rule 8 or does not opt for authentication of Aadhaar number; or

(b) the proper officer, with the approval of an officer authorised by the Commissioner not below the rank of Assistant Commissioner, deems it fit to carry out physical verification of places of business,

the registration shall be granted within thirty days of submission of application, after physical verification of the place of business in the presence of the said person, in the manner provided under rule 25 and verification of such documents as the proper officer may deem fit.";

(b) in sub-rule (2),-

(i) for the word "three", the word "seven" shall be substituted;

(ii) for the proviso, the following proviso shall be substituted, namely:-

"Provided that where-

(a) a person, other than a person notified under sub-section (6D) of section 25, fails to undergo authentication of Aadhaar number as specified in sub-rule (4A) of rule 8 or does not opt for authentication of Aadhaar number; or

(b) the proper officer, with the approval of an officer authorised by the Commissioner not below the rank of Assistant Commissioner, deems it fit to carry out physical verification of places of business, the notice in **FORM GST REG-03** may be issued not later than thirty days from the date of submission of the application.";

(c) for sub-rule (5), the following sub-rule shall be substituted, namely:-

"(5) If the proper officer fails to take any action,-

(a) within a period of seven working days from the date of submission of the application in cases where the person is not covered under proviso to sub-rule (1); or

(b) within a period of thirty days from the date of submission of the application in cases where a person is covered under proviso to sub-rule (1); or

(c) within a period of seven working days from the date of the receipt of the clarification, information or documents furnished by the applicant under sub-rule (2), the application for grant of registration shall be deemed to have been approved.".

4. In the said rules, in rule 21,-

(a) in clause (b), after the words "goods or services", the words "or both" shall be inserted;

(b) after clause (d), the following clauses shall be inserted, namely:-

"(e) avails input tax credit in violation of the provisions of section 16 of the Act or the rules made thereunder; or

(f) furnishes the details of outward supplies in **FORM GSTR-1** under section 37 for one or more tax periods which is in excess of the outward supplies declared by him in his valid return under section 39 for the said tax periods; or

(g) violates the provision of rule 86B.".

5. In the said rules, in rule 21A,-

(a) in sub-rule (2), the words ", after affording the said person a reasonable opportunity of being heard," shall be omitted;

(b) after sub-rule (2), the following sub-rule shall be inserted, namely:-

"(2A) Where, a comparison of the returns furnished by a registered person under section 39 with

(a) the details of outward supplies furnished in **FORM GSTR-1**; or

(b) the details of inward supplies derived based on the details of outward supplies furnished by his suppliers in their **FORM GSTR-1,**

or such other analysis, as may be carried out on the recommendations of the Council, show that there are significant differences or anomalies indicating contravention of the provisions of the Act or the rules made thereunder, leading to cancellation of registration of the said person, his registration shall be suspended and the said person shall be intimated in **FORM GST REG-31**, electronically, on the common portal, or by sending a communication to his e-mail address provided at the time of registration or as amended from time to time, highlighting the said differences and anomalies and asking him to explain, within a period of thirty days, as to why his registration shall not be cancelled.";

(c) in sub-rule (3), after the words, brackets and figure "or sub-rule (2)", the words, brackets, figure and letter "or sub-rule (2A)" shall be inserted;

(d) after sub-rule (3), the following sub-rule shall be inserted, namely:-

"(3A) A registered person, whose registration has been suspended under sub-rule (2) or sub-rule (2A), shall not be granted any refund under section 54, during the period of suspension of his registration.";

(e) in sub-rule (4),-

(i) after the words, brackets and figure "or sub-rule (2)", the words, brackets, figure and letter "or sub-rule (2A)" shall be inserted;

(ii) the following proviso shall be inserted, namely:-

"Provided that the suspension of registration under this rule may be revoked by the proper officer, anytime during the pendency of the proceedings for cancellation, if he deems fit."

6. In the said rules, in rule 22,-

(a) in sub-rule (3), after the words, brackets and figure "the show cause issued under sub-rule (1)", the words, brackets, figures and letters "or under sub-rule (2A) of rule 21A" shall be inserted;

(b) in sub-rule (4), after the words, brackets and figure "reply furnished under sub-rule (2)", the words, brackets, figures and letters "or in response to the notice issued under sub-rule (2A) of rule 21A" shall be inserted.

7. In the said rules, in rule 36, in sub-rule (4), with effect from the 1st day of January, 2021,-

(a) for the word "uploaded", at both the places where it occurs, the word "furnished" shall be substituted;

(b) after the words, brackets and figures "by the suppliers under sub-section (1) of section 37", at both the places where they occur, the words, letters and figure "in **FORM GSTR-1** or using the invoice furnishing facility" shall be inserted;

(c) for the figures and words "10 per cent.", the figure and words "5 per cent." shall be substituted.

8. In the said rules, in rule 59, after sub-rule (4), the following sub-rule shall be inserted, namely:-

"(5) Notwithstanding anything contained in this rule,-

(a) a registered person shall not be allowed to furnish the details of outward supplies of goods or services or both under section 37 in **FORM GSTR-1**, if he has not furnished the return in **FORM GSTR-3B** for preceding two months;

(b) a registered person, required to furnish return for every quarter under the proviso to sub-section (1) of section 39, shall not be allowed to furnish the details of outward supplies of goods or services or both under section 37 in **FORM GSTR-1** or using the invoice furnishing facility, if he has not furnished the return in **FORM GSTR-3B** for preceding tax period;

(c) a registered person, who is restricted from using the amount available in electronic credit ledger to discharge his liability towards tax in excess of ninety-nine percent of such tax liability under rule 86B, shall not be allowed to furnish the details of outward supplies of goods or services or both under section 37 in **FORM GSTR-1** or using the invoice furnishing facility, if he has not furnished the return in **FORM GSTR-3B** for preceding tax period.".

9. In the said rules, after rule 86A, with effect from the 1st day of January, 2021, the following rule shall be inserted, namely:-

"**86B. Restrictions on use of amount available in electronic credit ledger:**

Notwithstanding anything contained in these rules, the registered person shall not use the amount available in electronic credit ledger to discharge his liability towards output tax in excess of ninety-nine percent of such tax liability, in cases where the value of taxable supply other than exempt supply and zero-rated supply, in a month exceeds fifty lakh rupees:

Provided that the said restriction shall not apply where–

(a) the said person or the proprietor or karta or the Managing Director or any of its two partners, whole-time Directors, Members of Managing Committee of Associations or Board of Trustees, as the case may be, have paid more than one lakh rupees as income tax under the Income-tax Act, 1961(43 of 1961) in each of the last two financial years for which the time limit to file return of income under subsection (1) of section 139 of the said Act has expired; or

(b) the registered person has received a refund amount of more than one lakh rupees in the

preceding financial year on account of unutilised input tax credit under clause (i) of first proviso of sub-section (3) of section 54; or

(c) the registered person has received a refund amount of more than one lakh rupees in the preceding financial year on account of unutilised input tax credit under clause (ii) of first proviso of sub-section (3) of section 54; or

(d) the registered person has discharged his liability towards output tax through the electronic cash ledger for an amount which is in excess of 1% of the total output tax liability, applied cumulatively, upto the said month in the current financial year; or

(e) the registered person is–

(i) Government Department; or

(ii) a Public Sector Undertaking; or

(iii) a local authority;or

(iv) a statutory body:

Provided further that the Commissioner or an officer authorised by him in this behalf may remove the said restriction after such verifications and such safeguards as he may deem fit.".

10. In the said rules, in rule 138, in sub-rule (10), with effect from the 1st day of January, 2021,-

(i) in the Table, against serial number 1, in column 2, for the figures and letters "100 km.", the figures and letters "200 km." shall be substituted;

(ii) in the Table, against serial number 2, in column 2, for the figures and letters "100km.", the figures and letters "200 km." shall be substituted.

11. In the said rules, in rule 138E,-

(a) in clause (b), for the words "two months", the words "two tax periods" shall be substituted;

(b) after clause (c), the following clause shall be inserted, namely:-

"(d) being a person, whose registration has been suspended under the provisions of sub-rule (1) or sub-rule (2) or sub-rule (2A) of rule 21A.".

12. In the said rules, after **FORM GST REG-30**, the following **FORM** shall be inserted, namely-

"FORM GST REG–31

[*See rule 21A*]

Reference No. Date: <DD><MM><YYYY>

To,

GSTIN

Name:

Address:

Intimation for suspension and notice for cancellation of registration

In a comparison of the following, namely,

(i) returns furnished by you under section 39 of the Central Goods and Services Tax Act, 2017;

(ii) outwards supplies details furnished by you in **FORM GSTR-1**;

(iii) auto-generated details of your inwards supplies for the period_____to_____;

(iv) _____(specify)

and other available information, the following discrepancies/anomalies have been revealed:

□ Observation 1

□ Observation 2

□ Observation 3

(*details to be filled based on the criteria relevant for the taxpayer*).

2. These discrepancies/anomalies prima facie indicate contravention of the provisions of the Central Goods and Services Tax Act, 2017 and the rules made thereunder, such that if not explained satisfactorily, shall make your registration liable to be cancelled.

3. Considering that the above discrepancies/anomalies are grave and pose a serious threat to interest of revenue, as an immediate measure, your registration stands suspended, with effect from the date of this communication, in terms of sub-rule (2A) of rule 21 A.

4. You are requested to submit a reply to the jurisdictional tax officer within seven working days from the receipt of this notice, providing explanation to the above stated discrepancy/anomaly. Any possible misuse of your credentials on GST common portal, by any person, in any manner, may also be specifically brought to the notice of jurisdictional officer.

5. The suspension of registration shall be lifted on satisfaction of the jurisdictional officer with the reply along with documents furnished by you, and any further verification as jurisdictional officer considers necessary.

6. You may please note that your registration may be cancelled in case you fail to furnish a reply within the prescribed period or do not furnish a satisfactory reply.

Name: Designation:

NB : This is a system generated notice and does not require signature by the issuing authority.".

F.No.CBEC-20/06/04/2020-GST

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

Note: The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide Notification No.3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R.610(E), dated the 19th June, 2017 and last amended vide Notification No.82/2020-Central Tax, dated the 10th November, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.698(E), dated the 10th November, 2020.

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CBIC notifies Instructions for time bound processing of Duty Drawback claims - reg.

Instructions No. 21/2020-Customs, dated 16th December, 2020

To,
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive)/ Customs and Central Taxes & All Principal Directors General/ Directors General under CBIC.

1. The undersigned is directed to state that to reduce the pendency and improve the rate of disposal of duty drawback claims, various timelines relating to duty drawback scheme have been conveyed in the Action Plan of CBIC for 2020-21 through DGPM's D.O. letter F. No. 503/01/2020-T dated 04.08.2020.

2. Among the action points, it has been mentioned therein that all remaining drawback claims should be positively disposed of by 31.03.2021 and that while doing so the target of disposing drawback within 7 working days should be achieved.

3. It is to inform that in the 5th meeting of the National Committee on Trade Facilitation (NCTF), it has been instructed that **at least 90% of Drawback should be credited within a time period of 3 days. Further, the refund may be deposited into the customer account in T+2 days.**

4. As regard the time taken for payment of duty drawback by banks to the exporters accounts, it is to mention that as per the Circular dated 24.04.2018 issued by the Office of the Principal CCA, CBIC, it has already been instructed to the authorized banks that the credit/refund of the drawback amount to the exporters' account may be done either on the same day of receiving the Computerized Customs Drawback Advice along with the supporting cheque or on the next working day.

5. In supersession of the timeline referred in para 2 above relating to disposal of drawback claims within 7 working days, it is instructed that the above-cited time-limit given by NCTF for crediting of duty drawback within a period of 3 days should be strictly complied with. All Zones are requested to take necessary action accordingly. A report on action taken in this regard may be sent to the Board by 25.12.2020.

F. No. 609/41/2018-DBK

Hasan Ahmed,
OSD (Drawback),
Central Board of Indirect Taxes and Customs,
Drawback Division, Department of Revenue,
Ministry of Finance,
New Delhi.

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

Notification No.113/2020-Customs (N.T.), dated 17th December, 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.110/2020-Customs(N.T.), dated 3rd December, 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 December, 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	57.05	54.70
2.	Bahraini Dinar	201.70	188.95
3.	Canadian Dollar	58.90	56.80
4.	Chinese Yuan	11.45	11.10
5.	Danish Kroner	12.30	11.85
6.	EURO	91.50	88.25
7.	Hong Kong Dollar	9.65	9.30
8.	Kuwaiti Dinar	249.60	233.70
9.	New Zealand Dollar	53.85	51.50
10.	Norwegian Kroner	8.65	8.35
11.	Pound Sterling	101.25	97.85
12.	Qatari Riyal	20.85	19.60
13.	Saudi Arabian Riyal	20.25	19.00
14.	Singapore Dollar	56.40	54.50
15.	South African Rand	5.15	4.80
16.	Swedish Kroner	9.00	8.65
17.	Swiss Franc	84.90	81.45
18.	Turkish Lira	9.75	9.15
19.	UAE Dirham	20.70	19.40
20.	US Dollar	74.45	72.75

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	72.55	69.85
2.	Korean Won	6.95	6.55

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

Bullo Mamu, Under Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

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DGFT MATTERS

Amendment in Para 2.14 (Modification of IEC) of Chapter 2 of Handbook of Procedures, 2015-2020.

DGFT Public Notice No.34/2015-2020, dated 24th December, 2020

1. In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy, 2015-2020, the Director General of Foreign Trade hereby inserts the following new sub-paras after sub para (c) of the existing Para 2.14 (Modification of IEC) as laid down in Chapter 2 of Handbook of Procedures, 2015-2020:

(d) In case of change in constitution of a PAN based IEC by way of merger, acquisition, liquidation, inheritance etc such that PAN of the new entity so formed is different from the earlier one, an IEC can be availed against the new PAN, if not existing already. Previous IEC(s) can also be operationally linked to the PAN/IEC of the new entity.

(e) An application for linking the obligations under the old/previous IEC may be submitted online to the jurisdictional RA of the new entity along with supporting documents. Concerned RA may sanction the given linkage after due scrutiny of the evidence provided by the applicant including submission of affidavits etc. After RA's approval, previous IEC(s) shall be treated as surrendered.

2. Effect of this Public Notice:

Provisions for modifying PAN based IEC has been introduced vide para 2.14 (d) and 2.14 (e) under existing Para 2.14 of Chapter-2 of Handbook of Procedures, 2015-2020.

File No. 01/93/180/20/AM-3/PC-2(B)/E-5200

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

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Mandatory online submission of Annual Return by Food Businesses w.e.f. FY 2020-21 - reg.

F.No.15(31)2020/FOSCOS/RCD/FSSAI, dated 18th December 2020

To

1. *Commissioner of Food Safety of all States/UTs and all Central Licensing Authorities,*
2. *CITO, FSSAI - for uploading on FSSAI.*

1. Clause 2.1.13 (1) of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 mandates:

"Every manufacturer and importer who has been issued a license shall on or before 31st May of each year, submit a return electronically or in physical form as may be prescribed by the concerned Food Safety Commissioner, in 'Form D-1' provided in Schedule 2 of these Regulations to the Licensing Authority in respect of each class of food products handled by him during the previous financial year.

Provided however that every licensee engaged in manufacturing of milk and/or milk products shall file half yearly returns for the periods 1st April to 30th September and 1st October to 31st March of every financial year in the form D-2, as provided in Schedule-2 of these regulations. Such returns will be filed within a month from the end of the period."

2. In the absence of any online provision for Food Business Operators to file returns online, presently, the returns (whether annual or half-yearly) are being submitted physically to the authorities. In the COVID pandemic phase, the same has been facilitated by allowing the submission by email and the last date has been extended till 31st December 2020 vide FSSAI order number 15(6)2020/FLRS/RCD/FSSAI dated 31st July 2020. However, FBOs are required to maintain the record of submission of returns. An inadvertent lapse of non-submission or loss of submission proof renders FBOs liable for hefty penalties.

3. The revised format of Annual Return has already been incorporated in Food Safety Compliance System (FOSCOS) and utility for online submission of Annual Return is being used by food business voluntarily. The provision of mandatory online submission of returns would not only facilitate the food business operators but also ensure ease of doing business and help in creation of national level database. It would further lead to other benefits such as:

- The food business need not maintain receipts and records of physical nature.
- FBOs shall be saved from inadvertent penalties [laid down under clause 2.1.13 of existing FSS (Licensing and Registration of Food Businesses) Regulations, 2011.
- Reminders for submission of annual returns would be sent digitally.
- Country/State-wise analysis of data would be possible.
- Updated data would be available, as till now all analysis is based on the data provided by the food businesses at the time of obtaining of license.
- For food businesses involved in manufacturing of milk and milk products, the half-yearly return (Form D2) shall be discontinued. They shall be required to file the annual return for manufacturers as per the revised format online.
- The new returns are compliance specific and based on the conditions of license and clauses as laid down in the existing Food Safety and Standards Regulations. This would help in targeted enforcement activities with limited staff.

4. In view of the above, it is decided that **online submission of Annual Returns on Food Safety Compliance System (FoSCoS - https://foscos.fssai.gov.in) shall be made mandatory for food businesses involved in manufacturing and importing of food products, wef FY 2020-21 (window for return filing for FY 2020-21 will open wef 1st April 2021 onwards)**. All licensing authorities are directed to refrain from insisting physical submission of returns and ensure that FBOs are well informed and facilitated to file the returns online on FOSCOS.

5. This issues with the approval of the Competent Authority.

Dr Shobhit Jain, Executive Director, Compliance Strategy, Food Safety and Standards Authority of India, New Delhi.

Companies (Auditor's Report) Order, 2020 amended (Second Amendment of 2020) - reg.

Corporate Affairs Notification No.S.O.4588(E), dated 17th December, 2020.

(Published in the Gazette of India on 18th December, 2020)

In exercise of the powers conferred by sub-section (11) of section 143 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following Order further to amend the Companies (Auditor's Report) Order, 2020, namely:-

1. Short title, application and commencement;

(1) This Order may be called the **Companies (Auditor's Report) Second Amendment Order, 2020.**

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

2. In the Companies (Auditor's Report) Order, 2020, in paragraph 2, for the figures, letters and word "1st April, 2020", the figures, letters and word **"1st April, 2021"** shall be substituted.

F.No.17/45/2015-CL-V.Part-I

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

Note*: The Principal Order was published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (ii), vide number S.O.849(E), dated the 25th February, 2020 and was subsequently amended vide Number S.O.1219(E), dated the 24th March, 2020.*

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Ban on Freebies to Doctors by Pharmaceutical Companies

Lok Sabha Unstarred Question No: 2134

Shri 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 23rd 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)

Ban on Freebies to Doctors by Pharmaceutical Companies

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(d): No.

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

Guidelines to manage Bio-Medical waste

Unstarred Question No: 2139

Shri Sanjay Kumar Bandi:

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

(a): whether the Government has issued any guidelines to manage biomedical waste generated in the hospitals due to treatment of patients affected by COVID-19, if so, the details thereof;

(b): whether the Government of Telangana is following the protocol mandated for disposal of biomedical waste generated in COVID-19 hospitals in the State, if so, the details thereof; and

(c): whether Government/Indian Medical Association have received any complaints from doctors in the COVID-19 hospitals of Telangana State in this regard, if so, the details thereof and the action taken thereon?

Answered on 23rd September 2020

A. (a): As informed by Central Pollution Control Board (CPCB), Corona Virus Disease of 2019 (COVID-19) related bio-medical waste can be disposed safely with existing infrastructure complying with provisions under Bio-Medical Waste Management Rules, 2016. However, realizing Pandemic situation, CPCB has prepared the guidelines for 'Handling, Treatment & Disposal of bio-medical waste generated during Treatment/Diagnosis/Quarantine of COVID-19 patients'. These guidelines were initially issued on 19.03.2019, thereafter revised depending on ground situation and evolving technical guidance. Last revision of guidelines was issued on 17.07.2020.

Further, CPCB has also issued guidelines on 15.09.2020, for monitoring of Common Bio-medical Waste Treatment and Disposal Facilities (CBWTFs) to ensure safe handling and disposal of bio-medical waste.

(b): CPCB developed waste tracking App named "COVID19BWM". Both Android Mobile and Web versions of software application were designed for waste generators, Common Biomedical Waste Treatment and Disposal Facility (CBWTF) Operators, State Pollution Control Boards (SPCBs) / Pollution Control Committees (PCCs) and Urban Local Bodies (ULBs). 1st version of the App has been introduced and a demonstration was given to SPCBs/PCCs and other stakeholders in May, 2020. SPCBs including Telangana State Pollution Control Board were directed to ensure usage of Tracking App:

- 8 out of 11 CBWTFs located in Telangana State are using the aforesaid Tracking App. CPCB vide it's letter dated 21.07.2020 issued Show Cause Notice to remaining 3 CBWTFs for not using Tracking App.
- Directions under section 5 of Environment (Protection) Act, were also issued to Telangana SPCB vide letter dated 11.08.2020, to ensure compliance to CPCB guidelines for effective management of bio-medical waste.
- 160 COVID-19 waste generators are registered on Tracking Application.

(c) As informed by CPCB and Indian Medical Association (IMA), no such complaints from doctors in the COVID-19 hospitals of Telangana State have been received.

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

Vaccines being Developed to Combat Coronavirus

Lok Sabha Unstarred Question No: 2142

Smt Preneet Kaur:

Shri Manish Tewari :

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

(a): the number of vaccines being developed in the country to combat Corona virus, along with the progress of trials, stage-wise;

(b): the vaccines that have graduated to the stage of clinical/human trials;

(c): the details of the places where such trials are taking place and the success rate of these trials conducted on human beings so far; and

(d): whether a triage or vaccination schedule to inoculate the 130 crore people of India has been conceptualized by the Government, if so, the details thereof and action taken thereon?

Answered on 23rd September 2020

A. (a) to (c): Central Drugs Standard Control Organisation (CDSCO) has informed that it has granted test license permission for manufacture of COVID-19 Vaccine for preclinical test, examination and analysis to the following manufacturers in India:

1. M/s Serum Institute of India Pvt., Ltd., Pune.
2. Ms Cadila Healthcare Ltd., Ahmadabad.
3. M/s Bharat Biotech International Ltd., Hyderabad.
4. Biological E Ltd., Hyderabad.
5. M/s Reliance Life Sciences Pvt Ltd., Mumbai.
6. M/s Aurbindo Pharma Limited, Hyderabad.
7. M/s Gennova Biopharmaceuticals Limited, Pune.

The Indian Council of Medical Research (ICMR), an autonomous organisation under the Department of Health Research, has informed that it is facilitating the following studies related to COVID-19 vaccines:

(i): An inactivated whole virion candidate vaccine (BBV152) for SARS-CoV-2 has been developed by Bharat Biotech International Ltd (BBIL) using the virus isolate (NIV-2020-770) provided by

ICMR-National Institute of Virology (NIV), Pune. Characterization of the vaccine candidate has been undertaken at ICMR-NIV followed by safety and tolerability studies in small animals like rats, mice and rabbits. Status of Clinical Trials is as follows:

- Phase I Clinical Trials alongwith parallel studies in hamsters and rhesus macaques have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II Clinical Trials are ongoing.

(ii): A DNA vaccine (ZyCov-D) has been developed by Cadila Healthcare Ltd. Pre- clincial toxicity studies were conducted in small animals: mice, rats, rabbits and guinea pigs. The vaccine has been found to be safe and immunogenic. Cadila has partnered with ICMR for conduct of parallel pre-clinical studies in rhesus macaques. Status of Clinical Trials is as follows:

- Phase I Clinical Trials have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II Clinical Trials are ongoing.

(iii): Serum Institute of India (SII) and ICMR have partnered for clinical development of two global vaccine candidates:

- ChAdOx1-S, which is a non- replicating viral vector vaccine developed by University of Oxford/AstraZeneca. This vaccine is undergoing phase III Clinical Trials in Brazil. Phase II/III bridging studies have been initiated by ICMR at 14 Clinical Trial sites. ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai is the lead institution.

  ICMR and SII have also partnered for clinical development of a glycoprotein sub-unit nanoparticle adjuvanted vaccine developed by Novavax from USA. The trial will be initiated in second half of October after the vaccine is manufactured by SII. The trial is led by ICMR-National AIDS Research Institute (NARI), Pune.

As per details provided by Department of Biotechnology (DBT)/Department of Science and Technology (DST), more than 30 vaccine candidates have been supported which are in different stages of development.

CDSCO has informed that it has granted permission to conduct Clinical Trials in various clinical trial sites such as New Delhi, Chennai, Chandigarh, Jaipur, Kanpur, Surat, Hyderabad, Pune, Mumbai, Ahmadabad, Bhubaneswar, Patna, Gorakhpur etc and the trials are on going.

(d): Presently, under Universal Immunization Program (UIP) vaccine distribution is based on Electronic Vaccine Intelligence Network (eVIN) system. eVIN is an internet based digital system to track routine immunization, vaccine stocks, storage temperature in about 25,000 dedicated cold chain storage points across the country as well as movement of vaccine. The vaccine is distributed to health facilities and outreach station sites, so as to reach in all areas. eVIN system is regularly monitored by health authorities at state and district level. eVIN system is being enhanced to address the needs for distribution and tracking of COVID-19 vaccine, when it becomes available. Further, a National Expert Group on COVID-19 vaccine has been constituted to guide the Government on:

- Prioritization of population groups for vaccination.
- Selection of COVID-19 vaccine candidates.
- Inventory management and delivery mechanism of the vaccine including making of vaccination process.
- Selection of delivery platforms.
- Cold chain and associated infrastructure for roll-out of COVID 19 vaccination etc.

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

Draft Environment Impact Assessment, 2020

Lok Sabha Unstarred Question No: 2163

Shri Hibi Eden:

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

(a): whether the Hon'ble Supreme Court has observed that Post-facto Environment Clearance is violative of the fundamental principles of environmental jurisprudence, if so, the details thereof;

(b): whether the Government has given any undertaking before the Madras High Court that no more extension of time will be granted for post facto Environment Clearances, if so, the details thereof; and

(c): whether there is any provision for post facto clearance in the EIA 2020 draft notification; and

(d): if so, the details thereof?

Answered on 23rd September 2020

A. (a) to (d): The draft EIA Notification 2020 does not provide for ex post facto clearance to violation cases. The Environment Clearance shall be granted only prospectively as also held by the Hon'ble Supreme Court in the case of Common Cause Vs. Union of India. 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 Hon'ble High Court of Madras, in W.M.P.No.3361 and 3362 of 2018 in the matter of Appaswamy Real Estates Ltd. and ors vs. Puducherry Environment Protection Association vide order dated 14.03.2018 extended the time window of the notification dated 14.03.2017 up to 13.04.2018. Since then, the Hon'ble Supreme Court has enunciated the Principles of ''Polluter Pays' and 'Proportionality' in various decisions viz. Indian Council for Enviro-Legal Action Versus Union of India (the Bichhri village industrial pollution case) (1996 [3] SCC 212); and Alembic Pharmaceuticals Ltd. Versus Rohit Prajapati & Ors. (2020 SCC Online SC 347), which forms the basis of the provisions regarding treatment of cases involving Violation in the Draft Environment Impact Assessment Notification 2020.

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

Medical Research

Lok Sabha Unstarred Question No: 2175

Shri Amar Singh:

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

(a): whether the Government has any plans to identify medical research separately rather than clubbing it with commercial ventures;

(b): if so, the details thereof;

(c): whether digital incentivisation plan is completely missing, if so, the details thereof;

(d): whether 2019 saw various frameworks initiated such as the National Digital Health Blueprint; and

(e): if so, the steps taken/to be taken by the Government in this regard?

Answered on 23rd September 2020

A. (a) & (b): No Sir. The present strategy of Government for promotion and co-ordination of basic, applied and clinical research including Clinical Trials and operational research in areas related to medical, health, bio-medical and medical profession and education through development of infrastructure, manpower and skills in cutting edge areas and management of related information thereto continues.

(c): The Indian Council of Medical Research (ICMR), an autonomous organization of Department of Health Research has informed that it has digitized many documents and started using online services for many activities such as extra-mural research project proposal submission and processing, Senior Research Fellowship, Research Associate ship applications, etc. Junior Research Fellowship exam is also now conducted online. All the payments are transferred digitally.

(d) & (e): Ministry of Health and Family Welfare has finalized and released the National Digital Health Blueprint (NDHB) as an architectural

framework for digital health initiatives in country. On 15th August, 2020 implementation of National Digital Health Mission (NDHM) has been initiated in 6 UTs on pilot basis.

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

Research in Biotechnology

Lok Sabha Unstarred Question No: 2185

Shri Raja Amareshwara Naik:

Smt Sangeeta Kumari Singh Deo:

Shri Bhola Singh:

Shri Vinod Kumar Sonkar:

Shri Sukanta Majumdar:

Shri Jayanta Kumar Roy

Q. Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:-

(a): whether the Government has set up Biotechnology Industry Research Assistance Council to promote Research and Development in Biotechnology;

(b): if so, the details thereof including funds allocated, R&D projects undertaken and their output during the last three years and the current year;

(c): the steps taken/being taken by the Government for the development of biotechnology as well as physical and human infrastructure in this sector;

(d): whether Biotechnology has varied applications and far reaching impact and implications in prominent sectors and if so, the details thereof; and

(e): whether there is urgent need to formulate regulatory framework for Biotechnology sector at national level, if so, the details thereof?

Answered on 23rd September 2020

A. (a) & (b): Yes, Biotechnology Industry Research Assistance Council (BIRAC) has been established by Government of India as a Public Sector Enterprise under Department of Biotechnology (DBT) in March, 2012 to foster and nurture the Startup Ecosystem and promoting Academia –Industry Collaboration in Biotechnology.

BIRAC, through its various funding schemes, supports all stages of product development right from proof-of-concept demonstration to product commercialization. The schemes support entrepreneurs, start-ups, Companies and academic institutions, to work on research ideas that have translational potential. The details of Programs undertaken and their output during the last three years and the current year including funds allocated may please be seen at Annexure – A.

(c):The Department of Biotechnology has a major focus on promotion of Biotechnology through Research & Development and also in terms of Human resource and Infrastructure Development. The key areas of support are Research and Development, Demonstration, Product Development and Commercialization, Capacity building through Human Resource Development and Infrastructure strengthening.

DBT's major focus is on building Centre of Excellence in different areas. DBT also has 16 Autonomous Institutions under its administrative control with focus on promoting and strengthening Biotechnology through national and international partnerships. The key activities supported under Human Resource and Infrastructure is enlisted at Annexure B.

(d): Biotechnology sector is recognized as the key driver for contributing to India's $ 5 Trillion economy target by 2024. The biotechnology sector, mainly due to its multi-disciplinary approach holds the potential to provide an array of solutions for challenges in Health, Agriculture, Environment, Energy and Industrial Processes. This includes innovative solutions for various societal challenges, use of biosimilars for helping millions of people around the world in battling life-threatening medical issues, development and manufacture of vaccines for nearly 60% of Global immunization. Improved crop varieties for increased production and providing better yields to the farmers while reducing the dependence on heavy consumption of water and energy. Industrial biotechnology is being channeled to produce biofuels that can help in ensuring cleaner environment. Biotechnology impacts each sector and the Biotechnology Sector in the country is growing rapidly.

(e): The Biotechnology Research and Development activities involving use of r-DNA technology and/ or hazardous microorganism are being regulated in accordance with Rules for the manufacture, use, import, export & storage of hazardous

microorganisms, GE organisms or cells,1989 of the Environment Protection Act, 1986. The Review Committee on Genetic Manipulation (RCGM) established under the Department of Biotechnology, Ministry of Science and Technology to monitor the safety of on-going research projects and activities (including small scale field trials, import, export etc) involving genetically engineered organisms.

Minister of Health & Family Welfare; Minister of Science and Technology; and Minister of Earth Sciences (Dr Harsh Vardhan)

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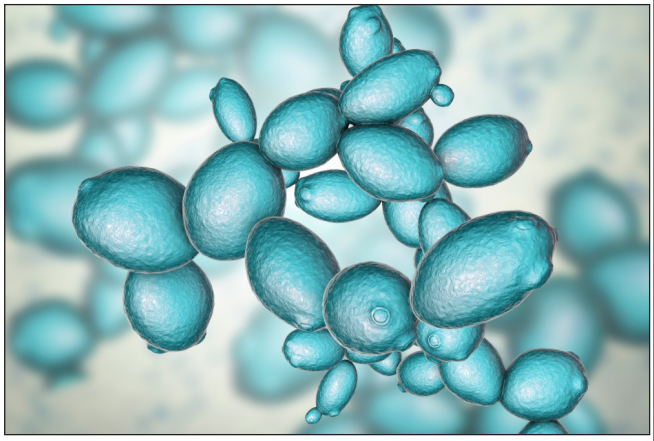
Brewprint: using yeast to make plant-based drugs

Many of our most important medicines are derived from nature, but the supply chain is vulnerable to upheavals such as wildfires or pandemics. Natalie Healey speaks to synthetic biologist Professor Christina Smolke who has successfully used yeast to produce plant-based drugs, such as opioids and tropane alkaloids.



Could yeast be an alternative way to develop drugs without undermining the supply chain? Credit: Shutterstock

It takes a lot of poppies to make serious painkillers:

Morphine is classed as an essential medicine by the World Health Organization, but it wouldn't exist without Papaver somniferum (better known as the opium poppy). Around 100,000 hectares of the flowers are cultivated every year – primarily in Australia, Spain, France, India, Turkey and Hungary – to meet demand for opioid medication worldwide. Approximately 800 tons of the natural opiates morphine and thebaine are extracted from the harvested straw, some of which are then chemically converted into higher value drugs, such as codeine, oxycodone and hydrocodone. Although fields of beautiful blooms sound idyllic, industrial poppy farming isn't easy.

Pests, disease and poor weather conditions can dramatically impact the yield. Plus, growing drugs from plants takes a long time and the poppies themselves contain very low levels of the active ingredient. If there is a spike in demand for opioid medicines, the supply chain can struggle to respond fast enough. These issues mean problems for the pharmaceutical industry, which in-turn means drug shortages for doctors and patients. Medicines derived from nature (as around 40% of our drugs are) are particularly vulnerable in times of uncertainty. During the Covid-19 crisis, we've seen that supply chain problems can have a human cost. In the spring, the US Food and Drug Administration reported a shortage of the opioids needed to safely keep patients on ventilators.

There could be a better way of making the rare compounds found in nature and avoiding similar supply chain issues, says Stanford University adjunct Professor Christina Smolke. In 2015, she and a small team of researchers proved that opioids could be produced using genetically-modified yeast.

Reimagine fermentation:

Smolke's breakthrough involved a process we've known about for centuries: fermentation. Give brewer's yeast a little sugar and under the right conditions it'll reward you with alcohol and carbon dioxide. Smolke figured fermentation had the power to speed up drug manufacturing – with yields seen in day or weeks, rather than months or years as with crop farming. It would mean supply could be easily increased if there was an unexpected event.

But plant-derived medicines are made from more complex stuff than ethanol or carbon dioxide. "If you look at the types of molecules plants make, they're incredibly complicated from a structural perspective," says Smolke. "The way they are able to survive and interact with their environment is through chemistry."

Source: Natalie Healey, Pharmaceutical Technology, 10.12.2020 (Excerpts)

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Coronavirus: How the virus interacts with cells

SARS-CoV-2 infections pose a global threat to human health and a formidable research challenge. One of the most urgent tasks is to gain a detailed understanding of the molecular interactions between the virus and the cells it infects. It must also be clarified, whether these interactions favour the multiplication of the virus or - on the contrary - activate defence mechanisms.

In order to multiply, SARS-CoV-2 uses proteins of the host cell. However, thus far no detailed information on the part of the human proteome - i.e. the total of all proteins occurring in human cells - that is in direct contact with the viral RNA existed.

Publication in Nature Microbiology:

This void has now been filled. Scientists from the Helmholtz Institute for RNA-based Infection Research (HIRI) Würzburg, the Julius-Maximilians-Universität Würzburg (JMU) and the Broad Institute (Cambridge, USA) have succeeded in creating the first global atlas of direct interactions between the SARS-CoV-2 RNA and the proteome of the human host. In addition, the authors identified important regulators of viral replication. Dr Mathias Munschauer from HIRI and Professor Jochen Bodem from the Institute of Virology and Immunobiology at JMU were responsible for the study. They present the results of their work in the latest issue of the journal Nature Microbiology.

In the biosafety level 3 suite at HIRI, the scientists infected human cells with the new Coronavirus, which uses RNA as genetic material. In a second step, they purified the viral RNA and identified the proteins bound to it. "Mass spectrometry allows us to accurately determine the host proteins that directly associate with the viral genome. In this particular case, we were able to perform quantitative measurements to identify the strongest specific binding partners," says Mathias Munschauer.

18 proteins, 2 key factors and 20 potential inhibitors:

"The atlas of RNA-protein interactions created in this way offers unique insights into SARS-CoV-2 infections and enables the systematic breakdown of central factors and defence strategies, a crucial prerequisite for the development of new therapeutic strategies," says Jochen Bodem. In total, the scientists identified 18 host proteins that play an important role during SARS-CoV-2 infection.

According to them, the two factors CNBP and LARP1 are particularly interesting. Using genetic tools, the authors identified the exact binding sites of these two host proteins in the viral genome and showed that they can specifically inhibit the replication of the virus. According to Mathias Munschauer, the characterisation of LARP1 as an antiviral factor is a major finding: "The way LARP1 binds to viral RNA is very interesting, because it is similar to the way LARP1 regulates certain cellular messenger RNAs that we already know. This in turn provides insights into possible mechanisms of action."

The multidisciplinary nature of the study also enabled the identification of 20 small molecule inhibitors of host proteins that bind SARS-CoV-2 RNA. The authors show that three out of four inhibitors tested actually inhibit viral replication in different human cell types. This result could open up new ways to treat infections with SARS-CoV-2 and other RNA viruses.

(Story: Materials provided by University of Würzburg. Original written by Tim Schnyder/Gunnar Bartsch. Note: Content may be edited for style and length).

Source/Courtesy: University of Würzburg, Science Daily, 21.12.2020 (Excerpts)

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IDMA HOLIDAYS FOR THE YEAR 2021

1.	**1st January**	Friday	New Year
2.	**26th January**	Tuesday	Republic Day
3.	**11th March**	Thursday	Maha Shivratri
4.	**29th March**	Monday	Holi (Second Day)
5.	**2nd April**	Friday	Good Friday
6.	**13th April**	Tuesday	Gudi Padwa
7.	**16th August**	Monday	Parsi New Year
8.	**31st August**	Tuesday	Gokulastami (Dahi Handi)
9.	**10th September**	Friday	Ganesh Chathurthi
10.	**15th October**	Friday	Dussehra (Vijaya Dashami)
11.	**4th November**	Thursday	Laxmi Puja
12.	**5th November**	Friday	Diwali Balipratida

India requires Rs.80,000 crore for vaccine distribution next year: SII

Pune-based vaccine-maker Serum Institute of India, which has partnered with AstraZeneca to manufacture the Oxford-AstraZeneca vaccine, on Saturday,19.12.2020 said that the country would require a massive funding of Rs.80,000 crore for distribution of the Covid vaccine for the next one year.

The Central Government plans to vaccinate nearly 30 crore people in the first phase of drive. It will be offered to one crore healthcare workers, along with two crore frontline and essential workers and 27 crore elderly, mostly above the age of 50 years with comorbidities.

Three vaccine candidates - Serum Institute-Oxford's Covishield, Bharat Biotech's Covaxin and Pfizer vaccine are in the fray for emergency use authorization. The Central Drugs Standard Control Organisation (CDSCO) has sought additional data from the Serum Institute as well as Bharat Biotech to get approval. Speaking about the logistics of the vaccine after it is granted approval, Dr Satish D Ravetkar, Executive Director of Serum

Institute of India said, "The funding for such large scale distribution would be huge, and India should be ready with a funding of around Rs.80,000 crore for next one year for distribution of the Covid-19 vaccine."

Source: IANS, The Times of India, 20.12.2020

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FSSAI forms three expert committees to examine non-food & food ingredients

The Food Safety and Standards Authority of India (FSSAI) has now constituted three expert committees to examine the approval of non-specified foods and food ingredients regulations 2017 among other things.

In order to fast track the scrutiny of applications in a time-bound manner, the competent authority has approved the formation of the three expert committees to examine all the applications. These committees, according to the FSSAI note, are expected to meet at frequent intervals to facilitate speedy clearances of applications.

On the key objective of the three expert groups, industry experts noted that it was much wanted especially when food processing companies were using new ingredients or a new food not known in India or an extract or herb coming from abroad which might not have safety data and come under the category of non-specified foods for which standards have not been given in the Food Safety and Standards Act, 2006. The food ingredients could be flavour, colour, additives, stabilisers, preservatives, stated industry experts.

"In the wake of so many regulations prescribing standards and the way things have to be done under the Food Safety and Standards Act had been put in place during various periods of time. Regulations for primary ingredient, additives, residues, milk and milk products, oil products including Nutraceuticals and Functional Foods are standards and not just specification which means the way a type of food product would be regulated. Therefore an expert committee comprising three groups will enable assessment of applications in an efficient and time-bound manner," they added.

Now these expert members depending on the food category in which the application is received could invite the Chairman of the concerned Scientific Panel as and when required.

The first Expert Committee comprises Prof H P Sachdev, Senior Consultant, Paediatrics and Clinical Epidemiology; Sita Ram Bharatia, Science and Research, New Delhi; Dr Suman Kapur, Dean, International Programmes and Collaborations, BITS Pilani, Hyderabad campus; Prof R K Khar, Principal (Retd), Pharmaceutical Scientist, BS Anangpuria Institute of Pharmacy, Faridabad; Dr Lalitha Gowda, former Chief Scientist, CFTRI; and Dr Supriya Bhalerao, Ayurveda, Interactive School of Research for Health Affairs (IRSHA), Bharati Vidyapeeth, deemed to be University, Pune.

Another Expert Committee has Dr Bikas Medhi, Professor, Pharmacology, PGI, Chandigarh; Dr V Kalaiselvan, Principal Scientific Officer, Indian Pharmacopeia Commission; Dr K Madhavan Nair, former Scientist, Micronutrient Research Group, Department of Biophysics, National Institute of Nutrition, (ICMR), Hyderabad; Dr R K Marwaha, Scientific Advisor, endocrinology, International Life Sciences Institute, India, and Advisor, Project, Department of Endocrinology, AIIMS, New Delhi; and Dr Balkumar Marthi, former Scientist in Biological Research, including

food and nutrition, besides expertise in human studies, claims substantiation, analysis, GMP and HACCP.

Expert Committee 3 is represented by Dr D B A Anantha Narayana, Expert Member (Retd), Indian Pharmacopeia Commission; Dr Renuka Munshi, Professor, BYL Nair Hospital; Dr Prema Ramachandra, Director, Nutrition Foundation of India; Dr Dheeraj Shah, Professor of Paediatrics, University College of Medical Sciences, New Delhi; and Dr B Dinesh Kumar, Scientist-F and HoD, Department of Toxicology, National Institute of Nutrition, Hyderabad.

The FSSAI has also provided Terms of Reference where the Expert Committee will need to undertake preliminary risk assessment of the applications under non-specified foods and food ingredients. The experts can seek clarification from FSSAI before granting approval and also could reject applications.

If need be, the Expert Committee could also refer the application to the concerned Scientific Panel for further safety evaluation or any other expert or institution for scientific opinion, according to Dr N Bhaskar, Advisor, Safety & Standards, FSSAI.

Source: Nandita Vijay, Pharmabiz, 23.12.2020

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Cipla to experiment with Covid drug Remdesivir Composition to reduce effect on Kidneys

Mumbai-based drug maker Cipla has submitted a proposal before the Government's Subject Expert Committee (SEC) to change Remdesivir's composition in order to reduce the Drug's Adverse Effects on the kidneys.

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Antiviral medicine Remdesivir is one of the most closely watched drugs in the Global Clinical Trials against the Covid-19 disease. In a meeting held on 17-18 December, the SEC had asked the company to conduct a bioequivalence study i.e., compare different proprietary preparations of the same drug — one which is presently available in the market and another with the proposed changes.

"SEC in the meeting noted that in the proposed formulation SBECD (sulfobutylether-b-cyclodextrin) is replaced with Polysorbate 80 and PEG 300 with the intention to reduce the renal toxicity," read the minutes of the meeting, uploaded on the Central Drugs Standard Control Organisation's (CDSCO) website Tuesday, 22.12.2020.

The CDSCO is the Health Ministry arm that regulates quality of drugs and vaccines in the country while the SEC advises the Drugs Controller General of India on applications seeking approvals for new drugs and vaccines. SBECD is used to make drugs more soluble for intravenous administration, whereas polysorbate is a thickening agent that is used in personal care products and also as a food additive. PEG is used as an inactive substance in drug manufacturing, as a vehicle for drug transportation in the human body.

Along with the bioequivalence study, the SEC has also asked Cipla to conduct Clinical Trials to assess renal toxicity of the new formulation. "Accordingly, the firm should submit bioequivalence study protocol and Clinical Trial protocol to CDSCO for further review by the committee," the minutes of the meeting noted.

Remdesivir's effects on kidneys:

The possible impact of Remdesivir on the kidneys is not yet known but an assessment of renal function in Covid-19 patients is recommended before and during treatment with Remdesivir.The European Medicines Agency, which is responsible for regulating drugs in the continent, had in October announced that it will determine whether there was a causal relationship between acute kidney injury and Remdesivir.

According to a study published in Journal of *American Society of Nephrology,* animal studies have associated SBECD accumulation with liver and renal diseases. However, these had occurred in animals at doses 50 to 100 times higher than expected in a five-to-10-day Remdesivir course. The study, however, also said that "available data from a single randomized, controlled trial in Covid-19 did not demonstrate an increased risk of Renal Adverse Events in patients randomized to receive Remdesivir".

Source: Himani Chandna, ThePrint, 23.12.2020

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Kerala Government Panel to suggest PPP model to set up COVID-19 vaccine production units

For representational purposes. (Photo | AP)

The five-member committee formed by the Government to explore the possibility of developing a vaccine against COVID-19 has concluded that it is impractical at this stage. However, it will recommend to set up vaccine manufacturing units on Public-Private Partnership (PPP) model with the manufactures of the vaccine candidates that are in trial phase. On November 16, the state constituted a five-member committee to explore possibilities of collaborations for vaccine production and having a vaccine development unit, including protein-based biologicals like enzymes and cancer drugs.

"There are some practical difficulties. The vaccine is the need of the hour. For developing it, painstaking research efforts, resources and funds are required. Most importantly, it will take time," said a member of the committee.

On collaborative efforts, the member said big pharmaceutical companies developed the leading vaccine candidates and persuading them to set up production units in the state is a herculean task.

"Convincing them requires efforts from the Chief Minister. It also remains doubtful whether such companies will make efforts to set up production units at their own cost. If they are unenthusiastic, setting up facilities on PPP model will have to be explored," added the member.

As per sources, a few days ago, the committee decided to prepare an agenda for making a firm proposal based on the need for setting up an effective manufacturing facility for biologicals. Meanwhile, the committee, which will submit its report to the Government, will highlight the possibility of having a PPP and bringing in institutions like the Kerala State Drugs and Pharmaceuticals Limited, Institute of Advanced Virology and State Public Health Lab for vaccine production.

Earlier, while forming the committee, Health Department officials said that it would hold talks with Pharmaceutical companies, which have claimed to have developed vaccines for making use of their manufacturing licence to set up production units. The companies under consideration are Serum Institute of India, Bharat Biotech and Zydus Cadila.

Following some talks with Bharat Biotech and their letter on September 15, the Chief Minister chaired a meeting on vaccine trials and a five-member committee was constituted with T Jacob John, former Head of the Departments of Clinical Virology and Microbiology at Christian Medical College, Vellore, as its Chairman.

Source: Dileep V Kumar, Express News Service, The New Indian Express, 22.12.2020 (Excerpts)

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India successfully shouldered its responsibility as Pharmacy of the World amid COVID: Vikas Swarup

India emerged as a net provider of health security and successfully shouldered its responsibility as the Pharmacy of the World, said Vikas Swarup, Ministry of External Affairs Secretary (West), at the UNGA Special Session on Covid-19 on Tuesday, 22.12.2020.

Speaking virtually at the 31st Special Session of the UN General Assembly in response to the Covid-19 Pandemic on Tuesday, 22.12.2020 Swarup said, "Within two months of the India testing to more than 2,000 today. From having almost no domestic manufacturing of PPE kits, we have become the second-largest manufacturer.

More than 17,000 dedicated Covid facilities were set up with 1.6 million isolation beds. Digital tools such as the Aarogya Setu App were developed and are being effectively used for extensive contact tracing." On India's role to combat the Covid-19 pandemic, the top official said that India has emerged as a net provider of health security and successfully shouldered its responsibility as the Pharmacy of the World, sending consignments of medicines and medical supplies to almost 150 partner countries.

He further said that India's "timely, graded and proactive" response to the Covid-19 pandemic and calculated measures were designed to protect the country's huge population and ensure that minimal damage is caused to the economy.

"The Government has also been doing its best to ensure that the economy and the livelihoods of people are not adversely hampered. We announced a massive USD 266 billion stimulus package, amounting to almost 10 percent of our gross domestic product, directed at helping low-income groups, marginal farmers, small businesses, migrants and those in the informal sector.

To ensure food security, the world's largest food transfer programme was initiated to give extra rations to 800 million people," Swarup said. Emphasising that the ongoing crisis has laid bare the gap that exists in global cooperation and governance structures of multilateral organisations, he said: "It is important that we make reformed multilateralism our guiding principle."

The MEA Secretary reiterated that India's vaccine production and delivery capacity will be used to help humanity in fighting this crisis. "India will also help all the countries in enhancing their cold chain and storage capabilities for delivery of the vaccine," he added.

Source: IANS, The New Indian Express, 22.12.2020 (Excerpts)

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Sync between Pharma Policies and Patient Safety: Need of the hour

The pandemic has brought along many revelations and lessons forthe pharmaceutical industry aswell, deliberating the need to rethink the policies we have been making so far. Along with India, the world witnessed the value of inter-dependence to ensure the demand to produce most essential drugs are met domestically. When we speak of *atmanirbhar* future, we should not ignore the fact that the contours of self-reliant India will take its own time to unveil. And most importantly, whether it is in the best interest of the patients or not at all?

We need to strengthen the domestic manufacturing before "promising big" and robust policy decisions are a crucial part of this story. The pandemic has highlighted certain areas of improvement for the Indian pharmaceutical industry inthe global pharmaceutical supply chain and our dependence on the global world for various drugs; the road to make India self-sufficient is not easy.

The Pharmaceutical Export Promotion Council wrote to the Government of India, raising their concerns about delay in consignment clearances of basic chemicals required to make drugs for COVID-19 treatment. The self-reliance rhetoric falls flatin the absence of quality drugs which are led by innovations, not just in India but around the world. What we need to understand at this point is that evidence-based solutions, and not policies that deter innovations from coming to India and making these innovative products unavailable to Indian patients.

In the middle of a pandemic, we also find ourselves struggling with policies that are critical to Indian pharmaceutical sector. For instance, until last year, Para 32 of the Drug Price Control Order (DPCO) says that the price cap won't apply if a newdrug is developed through a unique and indigenous process. So, for instance, if acompany, whether global or Indian, sets up its R&D centre here, and patented inIndia, would still be allowed to launch that product outside the purview of price control over a period of five years. Now, after many deliberations, the Government is looking at revoking the provision for global player, following which, if a product is researched abroad, and even they register for a patent in India, they cannot get exemption from price control. (Following an Amendment in January 2019, exemption isprovided if drug is patented in India irrespective of where is it is developed. Hence this para may be deleted)

Such restrictive policies deter global innovations from investing in the Indian pharmaceutical market. Global researchers deserve the value for the irinnovations, and such restrictions stand in the way. Moreover, until we strength enour own domestic market, it is important to support policies that foster innovation.

We need regulatory policies that welcome innovations. With self-reliance leading the healthcare space, we might lose out on what the world has to offer. Restrictive policies in imports can pose a threat to accessibility of quality healthcare in thecountry. The Government, for nearly a decade now has been pushing the use ofgeneric medicines with an intent of making healthcare affordable. However, wemust look at providing innovative healthcare solutions without compromising onthe patient safety and standard treatment guidelines. Looking at price of drugsalone to make treatment affordable and not the entire healthcare

system, will be aclassic case of missing the wood for the trees.

The pandemic also highlighted how NCDs continue to put many vulnerable group sat an added risk. From the rising CVD burden to be the diabetes capital of theworld, India has many battles to fight. These challenges can only be countered by using new innovations. The choice of these drugs should not be decided by geography but efficacy of the drugs. The argument should be around patient safety and not where the drug is manufactured. Considering the current situation, for drug companies and scientists worldwide, there is only one priority now— fight.

Source: Health News, ET Health World, 22.12.2020

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Pharma revenue, margins likely to remain healthy in next fiscal: ICRA

Representational image.

With inelastic demand for drugs and resumption of production to the near pre-Covid levels by Q3 FY2021, revenue growth for IPM (Indian Pharmaceutical Market) is expected to be 7-9 percent in FY2021 despite muted Growth in Q1 FY2021, ratings agency ICRA said in a report. The revenue growth in FY2022 is expected to be slightly better at 8-11 percent, though lower incidences of acute diseases, lesser OPDs and elective surgeries may continue to have some bearing on Growth and will depend upon the course of the pandemic, the report added.

The API/KSM (Key Starting Materials) supplies from China, which were initially hit due to the Covid-19, have resumed gradually since March 2020 and are nearing the normalcy levels. Approximately 60 percent of the APIs/ KSM consumed, is imported from China. Production disruptions owing to restrictions in mobility of manpower and materials eased significantly after the first few weeks of the lockdown.

At present, the production has reached 90-95 percent of the pre-Covid levels. The profitability has improved in H1 FY2021 owing to lesser overheads during the lockdown period - primarily travel, marketing and selling expenditure.

The trend is expected to reverse once the pandemic situation resolves and FY2022 margins will remain in line with the pre-Covid levels, the report said. The credit metrics of leading Pharma companies are expected to remain stable in view of future growth prospects in regulated markets and relatively strong balance sheets, ICRA said adding that the capital structure and coverage indicators are expected to remain strong despite pressure on profitability and a marginal rise in debt levels given the inorganic investments.

(Only the Headline and Picture of this Report may have been reworked by the Business Standard staff; the rest of the content is auto-generated from a syndicated feed.)

Source: IANS, Business Standard, 23.12.2020

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Health Ministry to hold talks with stakeholders to address huge demand-supply gap of CP for COVID-19 treatment

In order to encourage use of Convalescent Plasma (CP) therapy in COVID-19 patients, the Union Health Ministry will soon hold talks with stakeholders like blood banks and hospitals to address the huge demand-supply gap of CP in the country currently widely used for treatment of moderate to severely ill COVID-19 patients.

Repeated correspondences on the issue have been made to the Drugs Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) to encourage use of CP therapy in COVID-19 patients. An evidence based advisory of ICMR had also been issued to the stakeholders recently to address inappropriate use of CP in COVID-19 patients.

Barring a few states like Gujarat, Rajasthan and Delhi where CP therapy is going on successfully, Maharashtra has been struggling to keep its plasma banks functional due to price control issues which have not yet received its logical end despite several talks between the state Government and plasma banks.

Meanwhile, the Central Government has also been considering removing CP therapy from the National Clinical Management protocol for COVID-19. However, Clinicians have contested that Clinical Trial studies to prove the efficacy of CP therapy are still ongoing and need some more time to arrive at the right conclusion in the interest of patient safety.

As per the ICMR advisory, convalescent plasma therapy or passive immunotherapy has been tried in the past for treatment of viral infections like H1N11, Ebola and SARS-CoV-13 etc. Benefits of CP therapy in improving the clinical outcomes, reducing severity of disease, duration of hospitalization and mortality in COVID-19 patients are dependent on the concentration of specific antibodies in convalescent plasma that could neutralize the effects of SARS-CoV-2.

ICMR conducted an open label phase II multicentre randomised controlled trial in India across 39 Public and Private Hospitals on use of convalescent plasma in the Management of cases with moderate COVID-19 disease (PLACID Trial). It was concluded that CP therapy did not lead to reduction in progression to severe COVID-19 OR all-cause mortality in the group that received CP therapy as compared to the group that did not receive CP therapy.

PLACID is the world's largest pragmatic trial on CP therapy conducted in 464 moderately ill laboratory confirmed COVID-19 affected adults in a real world setting wherein no benefit of use of CP therapy could be established. Similar studies conducted in China and Netherlands have also documented no significant benefit of CP therapy in improving the clinical outcomes of hospitalised COVID-19 patients.

As per the ICMR advisory, indiscriminate use of CP therapy is not advisable. It is speculated that convalescent plasma having low concentration of specific antibodies against SARS-CoV-2 may be less beneficial for treating COVID-19 patients as compared to plasma with high concentration of such antibodies.

This advisory therefore embraces the principle that a potential donor for convalescent plasma should have sufficient concentration of antibody working against COVID-19 as narrated in the matrix below. It also highlights that presence of antibody against COVID-19 in a potential recipient makes transfusing convalescent plasma a futile intervention.

CP therapy therefore should only be used, as advised by ICMR for management of COVID-19 when specific criteria as mentioned are met. The appropriate age for CP donation is between 18 and 65 year three to seven days from onset of symptoms but not later than 10 days. There should be screening to rule out ABO incompatibility and blood borne pathogens such as HIV, HBV, HCV etc. There should be required concentration of IgG antibody against COVID-19 Titre of 1:640 (ELISA) or 13 AU (Absorbance Unit)/mL9 (CLIA) or Neutralising Antibody Titres of 1:80 (PRNT/MNT), as per the advisory.

Source: Shardul Nautiyal, Pharmabiz, 24.12.2020

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Strict Rules to bring in transparency in derma product landscape

Strict rules and the setting up of a Central Cosmetics Laboratory are expected to strengthen and bring in transparency to manufacture, quality control and market tracing on the derma product landscape. This according to experts not only provides better clarity on manufacture and imports to the fast growing derma care industry but prevents counterfeit versions to safeguard access to misbranded and adulterated products which are unsafe for use. Derma care covers face, hair and hand. Only the color cosmetics including hair dyes and lipsticks come specifically under the beauty classification.

Noting that the cosmetics regulations are now in a separate category with assigned rules under the purview of the Drugs and Cosmetics Act, Dr B R Jagashetty, former National Advisor to CDSCO, said that the industry will now have a proper direction. The creation of Central Cosmetics Lab and making it appellant lab will help a lot in the coming years. Even though the cosmetics rules have been carved out from the Drugs & Cosmetics Act into the new regulation, the Chapters and Rules have been expanded to include import, import registration and new cosmetics, said Dr D B A Narayana, expert on regulatory affairs.

However these rules would have introduced a norm for the regulation of sales either by way of licensing or registration which will help drug inspector to trace back the actual manufacturer in case of substandard or adulterated or spurious cosmetics are found in market, he added. Terming it as a long awaited regulation, Dr Narayan said all along cosmetics received 'band aid' treatment where rules were mostly patched up. Even though cosmetics do not need to be regulated as strictly as drugs, except for their safety on application and use, yet for hair dyes, lipsticks and eye liners the safety concern was much needed.

The new rules for import of cosmetics are now in place with provisions for registration with the CDSCO. This is because globally there could be several new ingredients and substances being added to cosmetics to improve the skin texture. But if these ingredients have not been used in

India, one would not know its impact on people of different natives, now with the central cosmetics lab all imported products will get tested. More over a dedicated facility is needed because testing for cosmetics is different from the drug analysis. While drug tests include analysis of impuritiesties, related substances and its dosage forms, in the case of testing is more on sensorial stability and safety of applications, said Dr Narayana.

Further, the new rules rightly insist that all imported cosmetics need to comply with the Bureau of Indian Standards where they exist. If there are no stipulations in BIS, then the manufacturer has to provide their own specifications against which the Central Cosmetics Lab will conduct comprehensive testing for contaminants which are heavy metals and microbiology related, he said.

Source: Nandita Vijay, Pharmabiz, 24.12.2020

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Haryana set to become hub of medical devices as around 100 industrial units set up plants in the state

Haryana, the erstwhile popular hub of pharmaceutical formulations in the northern part of the country, is now turning out to be the centre of the medical devices industry to manufacture and sell elite medical diagnostic instruments. Around 100 medical devices industrial units have already established their plants in the state at Karnal.

This exponential rise in the number of manufacturing units for medical instruments and equipment is happening at a time when many formulation units are closing down their production facilities and moving out of the business sector due to lack of supportive industrial policies, says P K Gupta, President of the Haryana Pharmaceutical Manufacturers' Association (HPMA). He said, among other issues, bureaucracy is the main hurdle for the development of the small scale industry sector in Haryana.

"The industry policies of the Government most often become detrimental to the growth of small scale units, or otherwise I would say that bureaucracy is the main hurdle for the growth of the SSI sector. This is not only for the Pharma manufacturing industry, but for all the industries. In Haryana, I understand that about 10% of the total units were closed down due to cumbersome regulatory policies and several more units are shrinking now without any growth. The industry cannot survive if there is no business growth as the day-to-day expenses are increasing without limit. In addition to this, the regulatory department is also acting not supportive to the industries."

However, Gupta said, the state Government brings out certain attractive projects to retain the existing units and tries to bring more companies to Haryana for a sustainable Pharma market. But the implementing agencies do not act properly for the development of the industry.

HPMA finds that the Government's industry as well as regulatory policies helps only the multinational giants and the medium level players. Such companies will remain, and the SSI units will vanish from the scene very shortly unless the Government takes a favorable stance towards the small scale players.

"In an interaction with Pharmabiz, the President of the HPMA said Haryana was once a prosperous industry base for Pharmaceutical formulations and it was on the top. On every one out of three strips of medicines, one Haryana based manufacturer's name was there. About 25 years ago there were 300 actively operating manufacturing units which supplied medications to the entire nation. When the rigorous Schedule M norms came, Haryana Pharmaceutical Manufacturers Association worked very hard along with the Government to upgrade the technologies in the facilities of the companies to become at par with global regulations and enhance the capacities.

However, in later years due to tax free benefits in Uttarakhand and Himachal Pradesh states, several units closed down their facilities here and moved to those states taking incentives. Gradually the Haryana Pharmaceutical sector lost its wonderful industry atmosphere", said Gupta.

On the side of challenges faced by the Pharma sector, the industry visionary said unlike south Indian states the pharmaceutical manufacturers in Haryana faces one crucial problem and that is with regard to technical personnel and skilled labourers. As regards raw materials and distributors, they have no issues. But availability of technical-hands for the industry still continues to be a burning issue.

Talking about the developmental activities in the manufacturing sector, P K Gupta said HPMA is taking initiative with the Government to set up one Pharma Park in Karnal. There is a proposal from the central Government to set up one API Park and a medical devices park somewhere in Haryana. State Government has good vision about the future prospects of the pharmaceutical

sector although they do not provide any help for the SSIs. "We are hopeful that one Pharma park will be set up in the state somehow".

Source: Peethaambaran Kunnathoor, Pharmabiz, 23.12.2020

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ASHC pitches for Madurai as the ideal location to set up proposed All India Institute of Siddha

Hailing the initiative being taken by the Tamil Nadu Chief Minister with the Central Government to approve one All India Institute of Siddha (AIIS) in the state, the Madurai-based Association of Siddha Hospitals and Clinics (ASHC) has wanted the Prime Minister and the Chief Minister to select Madurai as the ideal location for the proposed All India Institute. ASHC's demand comes in the wake of the Chief Minister's request to the Prime Minister to set up one All India Institute of Siddha in Chennai.

In Madurai district and nearby localities, there are around one hundred medicine manufacturing companies operating and out of them prominent 25 units are of Siddha and Ayurveda systems. ASHC argues that work for the central Government approved establishment of the All India Institute of Medical Sciences (AIIMS) in Madurai has already begun, so it will benefit the development of the all India Siddha institute. Further, the location is easily accessible through road, railway and air (Madurai Airport).

According to Dr Jayavenkatesh, President of ASHC, if the National Institute of Siddha is opened in Madurai, the city will become an iconic medical education hub for teaching and treating. Further, it will cater to the healthcare and medical education needs of thousands of people and students of southern Tamil Nadu. Madurai is surrounded by the districts Dindigul and Trichy (North), Sivagangai (East), Theni (West) and Virudhunagar (South) which depend on Madurai for medical and education facilities. Besides, the soil in these resourceful districts is fertile for herbs and medicinal plant cultivation.

"Chennai has already got one central institute, the National Institute of Siddha (NIS) at Thambaram. The Central Council of Research in Siddha (CCRS) under the Ministry of Ayush is also working in Chennai. In addition to this, one Siddha medical college and hospital is run there by the state Government. So, the Government should consider Madurai as the ideal place for the establishment of the All Institute of Siddha," says Dr Jayavenkatesh who has taken the initiative with the central and state Governments to shift the proposed institute from Chennai to Madurai.

He said apart from teaching and treating facilities, the proposed AIIS will generate employment for several people and help farmers to cultivate medicinal plants in the southern districts.

The Siddha practitioners in Madurai and nearby districts feel that since Madurai is a tourist centre, the domestic arrivals and the inflow of overseas tourists to the temple city will increase when these two national medical institutes, AIIMS and AIIS, are established once in Madurai. It is also accessible for people from Kerala, who visit the temples in Madurai and nearby districts during festival seasons. The Madurai District Tiny and Small Scale Industries Association (MADITSSIA) has also wanted the state Chief Minister to recommend for the proposed institution in Madurai. The President of the Association in his letter to the Chief Minister said Madurai is one of the important areas where practice of Siddha medicine was first started decades ago.

Meanwhile, Dr T Thirunarayanan, Secretary of the Chennai based Centre for Traditional Medicines and Research (CTMR), an exclusive research institute for Siddha medicines, has opined that if Siddha has to be popular across the country the Central Government sponsored institute should be established outside of Tamil Nadu. He suggested Bengaluru as the ideal place for the AIIS. However, he said, since the state Chief Minister has recommended it for the state, it can be set up either in Trichy or in Coimbatore.

Source: Peethaambaran Kunnathoor, Pharmabiz, 22.12.2020

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Government should come out with policies supportive to Pharma MSMEs engaged in formulations: Jagdeep Singh

Unless the Government comes out with effective Pharma policies supportive to the thousands of struggling Small and Medium Enterprises (SMEs) engaged in Pharma formulations, big Pharma companies and multinationals will take over the sector. The SMEs cannot get along with the present policies which are tilted towards big players, observes Jagdeep Singh, President of the Punjab Drug Manufacturers Association (PDMA) and Managing Director

of Parex Pharmaceuticals Pvt Ltd, Mohali. The PDMA President alleges that the Government policies are framed as per the interest of the big players and of the multinational companies. When a lot of MSMEs are struggling and closing down units for want of help, Government of India is not interested to listen to their issues.

He said the golden age of the Punjab Pharma industry vanished from the scene 20 years ago. It was doing more or less well until 2005 when suddenly the rate of excise rose to 25%. Following it, there was a big exodus of units from Punjab to the Excise Free Zones (EFZ) areas in Uttarakhand and Himachal Pradesh by diminishing the number of factories in Punjab. Even now the Pharma policies of the central and state Governments everywhere are not industry-friendly to the sector. This has to be changed to evade further setbacks.

"Even in the midst of struggle, the Pharma sector in Punjab is moving ahead with 200 Small and Medium scale Pharma units (MSMEs) and four big players. No MNC has presence in the state. If an industry-friendly atmosphere is created by the Government, it will help the small scale players' opportunities for indulging in exports. It is the central Government that should let the MSME sector grow without making frequent policy changes," says the leader while briefing Pharmabiz about the present situation of Pharmaceutical industry in Punjab.

He further said unlike the problems faced by other states, Punjab has no infrastructure or raw material issues. There is minor issue of skilled workers, but marketing often becomes a problem for the entire MSMEs. The domestic Pharma sector can address all these challenges provided Government introduces policies for the growth of small players rather than helping big players and MNCs.

Singh agrees on one point that the Government is introducing so many measures to bring up the bulk drug production (APIs) to promote indigenous manufacture of medicines. But, he says, the Pharma MSMEs engaged in formulations are facing myriad issues due to the Government policies. Punjab drugs manufacturers association is fighting for the development of the sector through representations and discussions with the Government authorities.

As regards the total development of the industry sector, he said PDMA is taking all efforts with the Government to set up one Pharma cluster. For the purpose, one Society was registered for promoting it. There also the industry faces the cumbersome policies of the Government. The association has only the memberships of 70 companies despite 200 units are operating in the state. Singh said Punjab will be a promising destination for pharmaceutical industry like Gujarat or Maharashtra if an industry friendly atmosphere is established. As long as the present situation continues, there will not be a progress in the pharma sector in the state. Even today, a good number of companies in Punjab export their products to eastern and western countries.

Source: Peethaambaran Kunnathoor, Pharmabiz, 21.12.2020

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Health Ministry notifies Cosmetics Rules, 2020 for effective regulation and compliance

In order to separately codify rules relating to cosmetics for effective compliance, the Union Health Ministry, through a Gazette Notification, has notified the Cosmetics Rules, 2020.

The Ministry issued the Notification in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics (D&C) Act, 1940 (23 of 1940). These rules shall be applicable to the cosmetic as defined in clause (aaa) of Section 3 of the D&C Act, 1940 (23 of 1940).

In these rules, unless the context otherwise requires, Act means the Drugs and Cosmetics Act, 1940 (23 of 1940); (b)? Actual manufacturer in relation to import of cosmetics, means a person who manufactures cosmetics at his own manufacturing site in a country other than India approved by National Regulatory Authority or any authorised competent authority in that country for that purpose, by whatever name called for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

As per the notified rules, authorised agent means a person in India authorised by the manufacturer. The authorised agent shall be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act and rules made thereunder for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment. Bureau of Indian Standards (BIS) means the Bureau of Indian Standards established under Section 3 of the Bureau of Indian Standards Act, 2016 (11 of 2016).

No cosmetic shall be imported into India unless the product has been registered in accordance with these

rules by the Central Licensing Authority or by any officer to whom such powers may be delegated under sub-rule (1) of rule 5.

An application for registration of a cosmetic product intended to be imported into India shall be made through the online portal of the Central Government in Form COS-1 either by the manufacturer himself or by his authorised agent or the importer in India or by the subsidiary in India authorised by the manufacturer. An authorisation by the manufacturer to his agent in India shall be duly authenticated either in India before a first class Magistrate or in the country of origin before the authority competent under the laws of that country or by an authority specified in the First Schedule.

The applicant referred to sub-rule (2) above shall furnish along with the application such other information and documents as specified in Part I of the Second Schedule provided also that in the event of application for import of bulk finished formulation ready to fill, the following additional documents shall also required to be furnished. A registration certificate granted under rule 13 shall remain valid in perpetuity, subject to payment of registration certificate retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

If the licensee fails to pay the required registration certificate retention fee on or before the due date as referred to in sub-rule (1), the registration certificate holder shall, in addition to the registration certificate retention fee, be liable to pay a late fee calculated at the rate of two percent of the registration certificate retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

In case of change in constitution of a registration holder or overseas manufacturer, after grant of registration under sub-rule (1) of rule 13, an application shall be made under sub-rule (2) of rule 12 for grant of fresh registration within a period of one hundred and eighty days from the date of such change in constitution provided that the existing registration shall be deemed to be valid till such time, fresh registration is issued or application is rejected by the Central Licensing Authority.

In case of any change in respect of labelling or composition or testing of registered product or its specifications, the Central Licensing Authority shall be informed by manufacturer or by the authorised agent or the importer or the subsidiary in India authorised by the manufacturer within fifteen days along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

Source: Shardul Nautiyal, Pharmabiz, 19.12.2020

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Patents and drug discovery data lucrative targets for cyber attackers: Ramesh Mamgain

Patents and drug discovery data which are critical for pharmaceutical companies are now lucrative to cyber attackers. Pharma industry has never been in the limelight for cyber-attacks than now and the threat of losing the valuable data has also never been greater, said Ramesh Mamgain, Country Manager, India and SAARC, Commvault.

The spike in cyber-attacks is attributed to the virtual nature of conducting business. Pharma companies' and customers' critical data are no longer confined and cocooned in a fortified single location because of online business practices. Many Pharma manufacturing plants have outdated operating and processing systems, which make it difficult to patch advanced technology, eventually making them vulnerable to attacks, he noted.

With SaaS (Software as a Service) booming in India also increased threat to concepts like Hack-for-Hire or Ransomware-as-service. Anyone with cash to spare can hire experienced hackers to sabotage someone's critical data easily, Mamgain told.

The most disastrous impact is data breach especially when enterprises are rushing to find lifesaving antidotes. During the drug discovery process, patients' information becomes crucial to ensure the authenticity of the vaccines being created. While firms are running to secure the formulas for vaccines, notorious players might indulge in corporate espionage to sabotage the progress made by their competitors. There are two critical aspects that come into play here, one is sensitive data Governance and the other is e-discovery tools for compliance that needs stringent attention, he noted.

Data breaches can cost a tremendous damage to industries which is both reputational and monetary. Quoting

a recent survey, Mamgain said, "Average cost of a data breach in India $2 million. Ransomware attacks will only continue to be more sophisticated and nefarious with time. The only solution to keep critical data safe is intelligent management from protection to disaster recovery, which are knights in shining armour."

Although the Pharma is traditionally known for a slower adoption of Information Technology, this COVID-19 pandemic has accelerated its digital transformation, especially when it comes to shorten the time duration and enhancing the quality of drug discovery process. Cloud migration is the new norm to secure and access the critical IP data in a better way, while intelligent data management and protection solutions empowered them to work remotely in a compliant and cost-effective manner, he said.

In the post-pandemic world, use of data-centric technologies like Machine Learning & Artificial Intelligences not only shorten the drug discovery process, but also help researchers predict modelling in a much better way than a human brain can possibly achieve.

This is where Pharma industry's Chief Information Officer (CIO) will need to primarily focus on the sustained digital transformation adopt constructive IT strategies. They will need to maximize data protection and propose cloud-based apps to proactively monitor and measure the company's data environment. There is need to ensure compliance to safeguard the interest companies. To reduce cost-based redundancies in disparate systems, CIOs are looking at managing data through a single pane of glass, to keep expenditures at bay to enable IT solutions, said the Chief of Commvault which is a data management and protection software company.

Source: Nandita Vijay, Pharmabiz, 19.12.2020

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M D Varadarajan of Kniss Laboratories elected President of TN PMA unopposed

The Tamil Nadu Pharmaceutical Manufacturers Association (TN PMA) has unanimously elected M D Varadarajan, Managing Director of Kniss Laboratories, Chennai, as the new President of the association for the term 2020-22.

The Annual General Body meeting, held last week, also elected six other office-bearers and eight members to the Executive Committee. In the new team of office-bearers, D Harirajan, Managing Director of Axon Drugs, Chennai, has been elected Honorary Secretary of the association. The veteran Pharma industry Expert and Director of Medopharm, R Sabapathy is the new Treasurer. Leading drug manufacturers S Madhavan and M Elangovan will act as Vice-Presidents and M R Chandramohan as the new Joint Secretary.

The election for new office-bearers for the association became imperative following the death of sitting President B Sethuraman who was an active industry captain in dealing with the regulatory and legal issues faced by Small, Medium and Micro level Pharma industrial units all over the country by representing them to the concerned departments of central and state Governments. He had taken several legal issues of the industry with various courts and obtained favorable verdicts for the Pharma sector.

Varadarajan said he will work for the improvement of the pharmaceutical manufacturing sector by mobilizing support of all units and representing them to the central and state Governments as and when problems arise. The association will also fight for the advantages of the member companies and support them to develop their infrastructure facilities. Varadarajan, with more than 30 years experience in the Pharma industry, was the Secretary of TN PMA from 1988 to 2000 and continued as Vice-President of the association till he was elevated to the President post.

Mr S V Veerramani, former National President of the Indian Drug Manufacturers' Association (IDMA) and Managing Director of Fourrts Laboratories, Chennai, said Varadarajan is a successful entrepreneur and an able leader whose leadership will largely help increase the status of the association and resolve all issues of the manufacturing companies, including the teething problems of the start-up units. Mr J Jayaseelan, Chairman of TN IPA and Managing Director of Delvin Formulations, Chennai, expressed the hope that Varadarajan and his team of office-bearers will do wonderful activities for the growth and welfare of the pharmaceutical manufacturing companies operating in the entire Tamil Nadu. He further said, being a Pharmacist, Varadarajan's services as President of the PMA will be helpful for the Pharmacist community also.

TN PMA was established in the year 1979 for the purpose of addressing the problems of the pharmaceutical

manufacturers in the state. The association takes up a lot of issues faced by the member units and finds solutions.

Source: Peethaambaran Kunnathoor, Pharmabiz, 19.12.2020 (Excerpts)

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A Right Step to Promote Ayush

In a welcome decision, the Union Ministry of Commerce and Industry and the Ministry of Ayush have decided to jointly set up an Ayush Export Promotion Council to boost Ayush exports. The decision to set up an exclusive Council on the lines of Pharmexcil was taken jointly by both the Central Ministries at a high level joint review meeting held to review Ayush trade and industry where both the Commerce & Industry Minister Piyush Goyal and Ayush Minister Shripad Naik were present. Both the Ministers have expressed strong resolve to work together to facilitate more exports of Ayush products from the country. The ministers have also resolved to expedite the standardisation of Harmonization System Code (HSC) for Ayush products which is used for global trade. As per the decision, the Ministry of Ayush, where the proposed Ayush Export Promotion Council will be housed, will work in collaboration with Bureau of Indian Standards to develop international standards for Ayush products as well as services. The Ministry of Ayush and the Ayush industry will identify best practices and success stories and promote them amongst the public. To promote the Ayush products, it was also decided that the Ayush industry will work on ensuring quality and standards of Ayush products as well as to become price-competitive. Besides, the Government has taken the decision that Ayush will figure in the Brand India activities which are aimed to boost exports.

The Government's decision cannot have come at a more opportune time as there is a growing global interest in Ayush-based solutions for disease resistance and treatment for the COVID-19. It is an undisputed fact that Ayush products played a key role in providing the much-needed immunity to the general public to fight the deadly Coronavirus Disease, which has taken a huge toll across the world, especially in the developed world including the US. The emerging evidence of a correlation between the low COVID-19 mortality rates and large-scale adoption of Ayush prophylactic solutions by the population in India is significant for the public health practice in the country. As the entire world was running amok for a timely solution to fight the deadly virus, the frontline role played by the Ayush sector in the fight against COVID-19 received kudos from one and all. The Ayush immunity protocols and the National Clinical Management Protocol for COVID-19 for Ayurveda and Yoga were timely interventions which provided relief to large section of the population. The protection offered by the Ayush systems to the common people during the pandemic neutralised the scepticism that many people had about the efficacy of the medicines and products offered by these systems. The spurt in exports of Ayush products in the recent months is a direct reflection of their growing popularity in many countries. Now, the sector should cash in on the prevailing situation and needed to upscale trade quickly in order to meet the growing demands from India and abroad, and to serve the larger number of people who are now looking up to Ayush systems for maintaining their health by boosting immunity. All said and done, the strong resolve shown by the Government should not be just in paper as was the case with several existing export promotion councils.

Source: Ramesh Shankar, Pharmabiz-Editorial, 23.12.2020

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US FDA takes key action in fight against COVID-19 by issuing Emergency Use Authorization for first COVID-19 vaccine

The US Food and Drug Administration issued the first Emergency Use Authorization (EUA) for a vaccine for the prevention of Coronavirus Disease 2019 (COVID-19) caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The Emergency Use Authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the US.

"The FDA's authorization for emergency use of the first COVID-19 vaccine is a significant milestone in battling this devastating pandemic that has affected so many families in the United States and around the world," said FDA Commissioner Stephen M Hahn, MD. "Today's action follows an open and transparent review process that included input from independent scientific and public health experts and a thorough evaluation by the agency's career scientists to ensure this vaccine met FDA's rigorous, scientific standards for safety, effectiveness, and manufacturing quality needed to support Emergency Use Authorization.

The tireless work to develop a new vaccine to prevent this novel, serious, and life-threatening disease in an expedited timeframe after its emergence is a true testament to scientific innovation and Public-Private Collaboration Worldwide."

The FDA has determined that Pfizer-BioNTech COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19. The data also support that the known and potential benefits outweigh the known and potential risks, supporting the vaccine's use in millions of people 16 years of age and older, including healthy individuals.

In making this determination, the FDA can assure the public and medical community that it has conducted a thorough evaluation of the available safety, effectiveness and manufacturing quality information. The Pfizer-BioNTech COVID-19 Vaccine contains messenger RNA (mRNA), which is genetic material. The vaccine contains a small piece of the SARS-CoV-2 virus's mRNA that instructs cells in the body to make the virus's distinctive "spike" protein. When a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

"While not an FDA approval, today's emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine holds the promise to alter the course of this pandemic in the United States," said Peter Marks, MD., Ph.D., Director of the FDA's Center for Biologics Evaluation and Research. "With science guiding our decision-making, the available safety and effectiveness data support the authorization of the Pfizer-BioNTech COVID-19 Vaccine because the vaccine's known and potential benefits clearly outweigh its known and potential risks.

The data provided by the sponsor have met the FDA's expectations as conveyed in our June and October guidance documents. Efforts to speed vaccine development have not sacrificed scientific standards or the integrity of our vaccine evaluation process. The FDA's review process also included public and independent review from members of the agency's Vaccines and Related Biological Products Advisory Committee. Today's achievement is ultimately a testament to the commitment of our career scientists and physicians, who worked tirelessly to thoroughly evaluate the data and information for this vaccine."

FDA Evaluation of Available Safety Data:

Pfizer BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart. The available safety data to support the EUA include 37,586 of the participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are US participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received saline placebo, were followed for a median of two months after receiving the second dose.

The most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose.

It is mandatory for Pfizer Inc and vaccination providers to report the following to the Vaccine Adverse Event Reporting System (VAERS) for Pfizer-BioNTech COVID-19 Vaccine: all vaccine administration errors, Serious Adverse Events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death.

FDA Evaluation of Available Effectiveness Data:

The effectiveness data to support the EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are US participants, who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received placebo.

The vaccine was 95% effective in preventing COVID-19 disease among these Clinical Trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. Of these 170 COVID-19 cases, one in the vaccine group and three in the placebo group were classified as severe. At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person.

The EUA Process:

On the basis of the determination by the Secretary of the Department of Health and Human Services on February 4, 2020, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and then issued declarations that circumstances exist justifying the Authorization of Emergency Use of unapproved products, the FDA may issue an EUA to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent COVID-19 when there are no adequate, approved, and available alternatives.

The issuance of an EUA is different than an FDA approval (licensure) of a vaccine. In determining whether to issue an EUA for a product, the FDA evaluates the available evidence and assesses any known or potential risks and any known or potential benefits, and if the benefit-risk assessment is favorable, the product is made available during the emergency.

Once a manufacturer submits an EUA request for a COVID-19 vaccine to the FDA, the agency then evaluates the request and determines whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to the FDA.

The EUA also requires that fact sheets that provide important information, including dosing instructions, and information about the benefits and risks of the Pfizer-BioNTech COVID-19 Vaccine, be made available to vaccination providers and vaccine recipients.

The company has submitted a Pharmacovigilance plan to FDA to monitor the safety of Pfizer-BioNTech COVID-19 Vaccine. The Pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing Clinical Trials. The Pharmacovigilance plan also includes other activities aimed at monitoring the safety profile of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

The FDA also expects manufacturers whose COVID-19 vaccines are authorized under an EUA to continue their Clinical Trials to obtain additional safety and effectiveness information and pursue approval (licensure). The EUA for the Pfizer-BioNTech COVID-19 Vaccine was issued to Pfizer Inc. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19 is terminated, and may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

Source: US FDA Press Release, 12.12.2020

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Five trends to watch out for in the Pharma Industry in 2021

Sanjeev Goel

Amongst the most significant trends to watch out for in the Pharma industry in 2021 is how consumer behaviour has witnessed a significant acceleration towards e-consultations through live video calls between doctors and patients, e-purchases of medicines by uploading doctor's e-prescriptions, and home-collection of blood samples. At the same time, the combined power of the Internet, data science, connected devices and AI have expedited the pace of digital transformation in Pharma organisations to improve quality and productivity. Skilled manpower in Artificial Intelligence (AI), Machine Learning (ML), cloud computing, Robotic Process Automation (RPA), and other technological areas are helping speed up drug repurposing and development of biomarkers.

Faster time-to-market for drug discovery:

AI algorithms, Big Data and early-stage experiments using new technologies are helping substantially lower time and costs in bringing new drug formulations to market. The entire Research and Development cycle spanning data management, Clinical Trials and testing are now so technology oriented that Pharma companies are increasingly on boarding 'health-tech' partners and tech start-ups in the journey to drug discovery, hitherto a pure science domain.

Digitization & Automation:

The manufacturing shop floor in Pharma was amongst the first to embrace digitization and automation. It was not just about paperless processes, but also to ensure that quality processes were robust and scalable, with minimal scope for human error. It ensured CGMP compliance in the manufacturing process. Besides, robotic technology and AI have been reducing manufacturing downtime and substantially reducing product wastage.

From a quality point of view, automation has curbed human intervention associated with increased risk of contamination as well as variability. Also, with serum-dependent processes with lot-to-lot variability, RPA mitigates any lack of proper cell characterization strategies. It has further mitigated business setbacks in the transition of the lab process to manufacturing or in the recurring failures during manufacturing runs. Developers and researchers are integrating their knowledge to develop and have common access to phase appropriate Process Development (PD) and Bio Assay Services (BAS), removing manufacturing bottlenecks, reducing their Cost of Goods (COGS), and preparing for commercial readiness in advance.

Biologics including Genetic Susceptibility and Pharmacogenetics, Epigenetics & Genomes:

Instead of developing medicines (Small Molecules and Generics) which start at the point when a disease disrupts the normal healthy life of an individual, the move towards biologics which studies how diseases are expressed or contracted through genetic susceptibility and/or prevented through genetic resistance have spawned a new and rapidly growing interest in Pharmacogenetics, Epigenetics and Genomes – e.g. Covid-19 research papers have primarily focused on studies of the virus at the protein levels and how they interact with RNA and DNA. Genetics is expected to generate the maximum amount of new Research and Development in the pharmaceutical industry moving forward.

Connected virtual & self-monitoring in patient care:

The advent of connected devices, wearables and IoT have ushered in a new trend in self-monitoring without having to physically visit a clinic or a doctor. Instead, they have the necessary equipment available at their homes at a fraction of the cost for most self-monitoring needs. The readings are transmitted to a central console of the monitoring healthcare provider or doctor for their review and analysis. Diagnostic healthcare is fast moving towards such connected devices, with AI and the Internet providing the first level diagnostics followed by a prognosis and final review by an expert doctor before actual prescription. This is empowering both patients (customers) and doctors to be connected virtually and has spawned a whole system of healthcare integrators

and aggregators bringing experts and patients on a self-monitoring virtual healthcare platform.

Governments across the globe are realising how such connected healthcare systems are not only more flexible but also extremely efficient. AI-enabled diagnosis and prognosis for review by consulting expert doctors has already gained substantial traction even in hospitals and clinics where the number of patients is high. Connected healthcare is going to be the new normal from 2021.

Global collaboration in compliance & regulatory conditions:

Covid-19 has ushered in collaboration, and not competition, amongst each country's pharmaceutical regulatory bodies. And though the US Government has voiced its displeasure with the WHO, this global collaboration in healthcare – both Research and Compliance – is only going to get more deeply entrenched moving forward.

Regulatory bodies like US FDA, and EMA are going to strengthen the WHO in its ways of working. Automation software for common standards and compliances are going to be universally implemented since it impacts humanity at large.

As the world rapidly takes to the convenience of healthcare solutions through technology, the Pharma industry is presented with the challenge to ensure that their workforce is as adept at addressing this demand and can keep up with the speed of adoption by customers. Pharma companies need to up skill and train their personnel in the latest developments and ways of working with customers at various touch points.

(Disclaimer: The writer - Sanjeev Goel is Business Head, Manipal ProLearn. Views expressed are a personal opinion.)

Source: E-Health Network, 08.12.2020 (Excerpts)

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Slowing sales a concern for Indian Pharma Companies

Clifford Alvares

Sales of Covid-19 drugs are also seen moderating due to the lower number of Coronavirus cases in November

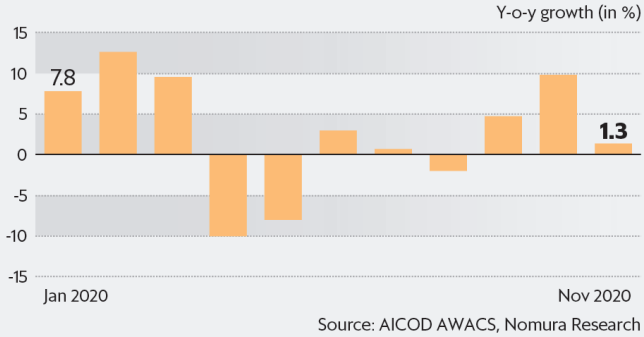
Having Covid-19 drugs in the portfolio is proving useful for some drug makers. With the Indian Pharma Market once again showing signs of slowing sales, drugs such as Favipiravir, Remdesivir and Toclizumab helped Glenmark Pharma Ltd, Cipla Ltd and Cadila Healthcare Ltd, with November sales rising 7-15% from a year ago. Overall Sales Growth, however, decelerated considerably in November, which is a surprise given that it had bounced back in October. Sales growth decelerated to about 1.3% year-on-year in November as against 9.8% in October. Note that growth in September stood at 4.7%, suggesting that the recovery has been short-lived.

One of the main reasons has been slower volume growth, which is showing signs of tapering off after monsoons. Volumes declined by 6.9% y-o-y in November as against a 0.6% growth in October. In the past eight months, volumes declined 7.6% on an average.

Some of this could be attributed to the slower patient inflows at clinics, say analysts. In fact, almost all therapies including derma, pain, gynaecological and neuro have shown a dip in sales growth. Sales of Covid-19 drugs are also seen moderating due to the lower number of cases in November. "Excluding the contribution from covid-19 drugs, growth for Glenmark, Cipla and Cadila were at -0.4%, 3.9% and -1.1% respectively," said analysts at Nomura Financial Advisory and Securities (India) in a note.

Pulse check

After picking up post the lockdown, growth in the Indian pharma market decelerated to 1.3% in November on low volumes growth due to lower patient visits to clinics.



Source: AICOD AWACS, Nomura Research

Another reason for the decline is the lower sales of acute therapy drugs due to better hygiene. Within acute therapies, anti-infective growth fell to 0.2% in November against 6.6% in October. In addition, there was some

stocking at user ends in October too, which led to a lower take-off in November, note analysts. However, chronic therapies such as cardiac have shown a growth of 8.7% in November, while anti-diabetic registered a modest growth of 1.9% in November.

For now, Pharma companies may not see growth normalize in the next few months. This could impact their revenue growth in the second half. But profits could still increase. "While top-line growth for the Indian formulation business may disappoint, profitability may remain high due to lower costs—particularly for travel, sales and marketing expenses. It is likely that cost savings of 1-1.5% are sustained beyond the pandemic," said analysts at Nomura in the note.

While this should continue to support the sector, note that the valuations of the Nifty Pharma index have been expanding due to the sharp increase in stock prices. The index's one-year forward price-earnings multiple is at 27 times as against 19 times a year ago, as per data from Bloomberg.

Source: Live Mint, 07.12.2020 (Excerpts)

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Pharma Industry has a new drug: Artificial Intelligence

Priya Dialani

AI-controlled platforms permit companies to change how they lead and screen Clinical Trials

It's almost difficult to talk about the future of any industry without referencing Artificial Intelligence (AI). Regardless of whether it's retail, health care industry, manufacturing, etc the conversation around the advantages proceeds. Increasingly, Pharma and Biotech Organizations are embracing more effective, automated processes that integrate data-driven decisions and utilize predictive analytics tools. The next development of this approach to deal with cutting-edge data analytics fuses machine learning and AI.

The absolute most discussed issues incorporate drug deficiencies, Clinical Trials, and the opioid epidemic, all within the difficulties of the COVID-19 pandemic. Despite the fact that these issues appear to be inauspicious and huge, AI is deliberately positioned to help us better address all challenges.

Development in Life Sciences:

The power and capability of AI-based innovation in Life Sciences have apparently never been more significant. The value of speedy and safe clinical advancement is clear, particularly since the crucial work of pharmaceutical organizations and healthcare organizations has been fundamentally disrupted by the Covid-19 pandemic. Right off the bat in the pandemic, at least 440 Clinical Trials in the US had been ended due to logistical challenges, wellbeing concerns or raised exposure risks to participants.

Some forefront solutions offer extensive AI-controlled platforms that permit companies to change how they lead and screen Clinical Trials. They incorporate everything from options for conducting smart, hybrid and virtual trials, digital study design tools, ability to provision devices and concierge on a unified platform — complete with automated information collection and organization, analytics and cognitive AI.

Drug Recalls:

Drug Recalls happen when a prescription in the supply chain is tainted or traded off, making the resulting drug risky for recommending. Drug recalls are another significant trouble spot for the Pharma business and can have intense ramifications for suppliers and patients.

Drugs are reviewed to shield patients from tainting or unfavorable impacts, yet patients may require that medication to endure, leaving suppliers in an exceptional predicament. Using AI, we can possibly pinpoint precisely where any contamination or deformity began in the inventory network, permitting teams to address or work around the issue more effectively than would be possible utilizing manual research-based processes.

With AI-empowered item level visibility software solutions, the drug production network can monitor each vial and needle from producer to patient, guaranteeing a review is executed as fast as possible and without making falling barriers to patient care.

Processing Biomedical and Clinical Information:

May be the most evolved utilization of AI so far is in algorithms intended to read, group and decipher enormous

volumes of textual data. This can be a big deal saver for analysts in the life sciences industry, giving a more productive approach to look at the huge amounts of data from the developing volume of research publications to approve or dispose of theories.

Moreover, numerous clinical examinations actually depend on paper journals in which patients log when they took a medication, what different meds they took, and any unfriendly reactions they had. Everything from manually written notes and test results to climate factors and imaging scans can be gathered and deciphered by AI. The advantages of utilizing AI in this manner incorporate quicker research and cross-referencing of data, as well as joining and extracting data into usable formats for analysis.

Social Listening:

One of the most interesting AI frontiers in the existence sciences is the extending ecosystem of social listening advances and solutions. Social listening, observing social media channels for brand and item mentions, competitor activity and other applicable data has detonated in prevalence as of late.

For life sciences companies, social listening isn't only an indispensable method to screen and comprehend the sentiment around their brand however, a tool that can address a range of significant issues.

Conclusion:

While the opportunities for utilizing AI in Pharma and Biotech improvement are self-evident, the genuine push toward embracing such advances can be painfully slow. Not exclusively do customary drug development and discovery processes require a more gradual adoption (as opposed to what some should think about a disruption by innovation), the cycle for training AI in what works for drug discovery can take longer than in different applications.

Source: Analytics Insight News, 11.12.2020 (Excerpts)

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

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

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

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

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

DOs:

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

DON'Ts:

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

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

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