PRICE
PER COPY
₹25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2018-20

IDMA BULLETIN

VOL. NO. 51 | ISSUE NO. 45 (PAGES: 40) | 01 TO 07 DECEMBER 2020 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: mail_ idma@idmaindia.com/
admin@idmaindia.com/ Website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 51 **Issue No. 45** **01 to 07 December 2020**

IDMA ACTIVITIES:

TAX ADVISORIES:

GOVERNMENT NOTIFICATIONS:

GOVERNMENT PRESS RELEASES:

CBIC MATTERS:

PARLIAMENT NEWS:

GST MATTERS:

NEW DEVELOPMENTS:

SPECIAL NATIONAL NEWS:

NATIONAL NEWS:

INTERNATIONAL NEWS:

FEATURE:

Draft 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 - IDMA Submission to CEO, FSSAI

The Association has submitted the following representation on 20th November 2020 to Mr Arun Singhal, IAS, Chief Executive Officer, Food Safety & Standard Authority of India (FSSAI), New Delhi on the above subject:

***"*Greetings from Indian Drug Manufacturers' Association.**

The draft regulations as above subject are scheduled to be finalized two months following their release. As per the Notification, the Nutraceutical Committee at Indian Drug Manufacturers' Association (IDMA) which focuses on providing consumer, and ensuring availability by Food Business Operators (FBOs), with best in Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods suggest few modifications which could beneficial for this healthcare vertical.

We have attached accordingly a table providing details of suggested changes in appropriate portions of the draft: **Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Functional Foods and Novel Foods) Amendment Regulations, 2020** and the reasons for the same as well.

Looking forward to ensuring your acceptance of our suggested changes positively for welfare of the consumer. We would be always available and willing to interact for any clarifications if so desired."

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)

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA NOTIFICATION

(New Delhi, the 29th October, 2020) [F. No. Stds./03/Notification (Nutra)/FSSAI-2017]

PROPOSED CHANGES / ALTERATIONS BY INDIAN DRUGS MANUFACTURERS' ASSOCIATION (IDMA)

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
1.	page: 51 Point 3 (ii)	for sub-regulation (21), the following shall be substituted, namely;- "(21) Mere combinations of vitamins, including use of single vitamin, in dosage formats such as tablets, capsules, syrups, at levels equal to one RDA or below shall be covered under these regulations."	for sub-regulation (21), the following shall be substituted, namely;- "(21) Mere combinations of vitamins, including use of single vitamin, in dosage formats such as tablets, capsules, syrups, at levels equal to ~~one RDA~~ **50% of TUL** or below shall be covered under these regulations."	RDA needs to be substituted with 50% of TUL as has been determined recently by NIN and accepted by FSSAI for FSDU.

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
2.	page: 52 Point 4 (i) ADD AFTER THAT (ii)	in the said regulations, in regulation 6, in sub-regulation (2), for clause (iii), the following shall be substituted, namely;- "The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission shall apply."	in the said regulations, in regulation 6, in sub-regulation (2), for clause (iii), the following shall be substituted, namely;- "The quantity of nutrients added to the articles of food shall not exceed the ~~recommended daily allowance~~ **50% of TUL** as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission **or any other global regulatory authority** shall apply."	RDA needs to be substituted with 50% of TUL as has been determined recently by NIN and accepted by FSSAI for FSDU.
3.	page: 52 Point 5 (ii)	in the said regulations, in regulation 6, in sub-regulation (2), for clause (v), the following shall be substituted, namely;- "(v) for the purposes of clause (iv), a food business operator shall apply to the food authority for Approval which shall be accompanied by documented history of safe usage of at least fifteen years In India and thirty years in the country of origin;"	for clause (v), the following shall be substituted, namely;- "(v) for the purposes of clause (iv), a food business operator shall apply to the food authority for Approval which shall be accompanied by documented history of safe usage ~~of~~ **in India, or** at least **four years globally** ~~fifteen years In India and thirty years in the country of origin~~;"	Periods of 15 years and thirty years defeats consumerism. It translates into making unavailable any beneficial ingredient for Indians whilst the same can be easily purchased for overseas OTC shelves and consumed; this will be detrimental for those who do not have easy access to overseas products.
4.	page: 52 Point 5 (ii) ADD AFTER THAT (iii)	in the said regulations, in regulation 7, in sub-regulation (1), for clause (iii), the following shall be substituted, namely;- "The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission shall apply;"	in the said regulations, in regulation 7, in sub-regulation (1), for clause (iii), the following shall be substituted, namely;- "The quantity of nutrients added to the articles of food shall not exceed the ~~recommended daily allowance~~ **50% of TUL** as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission **or any other global regulatory authority** shall apply;"	RDA needs to be substituted with 50% of TUL as has been determined recently by NIN and accepted by FSSAI for FSDU.
5.	page: 52 Point 6 (ii) (b)	in the said regulations, in regulation 8, in sub-regulation (1), for clause (ii), the following shall be substituted, namely,- "(ii) The food business operator shall clearly indicate on the label whether or not the food for special dietary use is to be taken under medical advice:	in the said regulations, in regulation 8, in sub-regulation (1), for clause (ii), the following shall be substituted, namely,- "(ii) The food business operator shall clearly indicate on the label whether or not the food for special dietary use is to be taken under medical advice~~:~~	The first sentence has established the need to state if the product requires to be taken under supervision or not. The same cannot be then made compulsory by adding another sentence. Compulsion of medical supervision is most suitable only for FSMP products only.

		Provided that Food for Special Dietary Use for Sportsperson shall only be used under medical advice or dietetic supervision."	~~Provided that Food for Special Dietary Use for Sportsperson shall only be used under medical advice or dietetic supervision~~."	
6.	page: 53 Point 6 (ii) (c)	in the said regulations, in regulation 8, in sub-regulation (1), for clause (iii), the following shall be substituted, namely,- "(iii) A food business operator may manufacture or sell an article of FSDU in single use packaging or in dosage form, namely, granules, jelly, semi-solid and other similar forms, sachets of powder, or any other similar forms of liquids and powders designed to be taken in measured unit quantities with a nutritional or physiological effect: Provided that FSDU products containing vitamins including single vitamin at levels equal to or below one RDA in formats/dosage forms of capsules, tablets, pills and syrups shall be permitted under these regulations;"	in the said regulations, in regulation 8, in sub-regulation (1), for clause (iii), the following shall be substituted, namely,- "(iii) A food business operator may manufacture or sell an article of FSDU in single use packaging or in dosage form, namely, granules, jelly, semi-solid and other similar forms, sachets of powder, or any other similar forms of liquids and powders designed to be taken in measured unit quantities with a nutritional or physiological effect: Provided that FSDU products containing vitamins including single vitamin at levels equal to or below **50% of TUL** ~~one RDA~~ in formats/dosage forms of capsules, tablets, pills and syrups shall be permitted under these regulations;"	50% of TUL has already been accepted by FSSAI for FSDU. This seems be a discrepancy and typo error.
7.	page: 54 Point 6 (v)	in the said regulations, in regulation 8, after sub-regulation (4), the following sub-regulation shall be inserted, namely,- "(5) No food business operator shall advertise FSDU for general public. (6) Prohibited substances declared by World Anti-Doping Agency (WADA) shall not be added in any of the articles of food specified for sport persons. Food Business Operator must ensure to check the list of prohibited substances which is published annually by World Anti-Doping Agency and is effective from January 1 every year."	in the said regulations, in regulation 8, after sub-regulation (4), the following sub-regulation shall be inserted, namely,- "(5) No food business operator shall advertise FSDU **containing prohibited substances** for general public. (6) Prohibited substances declared by World Anti-Doping Agency (WADA) shall not be added in any of the articles of food specified for sport persons. Food Business Operator must ensure to check the list of prohibited substances which is published annually by World Anti-Doping Agency and is effective from January 1 every year."	Only WADA banned ingredients containing FSDU must be restrained from being advertised for general public.
8.	page: 54 Point 7 (i)	in the said regulations, in regulation 9, in sub-regulation (1), in clause (ii), after para 1, the following shall be inserted, namely,-	in the said regulations, in regulation 9, in sub-regulation (1), in clause (ii), after para 1, the following shall be inserted, namely,-	FSDU has permitted 50% of TUL and thus there seems no concern in permitting the same for FSMP for sure.

		"FSMP products containing vitamins including single vitamin at levels equal to or below one RDA in formats/dosage forms of capsules, tablets, pills and syrups shall be permitted under these regulations;"	"FSMP products containing vitamins including single vitamin at levels equal to or below **50% of TUL** ~~one RDA~~ in formats/dosage forms of capsules, tablets, pills and syrups shall be permitted under these regulations;"	
9.	page: 54 Point 10	in the said regulations, in regulation 12, in sub-regulation (1), in clause (iii) the following shall be inserted, namely,- "(iii) The application for approval to the Food Authority shall be accompanied by documented history of safe usage of at least fifteen years in India and thirty years in the country of origin."	in the said regulations, in regulation 12, in sub-regulation (1), in clause (iii) the following shall be inserted, namely,- "(iii) The application for approval to the Food Authority shall be accompanied by documented history of safe usage of **in India, or** at least **four years globally** ~~fifteen years in India and thirty years in the country of origin~~."	Periods of 15 years and thirty years defeats consumerism. It translates into making unavailable any beneficial ingredient for Indians whilst the same can be easily purchased for overseas OTC shelves and consumed; this will be detrimental for those who do not have easy access to overseas products.
10.	page: 55 Point 12 (ii)	in the said regulations, in Schedule I, in clause (ii) after serial number B(15),in the note, for the words "Suitable esters and salts of vitamins and salts and chelates of mineral may be used", the following shall be substituted, namely,- "Suitable esters, derivatives and salts of vitamins and salts and chelates of minerals may be used."	in the said regulations, in Schedule I, in clause (ii) after serial number B(15),in the note, for the words "Suitable esters and salts of vitamins and salts and chelates of mineral may be used", the following shall be substituted, namely,- "Suitable esters, derivatives**,** **active moieties** and salts of vitamins and salts and chelates of minerals may be used."	There are many vitamins that are available as active moiety forms like benfotiamine and these should not be inadvertently disregarded.
11.	page: 55 Point 13	in the said regulations, in Schedule II, in the note, for the words "Suitable esters and salts of amino acids may be used", the following shall be substituted, namely;- "Suitable esters, derivatives, isomers and salts of amino acids may be used."	in the said regulations, in Schedule II, in the note, for the words "Suitable esters and salts of amino acids may be used", the following shall be substituted, namely;- "Suitable esters, derivatives, **complexes, chelates,** isomers and salts of amino acids may be used."	Amino acid complexes with minerals are widely in use for enhancing bioavailability for example iron bis-glycinate chelate.
12.	page: 55 Point 14	in the said regulations, in Schedule III, for the words and figures "[See regulations 3.(13), 4.(2), 8.(2)(i), 8.(2)(iv), 9.(2)(i), 9.(2)(iv) and 9.(2)(v)] Values for vitamins, minerals and trace elements allowed to be used in food for special dietary use and food for special medical purpose (other than those intended for use in infant formula)", the following shall be substituted, namely;-	in the said regulations, in Schedule III, for the words and figures "[See regulations 3.(13), 4.(2), 8.(2)(i), 8.(2)(iv), 9.(2)(i), 9.(2)(iv) and 9.(2)(v)] Values for vitamins, minerals and trace elements allowed to be used in food for special dietary use and food for special medical purpose (other than those intended for use in infant formula)", the following shall be substituted, namely;-	Logical need to eliminate unscientific capping table for vitamin and mineral intake based on calorie / energy values. In view of the TUL being formerly accepted the same can be substituted here.

		"[See regulations 3(13), 4(2), 9(2)(i), 9(2)(iv) and 9(2)(v)] Values for vitamins, minerals and trace elements allowed to be used in Food for Special Medical Purpose (other than those intended for use in Infant Formula)"	"[See regulations ~~3(13), 4(2),~~ **7(1)(iii), 8(1)(iii), 9(1)(ii)** ~~9(2)(i), 9(2)(iv) and 9(2)(v)~~] **50% of provided TUL** Values for vitamins, minerals and trace elements allowed to be used in **Health Supplements, Nutraceuticals, Food for Special Dietary Use and** Food for Special Medical Purpose (other than those intended for use in Infant Formula) **wherever specified**"	
13.	page: 88	**Add below the Schedule IV for List of Plants or Botanical Ingredients, as a footnote:-**	**The permitted range of usage for adults per day (given in terms of raw herb/material) implies that: label claims for ingredients' properties are permissible only if the amounts incorporated per day meets the minimum quantities wherever defined; and quantities exceeding the upper limits when specified cannot be exceeded.**	The range specified in column 4 of the table needs to be explained for its implications.
14.	page: 88 Note 1	Ingredients listed in the above Schedule shall be used after due processing or in their extract forms subject to permissible usage range given in the last column of the Table. Offering these ingredients, either alone or in combinations as such or minimally processed (cleaned, de-weeded, sorted, dried or powdered) is/are not permitted.	Ingredients listed in the above Schedule shall be used after due processing or in their extract forms subject to permissible usage range given in the last column of the Table. ~~Offering these ingredients, either alone or in combinations as such or minimally processed (cleaned, de-weeded, sorted, dried or powdered) is/are not permitted.~~	In the Schedule IV for List of Plants or Botanical Ingredients the permitted range already mentions the individual item as powder and these permitted ingredients are already available as powders. Hence, no processing may be required for many products. Thus, the sentence as indicated to be deleted is mandatorily a necessity.
15.	page 91	**Add below the Schedule VI for List of Ingredients as Nutraceuticals (PART A table), as a footnote:-**	**The permitted range implies that: label claims for ingredients' properties are permissible only if the amounts incorporated per day meets the minimum quantities wherever defined; and quantities exceeding the upper limits when specified cannot be exceeded.**	The range specified in column 5 of the table needs to be explained for its implications.

16.	page 92-97	**Incorporate already permitted vitamin forms in the alphabet sequencing order of Schedule Vi (Part B) of List of Ingredients as Nutraceuticals**	**Add / Incorporate the below mentioned:** **Adenosylcobalamin** **Benfotiamine / Benfothiamine** **L-methylfolate / L-methylfolate calcium** **Methylcobalamin / Mecobalamin** **Pyridoxal-5-phosphate**	**Important vitamin derivatives and active moieties that are especially beneficial for providing specific health benefits need to be mentioned under Nutraceuticals since these play a role with other nutraceutical ingredients for certain health benefits: eg. methylcobalamin, L-methylfolate, pyridoxal-5-phosphate with other nutraceutical ingredients for nerve support.**

Red text = additions suggested; Text striked out = words / sentences to be deleted

● ● ●

Streamlining the Process of Granting Environmental Clearance: IDMA and BDMAI joint Representation to MoEF&CC – reg.

IDMA and BDMAI have jointly submitted the following representation on 25th November 2020 to Shri Sharath Pallerla, Scientist 'F', Ministry of Environment, Forest and Climate Change, New Delhi with copies to Shri Rameshwar Prasad Gupta, IAS, Secretary, Ministry of Environment, Forest & Climate Change, Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers and Dr V K Saraswat, Member, NITI Aayog, New Delhi re. Streamlining the Process of Granting Environmental Clearance:

"We refer to OM F.No.22-35/2020-IA.III dated 18th November, 2020 (reproduced here – Please see Page No.10) and are appreciative of the Ministry for sensitising all State Boards for streamlining the process of Granting Environmental Clearances (EC)/Terms of Reference (ToRs). This will definitely help in faster disposal of the EC and ToR Applications.

While welcoming the efforts of the Ministry, we wish to highlight that grant of EC, and thus migration from one level to next higher level, is one single biggest hassle faced by Bulk Pharmaceutical Industries. For some reason or other, the process of ToR/EC takes much longer than what it looks on paper. At present the entire exercise from start till issue of Consent to Manufacture takes anything between 2 to 3 years.

Current Pandemic has highlighted the need for strengthening the Pharma production and rightly Central Government has taken note of it. Production Linked Incentive (PLI) Schemes are announced to boost Pharma Manufacturing in the country to reduce dependence on Chinese imports and to increase exports. However, success of these Schemes will depend squarely upon the ability of industry to quickly change products mixes and/or expand capacities.

Further, to genuinely reduce bureaucratic processes for faster clearance of all such applications of the 'project proponents', we need to look at completely omitting the step of ToR for B2 category units located in Notified Industrial Areas. After all it is just a duplication of EC appraisal, as almost the same data has to be submitted for both ToR and EC and that too, to the same office which ultimately amounts to duplication of work for both sides.

Lastly, we suggest following measures to streamline the manufacturing of Bulk Drugs by making suggested changes in the approval process. This changes will not in any way compromise on the pollution treatment and environmental monitoring:

1. Permissions to be given category wise as "APIs & Intermediates";
2. Monitor and control only the pollution load and not production quantity;.

3. Incentivise Waste reduction.

These measures will result in a quantum jump in much needed API production in the country and lead us towards the Prime Minister's dream of "*Atmanirbharta*" without any adverse impact on environment. We request you to kindly do the needful."

Encl: OM F. No. 22-35/2020-IA.III dated 18th November, 2020

MoEF&CC Office Memorandum

Streamlining the processes of granting Environmental Clearances - reg.

Ref. F.No.22-35/2020-IA.III, dated 18th November 2020

To
Chairman/Member Secretaries of all the Expert Appraisal Committees;
Chairperson/Member Secretaries of all the SEIAAs/SEACs;
All the Officers of IA Division.

1. During the review meetings held for streamlining the Environmental Clearances (EC) process it has come to notice that the grant of EC is delayed due to various reasons which could be avoided.

2. In this regard, the competent authority has desired that the Member Secretaries of the various sectors may strictly adhere to the following Guidelines to avoid unnecessary delay while granting ECs:

a. All EAC meetings shall be held at least twice a month to cut down the period of EC approval. There shall not be gap of more than 15 days between two EAC meetings.

b. All the fresh EC proposals which have been submitted up to 10 days before EAC meeting shall be taken up in the meeting. The Project Proponent shall be asked to submit the presentation also along with the EC application 85 other documents. However all the cases where ADS/EDS were raised and information submitted by Project Proponent even 2 days before the meeting shall be taken up.

c. Acceptance process shall be limited to just check if all the relevant documents have been submitted and all ToRs have been covered/addressed. The queries or issues, which the division may have, should be raised during the EAC meeting only. Member Secretary (MS) ought to ensure that the relevant queries of the division are also pointed out at the time of EAC meetings itself so as to avoid occasion for such queries before and after the examination by Expert Appraisal Committee (EAC). If any issue raised by the MS has not been considered by EAC, then the same may be brought to the notice of the Joint Secretary (JS) concerned. The concerned JS may take appropriate action in this regard.

d. All projects, placed in the agenda, should be considered by the EAC notwithstanding the non-attendance of the Project Proponent or his consultant in the EAC meeting to make a presentation. A clarification may however be sought from the consultant regarding reason for not attending the meeting.

e. In case a Project Proponent or his consultant did not attend the meeting or does not reply to the queries raised for more than six month, the MS should write to the Regional Office of the Ministry to carry out a site inspection so as to check if construction/operation of the project has started.

f. The MSs shall take up all the proposals to the EAC for which the reply to ADS has been received even after the agenda has been uploaded, until two working days before the date of EAC meeting.

g. All the above instructions apply to the cases of ToRs and amendments also to the extent relevant.

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

Sharath Kumar Pallerla, Director-IA (Policy), Ministry of Environment, Forest and Climate Change, (Impact Assessment Division), New Delhi.

● ● ●

Tax Calendar - December 2020 & January 2021

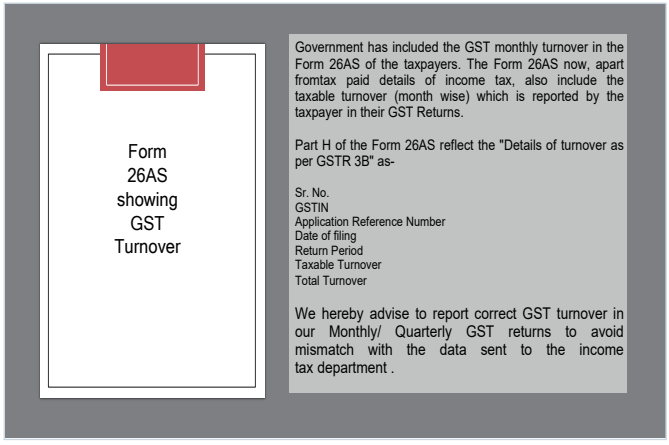
Mr B G Barve, Chairman, Excise & Taxation Committee, IDMA

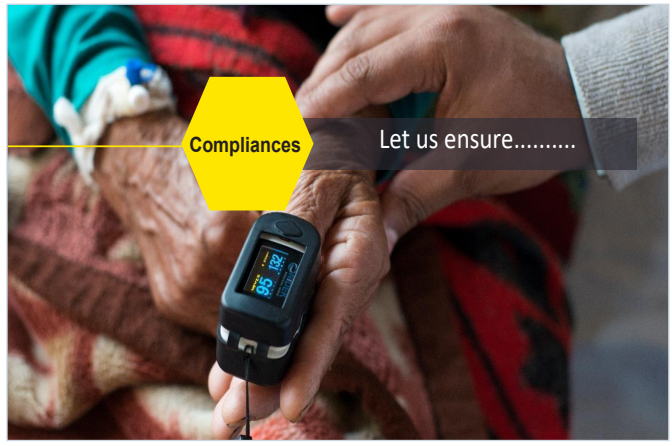
Particulars	Period	Due Date
TDS /TCS Liability Deposit	November 2020	07-12-2020
Advance Tax Payment	October to December, 2020	15-12-2020
PF/ESIC	November 2020	15-12-2020
Tax Audit Report filing	F.Y. 2019-20	31-12-2020
Income Tax Return filing in case of Individual	F.Y. 2019-20	31-12-2020
TDS /TCS Liability Deposit	December 2020	07-01-2021
PF/ESIC	December 2020	15-01-2021
Quarterly TCS return	October, 2020 to December, 2020	15-01-2021
Quarterly TDS return	October, 2020 to December, 2020	31-01-2021
Income Tax Return filing in case of Company/ where Audit is mandatory/ Transfer Pricing Audit/ a partner in a firm whose audit is mandatory	F.Y. 2019-20	31-01-2021
Bonus payment under Income Tax	F.Y. 2019-20	31-01-2021*
Bonus payment under Sec 9 of Payment of Bonus Act ("POBA")	F.Y. 2019-20	30-11-2020 (On or before 8 months from close of accounting year)
Filing of Bonus Return as per POBA	F.Y. 2019-20	30-12-2020 (Within 30 days after expiry of payment of bonus)

*As per Sec 43B of Income Tax Act ("the Act"), Bonus is payable on or before the date of furnishing Return of Income u/s 139(1) of the Act. However, as per POBA, Bonus payment is to be made on or before 30th November, 2020.

GST and Taxation Updates - November, 2020

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





E Invoice System implementation

Notification No. 88/2020 - Central Tax dated 10th November, 2020

Registered person, other than those referred to in sub-rules (2), (3), (4) and (4A) of rule 54 of the CGST rules, whose aggregate turnover in a financial year exceeds 100 crore rupees (earlier it was five hundred crore), shall prepare e-invoice w.e.f. 1st Janauary 2021.

We hereby advise to get ready well before 31st December 2020 for implementation of E Invoice template in SAP or Accounting platform.

Cost Audit for 2019-20 Last Date 30.11.2020

In view of the extraordinary disruption caused due to the pandemic, if Cost Audit Report for 2019-20 by the Cost auditor to the board of directors of companies is submitted by 30th November 2020 then the same would not be viewed as violation of Rule 6(5) of companies (cost records and audit) Rules 2014. Consequently, the cost audit report for 2019-20 shall be filed within 30 days from the date of receipt of the copy of the Cost audit report by the company.

Let us ensure Cost Audit Report from our Cost Auditors well before 30th November 2020.

GSTR 9 AND GSTR 9C

Last date for submission of GSTR 9 and GSTR 9C is 31.12.2020.

In view of the extraordinary disruption caused due to the pandemic, Most of our members were not ready to file GSTR 9 and GSTR 9C.

We had requested to authorities for extension of due dates to CBEC.

We hereby advise to file GSTR 9 and GSTR 9C well before 31st December 2020.

Notification No. 87/2020-CT, dated November 10, 2020

Time limit for furnishing the declaration in FORM GST ITC-04 extended

CBEC has extended the time limit for furnishing the declaration in FORM GST ITC-04, in respect of goods dispatched to a job worker or received from a job worker, during the period from July, 2020 to September, 2020 till the 30th day of November, 2020.

This notification shall be deemed to have come into force with effect from the 25th day of October, 2020.

Let us ensure filing of ITC 04 for the period from July, 2020 to September, 2020 till the 30th day of November, 2020.

Notification No. 85/2020-CT, dated November 10, 2020

Special procedure for making payment of 35% as tax liability in first two month

The registered persons, who have opted to furnish a return for every quarter or part thereof, as the class of persons who may, in first month or second month or both months of the quarter, follow the special procedure such that the said persons may pay the tax due under proviso to sub-section (7) of section 39 of the said Act, by way of making a deposit of an amount in the electronic cash ledger equivalent to, - **(i) 35% of the tax liability paid by debiting the electronic cash ledger in the return for the preceding quarter where the return is furnished quarterly; or (ii) the tax liability paid by debiting the electronic cash ledger in the return for the last month of the immediately preceding quarter where the return is furnished monthly**:

Provided that no such amount may be required to be deposited-

(a) for the first month of the quarter, where the balance in the electronic cash ledger or electronic credit ledger is adequate for the tax liability for the said month or where there is nil tax liability.

(b) for the second month of the quarter, where the balance in the electronic cash ledger or electronic credit ledger is adequate for the cumulative tax liability for the first and the second month of the quarter or where there is nil tax liability.

Provided further that registered person shall not be eligible for the said special procedure unless he has furnished the return for a complete tax period preceding such month.

Explanation– For the purpose of this notification, the expression "a complete tax period" means a tax period in which the person is registered from the first day of the tax period till the last day of the tax period.

Notification No. 84/2020-CT, dated November 10, 2020

Class of persons under proviso to section 39(1) notified

The Government has notified the registered persons, having an aggregate turnover of up to five crore rupees in the preceding financial year, and who have opted to furnish a return for every quarter, under sub-rule (1) of rule 61A of the Central Goods and Services Tax Rules, 2017 as the class of persons who shall furnish a return for every quarter from January, 2021 onwards, and pay the tax due every month in accordance with the proviso to sub-section (7) of section 39 of the said Act, namely: — (i) the return for the preceding month, as due on the date of exercising such option, has been furnished (ii) where such option has been exercised once, they shall continue to furnish the return as per the selected option for future tax periods, unless they revise the same.

A registered person whose aggregate turnover crosses five crore rupees during a quarter in a financial year shall not be eligible for furnishing of return on quarterly basis from the first month of the succeeding quarter.

For the registered person falling in the class specified in column (2) of the Table below, who have furnished the return for the tax period October, 2020 on or before 30th November, 2020, it shall be deemed that they have opted under sub-rule (1) of rule 61A of the said rules for the monthly or quarterly furnishing of return.

Notification No. 83/2020-CT, dated November 10, 2020

Time limit for furnishing the details of outward supplies in FORM GSTR-1 extended

CBIC has extended the time limit for furnishing the details of outward supplies in FORM GSTR-1 of the Central Goods and Services Tax Rules, 2017, for each of the tax periods, till the eleventh day of the month succeeding such tax period:

Provided that the time limit for furnishing the details of outward supplies in FORM GSTR-1 of the said rules for the class of registered persons required to furnish return for every quarter under proviso to sub-section (1) of section 39 of the said Act, shall be extended till the thirteenth day of the month succeeding such tax period.

This notification shall come into force with effect from the 1st day of January, 2021.

Notification No. 82/2020-CT, dated November 10, 2020

Thirteenth amendment (2020) to the CGST Rules, 2017.

Rule 59 related to Form and manner of furnishing details of outward supplies has been substituted which will come into effect from the 1st day of January, 2021.

Rule 60 related to Form and manner of ascertaining details of inward supplies has been substituted which will come into effect from 1st day of January, 2021.

Rule 61 related to Form and manner of furnishing of return has been substituted which will come into effect from 1st day of January, 2021.

After Rule 61, Rule 61A shall be inserted for manner of opting for furnishing quarterly return.

After FORM-2A, the "FORM-2B [See rule 60(7)] Auto drafted ITC Statement (From FORM GSTR-1, GSTR-5, GSTR-6 and Import data received from ICEGATE) shall be inserted.

Notification No. 81/2020-CT, dated November 10, 2020

Amendment carried out in sub-section (1), (2) and (7) of section 39 vide Finance (No.2) Act, 2019.

The Central Government hereby appoints the 10th day of November, 2020, as the date on which the provisions of section 97 of the said Act shall come into force to amend sub-section (1), (2) and (7) of section 39.

*Under section 39(1) "such form, manner and within such time as may be prescribed" has been deleted.

*Under section 39(2) a registered person paying tax under the provisions of section 10 (Composition levy), have to furnish return electronically for each financial year or part thereof, earlier it was for each quarter.

Amendment in section 39 (7) are as under:

At the time of filing return under this section, it must be done taking into account inward and outward supplies of goods or services or both, input tax credit availed, tax payable and such other particulars during a month, in such form and manner, and within such time, as may be prescribed,

At the time of filing return under Composition Scheme, every registered person shall pay to the Government the tax due taking into account turnover in the State or Union territory, inward supplies of goods or services or both, tax payable, and such other particulars during a quarter, in such form and manner, and within such time, as may be prescribed.

Supreme Court on Hand Sanitisers classification

The Supreme Court on hallenging the levy of GST on hand sanitizers under the same Tariff Heading as insecticides etc.

The Supreme Court has directed the petitioner challenging the levy of GST on hand sanitizers under the same Tariff Heading as insecticides etc. to file the petition in the High Court.
The controversy revolves around the levy of GST on sanitizers primarily concerned with two Tariff Headings i.e. 3808 and 3004.
The Headings 3808 relates to disinfectants, apart from insecticides, herbicides, plant-growth regulators, etc. and attracts the GST rate of 18%.
However, the Heading 3004 relates to Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses and attracts the GST rate of 12%.
The sanitizer manufacturers or importers have stressed on the need to reclassify sanitizers as "Medicaments" given that it is being used as a protection from Coronavirus.

The petitioner contended, "this is the concern of manufacturers all over India. Sanitizer is being treated as an insecticide. But it is not an insecticide. I have come under 32."

Justice A. M. Khanwilkar asked, "32 is available to all. But every matter cannot be entertained under 32. You are espousing the cause of manufacturers as a public interest? How is this a PIL?"

The petitioner answered that he was before the Court in a writ petition.

The bench consisted of Justice Khanwikar, Justices B. R. Gavai, and Krishna Murari, while granting the liberty to move the appropriate forum said, "this is an issue of classification of items under different heads. That is case-specific and a general direction cannot be issued. Whether sanitizers, insecticides etc should be classified in one head would depend on contents and other factors. Go to the High Court, if you want. We cannot issue a writ in this matter".

MoH&FW Notification *re.* Import Licence in Form 10 - reg.

Gazette Notification No. S.O.4244(E), dated 26th November, 2020

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

And whereas, several import licences in Form-10 are in existence and their validity periods of three years are likely to expire shortly;

And whereas, pharmaceutical companies and their associations have requested for extension of the validity of import licence (Form-10) for six months in the wake of COVID-19 pandemic;

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

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

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

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

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

● ● ●

MoEF&CC issues amendment Notification *re.* Paragraph 9 of Environment Impact Assessment Notification No.S.O.1533(E), dated 14th September 2020 - reg.

Gazette Notification No.S.O.4254(E), dated 27th November, 2020

Whereas, the Central Government in the erstwhile Ministry of Environment and Forests, in exercise of its powers under sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 has published the Environment Impact Assessment Notification, 2006 (hereinafter referred to as the said notification) vide number S.O.1533(E), dated the 14th September, 2006, making the requirement of prior environmental clearance from the concerned regulatory authority mandatory for all new projects or activities listed in the Schedule to the said notification, their expansion and modernization and/or change in product mix, as the case may be, before any construction work or preparation of land by the project management except for securing the land;

And whereas, in view of the outbreak of Corona Virus (COVID-19) and subsequent lockdowns (total or partial) declared for its control, implementation of projects or activities in the field has been affected. Ministry is in receipt of number of requests for extension of the validity of prior environmental clearances beyond the maximum period allowed in the said Notification, as the COVID-19 pandemic has not yet come to an end. The matter has been examined in the Ministry and the concern is genuine keeping in view the fact that due to lockdowns (total or partial), continuation of activities in the field may be difficult.

Now, therefore, in exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of

section 3 of the Environment (Protection) Act, 1986 (29 of 1986), read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government, after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the said rules in public interest, hereby makes the following further amendments in the notification of Government of India, in the erstwhile Ministry of Environment and Forests, vide number S.O.1533(E), dated the 14th September, 2006, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (II), namely:-

In the said notification, after paragraph 9 and before paragraph 10, the following shall be inserted, namely:-

"9A. Notwithstanding anything contained in this notification, the validity of prior environmental clearances granted under the provisions of this notification in respect of the projects or activities whose validity is expiring in the Financial Year 2020-2021 shall deemed to be extended till the 31st March, 2021 or six months from the date of expiry of validity, whichever is later. Such extension is subject to same terms and conditions of the prior environmental clearance in the respective clearance letters, to ensure uninterrupted operations of such projects or activities which have been stalled due to the outbreak of Corona Virus (COVID-19) and subsequent lockdowns (total or partial) declared for its control".

F. No. 22-25/2020-IA.III

Geeta Menon, Joint Secretary, Ministry of Environment, Forest and Climate Change, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O.1533(E), dated the 14th September, 2006 and was last amended vide the Notification number S.O. 3752(E), dated the 20th October, 2020.*

● ● ●

GOVERNMENT PRESS RELEASES

Very Positive response from Pharmaceutical and Medical Device Industry to PLI Schemes for Bulk Drugs and Medical Devices which closed on 30.11.2020

Received 215 applications from Manufacturers of Bulk Drugs and 28 Applications for Manufacturing Medical Devices under PLI schemes

Ministry of Chemicals & Fertilizers Press Release dated 1st December 2020

Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices have shown a very positive response from the Pharmaceutical as well as the Medical Device Industry. The industry has shown a very good response to these schemes whereby 215 applications made by 83 Pharmaceutical manufacturers have been received under the PLI Scheme for bulk drugs. Similarly, 28 applications made by 23 medical device manufacturers have been received under the PLI Scheme for medical devices. The closing date of applications was 30.11.2020. IFCI Ltd is the Project Management Agency (PMA) for implementation of both the schemes.

The appraisal process of the applications will commence from today (01.12.2020) onwards and a maximum of 136 applications under the PLI scheme for bulk drugs and a maximum of 28 applications under the PLI scheme for medical devices will be approved. The time duration for giving approval to the applicants is 90 days under the PLI scheme for bulk drugs and 60 days under the PLI scheme for medical devices. However, best efforts will be done by the PMA and the Department of Pharmaceuticals to give early approvals to the participants under the scheme.

Looking at the increasing imperative of drug security, support to domestic production capability in bulk drugs would ensure higher resilience of the Indian Pharmaceutical industry to external shocks. The PLI scheme for medical devices will help meet the objective of product diversification and production of innovative and high value medical devices in India. These initiatives have the potential to contribute significantly to achieving

higher objective of affordable healthcare in the country and globally on a sustained basis.

The PLI Schemes for Bulk Drugs and for Medical Devices was approved by the Government on 20.03.2020. The initial Guidelines for implementation of both the schemes which were initially issued on 27.07.2020 were amended based on the feedback received from the industry. These revised Guidelines were issued on 29.10.2020. Both the schemes have shown a very encouraging response from the Pharmaceutical as well as the Medical Device Industry.

Courtesy: PIB, MoC&F Press Release, 01.12.2020

● ● ●

India signs MoU with USA on Intellectual Property Cooperation

DPIIT Press Release dated 3rd December 2020

India, USA sign MoU on Cooperation. Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry has signed a Memorandum of Understanding (MoU) on 2nd December 2020, in the field of Intellectual Property Cooperation with the United States Patent and Trademark Office (USPTO), Department of Commerce of the United States of America. Dr Guruprasad Mohapatra, Secretary, DPIIT and Mr Andrei Iancu, Under Secretary of Commerce for Intellectual Property & Director, United States Patent and Trademark Office (USPTO) conducted a virtual signing ceremony for the same.

The Union Cabinet in its meeting dated 19.02.2020 gave the approval for signing the MoU with United States Patent and Trademark Office (USPTO) in the field of IP Cooperation. The MoU aims at increasing IP Cooperation between the two countries by way of:

(a): Facilitating exchange and dissemination of Best Practices, Experiences and Knowledge on IP among the Public, between and among the Industry, Universities, Research and Development (R&D) Organizations, and Small and Medium-sized Enterprises through participation in programs and events organized singly or jointly by the Participants;

(b): Collaboration in training programs, exchange of experts, technical exchanges and outreach activities;

(c): Exchange of Information and Best Practices on processes for registration and examination of Applications for Patents, Trademarks, Copyrights, Geographical indications, and Industrial Designs, as well as the Protection, Enforcement and use of IP rights;

(d): Exchange of information on the Development and Implementation of Automation and Modernization Projects, new documentation and information systems in IP and procedures for management of IP Office services;

(e): Cooperation to understand various issues related to traditional knowledge, and the exchange of best practices, including those related to traditional knowledge databases and awareness raising on the use of existing IP systems for the protection of traditional knowledge; and

(f): Other Cooperation activities as may be mutually decided by the Participants.

The two side will draw up Biennial Work Plan to implement the MoU which will include the detailed planning for carrying out of the Cooperation activities including the scope of action. The MoU will go a long way in fostering the Cooperation between India and USA, and provide opportunities to both countries to learn from the experience of each other, especially in terms of best practices followed in the other country. It will be a Landmark step forward in India's journey towards becoming a major player in global innovation and will further the objectives of National IPR Policy, 2016.

Source: DPIIT Press Release, 03.12.2020

● ● ●

CBIC notifies New Exchange Rates w.e.f. 20th November 2020 - reg.

Notification No.108/2020-Customs (N.T.), dated 19th November, 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.105/2020-Customs(N.T.), dated 5th November, 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 20th November, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	55.40	53.10
2.	Bahraini Dinar	203.55	191.10
3.	Canadian Dollar	57.80	55.80
4.	Chinese Yuan	11.50	11.15
5.	Danish Kroner	12.00	11.60
6.	EURO	89.65	86.45
7.	Hong Kong Dollar	9.75	9.40
8.	Kuwaiti Dinar	251.05	235.40
9.	New Zealand Dollar	52.70	50.40
10.	Norwegian Kroner	8.35	8.10
11.	Pound Sterling	100.05	96.65
12.	Qatari Riyal	20.80	19.45
13.	Saudi Arabian Riyal	20.45	19.20
14.	Singapore Dollar	56.30	54.40
15.	South African Rand	4.95	4.65
16.	Swedish Kroner	8.80	8.50
17.	Swiss Franc	83.20	79.95
18.	Turkish Lira	9.90	9.35
19.	UAE Dirham	20.90	19.60
20.	US Dollar	75.20	73.50

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	73.00	70.35
2.	Korean Won	6.90	6.45

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

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

● ● ●

In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Uniform Code for Pharmaceutical Marketing Practices (UCPMP)

Rajya Sabha Unstarred Question No. 702

Shri Jyotiraditya M Scindia:

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

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

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

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

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

Answered on 18th September 2020

A. (a): No Sir.

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

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

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

Dr Eshwara Reddy Committee Report

Rajya Sabha Unstarred Question No.703

Shri V Vijayasai Reddy:

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

(a): whether Dr Eshwara Reddy Committee has submitted its report;

(b): if so, the details of each of the recommendation made by the Committee;

(c): how has the Indian pharma sector been coping since Hubei province, the main place of manufacture of Active Pharmaceutical Ingredients (APIs) in China closed factories in view of COVID-19; and

(d): how Government will ensure that APIs are made available domestically to Indian Pharma companies at affordable price?

Answered on 18th September 2020

A. (a) & (b): Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers had constituted a Committee under the Chairmanship of Dr S Eswara Reddy, to address the issue of drug security in the country in the context of Novel Corona Virus outbreak in China on 06.02.2020. The committee had submitted its report on 27.02.2020. The Committee reviewed the situation regarding impact on import of APIs and KSMs due to outbreak of Corona virus and identified four core issues viz:

(1): Disruption of manufacturing activity in China due to holidays;

(2): Logistics issues;

(3): Restriction on movement of personnel and

(4): Availability of raw materials for manufacturing of APIs/KSMs. The committee has observed that there could be major impact on import of certain APIs and KSMs which are manufactured in Hubei province in China. The recommendations made by the Committee are as under:-

(i): As Hubei province is seriously affected due to outbreak of the Coronavirus and the manufacturing units located in this province

are expected to resume their activities after control of Coronavirus, Government may consider for requirement of prior NOC from competent authority like DGFT for export of following APIs and its formulations where there may be a shortage:-

- Chloramphenicol, Neomycin, Progesterone, Vitamin B1, Vitamin B 12, Vitamin B 6, Acyclovir Erythromycin salts, Metronidazole, Tinidazole, Ornidazole, Clindamycin, Paracetamol.

(ii): It is given to understand that some of the traders/importers have started raising the prices of APIs/KSMs. Therefore, Government should take necessary steps under the Essential Commodities Act to ensure that there is no rise in the prices of APIs/KSMs in the country.

(iii): Government should also issue advisory to all the State/UT Governments to ensure that merchant importers/stockists as well as indigenous manufacturers of APIs do not hoard and create artificial scarcity of APIs/KSMs in the country.

(iv): As the logistics seems to be a major issue in China, in case of scarcity, the Government should make special arrangements by providing logistic support for importing these APIs/KSMs from China by air.

(v): The DGFT should provide import and export data of these 58 APIs identified and their KSMs on daily basis to Department of Pharmaceuticals to monitor and assess the impact on their import/export.

(vi): CDSCO should process applications received from Countries other than China for import & registration of these 58 APIs, if any, expeditiously to facilitate their import from these country.

(vii): The Government should establish "Drug Security Authority" under the Department of Pharmaceuticals not only to make India self-sufficient but also global leader in manufacturing of APIs/KSMs/Intermediate/Chemicals for domestic as well as export. Such authority will ensure complete ecosystem in terms of infrastructure, technology, business model, etc for the manufacturing from basic chemicals/reagents to APIs in India. Making India self-sufficient for APIs/KSMs will save around INR 30000 Cr of foreign exchange which is currently spent for import. The authority should consider taking measures for addressing various challenges faced by Indian API industry which include, but not limited to the following:-

(a): Large fermentation plants are needed to be set up with lower land cost, continuous supply of electricity and other utilities at lower prices for augmenting the manufacturing of APIs such as antibiotics, sartans, vitamins etc.

(b): Provision for setting up of common facilities like Common Effluent Treatment Plant (CETP), solvent recovery plant, power and steam units, quality control laboratory, logistics centres(ware houses) etc.

(c): Similar measures need to be taken for other APIs and intermediates/KSMs, Catalysts, Solvents, etc which are not made in India and where there is high dependence on imports.

(d): To streamline the process of Environmental approval for APIs/KSMs industry by the way of introduction of system of granting such approval facility wise (irrespective of number of products) based on submission of Self Certification.

(viii): To meet budgetary requirement to establish the said authority and support the API industry, Government should consider imposing CESS on import of APIs/KSMs.

(ix): Since Manufacture of APIs and KSMs requires considerable infrastructure and Investment, this industry may be declared as an Infrastructure industry to provide for facility of easy finance, etc.

(x): Formulations manufactured by utilizing the indigenous APIs in respect of the identified 58 drugs should be given price incentives both for Scheduled and non-scheduled categories.

(xi): To make it attractive and profitable for manufacturing these products, Tax Holiday for 10 years may be declared.

(xii): The committee also recommended that in case of emergency, Government may also consider invoking of Rule 24(2) of Drugs and Cosmetic Rules 1945 for grant of Import License for import of specific drugs exempting the requirement of obtaining registration certificate.

(xiii): Incentives to be offered by the Government shall be prioritized to those APIs/KSMs (Out of 58 APIs/KSMs) for which India is heavily dependent on imports.

(xiv): Special incentives shall be provided to the first five manufacturers showing their interest to establish such APIs/KSMs industry.

(xv): Government should also constitute a Technical Committee to make recommendations for the revival of fermentation industry, new technologies for manufacturing of APIs including its backward integration, costing of the projects and identification of strategic business models. This Technical Committee should consist of one drug regulator, minimum two R&D Scientists, one expert with financial background, two experts handling such projects/manufacturing activities, etc.

(c): During the closure of Hubei Province there were apprehensions that supplies of essential raw materials for making drugs will get affected. However, major indian pharmaceutical companies had adequate stocks of the raw materials which were closely monitored by the government. The regular supply chain was restored in few months once the Hubei Province was opened.

(d): With a view to attain self-reliance and reduce import dependence in APIs/Bulk drugs, the department of pharmaceuticals has rolled two schemes viz.

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

(ii): "Promotion of Bulk Drug Parks". The Guidelines of both the schemes were released on 27th July, 2020.

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

Addressing the Issues Pertaining to Exporters

Rajya Sabha Unstarred Question No.707

Shri Kanakamedala Ravindra Kumar:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether Government has taken any initiative to discuss and address the issues of exporters that have arisen due to COVID-19 pandemic;

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

(c): if not, the reasons therefor?

Answered on 18th September 2020

A. (a) to (c): Since March 2020, during COVID-19 pandemic, regular meetings were held with the Export Promotion Councils (EPCs), Chambers of Commerce and Industry, Industry bodies and Associations to discuss issues and problems faced by the exporters and ways to promote exports during the pandemic. The issues raised by them were taken up with the concerned Ministries/Departments for an early redressal.

Government has taken the following key steps to boost exports:

(i): The validity of Foreign Trade Policy (2015-20) extended by one year i.e. upto 31.03.2021 and relaxations granted and time lines extended due to COVID-19.

(ii): Extension of export obligation period in respect of Advance Authorizations and Export Promotion capital Goods (EPCG) authorizations under Foreign Trade Policy (FTP), extension of Letter of Permissions (LoP)/Letter of Intents (LoI) of Export Oriented Units, various relaxations to SEZ units as a measure to make them functional and to ease compliances and simplification and liberalization of procedures of trade remedial investigations.

(iii): Interest Equalization Scheme on pre and post shipment rupee export credit has been extended by one year.

(iv): Line Ministries have notified various sectoral incentive packages, such as Production Linked Incentive Scheme (PLI) by Ministry of Electronics and Information Technology (MeitY) and PLI Scheme by Department of Pharma for Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs).

(v): Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase the Free Trade Agreements utilization by exporters.

(vi): A comprehensive "Agriculture Export Policy" is under implementation to provide an impetus to agricultural exports related to agriculture, horticulture, animal husbandry, fisheries and food processing sectors.

(vii): Promoting and diversifying services exports by pursuing specific action plans for the 12 Champion Services Sectors.

(viii): Promoting districts as export hubs by identifying products with export potential in the District, addressing bottlenecks for exporting these products, supporting local exporters/manufacturers to scale and generate employment in the District.

(ix): Strengthening eco-system for adoption/ implementation of mandatory technical standards for goods, services and skilling.

(x): Energising Indian missions abroad towards promoting our Trade, Tourism, Technology and Investment goals.

(xi): Package announced to support domestic industry, including through various banking and financial sector relief measures, especially for Micro, Small & Medium Enterprises (MSMEs), which constitute a major share in exports.

The Minister of Commerce and Industry
(Shri Piyush Goyal)

● ● ●

GST MATTERS

CBIC waives penalty payable for noncompliance of provisions of Notification No.14/2020–Central Tax, dated 21st March, 2020 - reg.

Notification No.89/2020-Central Tax, dated 29th November, 2020

In exercise of the powers conferred by section 128 of the Central Goods and Services Tax Act, 2017 (12 of 2017) (hereafter in this Notification referred to as the said Act), the Government, on the recommendations of the Council, hereby waives the amount of penalty payable by any registered person under section 125 of the said Act for non-compliance of the provisions of Notification No.14/2020–Central Tax, dated the 21st March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.197(E), dated the 21st March, 2020, between the period from the 01st day of December, 2020 to the 31st day of March, 2021, subject to the condition that the said person complies with the provisions of the said Notification from the 01st day of April, 2021.

F.No-CBEC-20/16/38/2020-GST

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

● ● ●

CCMB Scientists develop new COVID-19 testing technique that helps in scaling up samples and reduce cost & time

A team of Scientists from Centre for Cellular and Molecular Biology (CCMB) in Hyderabad has developed an innovative and most effective COVID-19 testing technique using dry swabs which will help in scaling up samples as well as reduce cost and time. With this, the CCMB Scientists' claim that the testing of samples collected from the suspected Coronavirus infected can be speeded up 2-3 times compared to the present method and at the same time the new technique is more safer and involves less complexities with regard to transportation of samples from one place to the other during testing.

According to Dr Rakesh Mishra, Director of CCMB, the new dry swab RT-PCR technique to detect Covid-19 has already got approval from the Indian Council of Medical Research (ICMR). "The new testing technique developed by CCMB is approved by ICMR and regarded as most equally effective compared to the present technique and at the same time it can be scaled up by at least two to three times without any additional resources to conduct large number of COVID-19 tests within a short span of time period," informed the CCMB Director.

Explaining further, the CCMB Director said that the new COVID-19 testing technique does not even require transportation of the collected samples in Viral Transport Medium (VTM) and also eliminates the RNA extraction step in the RT-PCR tests, which will save time and money. In the earlier testing method, it involves collection of nasopharyngeal swab samples and transporting them to RT-PCR testing centers. For safety, the swab samples are placed in a liquid called VTM and to avoid leakage and later they are packed heavily that adds to the samples processing time at both sample collection and also testing centers.

However in the new technique of dry swab testing developed by the Scientists, there is no need for the samples to be placed in the VTM and there does not involves the complex process of packing heavily to make sure there is no leakage. And also the testing staff at the testing laboratories can handle a large number of samples and go straight to RT-PCR, without wasting hours of time for extracting RNA. It is learnt that in the present old technique, it roughly takes at least 4-5 hours of time to extract RNA for nearly 500 samples. The VTM and RNA extraction process takes not only time but it also costs a lot of expenditure. The CCMB Scientists also said that the new testing technique also holds good for all kinds of settings and has the potential to reduce the cost of testing up to 50 percent.

Source: A Raju, Pharmabiz, 01.12.2020

● ● ●

Predict cellular drug targets against COVID-19

A computational model of a human lung cell has been used to understand how SARS-CoV-2 draws on human host cell metabolism to reproduce by researchers at the University of Warwick. This study helps understand how the virus uses the host to survive, and enable drug predictions for treating the virus to be made.

Viruses rely on their host to survive, a crucial step of lifecycle is the synthesis of the virus particles within the host cell, therefore understanding this process is key to finding ways to prevent the virus from surviving.

Using a computer model of a human lung cell metabolism, scientists from the School of Life Sciences at the University of Warwick have captured the stoichiometric amino and nucleic acid requirements of SARS-CoV-2, the virus that causes COVID-19. Publishing their results in the paper, 'Inhibiting the reproduction of SARS-CoV-2 through perturbations in human lung cell metabolic network', in the journal Life Science Alliance.

Their model has identified host-based metabolic perturbations inhibiting SARS-CoV-2 reproduction, highlighting reactions in the central metabolism, as well as amino acid and nucleotide biosynthesis pathways. In fact, researchers found that only few of these metabolic perturbations are able to selectively inhibit virus reproduction.

Researchers have also noted that some of the catalysing enzymes of such reactions have demonstrated interactions with existing drugs, which can be used for experimental testing of the presented predictions using gene knockouts and RNA-interference techniques. Professor Orkun Soyer, from the School of Life Sciences at the University of Warwick comments: "We have created a stoichiometric biomass function for the COVID-19-causing SARS-CoV-2

virus and incorporated this into a human lung cell genome scale metabolic model.

"We then predicted reaction perturbations that can inhibit SARS-CoV-2 reproduction in general or selectively, without inhibiting the host metabolic maintenance. The predicted reactions primarily fall onto glycolysis and oxidative phosphorylation pathways, and their connections to amino acid biosynthesis pathways."

Dr Hadrien Delattre, from the School of Life Sciences at the University of Warwick adds: "Together, these results highlight the possibility of targeting host metabolism for inhibition of SARS-CoV-2 reproduction in human cells in general and in human lung cells specifically. He added, "More research needs to be carried out to explore SARS-CoV-2 infected cells and their metabolism, however the model developed here by the researchers can be used as a starting point for testing out specific drug predictions".

Source: University of Warwick, Science Daily, 25.11.2020 (Excerpts)

● ● ●

Pharma hiring to remain conservative despite pace in vaccine development: Study

The Indian Pharma sector is expected to remain muted with its headcount additions, irrespective of the pace in vaccine development, according to a study by executive search firm Xpheno.

The top 25 Pharma brands by size have a total active job openings count of about 4,500 jobs globally and only 6% of these active openings are currently open in India, according to the study on human capital and job information. The data collected for the study is from top job boards, company career pages, and official company pages on social media.

Stagnation - if not reduction in net addition figures - should be expected for the year ending March 2021, because core Pharma functions of research, product development and manufacturing are already built for scale and spike, the study suggested.

"Support functions in the Pharma space are typically optimised and hence are not expected to shed headcounts or have short-term spike in additions," said Kamal Karanth, co-founder, Xpheno. The impact of a vaccine release would be largely visible at the logistics and sales end of the Pharma sector.

Short-term reduction of headcounts in marketing and sales by some brands would be reversed once the sales machinery kicks in on new competitive vaccines, said Karanth.

Source: Rica Bhattacharyya, The Economic Times, 28.11.2020

● ● ●

Cambridge's Chemistry Department named after Dr Y K Hamied

A supplied Photo of Indian Scientist Yusuf Hamied (University of Cambridge)

The Department at the University of Cambridge where Indian Scientist Yusuf Hamied, Chairman of Pharma Major Cipla, studied has been named the Yusuf Hamied Department of Chemistry until 2050, the University announced on Tuesday, 01.12.2020.

Hamied, 84, who was a student at Christ's College, has retained close links with Cambridge over the past 66 years, the university said, adding that in 2018, he endowed one of the world's oldest academic chairs in chemistry, now known as the Yusuf Hamied 1702 chair.

The naming of the Department follows a "generous benefaction" from Hamied, whose father, K A Hamied, started Cipla in Mumbai. He has pioneered the supply of HIV/AIDS medicines to developing countries at lost cost.

He said, "Cambridge gave me the foundation of an education in chemistry, taught me how to live and showed me how to contribute to society. As a scholarship student myself, I am delighted to be able to support future generations of students. I will always be indebted to this great institution and everything it stands for."

The university said that Hamied's gift endows both a fund to attract and support the world's brightest academic talent in chemistry, including exceptional early career researchers in disciplines such as synthetic organic chemistry, and outstanding doctoral students from the UK and around the world through the new Hamied Scholars Programme.

Vice-Chancellor Stephen J Toope said, "Yusuf Hamied has demonstrated an unequivocal commitment to changing and improving lives since his time at Cambridge. I am profoundly grateful for his remarkable gift to the Department of Chemistry, which will benefit generations of students and researchers."

Hamied's honours include an honorary fellowship of Christ's College in 2004; the Padma Bhushan in 2005; an honorary fellowship of the Royal Society of Chemistry in 2012; and an honorary Doctorate of Science from the University of Cambridge in 2014. In 2019, he was elected an Honorary Fellow of the Royal Society and a Fellow of the Indian National Science Academy.

Head of the Chemistry Department James Keeler said, "We are extremely thankful to Dr Hamied for his visionary support for Chemistry at Cambridge, which will allow us to respond flexibly to future opportunities. His gift will ensure we continue to attract outstanding Scientists who will make the discoveries that help tackle some of the most pressing challenges in global society."

Source: Prasun Sonwalkar, The Hindustan Times, 02.12.2020

● ● ●

Government moots Covid-19 vaccine development unit in Kerala

The state Government has decided to constitute a five member committee to explore the possibility of setting up a Covid Vaccine Development unit in Kerala. The decision was taken in a meeting on the "vaccine trial" chaired by the Chief Minister.

Explaining the purpose of the committee, the order signed by Principal Health Secretary Dr Rajan Khobragade on November 16 states that they have to "explore the possibility of establishing a vaccine production unit in Kerala which can be used for the manufacture of other protein-based Biologicals like enzymes and cancer drugs". Secondly, the committee also has to explore "various collaboration possibilities for vaccine production". The committee will be headed by Dr Jacob John T, former Professor, Department of Clinical Virology and Microbiology, CMC Vellore.

At present, the state doesn't have a single Pharma unit developing any sort of vaccines. Even the Government's Kerala State Drugs and Pharmaceuticals Ltd doesn't have the infrastructure or manpower skills to produce vaccines at such large scale immediately. Establishing a vaccine production unit may take at least two years. At present, most of the Pharma units producing vaccines are mainly concentrated in Maharashtra and Tamil Nadu.

"Kerala in the past used to manufacture its own anti-rabies vaccine in public health labs but that was stopped long ago. Now, there are 50 registered Pharma units in the state but none of manufacture human-based vaccines here nor do they have the facility. The investment to establish such a production plant is huge," said pharmacologist Dr T G Ravikumar. The state Government is already in the process of preparing its vaccine priority list to know who needs the vaccine first.

Also, they are strengthening the vaccine delivery system, especially cold chain systems, to ensure they can accommodate more vaccines. "At the moment, we don't know for sure about the quantity of vaccines that Kerala will get from the Centre. So, there are discussions about whether we need to purchase vaccines separately and if so, how to go about it. It's all at the early discussion stage now," said a senior "health official.

Source: The Times of India, 21.11.2020

● ● ●

Pharma Industry expected to grow in double digits

Pharma companies are betting big on the prospects of the Indian market. Analysts expect the market to grow in double digits over the next few years, the fastest in the world. The industry was badly affected during the first quarter with the Covid-19 pandemic and the resulting lockdown affecting patient visits to doctors. However, with the easing of restrictions and drug firms adopting digital methods, their performance turned out to be better-than expected. This is expected to improve further during the third quarter of this fiscal.

For instance, domestic sales of Lupin fell 0.7 percent in the second quarter from a year ago because of the pandemic's impact on demand, particularly on acute drugs. With the market now turning around, the company is looking at a growth of 6-8 percent from the Indian market. In the last fiscal, the Indian market contributed in the range of 17 percent to 100 percent to the revenues of the companies. (It was 100 percent for Abbot Laboratories).

According to analysts at Bernstein, while the US market has been in the driver's seat dictating valuations, the domestic market remains the ever-reliable vertical for most generic companies. During the next 4-5 years, it will be the largest contributor to their profitability. Bernstein said the India formulations and life sciences market is worth $73 billion: of this the formulations market, which is the tenth largest in the world in terms of value, is worth

$24 billion in 2019. This is slated to grow at 11-12 percent annually over the next four years.

Bernstein said the Indian formulations market was slated to be the fastest grow-sing across the world in the next four years. According to the brokerage, the market has a unique set of factors that make it one of the most profitable: more than 25 percent Earnings Before Interest, Tax, Depreciation and Amortisation (EBITDA) and more than 20 percent return on capital employed.

Other factors include a high share of branded generics, less stringent regulations around product approval and manufacturing and free pricing in non-essential medicines, the analysts at Bernstein added. They pointed out that growth in the next 4-5 years will be driven by population growth, penetration of healthcare infrastructure and improving accessibility into smaller towns, increase in prevalence of chronic diseases, pricing growth and launches, including high-priced patented products.

The forecast comes at a time Covid-19 has brought about some key changes in the industry. With companies also tapping the digital way to market drugs and communicate with doctors, companies are expected to see some savings in sales and marketing expenses.

Source: The Telegraph online, 30.11.2020

● ● ●

Covid-19: PM virtually reviews vaccine progress of 3 more Pharma companies

PM Modi also discussed matters related to regulatory approvals of the vaccine candidates

Prime Minister Narendra Modi (File photo)

Prime Minister Narendra Modi on Monday, 30.11.2020 had virtual meetings with three teams working on developing and manufacturing vaccine for Coronavirus Disease (Covid-19). These teams were from Gennova Biopharmaceuticals Ltd in Pune, Biological E Ltd, and Dr Reddy's Laboratories Ltd, in Hyderabad, according to the statement released by PMO.

"The PM appreciated the efforts being taken by the Scientists in these companies to come out with a vaccine solution to tackle Covid-19. The potential of various platforms for vaccine development was also discussed," the statement read. PM Modi also discussed matters related to regulatory approvals of the vaccine candidates. "PM also asked the companies to come out with their suggestions and ideas regarding the regulatory processes and related matters," the statement said.

The PM also suggested the companies to have a vaccine outreach initiative in place for the general public so as to dispel myths or doubts about it."He suggested that they should take extra efforts to inform the general public in simple language about the vaccine and related matters such as its efficacy etc," read the statement.

Matters relating to logistics, transport and cold chain etc; in respect of delivering the vaccines were also discussed in the meeting. All the vaccine candidates discussed are at different stages of trials -- between phase 1 and phase 3 -- and detailed data and results are expected from early next year. Dr Reddy's Laboratories has tied up with the Russian Covid-19 vaccine developers to conduct phase 2/3 Clinical Trials for their Sputnik V in India.

Biological E has also recently started phase 1/2 Clinical Trials of its Covid-19 vaccine candidate. Gennova Biopharmaceuticals is also ready to test its m-RNA vaccine candidate against Covid-19. On Saturday, 28.11.2020 PM Modi had taken a three-city tour to physically review progress at three companies that are in advanced stages of developing and testing Covid-19 vaccine candidate. The companies he visited were Zydus Cadila in Ahmadabad, Bharat Biotech in Hyderabad, and Serum Institute of India in Pune.

Source: Rhythma Kaul, The Hindustan Times, 01.12.2020

● ● ●

SC says everybody can't be permitted to treat Covid, seeks Centre response on alternative Medicines

The Supreme Court on Thursday, 19.11.2020 sought response from Centre on the manner and extent of alternative medicine that can be permitted as an immunity booster against Covid-19 disease.

A bench headed by Justice Ashok Bhushan was hearing a plea filed by Dr A K B Sadbhavana Mission School of Homeopharmacy against the Kerala High Court decision in August this year holding that doctor under AYUSH (Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy) can prescribe immunity boosters in the backdrop of Covid-19, but it cannot be prescribed as a cure for the viral infection.

The bench also comprising Justices Subhash Reddy and M R Shah asked Solicitor General Tushar Mehta, representing the Centre, to file a counter affidavit detailing to what extent the alternative medicine could be are permitted in view of COVID.

The bench queried Mehta, are there any Guidelines by the Ministry of Ayush? This has effect all over the country. The bench emphasised that everybody cannot be permitted to treat. Mehta cited the advisory where all the details of usage of medicines was mentioned and submitted that he would place Guidelines on record.

The bench noted, "these can be taken not as a cure but as an immunity booster." Mehta replied, "Yes, they are not a cure, but only a booster." Concluding the hearing, the bench asked Mehta to file counter affidavit. The Government had submitted before the High Court as per AYUSH advisory tablets are given as immunity boosters and not as a cure for Covid-19.

According to March 6 Notification, preventive and prophylactic use specified includes Samshamani Vati 500 mg twice a day with warm water for 15 days under Ayurveda and Nilavembu Kudineer decoction 60 ml twice a day for 14 days was mentioned under Siddha. For Unani, the preparation prescribed was a decoction by boiling Behidana (Cydonia oblonga) 3 gm, Unnab (Zizyphus jujuba) 5 in number, and Sapistan (Cordia myxa) 9 in number in water.

These were to be boiled in 250 ml water until only half of the water remains and to be kept in a glass bottle and used when lukewarm. Under Homeopathy, Arsenicum Album 30, daily once in an empty stomach for three days was prescribed. The dose was to be repeated after one month by following the same schedule till Coronavirus infections are prevalent in the community, the Notification had stated.

According to the AYUSH Ministry Notification state Governments shall take steps to adopt alternative medicines to counter Covid-19. A lawyer moved the High Court seeking a direction to the state Government to implement a Notification issued by Ministry of AYUSH.

Source: IANS, ET-Health World, 21.11.2020

● ● ●

Health Ministry to amend Rule 43A of D&C Rules to allow import of drugs into country through ICD Tihi, Indore

The Union Health Ministry will soon amend Rule 43A of the Drugs and Cosmetics (D&C) Rules, 1945 to allow import of drugs into the country through Inland Container Depot Tihi, Indore in Madhya Pradesh based on Drugs Technical Advisory Board (DTAB) recommendation. DTAB in its 85th meeting (virtual) held on July 29, 2020 deliberated the matter and recommended for amendment of Rule 43A of the Drugs and Cosmetics Rules, 1945 based on representation from the Chief Manager, Container Corporation of India Ltd (CONCOR), a Public Sector Unit (PSU) under Ministry of Railways to include Inland Container Depot (ICD), Tihi, Indore in the approved list of ICD for import of drugs or Pharmaceuticals under Rule 43A of the Drugs and Cosmetics Rules, 1945.

CONCOR has shifted its ICD operations to ICD at Tihi, Indore. ICD, Tihi is the largest ICD catering to Industries of Indore, Pithampur, Dewas, Ratlam and Ujjain regions, including all Pharma industries in these regions. Therefore, considering the volume of business handled at ICD, Tihi and its strategic location with respect to surrounding industrial zones, Inland Container Depot (ICD), Tihi, Indore should be included in the approved list of ICD for import of drugs or pharmaceuticals under Rule 43-A of the Drugs and Cosmetics Rules, 1945.

DTAB deliberated the matter and recommended for amendment of Rule 43A of the Drugs and Cosmetics Rules, 1945 allowing import of drugs into the country through Inland Container Depot Tihi, Indore in Madhya Pradesh. Earlier on January 10, 2019, the Union Health Ministry had issued Gazette Notification adding Kamrajar Port and Mundra Port in Rule 43A. Rule 43A states that no drug shall be imported into India except through one of the following places, namely Ferozepore Cantonment and Amritsar railway stations in respect of drugs imported by rail across the frontier with Pakistan.

Ranaghat, Bongaon and Mohiassan railways stations in respect of drugs imported by rail across the frontier with Bangladesh. Petrapole Road in West Bengal, Sutarkandi

in Assam, Old Raghna Bazar and Agartala in Tripura in respect of drugs imported by road from Bangladesh. Raxaul in respect of drugs imported by road and railway lines connecting Raxaul in India and Birganj in Nepal

Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla and Inland Container Depots at Tuglakabad and Patparganj in Delhi and Tuticorin in Tamil Nadu and Marmugao port in Goa and Visakhapatnam in Andhra Pradesh in respect of drugs imported by sea into India. Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa, Bengaluru and Visakhapatnam in respect of drugs imported by air into India.

Source: Shardul Nautiyal, Pharmabiz, 01.12.2020

● ● ●

India-made Covid-19 vaccine could be launched as early as February: Government Scientist

An Indian Government-backed Covid-19 vaccine could be launched as early as February – months earlier than expected - as last-stage trials begin this month and studies have so far showed it is safe and effective, a senior Government Scientist told. Bharat Biotech, a private company that is developing COVAXIN with the Government-run Indian Council of Medical Research (ICMR), had earlier hoped to launch it only in the second quarter of next year.

"The vaccine has shown good efficacy," senior ICMR Scientist Rajni Kant, who is also a member of its Covid-19 task-force, said at the research body's New Delhi Headquarters on Thursday, 05.11.2020. "It is expected that by the beginning of next year, February or March, something would be available." Bharat Biotech could not immediately be contacted.

A launch in February would make COVAXIN the first India-made vaccine to be rolled out. India's cases of Coronavirus infections rose by 50,201 cases on Thursday (05.11.2020) to 8.36 million, second only to the United States. Deaths rose by 704, with the total now at 124,315. The daily rise in infections and deaths has slowed since a peak in mid-September.

Kant, who is the head of ICMR's Research Management, Policy, Planning and Coordination cell, said it was up to the Health Ministry to decide if COVAXIN shots can be given to people even before the third-stage trials are over. "It has shown safety and efficacy in the phase 1 and 2 trials and in the animal studies - so it is safe but you can't be 100% sure unless the phase 3 trials are over," Kant said.

"There may be some risk, if you are ready to take the risk, you can take the vaccine. If necessary, the Government can think of giving the vaccine in an emergency situation." Health Minister Harsh Vardhan said in September the Government was considering granting an emergency authorisation for a Covid-19 vaccine, particularly for the elderly and people in high-risk workplaces. Several leading vaccine candidates are already in final-stage testing. An experimental vaccine developed by Britain's AstraZeneca is among the most advanced ones, and Britain expects to roll it out in late December or early 2021. AstraZeneca has signed several supply and manufacturing deals with companies and Governments around the world, including with the Serum Institute of India. Other late-stage vaccines are developed by Moderna Inc, Pfizer Inc with partner BioNTech SE, and Johnson & Johnson.

Source: Reuters/ET-Health World, 06.11.2020

● ● ●

FPME urges Commerce Ministry to allow MEIS scrips for exporters

The Federation of Pharmaceutical Merchant Exporters and Allied Products (FPME) has urged Union Commerce and Industry Minister Piyush Goyal to allow Merchandise Exports from India Scheme (MEIS) scrips for all period immediately so that exporters can utilize their benefits. "Exporters have completed their exports and also realized their payments in foreign exchange. They have completed all their export obligations, but they are not able to apply for MEIS. We are aware of the Notification caping benefits of MEIS for exports from September to December 2020.

However, currently the MEIS module does not apply for MEIS for April 2020 to August 2020 as well," says Kamlesh Shah, President, FPME. Recently, MEIS module was removed for system upgrading which left exporters who received previous years export payments as they could not apply for MEIS. FPME stated, "This has become difficult that exporters, who were able to file MEIS for FY19-20 are not able to file claim at all. We are aware that MEIS is to be phased out and new scheme of RoDTEP will start from January 2021.

Exporters have been struggling to keep their cash flow and liquidity in these difficult times and such system

closure will add salt to the wound of the struggling exporters, especially the MSME exporters." Various pharmaceutical and allied products merchant exporters have been working hard to bring in the foreign exchange to India by exporting various Pharma and allied products. "Many exporters have faced several hardships with lack of facilities, manpower and logistical challenges but have made sure to successfully complete their export commitment not only to fulfill their commitment to their buyer, but also keep the India's promise.

In this competitive global market, lot of factors play important role in the pricing and export incentives like MEIS have been also quite important. In these challenging times, where cash flows and funds are stressed, these incentives however small are very important to keep the business rolling," stated Shah.

Source: Yash Ved, Pharmabiz, 01.12.2020

● ● ●

DoP to appoint Project Management Consultants to assist industry for common facilities scheme

The Department of Pharmaceuticals (DoP) has invited Request For Proposals (RFP) from Central Public Sector Enterprises (CPSEs) for Project Management Consultants (PMC) Service for Assistance to Pharmaceutical Industries for Common Facilities (API-CF) scheme. A Project Management Consultants (PMC) Service shall be selected by the DoP for providing Secretarial, Supervisory, Technical, Managerial and Implementation support to DoP for effective implementation of the Scheme.

DoP provides financial assistance for creation of common facilities to pharmaceutical industry. **Proposals must be received at the address specified below latest by December 14, 2020 at 5 pm at Navin Kishor Joshi, US (Scheme), Room No. 235, A-wing, Shastri Bhawan, New Delhi -110 001 (Address) by hand or by speed post.** Any proposal received by the DoP after the above deadline shall be rejected and returned unopened to the Bidder.

Common Facilities under the Assistance to Pharmaceuticals Industry-Common Facilities (API-CF) scheme which helps to create tangible "assets" as Common Facility Centres (CFCs). Some of the indicative activities under the Common Facilities are Common Testing Centres, Training Centres, R&D Centres, Effluent Treatment Plants and Common Logistics Centres. The above list of common facilities is illustrative and each cluster could have its own specific requirement based on the nature of units being set up and the products proposed to be manufactured.

The successful Bidder will provide consultancy services in accordance with the specifications provided in the scheme Guidelines and in the scope of work. The RFP for the bid is in two stages like the pre-qualification criteria and the financial evaluation criteria. The Scheme Steering Committee (SSC) shall approve the project components and funding thereof depending upon the merits of the proposal.

The PMC would be responsible for sensitization of the Industry/potential beneficiaries on the scheme and its benefits and also guiding them to form Special Purpose Vehicle (SPV), in drafting its Memorandum and Article of Association, to assist DoP in drafting and issuing invitation of expression of interest (EoI) or request for proposal for inviting projects under the scheme, formulating evaluation criteria and to assist DoP in the selection of projects from the proposals received in response to EOI/RFP, preliminary examination of the proposals received from states/UTs/ SPVs and seeking additional/necessary information including documents from States/UTs/SPVs if required for completeness of the proposals, appraisal of proposals and making appropriate recommendations to the Scheme Steering Committee (SSC) for approval of proposals under the Scheme, appraisal of DPRs including financial viability, commercial sustainability and socio-economic impact of the projects, in totality, determining project worthiness of DPR received, assisting the SPVs in the selection of agencies/experts for various services such as capacity building, business development, technical, engineering, etc.

PMC will also assist the SPVs in developing suitable O&M framework for making it more effective and enforceable so as to ensure that there is no conflict of interest, assist DoP in periodic monitoring and review of the projects and timely disbursement of the funds to the SPVs and their utilization of the funds, monitoring approved projects through implementation schedule based on Program Evaluation and Review Technique (PERT), monitoring event report at every stage, an ex-post activity chart with a complete breakdown of activities, the originally expected dates and actual dates along with the flow of fund requirements, periodic physical inspection of the Approved Projects, to assist the SPV in achieving financial closure and obtaining necessary clearances from various authorities for the project, any other matter pertaining to the Scheme assigned by DoP or SSC.

The procedure for submission of proposal stipulates that the financial bid shall be quoted in a percentage form of the grant-in-aid of the project cost. The Project cost can be different/varied from the actual project cost submitted by the SPV. The grant-in-aid shall be decided by SSC as per scheme Guidelines. Maximum grant-in-aid is Rs.20 crore for each project under the API-CF scheme.

Any attempt by a bidder to influence the bid evaluation process may result in the rejection of its RFP. As per the Scheme API-CF, maximum 10 projects can be considered by the DoP for granting the financial assistance over a period of FY 2020-21 to FY 2024-25. The time period for the implementation of the scheme may be truncated or extended beyond the FY 2024-25. The number of projects mentioned as above may be increased or decreased as per the decision of DoP.

Source: Shardul Nautiyal, Pharmabiz, 30.11.2020

● ● ●

Efforts to amend Schedule V of D&C Act to seek approval from FSSAI for vitamins need coordination: Experts

Just as the Government is preparing to amend provisions of Schedule V of the Drugs and Cosmetics (D&C) Rules, 1945 to ensure vitamins and minerals with doses up to one Recommended Dietary Allowance (RDA) to be regulated under Food Safety and Standards Authority of India (FSSAI) regulations, industry experts are of the view that the move would require coordination and accurate data submission to the new regulatory authority.

For all vitamins listed in Schedule V with doses of up to one RDA should be regulated under FSS Act, notes Drugs Technical Advisory Board (DTAB) after it assessed the Indian Council of Medical Research (ICMR) recommendations. Those vitamin preparations having prophylactic and therapeutic claims should be regulated under the D&C Act, 1940 and Rules, 1945 including Schedule V of the D&C Rules.

Dr D B A Narayana, who is the face behind the move as the former Scientific Member of FSSAI and now Chairman, Scientific Panel, Nutraceuticals for the Union Government, said that it was a step in the right direction. It will bring in the required clarity to both the Pharma/food industry and consumer. "As experts from the FSSAI, we saw that there was a need for clarity for vitamin and mineral preparations. We suggested that a very old Notification like Schedule V required to be amended," Dr Narayana told.

"DTAB proposed that necessary review of doses specified under Schedule V may be undertaken subsequently. Board was apprised that a proposal has been received from FSSAI proposing that D&C Rules, 1945 may be amended to delete the preparations containing the prophylactic doses under Schedule V considering the provision of doses under Section 22 of FSS Act, 2006 especially products formulated in tablets, capsules, liquids, etc meant for oral administration," stated a recent report in the public domain.

Section 22 of FSS Act, 2006, noted vitamin drugs as tablets, capsules covered under FSS Act below RDA also come under prophylactic and some of the therapeutic doses prescribed in Schedule V of the D&C Rules, 1945. FSSAI has also proposed amending the Schedule K (10) to revise the scope of substances used both as food and drugs so that same are exempted from the provisions of Chapter IV of the D&C Act and Rules.

According to Dr Vaibhav Kulkarni, Global ILSI Chair for ILSI Board Assembly & Board Member and Hon Secretary, Health & Dietary Supplements Association (HADSA), all vitamins and minerals, below therapeutic dosage, covered under Schedule V of the D&C Act may now have to be approved by the FSSAI. This essentially means, Pharma companies manufacturing Nutraceuticals in various forms like capsules and tablets etc with no therapeutic dose claim will now have to approach a new regulator, the FSSAI, since the DCGI will no longer license these products.

While, it is premature to tell whether this is a good move unless we have clarity on the details of the draft regulations, Pharma companies, who presently had limited interaction with the food regulator, will have to adapt to this new norm. Only time will tell what the advantages and disadvantages are. For successful implementation, close coordination between the industry, DCGI and the food regulator will be required. Also, how they deal with it maturely will determine the future course of action, added Dr Kulkarni.

Source: Nandita Vijay, Pharmabiz, 30.11.2020

● ● ●

Committed investment to improve success of Rs.25,000-cr PLI scheme to boost API industry: Expert

Committed investment instead of threshold investment and export sales could significantly improve the success of Production Linked Incentive (PLI) scheme launched

by the Centre to boost bulk drugs industry in the country. Overall, the PLI scheme demonstrates commitment of the Government towards building a self-sustaining and robust manufacturing ecosystem for the Pharmaceutical and medical devices industries, experts have recommended.

"Additionally, with the Foreign Direct Investment (FDI) policy in these sectors being substantially liberal coupled with the new effective Corporate Tax Rate of about 17% which includes surcharge and cess, the industry should be able to respond positively to the new PLI scheme," said Raviindranath Menon, Senior Business Adviser APAC Healthcare, South India, Nexdigm. Nexdigm (SKP) is a multidisciplinary group which provides customized solutions to the pharmaceutical industry including other key sectors that meet the needs of a dynamic business environment.

With the introduction of these schemes, the Government is helping create a manufacturing ecosystem in these segments so that the entire value chain is active in the country leading to a more robust and sustainable industry. The threshold investment requirement in bulk drugs production was a constraint for the manufacturers who can make minimum investment to produce identified products considering they already have common surplus utilities available to them.

As per PLI scheme Guidelines dated July 27, 2020, threshold investment was Rs.400 crore for four fermentation based products and Rs.50 crore for ten fermentation based products. Similarly, threshold investment was Rs.50 crore for four chemically synthesised products and Rs.20 crore for 23 chemically synthesised products.

The Government of India's Rs.25,000 crore consolidated Production Linked Incentive (PLI) scheme for promoting bulk drugs including the newly approved Rs.15,000 crore PLI scheme for boosting existing Brownfield Active Pharmaceutical Ingredients (API) units in the country has been hailed by the industry as a game changer. The Government, along with the relevant stakeholders, identified areas where domestic production is low, leading to higher imports. The PLI scheme will provide the dual benefit of reduction in imports as well as help in the creation of a manufacturing ecosystem where India is present end-to-end in the value chain.

"The manufacturers focusing on advanced technologies will benefit more as they will be given priority consideration. India lacks manufacturing in fermentation-based products which are imported from China. Currently, manufacturing them in India is more expensive and environmental clearances are difficult to obtain. With this incentive scheme, manufacturing will become more competitive and there would also be more support to provide faster environmental clearances," Menon further added.

The industry has given a very positive reaction to the scheme and believes it is a welcome step towards strengthening India's participation in the global supply chain. "While the introduction of these new schemes have been primarily focused on reducing import dependencies, it would have been beneficial to include more segments or products, especially for the medical devices sector," Menon added.

The schemes for both sectors of bulk drugs and medical devices are specific and targeted and address important concerns of the industry with respect to incentivizing local manufacturing. "The scheme should be open to all investments including Brownfield projects. For a scheme of this scale, there should have been a longer application window. The industry also believes that while the incentives are welcome, it is crucial to ramp-up utilization of idle capacity to invest in new infrastructure. Addressing these issues would also lead to greater participation," Menon concluded.

Source: Shardul Nautiyal, Pharmabiz, 26.11.2020

● ● ●

Pharma PLI Scheme: Industry worried about large capex & tough competition

Pharmaceutical companies have been lukewarm to the Government's production linked incentive scheme announced for the sector. This scheme was announced back in April and till now not a lot of them have applied for it. Speaking in an interview to CNBC-TV18, Vijay Garg, Joint MD of IOL Chemicals & Pharmaceuticals said, "We will not be applying for the pharma PLI scheme."

The last date for application of pharma Production Linked Incentive (PLI) scheme for Active Pharmaceutical Ingredients (APIs) and bulk drugs is November 30. However, players in the pharma sector have said that there is only a lukewarm response to the government's Production Linked Incentive scheme and some suggest more incentives and tweaks may be needed to ignite interest. Garg said, "The major thrust under PLI is on fermentation based products, which isn't IOL's area of expertise."

According to him, industry is worried about large capex and tough competition from China. "2-3 years is a short

time to bring in robust technology to compete with Chinese products," he said. Meanwhile, Adhish Patil, CFO of Aarti Drugs said that the company will be applying for the pharma PLI scheme. "However, the government will take 4 months to decide on who is eligible under PLI scheme," he said.

According to Sujay Shetty, Partner & Pharma Head of PWC India, the capex required to set up capacities under PLI scheme is a concern. Shetty also said, "Some API plants are subject to green clearance norms which could be a concern.

Source: Latha Venkatesh & Sonia Shenoy, cnbctv18.com, 29.11.2020 (Excerpts)

● ● ●

India becoming 'Pharmacy of the World'; foreign companies willing to tie-up with Indian Pharma companies

Sweden has acknowledged India's role as the 'Pharmacy of the World' and is focusing on expanding bilateral cooperation in the areas of health and life sciences in view of the Coronavirus pandemic.

Prime Minister Narendra Modi on 30.11.2020 asked Indian Pharma companies, involved in making Coronavirus vaccines, to give suggestions and ideas regarding the regulatory processes and related matters. Recently, there has been a surge in interest from foreign companies towards partnering with India's pharma companies.

Ambassadors of 100 countries are scheduled to arrive in Pune on December 4, to visit the Serum Institute of India, and Gennova Biopharma, said the Prime Minister's Office (PMO).

While Sweden has already acknowledged India's role as the 'Pharmacy of the World' and is focusing on expanding bilateral cooperation in the areas of health and life sciences in view of the Coronavirus pandemic, Luxembourg based company B Systems is partnering with India to produce portable vaccine refrigeration equipment, which will address the issue of vaccine distribution in India.

It is to be noted that PM Modi had recently held a virtual summit with his Luxembourg counterpart Xavier Bettel, during which he had stressed on intensifying bilateral cooperation. The Indian Government has also allocated Rs.900 crore for Mission Covid Suraksha, which is launched to accelerate vaccine development. This grant is to be provided to the Department of Biotechnology for Research & Development of Indian Covid-19 vaccines, and the Government will likely ensure that they are fast-tracked in public health systems, subject to all regulatory clearances.

So far, at least five Indian Pharmaceutical companies are engaged in vaccine development, and Serum Institute has been chosen for mass production of Covishield vaccine developed by Oxford – Astra Zeneca. The Government has further initiated a Covid-19 vaccine manufacturing and delivery ecosystem to meet the demand, PMO added. Meanwhile, in a three-city visit to the facilities of Zydus in Ahmedabad, Serum Institute in Pune, and Bharat Biotech in Hyderabad, PM Modi reviewed the progress of indigenous vaccine development. He further discussed matters related to logistics, transport, cold chain, etc, for delivering the vaccines.

Source: Samrat Sharma, The Financial Express, 01.12.2020 (Excerpts)

● ● ●

INTERNATIONAL NEWS

European Commission approves contract with Moderna to ensure access to a Potential Vaccine

The European Commission approved a sixth contract under the EU Vaccines Strategy, this time with the pharmaceutical company Moderna. The contract provides for the initial purchase of 80 million doses on behalf of all EU Member States, plus an option to request up to a further 80 million doses, to be supplied once a vaccine has proven to be safe and effective against COVID-19.

The contract with Moderna will enlarge the already broad portfolio of vaccines to be produced in Europe, including the contracts signed with AstraZeneca, Sanofi-GSK, Janssen Pharmaceutica NV, BioNTech-Pfizer and the contract approved with CureVac. This diversified vaccines portfolio will ensure Europe is well prepared for vaccination, once the vaccines have been proven to be safe

and effective. Member States can also decide to donate the vaccine to lower and middle-income countries or to re-direct it to other European countries.

President of the European Commission, Ursula vonder Leyen, said: "I'm very happy to announce today's agreement with the company Moderna to purchase up to 160 million doses of their future vaccine. This is our sixth contract with a vaccine producer, and we are working on yet another one. We are setting up one of the most comprehensive COVID-19 vaccine portfolios in the world, providing Europeans access to the most promising future vaccines under development so far. A safe and effective vaccine can help us end the pandemic, and return gradually to normal life."

Stella Kyriakides, Commissioner for Health and Food Safety, said: "Today's agreement with Moderna is yet another important milestone of our EU Vaccines Strategy. I am happy that we have now concluded six vaccine agreements so far.

This is a clear demonstration of the European Health Union in action: a European Union that delivers tangible results for its citizens and a blueprint for our cooperation in the area of health in the future. A safe and effective vaccine is more important than ever in helping to restore normality and overcome this pandemic. No one is safe until everyone is safe."

Moderna is a US based company pioneering the development of a new class of vaccines based on messenger RNA (mRNA) transported into cells by lipid nanoparticles. The vaccine platform has been developed over the last decade. The basic principle is the use of this molecule as a data carrier, with the help of which the body itself can make proteins and trigger lasting immunity to COVID-19.

The Commission has taken a decision to support this vaccine based on a sound scientific assessment, the technology used, and its production capacity in Europe to supply the whole of the EU.

Background:

The European Commission presented on 17 June a European strategy to accelerate the development, manufacturing and deployment of effective and safe vaccines against COVID-19. In return for the right to buy a specified number of vaccine doses in a given timeframe, the Commission finances part of the upfront costs faced by vaccines producers in the form of Advance Purchase Agreements. Funding provided is considered as a down-payment on the vaccines that will actually be purchased by Member States on the basis of the Advance Purchase Agreements.

Since the high cost and high failure rate make investing in a COVID-19 vaccine a high-risk decision for vaccine developers, these agreements will therefore allow investments to be made that otherwise might not happen.

Once vaccines have been proven to be safe and effective and have been granted market authorisation by the European Medicines Agency, they need to be quickly distributed and deployed across Europe. On 15 October, the Commission set out the key steps that Member States need to take to be fully prepared, which includes the development of national vaccination strategies. The Commission is putting in place a common reporting framework and a platform to monitor the effectiveness of national vaccine strategies.

The European Commission is also committed to ensuring that everyone who needs a vaccine gets it, anywhere in the world and not only at home. No one will be safe until everyone is safe. This is why it has raised almost 16 billion since 4 May 2020 under the Coronavirus Global Response, the Global Action for Universal access to tests, treatments and vaccines against Coronavirus and for the global recovery and has confirmed its interest to participate in the COVAX Facility for equitable access to affordable COVID-19 vaccines everywhere.

As part of a Team Europe effort, the Commission announced is contributing with 400 million in guarantees to support COVAX and its objectives in the context of the Coronavirus Global Response. On 12 November, the European Union announced the contribution of an additional 100 million in grant funding to support the COVAX Facility.

Source: World Pharma News, 25.11.2020 (Excerpts)

● ● ●

Countries around the world prefer Indian-origin generics: Prof Bejon Kumar Misra

*by **Prof Bejon Kumar Misra,** Founder-Director, Patient Safety, and Access Initiative of India Foundation*

Indian Pharma products have passed several quality studies by various bodies such as US FDA, NIB, etc and have been found acceptable for patient usage

Indian-manufactured generics and other drugs have significantly contributed to the growth of the Indian Pharmaceutical industry through the decades and even more so during the pandemic. With immense manufacturing capacity and high export volume, the Pharma Industry not just contributes to the Indian economy but net foreign exchange for the country. Having said that, the industry has promoted the betterment of the global public health outcomes by lowering the treatment costs of diseases such as Leukaemia and Hepatitis C through affordable therapeutics. The unceasing demand for Indian origin pharmaceutical products has enabled the industry to carve a niche for itself in the global ecosystem. In true sense, what 'Atmanirbhar Bharat' should be as a success model.

India contributed to one-fifth of the world's exports of generic drugs in 2019. The country also accounts for 26% of generic drug imports in European markets and 40% in the US. Despite this, there are several misconceptions regarding the quality of Indian generics, especially in the US, which is industry's largest market. A survey conducted by WebMD in collaboration with the US FDA suggested that close to 75% of the healthcare practitioners and patients in the US believe that the quality of drugs manufactured outside the US are of lower quality. There are several such studies instituted by organizations at more local scale, limited to individual countries. While necessary, such studies which consider limited variables and more specific sample sizes tend to project a skewed perspective.

Taking cognizance of this, a couple of years ago the Government of India launched one of the largest qualitative studies to assess the quality of drugs manufactured in India. Spearheaded by the National Institute of Biologicals (NIB), the exhaustive study spanned over two years and a project report on '*Survey on the Extent of the Problem of Spurious and Not of Standard Quality (NSQ) Drugs in India*' was released. India was one of the first countries in the world to institute such a large scale study with vast sample size.

In this context, it is extremely encouraging that the US has come forward to commission extensive and exhaustive studies to assess the quality of drugs imported. The US FDA's recently released study on '*Quality Testing of Difficult-to-Make Prescription Pharmaceutical Products Marketed in the US*' is a step in the right direction. The US FDA's report concludes that the quality of drugs imported and legally marketed in the US are on-par with those manufactured domestically. With Indian generics accounting for 36% of the sampled products and 9% of finished formulations, the drugs were marked acceptable for patient usage.

Why do studies and statistics matter?

With patient centricity and quality as key tenets, the Indian Pharma industry manufactures exports pharmaceutical products to more than 200 countries. India has been supplying life-saving drugs to most of the countries for decades. It is alarming for experts who work in the interest of patients to read media reports claiming India to be a hub of substandard and spurious medicines. The best way to address these misnomers is to conduct more qualitative and quantitative research studies at various capacities. Furthermore, as India is expanding and establishing its footprint in Pharma markets across the world, it is imperative to evidence the reality with academic research. The country passed the highest number of US FDA inspections between 2009 and 2016 with 840 FDA inspections in 2016. Such nuances ought to be highlighted to ensure elimination of dubious reports. This is only possible if global organizations like the World Health Organization collaborate with various regulatory authorities and work towards protecting the interests of countries with robust pharmaceutical ecosystems.

Bridging the necessary gaps:

The high volume of drugs exported by India is an evidence that countries around the world prefer Indian-origin generics. This should also act as a trigger

for the Indian Government to heavily invest in the pharmaceutical industry and foster an environment conducive to nurture R&D and innovation which would translate into creation of jobs. India's total healthcare spending stands at 3.6% of GDP which is significantly lower than that of other countries. There is a need to increase the spend to at least 5% of the GDP, in the near future.

The Pandemic has provided the industry to recalibrate and leverage the use of digital technologies. This increasing penetration of digital technologies in the ecosystem has given a rise to online pharmacies. The government should rethink the regulations governing this growing market and ensure that online players come under the gambit of stringent laws and regulations the Pharma industry is subject to. The industry and government should also work in tandem towards harmonizing the Drugs and Cosmetics Act of India with best global practices.

These regulatory overhauls must be accompanied by incentivizing pharmaceutical companies venturing into new drug discovery and vaccine development with a focus on quality. Furthermore, there is a dire need for the development of a robust distribution system along with non-clone-able tracking and tracing mechanism in place to ensure that medicines are not subject to tampering, thus assuring quality. The industry must also look at an operational process wherein the safe disposal of expired medicines is addressed.

The time is right for India to mobilize resources for manufacturing of pharmaceutical products and reduce taxes on medicines, which are currently high. The country should also consider bringing rational competitiveness by using Good Marketing and Ethical Practices, keeping patient centricity and quality at the centre of all policies.

Source: ET-Health World, 20.11.2020

● ● ●

Changes in the policies of Down Syndrome: Need of the hour

*by **Yashodhara Bhattacharya,** Clinical Genetic Counselor, Redcliffe Lifesciences and Crysta*

Down syndrome is a chromosomal disorder affecting 1 in 850-900 live births in India every year. It is the most common chromosomal anomaly and can be easily detected through various screening methods during the antenatal period. For the longest time, increased maternal age was considered as a major cause of Down syndrome.

However, extensive research in the field has found that even young mothers might be at a risk of having a child with Down syndrome. Such children experience intellectual disability along with other congenital anomalies which cause financial as well as an emotional strain on the parents. Research into the disease and further screening methods were developed to help detect this condition during pregnancy which would help reduce the burden of the disorder.

Until now, the first line of screening was limited to Serum marker testing in the form of Double Marker, Combined Test, Triple Marker and Quadruple Marker Test, prescribed to women with advanced age to identify the probable risk of the child being affected. However, these tests had an accuracy rate of only about 60%-70% and required further investigations in case of an abnormal screen.

With the progress in the field of genetics, cytogenetic tests were routinely made available for the confirmation of these disorders by directly testing the foetal sample through an invasive procedure (CVS/Amniocentesis) – a procedure that brought along with it a risk of miscarriage. Over time, advancements in the field of genetics have brought forward a revolutionary technology called Next Generation Sequencing (NGS), a high-through-put approach to DNA sequencing.

This contemporary technology is being offered as a part of antenatal screening though the NIPS (Non-Invasive Prenatal Screening)test. It is recommended to pregnant women post 10 weeks of gestation and uses freely floating

foetal DNA in the maternal blood stream to screen for Down syndrome and other chromosomal aneuploidies. The NIPS test has an accuracy rate of 99% in detecting high-risk pregnancies without the risk of miscarriage as compared to invasive testing.

Earlier, NIPS was recommended for screening in only high-risk pregnancies, but a recent Guideline passed by the American College of Obstetricians and Gynaecologists (ACOG) in August of 2020, recommends it for all women, regardless of their age and other risk factors. This is as part of their routine antenatal screening for Down syndrome and other chromosomal aneuploidies. The use of NIPS as a consistent screening method in pregnancy holds a promise to greatly reduce the burden of genetic disorders such as Down Syndrome globally.

The test must be adopted as a first-line screening test and for this to happen, the Government and private sectors must work together, among other things, to reduce costs, as well. As in other screening tests, NIPT also needs to be validated within our population before widespread adoption can be prescribed. Recently, as per a judgement passed by the Delhi High Court, it is illegal for insurance companies to exclude genetic disorders from their scope of coverage.

This can help encourage more couples to get testing done in a timely manner which will further help in early detection and management of Down Syndrome. Though prenatal screening and diagnosis of Down syndrome are practical in the Indian context, basic aspects such as generating awareness, understanding the risks, and timely screening must be established on an urgent basis. Among other things, this will require nationwide integrated large-scale data sharing and for relevant stakeholders to join hands and work towards it.

(Disclaimer: The views expressed are solely of the author and ETHealthworld.com does not necessarily subscribe to it. ETHealthworld.com shall not be responsible for any damage caused to any person/organization directly or indirectly.)

Source: ET-Health World, 21.11.2020

● ● ●

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

***Kindly note**:*

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association".***
- For **RTGS / NEFT**: Account Name***: Indian Drug Manufacturers' Association, Bank****: CITIBANK N.A,* ***Bank Account Number:****0036274115,* ***IFSC Code****: CITI0100000,* ***Branch****: Fort Branch, Mumbai – 400 001.*
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, "A"-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018.Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723
E-mail: **admin@idmaindia.com/mail_idma@idmaindia.com,** *Website:* **www.idma-assn.org / www.indiandrugsonline.org**

IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  Please see the NEFT/RTGS details:

  ACCOUNT NAME : *Indian Drug Manufacturers' Association,*

  RTGS to BANK: *CITIBANK N.A.,* ***BANK Account number :*** *0036274115.*

  IFSC Code: CITI 0100000,BRANCH: *FORT BRANCH, MUMBAI — 400 001.*
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Mr T R Gopalakrishnan — Cell: +98190 35076 (Email: admin@idmaindia.com)/
Mr *C* K S Chettiar— Cell: +98206 29907 (Email: mail_idma@idmaindia.com)
PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2018-20
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 07.12.2020

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**