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RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 04 (PAGES: 44) | 22 TO 30 JANUARY 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **MoEFCC approves Environmental Clearance for API and Intermediates as Single category instead of individual products** *(Page No. 17)*

★ **Could Vitamin D be an effective adjuvant to help mitigate the COVID-19 pandemic?** *(Page No. 20)*

★ **WHO Chief thanks India, PM Modi for 'support to Global Covid-19 response'** *(Page No. 23)*

★ **Vaccine diplomacy a Game-Changer for Pharma sector** *(Page No. 23)*

★ **AI to be most disruptive technology across Pharma Industry in 2021 and beyond** *(Page No. 35)*

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

Annual Subscription
₹ 1000/- *(for IDMA members)*
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₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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IDMA welcomes new FDA Commissioner, Mr A B Kale

Mr Mahesh Doshi, our National President welcoming the new FDA Commissioner, Mr A B Kale on 25.01.2021 at IDMA office. With him are Mr Bharat Shah, Mr Sundeep Bambolkar, Mr B G Barve, Dr George Patani and Mr Daara B Patel.

The courtesy call and meeting was highly appreciated by the new Commissioner.

The Commissioner mooted the idea of procuring high end medicines at concessional rates for the poor patients.

Our National President readily agreed for the same.

● ● ●

IDMA Congratulates and Welcomes Mr Sahil Munjal the New Chairman of Pharmexcil

In the 16th AGM-Annual General Meeting of Pharmexcil held on the 18th January 2021 in Hyderabad, Mr Sahil Munjal, Executive Director of Ind-Swift Laboratories Ltd, after serving as Vice-Chairman for 2 years, took over as the Chairman of Council. He will be serving the Council as Chairman for two years i.e. for 2020-2022.

Mr Sahil Munjal has taken over the responsibility from Dr Dinesh Dua.

The AGM also took on record the results of e-Voting held for appointment of the members of Committee of Administration who have been elected through e-voting process in place of those retiring at the conclusion of the 16th AGM.

● ● ●

Companies (Corporate Social Responsibility Policy) Amendment Rules, 2021 notified – reg.

Corporate Affairs Notification No.G.S.R.40(E), dated 22nd January, 2021

In exercise of the powers conferred by section 135 and sub-sections (1) and (2) of section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Corporate Social Responsibility Policy) Rules, 2014, namely:-

1. Short title and Commencement:

(1) These rules may be called the **Companies (Corporate Social Responsibility Policy) Amendment Rules, 2021.**

(2) They shall come into force on the date of their publication in the Official Gazette unless explicitly provided elsewhere in this notification.

2. In the Companies (Corporate Social Responsibility Policy) Rules, 2014 (hereinafter referred to as the said rules), for rule 2, the following rule shall be substituted, namely:-

"2. Definitions;

(1) In these rules, unless the context otherwise requires,-

(a) "Act" means the Companies Act, 2013 (18 of 2013);

(b) "Administrative overheads" means the expenses incurred by the company for 'general management and administration' of Corporate Social Responsibility functions in the company but shall not include the expenses directly incurred for the designing, implementation, monitoring, and evaluation of a particular Corporate Social Responsibility project or programme;

(c) "Annexure" means the Annexure appended to these rules;

(d) "Corporate Social Responsibility (CSR)" means the activities undertaken by a Company in pursuance of its statutory obligation laid down in section 135 of the Act in accordance with the provisions contained in these rules, but shall not include the following, namely:

(i) activities undertaken in pursuance of normal course of business of the company:

Provided that any company engaged in Research and Development activity of new vaccine, drugs and medical devices in their normal course of business may undertake Research and Development activity of new vaccine, drugs and medical devices related to COVID-19 for financial years 2020-21, 2021-22, 2022-23 subject to the conditions that:

(a) such research and development activities shall be carried out in collaboration with any of the institutes or organisations mentioned in item (ix) of Schedule VII to the Act;

(b) details of such activity shall be disclosed separately in the Annual report on CSR included in the Board's Report;

(ii) any activity undertaken by the company outside India except for training of Indian sports personnel representing any State or Union territory at national level or India at international level;

(iii) contribution of any amount directly or indirectly to any political party under section 182 of the Act;

(iv) activities benefitting employees of the company as defined in clause (k) of section 2 of the Code on Wages, 2019 (29 of 2019);

(v) activities supported by the companies on sponsorship basis for deriving marketing benefits for its products or services;

(vi) activities carried out for fulfilment of any other statutory obligations under any law in force in India;

(e) "CSR Committee" means the Corporate Social Responsibility Committee of the Board referred to in section 135 of the Act;

(f) "CSR Policy" means a statement containing the approach and direction given by the board of a company, taking into account the recommendations of its CSR Committee, and includes guiding principles for selection, implementation and monitoring of activities as well as formulation of the annual action plan;

(g) "International Organisation" means an organisation notified by the Central Government as an international organisation under section 3 of the United Nations (Privileges and Immunities) Act, 1947 (46 of 1947), to which the provisions of the Schedule to the said Act apply;

(h) "Net profit" means the net profit of a company as per its financial statement prepared in accordance with the applicable provisions of the Act, but shall not include the following, namely:-

(i) any profit arising from any overseas branch or branches of the company, whether operated as a separate company or otherwise; and

(ii) any dividend received from other companies in India, which are covered under and complying with the provisions of section 135 of the Act:

Provided that in case of a foreign company covered under these rules, net profit means the net profit of such company as per profit and loss account prepared in terms of clause (a) of sub-section (1) of section 381, read with section 198 of the Act;

(i) "Ongoing Project" means a multi-year project undertaken by a Company in fulfilment of its CSR obligation having timelines not exceeding three years excluding the financial year in which it was commenced, and shall include such project that was initially not approved as a multi-year project but whose duration has been extended beyond one year by the board based on reasonable justification;

(j) "Public Authority" means 'Public Authority' as defined in clause (h) of section 2 of the Right to Information Act, 2005 (22 of 2005);

(k) "section" means a section of the Act.

(2) Words and expressions used and not defined in these rules but defined in the Act shall have the same meanings respectively assigned to them in the Act.".

3. In the said rules, in rule 3, in sub-rule (2), in clause (b), for the words, brackets and figure "sub-section (2) to (5)", the words, brackets and figure "sub-section (2) to (6)" shall be substituted.

4. In the said rules, for rule 4, the following rule shall be substituted, namely:-

"**4. CSR Implementation:**

(1) The Board shall ensure that the CSR activities are undertaken by the company itself or through;

(a) a company established under section 8 of the Act, or a registered public trust or a registered society, registered under section 12A and 80 G of the Income Tax Act, 1961 (43 of 1961), established by the company, either singly or along with any other company, or

(b) a company established under section 8 of the Act or a registered trust or a registered society, established by the Central Government or State Government; or

(c) any entity established under an Act of Parliament or a State legislature; or

(d) a company established under section 8 of the Act, or a registered public trust or a registered society, registered under section 12A and 80G of the Income Tax Act, 1961, and having an established track record of at least three years in undertaking similar activities.

(2) (a) Every entity, covered under sub-rule (1), who intends to undertake any CSR activity, shall register itself with the Central Government by filing the form CSR-1 electronically with the Registrar, with effect from the **01st day of April 2021:**

Provided that the provisions of this sub-rule shall not affect the CSR projects or programmes approved prior to the **01st day of April 2021.**

(b) Form CSR-1 shall be signed and submitted electronically by the entity and shall be verified digitally by a Chartered Accountant in practice or a Company Secretary in practice or a Cost Accountant in practice.

(c) On the submission of the Form CSR-1 on the portal, a unique CSR Registration Number shall be generated by the system automatically.

(3) A company may engage international organisations for designing, monitoring and evaluation of the CSR projects or programmes as per its CSR policy as well as for capacity building of their own personnel for CSR.

(4) A company may also collaborate with other companies for undertaking projects or programmes or CSR activities in such a manner that the CSR committees of respective companies are in a position to report separately on such projects or programmes in accordance with these rules.

(5) The Board of a company shall satisfy itself that the funds so disbursed have been utilised for the purposes and in the manner as approved by it and the Chief Financial Officer or the person responsible for financial management shall certify to the effect.

(6) In case of ongoing project, the Board of a Company shall monitor the implementation of the project with reference to the approved timelines and year-wise allocation and shall be competent to make modifications, if any, for smooth implementation of the project within the overall permissible time period.".

5. In the said rules, in rule 5, for sub-rule (2), the following sub-rule shall be substituted, namely:-

"(2) The CSR Committee shall formulate and recommend to the Board, an annual action plan in pursuance of its CSR policy, which shall include the following, namely:-

(a) the list of CSR projects or programmes that are approved to be undertaken in areas or subjects specified in Schedule VII of the Act;

(b) the manner of execution of such projects or programmes as specified in sub-rule (1) of rule 4;

(c) the modalities of utilisation of funds and implementation schedules for the projects or programmes;

(d) monitoring and reporting mechanism for the projects or programmes; and

(e) details of need and impact assessment, if any, for the projects undertaken by the company:

Provided that Board may alter such plan at any time during the financial year, as per the recommendation of its CSR Committee, based on the reasonable justification to that effect.".

6. In the said rules, rule 6 shall be omitted.

7. In the said rules, for rule 7, the following rule shall be substituted, namely:-

"7.CSR Expenditure:

(1) The board shall ensure that the administrative overheads shall not exceed five percent of total CSR expenditure of the company for the financial year.

(2) Any surplus arising out of the CSR activities shall not form part of the business profit of a company and shall be ploughed back into the same project or shall be transferred to the Unspent CSR Account and spent in pursuance of CSR policy and annual action plan of the company or transfer such surplus amount to a Fund specified in Schedule VII, within a period of six months of the expiry of the financial year.

(3) Where a company spends an amount in excess of requirement provided under sub-section (5) of section 135, such excess amount may be set off against the requirement to spend under sub-section (5) of section 135 up to immediate succeeding three financial years subject to the conditions that:

(i) the excess amount available for set off shall not include the surplus arising out of the CSR activities, if any, in pursuance of sub-rule (2) of this rule.

(ii) the Board of the company shall pass a resolution to that effect.

(4) The CSR amount may be spent by a company for creation or acquisition of a capital asset, which shall be held by:

(a) a company established under section 8 of the Act, or a Registered Public Trust or Registered Society, having charitable objects and CSR Registration Number under sub-rule (2) of rule 4; or

(b) beneficiaries of the said CSR project, in the form of self-help groups, collectives, entities; or

(c) a public authority:

Provided that any capital asset created by a company prior to the commencement of the Companies (Corporate Social Responsibility Policy) Amendment Rules, 2021, shall within a period of one hundred and eighty days from such commencement comply with the requirement of this rule, which may be extended by a further period of not more than ninety days with the approval of the Board based on reasonable justification.".

8. In the said rules, for rule 8, the following rule shall be substituted, namely:-

"8. CSR Reporting:

(1) The Board's Report of a company covered under these rules pertaining to any financial year shall include an annual report on CSR containing particulars specified in Annexure I or Annexure II, as applicable.

(2) In case of a foreign company, the balance sheet filed under clause (b) of sub-section (1) of section 381 of the Act, shall contain an annual report on CSR containing particulars specified in Annexure I or Annexure II, as applicable.

(3) (a) Every company having average CSR obligation of ten crore rupees or more in pursuance of sub-section (5) of section 135 of the Act, in the three immediately preceding financial years, shall undertake impact assessment, through an independent agency, of their CSR projects having outlays of one crore rupees or more, and which have been completed not less than one year before undertaking the impact study.

(b) The impact assessment reports shall be placed before the Board and shall be annexed to the annual report on CSR.

(c) A Company undertaking impact assessment may book the expenditure towards Corporate Social Responsibility for that financial year, which shall not exceed five percent of the total CSR expenditure for that financial year or fifty lakh rupees, whichever is less.".

9. In the said rules, for rule 9, the following rules shall be substituted, namely:-

"9. Display of CSR activities on its website:

The Board of Directors of the Company shall mandatorily disclose the composition of the CSR Committee, and CSR Policy and Projects approved by the Board on their website, if any, for public access.

10. Transfer of unspent CSR amount:

Until a fund is specified in Schedule VII for the purposes of sub-section (5) and(6) of section 135 of the Act, the unspent CSR amount, if any, shall be transferred by the company to any fund included in schedule VII of the Act.".

10. In the said rules,-

(i) The Annexure shall be numbered as "Annexure–I" and in the heading of Annexure I as so numbered, after the words "BOARD'S REPORT", the words and figures "FOR FINANCIAL YEAR COMMENCED PRIOR TO 1st Day of April, 2020" shall be inserted;

(ii) after Annexure –I as so numbered, the following Annexure shall be inserted, namely:-

"ANNEXURE -II

FORMAT FOR THE ANNUAL REPORT ON CSR ACTIVITIES

TO BE INCLUDED IN THE BOARD'S REPORT FOR FINANCIAL

YEAR COMMENCING ON OR AFTER 1ST DAY OF APRIL, 2020

1. Brief outline on CSR Policy of the Company.

2. Composition of CSR Committee:

Sl. No.	Name of Director	Designation / Nature of Directorship	Number of meetings of CSR Committee held during the year	Number of meetings of CSR Committee attended during the year

3. Provide the web-link where Composition of CSR committee, CSR Policy and CSR projects approved by the board are disclosed on the website of the company.

4. Provide the details of Impact assessment of CSR projects carried out in pursuance of sub-rule (3) of rule 8 of the Companies (Corporate Social responsibility Policy) Rules, 2014, if applicable (attach the report).

5. Details of the amount available for set off in pursuance of sub-rule (3) of rule 7 of the Companies (Corporate Social responsibility Policy) Rules, 2014 and amount required for set off for the financial year, if any

Sl. No.	Financial Year	Amount available for set-off from preceding financial years (in Rs)	Amount required to be set-off for the financial year, if any (in Rs)
1			
2			
3			
	TOTAL		

6. Average net profit of the company as per section 135(5).

7. (a) Two percent of average net profit of the company as per section 135(5)

(b) Surplus arising out of the CSR projects or programmes or activities of the previous financial years.

(c) Amount required to be set off for the financial year, if any

(d) Total CSR obligation for the financial year (7a+7b-7c).

8. (a) CSR amount spent or unspent for the financial year:

Total Amount Spent for the Financial Year. (in Rs.)	Amount Unspent (in Rs.)				
	Total Amount transferred to Unspent CSR Account as per section 135(6).		Amount transferred to any fund specified under Schedule VII as per second proviso to section 135(5).		
	Amount.	Date of transfer.	Name of the Fund	Amount.	Date of transfer.

(b) Details of CSR amount spent against **ongoing projects** for the financial year:

(1)	(2)	(3)	(4)	(5)		(6)	(7)	(8)	(9)	(10)	(11)	
Sl. No.	Name of the Project.	Item from the list of activities in Schedule VII to the Act.	Local area (Yes/No).	Location of the project.		Project duration.	Amount allocated for the project (in Rs.).	Amount spent in the current financial Year (in Rs.).	Amount transferred to Unspent CSR Account for the project as per Section 135(6) (in Rs.).	Mode of Implementation - Direct (Yes/No).	Mode of Implementation - Through Implementing Agency	
				State.	District.						Name	CSR Registration number.
1.												
2.												
3.												
	TOTAL											

(c) Details of CSR amount spent against **other than ongoing projects** for the financial year:

(1)	(2)	(3)	(4)	(5)		(6)	(7)	(8)	
Sl. No.	Name of the Project	Item from the list of activities in schedule VII to the Act.	Local area (Yes/ No).	Location of the project.		Amount spent for the project (in Rs.).	Mode of implementation - Direct (Yes/No).	Mode of implementation - Through implementing agency.	
				State.	District.			Name.	CSR registration number.
1.									
2.									
3.									
	TOTAL								

(d) Amount spent in Administrative Overheads

(e) Amount spent on Impact Assessment, if applicable

(f) Total amount spent for the Financial Year (8b+8c+8d+8e)

(g) Excess amount for set off, if any

Sl. No.	Particular	Amount (in Rs.)
(i)	Two percent of average net profit of the company as per section 135(5)	
(ii)	Total amount spent for the Financial Year	
(iii)	Excess amount spent for the financial year [(ii)-(i)]	
(iv)	Surplus arising out of the CSR projects or programmes or activities of the previous financial years, if any	
(v)	Amount available for set off in succeeding financial years [(iii)-(iv)]	

9. (a) Details of Unspent CSR amount for the preceding three financial years:

Sl. No.	Preceding Financial Year.	Amount transferred to Unspent CSR Account under section 135 (6) (in Rs.)	Amount spent in the reporting Financial Year (in Rs.).	Amount transferred to any fund specified under Schedule VII as per section 135(6), if any.			Amount remaining to be spent in succeeding financial years. (in Rs.)
				Name of the Fund	Amount (in Rs).	Date of transfer.	
1.							
2.							
3.							
	TOTAL						

(b) Details of CSR amount spent in the financial year for **ongoing projects** of the preceding financial year(s):

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Sl. No.	Project ID.	Name of the Project.	Financial Year in which the project was commenced.	Project duration.	Total amount allocated for the project (in Rs.).	Amount spent on the project in the reporting Financial Year (in Rs).	Cumulative amount spent at the end of reporting Financial Year. (in Rs.)	Status of the project - Completed /Ongoing.
1.								
2.								
3.								
	TOTAL							

10. In case of creation or acquisition of capital asset, furnish the details relating to the asset so created or acquired through CSR spent in the financial year

(asset-wise details).

(a) Date of creation or acquisition of the capital asset(s).

(b) Amount of CSR spent for creation or acquisition of capital asset.

(c) Details of the entity or public authority or beneficiary under whose name such capital asset is registered, their address etc.

(d) Provide details of the capital asset(s) created or acquired (including complete address and location of the capital asset).

11. Specify the reason(s), if the company has failed to spend two per cent of the average net profit as per section 135(5).

Sd/- (Chief Executive Officer or Managing Director or Director).	Sd/- (Chairman CSR Committee).	Sd/- [Person specified under clause (d) of sub-section (1) of section 380 of the Act] (Wherever applicable).

"

11. In the said rules, after annexure-II, following e-form shall be inserted, namely:

"

CSR-1

(Pursuant to section 135 of the Companies Act, 2013 and rule 4(1) and (2) of the Companies (CSR Policy) Rules, 2014)

सत्यमेव जयते

Registration of Entities for undertaking CSR Activities

Form language o English o Hindi

Refer the instruction kit for filing the form.

1. *Nature of the Entity:

- ◯ Company established under section 8 of the Companies Act, 2013 with section 12A and section 80G registrations under the Income Tax Act, 1961.
- ◯ Registered Public Trust with section 12A and section 80G registrations under the Income Tax Act, 1961.
- ◯ Registered Society with section 12A and section 80G registrations under the Income Tax Act, 1961.
- ◯ Company established under section 8 of the Companies Act, 2013 or Registered Trust or Registered Society established by the Central Government or State Government.
- ◯ Entity established under an Act of Parliament or State Legislature.

2. (a)Whether the Entity is established by any company or group of companies:

◯ Yes ◯ No

(b)(i) If yes, then provide the details of such company (s):

CIN of Company	Pre-fill	Add

Name of Company

(ii) If no, whether the entity has an established track record of three years in undertaking similar activities : ○ Yes ○ No

3. (a)* Type of existing entity:

*CIN/ Registration Number: Pre-fill

(In case of a section 8 company, enter CIN. Else, enter registration number)

(b) *Name of the entity

(c) *Date of incorporation of the entity (DD/MM/YYYY)

(d) *Address of the entity:

Line I

Line II

City

State/ Union territory

District Pin Code

(e)* E-Mail ID of the entity Send OTP

(f)*Enter OTP for email ID Verify OTP

(g) *PAN of the entity

4.*Details of Directors/ Board of Trustees/ Chairman/ CEO/ Secretary/ Authorised Representatives of the entity:

Sl. No.	Name	Designation	DIN/PAN	Email ID

Attachments:

List of Attachments

1.* Copy of Certificate of Registration; Attach

2.*Copy of PAN of entity ; Attach

Remove Attachment

***Declaration**

I am authorized by the Entity vide *resolution number _____ *dated _____ to sign this form and declare that the particulars given in the form herein above are true and also are in agreement with the documents maintained by the Entity.

To be digitally signed by one director in case of Section 8 company

To be digitally signed by one of the Trustee/ CEO in case of Registered Public Trust

To be digitally signed by Chairperson/ CEO/ Secretary in case of Registered Society

To be digitally signed by Authorised Representative in case of Entity established under an Act of Parliament or State Legislature

***To be digitally signed by** DSC Box

*Designation

*DIN of the director; or DIN or PAN of the Trustee or CEO or Chairperson or Chief functionary or authorised representative of the Entity;

***Certificate by Practicing Professional**

I declare that I have been duly engaged for the purpose of certification of this form. It is hereby certified that I have gone through the provisions of the Companies Act, 2013 and Rules thereunder for the subject matter of this form and matters incidental thereto and I have verified the above particulars (including attachment(s)) from the original/certified records maintained by the Company/ applicant which is subject matter of this form and found them to be true, correct and complete and no information material to this form has been suppressed. I further certify that:

1. The said records have been properly prepared, signed by the required officers/ authorised representatives of the entity and were found to be in order;

2. All the required attachments have been completely and legibly attached to this form;

3. It is understood that I shall be liable for action under Section 448 of the Companies Act, 2013 for wrong certification, if any found at any stage.

***To be digitally signed by** DSC Box

◯ Chartered accountant (in whole-time practice) ◯ Company secretary (in whole-time practice)

○ Cost accountant (in whole-time practice)

*Whether associate or fellow ○ Associate ○ Fellow

*Membership number

Certificate of practice number

Note: Attention is drawn to provisions of Section 448 and 449 of the Companies Act, 2013 which provide for punishment for false statement/ certificate and punishment for false evidence respectively.

Modify | **Check form** | **Pre Scrutiny** | **Submit**

This e-form has been taken on file maintained by the registrar of companies through electronic mode on the basis of statement of correctness given by the authorised person and professional."

E-F.No.CSR-05/3/2020-CSR-MCA

Gyaneshwar Kumar Singh, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

Note:- *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide Number G.S.R.129(E), dated the 27th February, 2014 and were subsequently amended by notification number G.S.R.644(E), dated the 12th September, 2014, Notification Number G.S.R.43(E), dated the 19th January, 2015, Notification Number G.S.R.540(E), dated the 23rd May, 2016, Notification Number G.S.R.895(E), dated the 19th September, 2018 and Notification Number G.S.R.526(E), dated the 24th August, 2020.*

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Approval accorded under PLI Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs

Ministry of Chemicals and Fertilizers Press Release dated 22nd January 2021

The Applications of following companies, which have committed more than the minimum proposed annual production capacities and fulfil the prescribed criteria have been approved under Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country:

Sr. No.	Name of approved Applicant	Name of Eligible Product	Committed Production Capacity (in MT)	Committed Investment (in Rs. crores)
1.	M/s Aurobindo Pharma Limited (through Lyfius Pharma Pvt Ltd)	Penicillin G	15000	1392
2.	M/s Karnataka Antibiotics & Pharmaceuticals Ltd	7 - ACA	1000	275
3.	M/s Aurobindo Pharma Limited (through Lyfius Pharma Pvt Ltd)		2000	813
4.	M/s Aurobindo Pharma Limited (through Qule Pharma Pvt Ltd)	Erythromycin Thiocyanate (TIOC)	1600	834
5.	M/s Kinvan Pvt Ltd	Clavulanic Acid	300	447.17

The setting up of these plants will lead to total committed investment of Rs.3,761 cr by the companies and employment generation of about 3,825. The commercial production is projected to commence from 1st April, 2023 and the disbursal of Production Linked Incentive by the Government over the six years period would be up to a maximum of Rs.3,600 cr Setting of these plants will make the country self-reliant to a large extent in respect of these Bulk drugs.

With an objective to attain self-reliance and reduce import dependence in these critical Bulk Drugs - Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for promotion of their domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four different Target Segments (In Two Fermentation based - at least 90% and in the Two Chemical Synthesis based – at least 70%) with a total outlay of Rs.6,940 cr for the period 2020-21 to 2029-30.

The applications under four different Target Segments were invited with 30th November, 2020 as the last date. In total, 215 applications have been received for the 36 products spread across the 4 Target Segments. The guidelines prescribed that the applications would be processed and decided within a period of 90 days, i.e., up to 28th February, 2021.

The Target Segment-I includes 4 Eligible Products, viz., Penicillin G; 7-ACA; Erythromycin Thiocyanate (TIOC) & Clavulanic Acid, in which the country is presently fully import dependent, were considered on priority as per the decided evaluation and selection criteria.

Further, applications under the other three segments are proposed to be taken up for approval in the next 45 days.

The Indian pharmaceutical industry is the 3rd largest in the world by volume. It has high market presence in several advanced economies such as the US and EU. The industry is well known for its production of affordable medicines, particularly in the generics space. However the country is significantly dependent on the import of basic raw materials, viz., Bulk Drugs that are used to produce medicines.

Source: PIB, MoC&F Press Release, 22.01.2021

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MOEF&CC MATTERS

MoEFCC approves Environmental Clearance for API and Intermediates as Single category instead of individual Products - reg.

MoEF&CC Office Memorandum Ref.F.No.22-33/2019-IA.III, dated 28th January 2021

1. *Chairman/Member Secretaries of all the Expert Appraisal Committees,*
2. *Chairperson/Member Secretaries of all the SEIAAs/SEACs,*
3. *All the Officers of IA Division.*

1. The Ministry is in receipt of representations for issuance of Prior Environmental Clearance under the provisions of EIA Notification, 2006 and subsequent amendments, for the 'API and Intermediates' as single category instead of individual products in order to provide flexibility to the industry to change the raw material mix and/or product mix within the sanctioned pollution load.

2. The matter has been examined in the Ministry. It is hereby directed that henceforth all the EACs/SEACs shall appraise the proposals for Prior Environmental Clearance under the provisions of EIA Notification, 2006 and subsequent amendments under the category of the schedule of EIA Notification, 2006, for the 'API and Intermediates' as single category instead of individual products. Accordingly, the EAC/SEAC shall clearly recommend the permissible pollution load i.e. quantity and quality, including composition, of emissions, discharges and solid waste generation from such activity for inclusion in the Prior Environmental Clearance.

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

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

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We expect that Pharma and agro-business segments will grow at about 15% CAGR: Tarak Patel, GMM Pfaudler

Tarak Patel, *Managing Director, GMM Pfaudler Limited*, talks about Q3FY21 numbers, order book, budget expectations and incremental revenue after integration of DDPSI's facility among others during a candid chat with ***Swati Khandelwal,*** *Zee Business.*

Edited Excerpts:

The Company has posted a stable set of numbers in terms of margin and profit. Run us through the key highlights of the quarter and is it sustainable?

The backlog that we had, from Q1 to the present day, remains very strong. We have two industry segments, Chemical and Pharmaceuticals, and both are going into a lot of investment and are also doing it. In pharmaceuticals, we have seen a very sharp recovery, which was quite may be for two-three years, but we are seeing a lot of activities in that space, as well. So, having said that, our Q3 performance was expected as the backlog was there, the only issue there was to execute. Some of the highlights of this quarter, I would also like to mention is that our new facility in Hyderabad - that was acquired from our competitor a few months ago - is now up and running, so there is an additional output coming from there. The new gas furnaces that we brought in place in October have been commissioned and are up and running in the Gujarat facility, as well. So, all in all, the increase in capacity has happened at a right time and when the market is growing, we are finding that we are ahead of time in terms of being able to supply to our customers and increase our market share.

What kind of orders did you win in this quarter and what kind of order book growth do you expect in the coming years?

The growth rate Guidance that we provide, we expect both Pharma and agro to grow at about 15% CAGR, hopefully, a little bit more than that. But we have outperformed the market and had a 20%+ growth in the last few years, so we are hoping that we will maintain that level of growth. I am quite confident that we can. I think, the Indian companies are also changing now, the need for high-quality equipment has improved and has increased also. Indian companies are now setting up a world-class facility, they are catering to international markets because of that the need for good quality equipment is increasing. Besides, the backlog that we have is well spread between all our three product lines. In our Glass Lined business around 70% of the revenue comes from the Glass Lined, it is our most profitable business line and it has a very large backlog. We have also seen good traction in our new products line of heavy engineering, we have made significant breakthroughs in new industry segments, like Oil & Gas, Petrochemicals, so that is something also, we are very excited about. Lastly, our propriety products, which is complementary to glass-lined, we have seen a good amount of traction.

Budget is round the corner, what are your expectations from the Government this time that can give a boost to your company as well as your sector?

For us, the end-user is the pharmaceutical industry and the PLI scheme has started in it. There is definitely more traction because of some of the specific schemes that those industry segments have got. I would also look at something similar for our industry segments as we look to manufacture in India, make India self-reliant, under the Atmanirbhar Program. So, we are looking to move manufacturing out of other geographies and move them to India, so, if there are some benefits that we could get because of this that would be definitely helpful because India is a low cost and quality levels in India is as good as people manufacture in Europe and the US. So, there is no reason, why we should not take advantage of the situation.

What kind of incremental revenue is expected as you have completed the integration of DDPSI's facility? Will we see its impact on your books in this or next quarter?

In Q3FY21, our output was in the region of Rs.4-4.50 crores about 30 equipment were shipped out, which is incredible because we only got the factory in

October and we lost some time because of the heavy rains and floods in Hyderabad. Our plan for Hyderabad for the next quarter is about Rs.15-20 crores. So, on a full-year basis, we can easily have revenues close to Rs.60-80 crores from that facility, which is a big change from what that facility used to manufacture in the past at our competitors time and it used to Rs.25-30 crores of revenue. So may be twice or little more than twice is the output that we are planning and we are quite confident that we can achieve that.

Source: Zee News, 22.01.2021

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CBIC MATTERS

CBIC notifies New Exchange Rates w.e.f. 22nd January 2021 - reg.

Notification No.05/2021-Customs (N.T.), dated 21st January, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.03/2021-Customs(N.T.), dated 7th January, 2021 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 22nd January, 2021,** 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	58.00	55.60
2.	Bahraini Dinar	199.80	187.50
3.	Canadian Dollar	58.90	56.80
4.	Chinese Yuan	11.45	11.10
5.	Danish Kroner	12.10	11.65
6.	EURO	90.15	86.95
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	249.10	233.35
9.	New Zealand Dollar	53.95	51.60
10.	Norwegian Kroner	8.80	8.45
11.	Pound Sterling	101.60	98.10
12.	Qatari Riyal	20.70	19.40
13.	Saudi Arabian Riyal	20.10	18.85
14.	Singapore Dollar	56.10	54.15
15.	South African Rand	5.05	4.75
16.	Swedish Kroner	8.90	8.60
17.	Swiss Franc	83.80	80.45
18.	Turkish Lira	10.15	9.50
19.	UAE Dirham	20.50	19.25
20.	US Dollar	73.85	72.10

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	71.85	69.20
2.	Korean Won	6.85	6.45

F.No. 468/01/2021-Cus.V

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

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Could Vitamin D be an effective adjuvant to help mitigate the COVID-19 pandemic?

As the Coronavirus pandemic continues to wreak havoc across the globe, there is a dire need for effective and safe therapeutics and vaccines. Overall, the pandemic has infected more than 90.87 million people and taken more 1.94 million lives. Previous studies have shown the impact of vitamin D supplementation on Coronavirus disease (COVID-19) patients. Further, vitamin D deficiency has been linked to poor clinical outcomes in patients infected with the severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19.

A team of researchers at the University of Medicine and Pharmacy of Craiova in Romania and the National and Kapodistrian University of Athens in Greece aimed to determine the role of key biological variables that could interplay with virus spread and severity. The team found that vitamin D may turn into an effective adjuvant to reduce the impact of the Coronavirus pandemic, particularly in regions where vitamin D deficiency is prevalent.

The study:

In the review, published in the *International Journal of Molecular Medicine,* the researchers aimed to unravel the roles of vitamin D status and melanin during COVID-19 infection. The researchers discussed how vitamin D status and melanin on the skin interplay to determine a patient's clinical outcome. Given the supportive role of vitamin D in immune responses against respiratory viruses, including SARS-Cov-2, the team wanted to know how vitamin D status can influence clinical outcomes in patients with COVID-19.

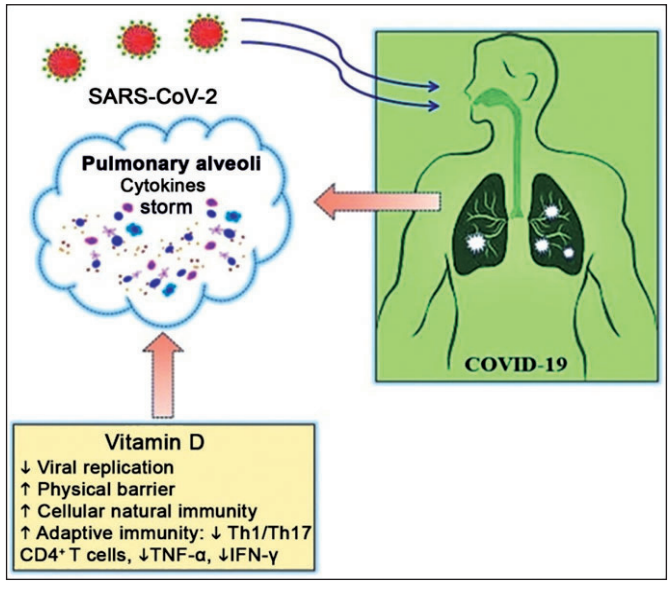
Since vitamin D results from endogenous skin production after being exposed to ultraviolet solar radiation, skin pigmentation may also play a role in non-white ethnic variations of COVID-19, since melanin can reduce the capacity of the skin to effectively absorb sunlight and synthesize vitamin D3. Hence, the team wanted to explore the evidence related to vitamin D status and melanin pigmentation on the skin that may lead to clinical implications on the course of COVID-19 disease and patient clinical outcome.

Vitamin D and COVID-19:

The reports on clinical outcomes and risk factors for disease and death tied to COVID-19 are increasingly emerging. Though there are differences in countries and populations, several factors may account for this discrepancy. These include general health, age distribution, and socioeconomic status. Since the pandemic started, many studies have shown the link between vitamin D deficiency and a higher risk of developing severe COVID-19 and of COVID-19-related mortality. Further studies have noted that taking Vitamin D can reduce a patient's chances of severe SARS-CoV-2 infection.

Since vitamin D plays a pivotal role in the clinical outcomes of patients with COVID-19, the research study focused on the potential impact of vitamin D status on COVID-19 outcomes. The researchers noted that evidence suggests that the vitamin D endocrine system is involved in several biologic processes and pathways, which affect not only musculoskeletal health but also the emergence of other diseases. For instance, it has been known that vitamin D status may affect outcomes of respiratory and infectious diseases, hence, hinting at the role of vitamin D in the immune system.

Vitamin D has also been tagged in its many roles in immunity, inflammation, and epithelial repair. Specifically, 1,25-dihydroxyvitamin D3 ($1,25(OH)_2D_3$), the active metabolite of Vitamin D has long been recognized to contain immune regulatory properties. Many past studies have demonstrated that vitamin D can contribute to the defense against viral infections, specifically acute respiratory tract infections.



Potential antiviral mechanisms of vitamin D in COVID-19. COVID-19, coronavirus disease 2019; IFN-γ, interferon-γ; SARS-CoV-2, severe acute respiratory syndrome Coronavirus 2; Th, T helper; TNF-α, tumor necrosis factor-α.

Melanin pigments are drivers of human pigmentary status. In the course of the Coronavirus pandemic, there is a disparity in the severity of COVID-19 illness in some racial groups. In the study, the researchers noted that increased melanin levels in the skin are known to be inversely proportional to the vitamin D status. Thus, this may account for the observed differences in vitamin D deficiency.

Fair-skinned people only need about 20 to 30 minutes of midday sunlight exposure about 2 to 3 times a day to get a sufficient amount of vitamin D. On the other hand, darker skin people may need higher weekly ultraviolet ray doses to meet their vitamin D needs. In summary, the review aimed to expand the current knowledge of vitamin D status and melanin and their effects on COVID-19 outcomes. The team noted that vitamin D may be an effective way to reduce the impact of COVID-19 on high-risk populations.

Given that vitamin D is a safe, inexpensive, and widely available agent, even in countries with limited resources, vitamin D inadequacy is an easily modifiable risk factor," the team explained. Overall, the researchers suggest that vitamin D may prove an effective adjuvant to vaccines and antiviral therapeutics in the fight against COVID-19.

Source: Angela Betsaida B. Laguipo, BSN, www.news-medical.net/news , 12.01.2021

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Algernon Pharma receives DSMB nod to conduct phase 3 study of Ifenprodil to treat Covid-19

Algernon Pharmaceuticals announced that the external Data and Safety Monitoring Board (DSMB) has completed its latest review of the phase 2b part of the company's phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of covid-19, and has provided approval for the company to continue on with the phase 3 part of the study. The DSMB is a committee of clinical research experts, including physicians, statisticians, and patient advocates, who are monitoring the progress of the Company's Clinical Trial, and are reviewing safety and effectiveness data while the trial is ongoing.

"While we await final data from the phase 2b part of our Ifenprodil Covid-19 study, it is critical for us to know that from a safety perspective, we are now clear to move into the phase 3 part of the study," said Christopher J. Moreau, CEO of Algernon Pharmaceuticals. The Company is not making any express or implied claims that Ifenprodil has the ability to eliminate, cure or contain the covid-19 (or SARS-2 Coronavirus) at this time.

NP-120 (Ifenprodil) is an N-methyl-D-aspartate (NMDA) receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B). Ifenprodil prevents glutamate signalling. The NMDA receptor is found on many tissues including lung cells, T-cells, and neutrophils. The Company believes Ifenprodil may reduce the infiltration of neutrophils and T-cells into the lungs where they can release glutamate and cytokines respectively. The latter can result in the highly problematic cytokine storm that contributes to the loss of lung function and ultimately death as has been reported in covid-19 infected patients.

Source: Pharmabiz, 21.01.2021

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COVID-19 has multiple faces

According to current studies, the COVID-19 disease which is caused by the SARS-CoV-2 Coronavirus comprises at least five different variants. These differ in how the immune system responds to the infection. Researchers from the German Center for Neurodegenerative Diseases (DZNE) and the University of Bonn, together with other experts from Germany, Greece and the Netherlands, present these findings in the scientific journal "Genome Medicine". Their results may help to improve the treatment of the disease.

Infection with SARS-CoV-2 can manifest in different ways: Many of those affected do not even seem to notice the presence of the virus in their bodies. In other cases, the effects can include flu-like symptoms and neurological disorders to severe and even life-threatening pneumonia. "The classification of COVID-19 into mild and severe courses falls short. The disease is much more diverse, and for each affected person, one certainly would want a therapy that is tailored to fit. What helps one person may be ineffective for another," said Dr Anna Aschenbrenner, a scientist of the LIMES Institute at the University of Bonn and the DZNE's Systems Medicine division. "In this respect, it is obvious to want to understand what underlies these differences. If we can pin them down to scientific criteria and categorize patients accordingly, this increases the chances of effective treatment. We therefore took a look at the immune system. Because many studies are indicating that its response to infection with SARS-CoV-2 plays a crucial role in the course of COVID-19," said Aschenbrenner, who is a member

of the Cluster of Excellence "ImmunoSensation" of the University of Bonn.

International Cooperation:

In light of this, a team led by Anna Aschenbrenner, along with colleagues in Germany and abroad, analyzed the blood of people with and without COVID-19. The samples came from a total of 95 people distributed among Bonn, Athens and Nijmegen. The research was done in collaboration with the "German COVID-19 OMICS Initiative" (DeCOI) - a network of German universities and research institutions. In Bonn, the DZNE and the University of Bonn were involved, as well as the University Hospital. Partners abroad were the Attikon University Hospital as well as the Sotiria Hospital in Athens, Greece, and the Radboud University Medical Center in Nijmegen in the Netherlands.

For each patient, the so-called transcriptome of the immune cells in the blood was determined. This requires the analysis of large amounts of data using bioinformatics methods. Based on the molecular fingerprint generated in this way, the researchers were able to identify which genes within the immune cells were switched on or off. Such signatures of gene activity - known as "expression patterns" - provide information about the condition of cells and thus about their properties and functions, which can change depending on the situation.

Interestingly, the picture obtained in this way was largely determined by the family of "neutrophils", which are the most abundant of the so-called white blood cells and quite up front in the reaction chain of the immune response. These cells are thus mobilized very early to defend against infections. They act upon the formation of antibodies and, moreover, on other cells that contribute to immunity.

Five Manifestations:

"First of all, it is important to note that the expression patterns of immune cells in people with COVID-19 differ fundamentally from those in healthy individuals. The gene activity we can detect in the blood is strongly altered. But there are also striking differences among patients. On this basis, we have identified five different groups. We refer to them as molecular phenotypes," said Dr Thomas Ulas, an expert in bioinformatics at the DZNE. "Two of them represent severe disease courses. The others have more moderate symptoms." The classification was based solely on transcriptome data. Only in retrospect, molecular phenotypes were matched to registered clinical courses.

COVID-19 is different:

The researchers used their findings to compare COVID-19 with other diseases and also with data from healthy individuals. For this purpose, they were able to draw on data from the "Rhineland Study" - a population study conducted by the DZNE in the Bonn area - as well as on data from scientific databases. For the comparison, a large spectrum of diseases was considered: including viral infections such as influenza, infections with HIV and Zika, bacterial infections such as tuberculosis and bacterial sepsis, and inflammatory diseases such as rheumatoid arthritis. "All five COVID-19 phenotypes are different from the other diseases we studied," Ulas said, summing up the findings. "Apparently, COVID-19 has a unique biology that is reflected in the gene activity of immune cells in the blood. Insofar, expression analysis could be used to diagnose COVID-19. This would be an alternative or complement to current methods."

Searching for Drugs:

The scientists also searched for potential drugs against COVID-19. For this, they drew on the effects registered in databases of around 900 approved drugs on the expression patterns of cells. "We calculated which pharmaceuticals could counteract the altered gene activity profiles of the individual COVID-19 phenotypes," said Aschenbrenner. On this basis, drug candidates for therapy were identified. "Already in April of last year, we calculated a potential efficacy for example for dexamethasone and baricitinib in one of the patient groups with severe course that we identified.

These types of analyses, it must be clearly stated, are not treatment recommendations. They do, however, very much provide starting points for therapy development, which then need to be tested in appropriate trials. In the case of dexamethasone and baricitinib, our predictions turned out to be correct. This is an indication of the strength of our approach of using blood transcriptomes to better characterize and classify patients."

Source: World Pharma News, 19.01.2021 (Excerpts)

WHO Chief thanks India, PM Modi for 'support to Global Covid-19 response'

Director-General of World Health Organization Tedros Adhanom Ghebreyesus on Saturday, 23.01.2021 thanked India and Prime Minister Narendra Modi for their continued support to global Covid-19 response

© FABRICE COFFRINI/AFP via Getty Images

"Thank you, India and Prime Minister Narendra Modi for your continued support to global Covid-19 response. Only if we act together, including sharing of knowledge, can we stop this virus and save lives and livelihoods," Tedros said. In the last few days, India has supplied Covid-19 vaccines, being manufactured in the country, to neighbouring countries including Bhutan, Maldives, Nepal, Myanmar and Bangladesh.

Prime Minister Narendra Modi had stated that India's vaccine production and delivery capacity will be used for the benefit of all humanity to fight the COVID-19 pandemic. On January 19, New Delhi announced its grant assistance of vaccines to the neighbouring countries. On January 20, 1.5 lakh doses of vaccines were supplied to Bhutan and one lakh doses to the Maldives as grant assistance.

On Thursday, 21.01.2021 New Delhi supplied 10 lakh doses to Nepal and 20 lakh doses to Bangladesh. Large consignments of Covishield vaccine doses were flown in special Indian aircraft to Seychelles, Mauritius and Myanmar on Friday, 22.01.2021. Ministry of External Affairs (MEA) on Friday, 22.01.2021 said that the supplies of COVID-19 vaccine as grant assistance to Sri Lanka and Afghanistan will be undertaken after receiving confirmation of regulatory clearances from these two countries.

Contractual supplies are also being undertaken to Saudi Arabia, South Africa, Brazil, Morocco, Bangladesh and Myanmar, MEA spokesperson Anurag Srivastava said. India has already rolled out a massive Coronavirus vaccination drive using two vaccines, Covishield and Covaxin.

Covishield has been developed by AstraZeneca and Oxford University and is being manufactured by Serum Institute of India. Meanwhile, Covaxin is an indigenous vaccine developed by Bharat Biotech in collaboration with Indian Council of Medical Research (ICMR).

Source: Susmita Pakrasi, www.ndtv.com/Hindustan Times, 24.01.2021

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Vaccine diplomacy a Game-Changer for Pharma sector

In the years ahead, analysts and business historians would probably call this the defining moment of India's economic diplomacy

On a wintry morning earlier this week, as the country shivered from a drop in mercury levels, loaders at Mumbai airport gingerly passed along boxes of vaccines, marked 'fragile', into the waiting hold of an Air India flight. The aircraft would be the first of many carrying 'Made in India' Covid-19 vaccines from Poona's Serum Institute to capitals in countries far and wide to help combat the global pandemic.

In the years ahead, analysts and business historians would probably call this the defining moment of India's economic diplomacy. Some 4.9 million doses are being sent as gifts to neighbours, while millions more are being exported for profit. "The vaccine flights are helping bolster our position as a reliable medicine manufacturing power. As it is, the pandemic helped push Indian Pharma exports by

20 percent and we are expecting to end the year with $25 billion sales... with this we can expect even better growth in the coming financial year," said Prof Biswajit Dhar of JNU, a former member of the Board of Trade.

Except Pakistan, which has opted for China's Sinovac vaccine, India's "supplies under grant assistance" are being shipped to all neighbouring countries including Bangladesh, Nepal, Bhutan, Maldives, Myanmar, Afghanistan, Sri Lanka, Mauritius, and Seychelles. India has also contracted to sell Covishield, the vaccine developed by Oxford-Astra Xeneca and manufactured by Serum Institute of India, to Brazil, Morocco, South Africa, and Saudi Arabia, with flights carrying the precious cargo taking off to these countries last Friday, 22.01.2021. Exports to more nations are to follow.

"Despite our growing strength, there was an undercurrent of propaganda in the global market about the reliability of our medicines ever since the US Food and Drugs regulator started dishing out notices to Indian drug companies. However, by becoming a reliable vaccine maker, we can now counter that propaganda effectively," said Siddhartha Dasgupta, Advisor, East India Pharmaceuticals.

India has become the preferred partner for vaccine sales partly because reports on rival China's vaccine candidates are unclear, according to medical experts, and partly since prices at between $3-5 a dose are among the lowest globally. It is also easier to store and distribute compared to Pfizer's and Moderna's vaccines that are being extensively used in the US.

Meant to rival China's offerings, India's 'gifts' and paid for vaccines have not only helped India sell its soft power—earning thanks from Brazilian President J M Bolsonaro among others—but also push its stature as the "Pharmacy of the World" throughout the world. The shipments began within 3 days of India starting its own massive inoculation drive.

Source: Jayanta Roy Chowdhury, Express News Service, 24.01.2021

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CDSCO issues Guidance document on license for import or manufacture of Cosmetics in India

In order to streamline the process of import registration of cosmetics, the Central Drugs Standard Control Organisation (CDSCO) has issued Frequently Asked Questions (FAQs) and guidance document for grant or retention of Registration Certificate (RC) or license for import or manufacture of cosmetics in India under the new Cosmetics Rules 2020. The Cosmetics Rules 2020 have been recently published through a Gazette Notification dated December 15, 2020 and is in effective from December 15, 2020.

"Aimed at ease of doing business, FAQs and Guidance document have been prepared in light of the Cosmetics Rules 2020 and uploaded on CDSCO website. The approvals/licenses/permissions/certificate issued under the provisions of the Drugs and Cosmetics Act, 1940 and D&C Rules, 1945 in respect of cosmetics prior to commencement of these Rules shall be deemed to be valid for all purposes till its expiry or for a period of eighteen months from the date of notification of these Rules whichever is later under the compounding provisions of the said Rules," as per the DCGI notice.

The Union Health Ministry, through a Gazette Notification, has notified the Cosmetics Rules, 2020 to separately codify Rules relating to cosmetics for effective compliance. The Ministry issued the notification in exercise of the powers conferred by section 12 and Section 33 of the Drugs and Cosmetics (D&C) Act, 1940 (23 of 1940). These rules shall be applicable to the cosmetic as defined in clause (aaa) of Section 3 of the D&C Act, 1940 (23 of 1940).

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

As per the notified Rules, authorised agent means a person in India authorised by the manufacturer. The authorised agent shall be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act and rules made there under for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

No cosmetic shall be imported into India unless the product has been registered in accordance with these rules by the Central Licensing Authority or by any officer to

whom such powers may be delegated under sub-rule (1) of Rule 5. An application for registration of a cosmetic product intended to be imported into India shall be made through the online portal of the Central Government in Form COS-1 either by the manufacturer himself or by his authorised agent or the importer in India or by the subsidiary in India authorised by the manufacturer.

An authorisation by the manufacturer to his agent in India shall be duly authenticated either in India before a first class Magistrate or in the country of origin before the authority competent under the laws of that country or by an authority specified in the First Schedule. A registration certificate granted under rule 13 shall remain valid in perpetuity, subject to payment of registration certificate retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

Source; Shardul Nautiyal, Pharmabiz, 22.01.2021

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Union Budget 2021: Covid-19 pandemic underlines need for higher allocation for healthcare sector

Representative image. Credit: iStock.

The Covid-19 pandemic has emphasised the key role of healthcare in the lives of people, underlining the importance of higher budget allocation for improving the healthcare infrastructure in the country, sectoral players said. The Pharma sector which has played a leading role as the 'Pharmacy of the World' said it expects support and incentives especially for Research & Development and innovation in the coming budget. The pandemic has completely changed the dynamics of the Indian healthcare ecosystem, NATHEALTH President and Apollo Hospitals Executive Vice-Chairperson Preetha Reddy told. "It has reiterated the need for increased investment in healthcare infrastructure, national level programmes for skill development and training of healthcare staff, increase in number of medical colleges, effective PPP models and further boost for local manufacturing," she added. These should be the key priorities for the Government this time, Reddy said.

"Private healthcare providers are hopeful that there will be additional incentives to aid the sector in business recovery and also enable expansion across tier 2-3 cities - through provision of land at subsidised rates to set up hospitals, tax relief for new infrastructure creation, import duty relief for life saving equipment and ease of GST regulations for healthcare services," she added. Reddy said that public spending in healthcare should increase to deal with future pandemics and for sustained preventive care. Digital Health services found their rightful space during the pandemic and there is a need to expand and support the essential backup services to enable digital healthcare to function efficiently in all primary and secondary healthcare centres, she added.

In a similar vein, Fortis Healthcare MD and CEO Ashutosh Raghuvanshi said the Covid pandemic has underlined the importance of higher budget allocation for healthcare. "The current situation demands increased budgetary impetus for improving healthcare infrastructure at primary, secondary and tertiary levels, and also to enable the healthcare sector's speedy recovery," he added. It is important to note that the healthcare sector is not only a potential foreign exchange earner but also a significant employment generator, Raghuvanshi said. "Our overall strategy must integrate preventive and curative services and make healthcare more affordable and accessible for the people of India", he added.

Highlighting the need for increasing the budget allocation for healthcare, Aster DM Healthcare Founder Chairman and MD Azad Moopen said the Covid-19 pandemic hit home the fact that a strong healthcare infrastructure is absolutely essential to ensure a sustainable economy. "It is important to at least double the healthcare budget from last year's meager allocation. This would help improve access to affordable care for the masses," he added. Emphasising expectations from the budget for the Pharma sector, Indian Pharmaceutical Alliance (IPA) Secretary General Sudarshan Jain said: "The overall policy ecosystem should help increase thrust on healthcare and build healthcare infrastructure to cater to the societal needs as healthcare is fundamental".

The Pharma industry is looking for support and incentives in Research & Development, and innovation, he added. Specifically, the industry is asking for measures such as incentivising investment by pharmaceutical companies in R&D and Innovation by reintroduction of 200 percent tax deductions on R&D related expenses, providing direct funding support to academia and industry and easing access to external sources of funding, Jain said. "Pharma industry is a knowledge-driven industry and India needs to move forward to Make and Discover in India from Make in India," he added. **Batting for the incentives for the Pharma sector, Indian Drug Manufacturers' Association (IDMA) Executive Director Ashok Kumar Madan said, "For the ensuing budget, we have proposed for the restoration of the 200 percent weighted tax deduction under section 35(2AB) of the Income Tax Act for the Pharma sector". To promote innovation we need to provide impetus to R&D as Pharma is knowledge intensive, he added. "We have suggested the withdrawal of customs duty exemption on the APIs which are being and can be manufactured in the country to provide a level playing field to Indian Pharma industry," Madan said**.

On the other hand, Medical Technology Association of India (MTaI) urged the Government to reduce customs duties and rollback health cess in Union Budget 2021-22 to help the medical device sector overcome the severe financial crisis created by Covid-19 pandemic. MTaI Chairman and Director General Pavan Choudary said respecting the PM's appeal to save livelihood, the MedTech industry strived to protect jobs even in this inclement weather. "The industry seeks immediate Government assistance by removal of health cess and reduction in customs duties in the upcoming budget," MTaI Director Sanjay Bhutani said.

Source: PTI, Deccan Herald, 24.01.2021 (Excerpts)

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Pharma Retail Market bounces back to robust growth in December

Domestic Pharma Retail Market bounced back with a substantial growth of 8.4% y-o-y (year-on-year) in December, after a weak performance during the year, led by a higher number of prescriptions, OPD (outpatient department) visits, and increased marketing push by drug companies. During 2020, October was the lone month which posted a robust growth of nearly 10%, while the market dipped to 1% growth in November.

The acute segment (45% of market) grew 6% y-o-y while chronic (55%) rose nearly 11% y-o-y in the month. Overall, the high-margin chronic segment will continue to do well compared to the low-margin acute segment, due to the longer duration of diseases, changes in lifestyle and poor food habits coupled with an increasing disposable income, according to India Ratings and Research (Ind-Ra).

Source: Rupali Mukherjee, The Times of India, 22.01.2021

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Gujarat FDCA, US FDA officials share experiences of regulatory interventions to tackle Covid-19 pandemic

Officials from Gujarat Food and Drug Control Administration (FDCA) shared their experiences of Covid-19 pandemic with US FDA officials regarding timely policy interventions and regulatory initiatives done to scale up accessibility of medicines and healthcare at the point of care to help patients and public at large.

During the recent US FDA-Gujarat FDCA Regulatory Forum meet held virtually, Gujarat FDCA discussed plans to scale up presence of more US FDA and WHO-GMP compliant units in Gujarat towards enhancing production of quality medicines for the benefit of patient safety and compliance. The US FDA-Gujarat FDCA Regulatory Forum meet is a relevant step towards enhancing global competitiveness as Gujarat is aggressively moving towards upgradation of Schedule M units to WHO-GMP compliant drug manufacturing units as part of the global harmonization programme. The meet also discussed plans towards capacity building, training, networking, knowledge sharing and compliance.

"During the discussion, we also highlighted how essential commodities like masks and sanitisers production was enhanced 10 times and 3 times respectively besides scaling up production of medicines and vaccines like HCQ, favipiravir and remdesivir five times during the course of lockdown when the entire world was grappling to find a cure to the dreaded virus," explained Gujarat FDCA Commissioner Dr H G Koshia.

US FDA-Gujarat FDCA Regulatory Forum was started in the year 2008 to usher in dialogue between senior leaderships of the US FDA and the Gujarat FDCA for future strategic collaborations and knowledge sharing on drug and medical device compliance. US FDA-Gujarat FDCA

Regulatory Forum has also played a pivotal role in equipping Indian regulators and industry on Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Lab Practices (GLP). It has enhanced the knowledge level of Indian regulators in understanding regulatory requirements of US FDA.

It was reiterated during the regulatory forum meeting that there is a need for risk based inspections and embracing global standards through upgradation of Schedule M units to WHO-GMP compliant units to retain India's position as pharmacy of the world. Gujarat has over 700 plus WHO-GMP units and 130 US FDA approved drug manufacturing units in the country. Gujarat also has the distinction of having 28 percent of drug exports to developed markets including the US.

Source: Shardul Nautiyal, Pharmabiz, 21.01.2021

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Drug Manufacturers hope new US Government will see them as 'allies'

But experts caution on resurrection of TPP with the US on board

With one in every third tablets consumed in the US being made in India, domestic drug-makers hope that the new US President, Joe Biden, sees them as a "dependable ally" in bringing down healthcare costs. Indian Pharmaceutical companies can help bring down US healthcare costs if the Government opens up procurement from them, said Sudarshan Jain, Secretary-General of the Indian Pharmaceutical Alliance, a platform for large domestic drug-makers. At present, foreign companies are not allowed to participate in Government procurement programmes, he added.

With the future of medicine being Biosimilars, Indian Companies can play a role in this segment as well, he pointed out. The Covid-19 pandemic forced countries and companies to re-look at their dependence on procurement from a single country, China in this case. Jain pointed out that India and the US could work together to develop and produce Active Pharmaceutical Ingredients, an area where both countries relied heavily on China.

Some Pharma industry representatives, who did not want to be named, are watching if the new President would continue with the "America First" policy. The policy direction from the Trump administration was to have companies make their products in America, to sell in the country. And, to have the lowest price at which an American Company sold a drug anywhere in the world as its reference price for the US. The Trump administration had major run-ins with the US Pharma industry, for instance, signing four executive orders on pricing last July to prevent what he called "Global Freeloading ".

Resurrection of TPP:

Indian industry-watchers also caution on the "resurrection of the TPP (Trans-Pacific-Partnership)" with the US in it. The Obama-administration-supported TPP, often described as the "mother of all trade-deals", involving 12 major countries including the US, Australia, Japan and Canada. But outgoing President Trump pulled the US out. The remaining 11 went ahead with a similar deal. Pro-health voices criticized the secrecy that surrounded TPP negotiations and warned against giving too much away on health, environment and Intellectual Property Rights (IPR), among other things. IP expert Gopakumar Nair says that India need not shy away from trade agreements, and should instead negotiate from a position of strength, as a critical supplier of drugs and vaccines to the world. Striking a different note, K M Gopakumar with Third World Network pointed out that the Democrats were tough negotiators and resurrection of the TPP with the US would not be in India's interest.

Source: P T Jyothi Datta, The Hindu Business Line, 20.01.2021 (Excerpts)

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Ayush Ministry prohibits misleading advertisement and claims of ASU drugs

The Union Ministry of Ayush has issued a directive to the state licensing authorities for Ayurvedic, Siddha and Unani drugs and all Ayurvedic, Siddha and Unani Drug manufacturers to prevent misleading advertisement and claims of classical/shastriye Ayurvedic, Siddha and Unani (ASU) drugs.

In a circular issued on January 19, 2021, the Ayush Ministry stated that recently certain instances of ambiguous statements and unfounded claims to denigrate classical/ shastriye ASU drugs have been brought to the notice of Central government, which tantamount to be misleading to the public and appear to be in contravention of the legal provisions for prohibition of advertisement of drugs as well as desist public from consuming such ASU formulations.

All the ASU drug manufacturers in the country are hereby advised not to make and publicize any inappropriate statement or misleading claim against classical/shastriye ASU drug and the State/UT licensing authorities/drug controllers may take necessary action on the instance of denigrating classical ASU formulation in terms of its name and use amounted to misleading in nature under the provisions of Drugs and Magic Remedies Act (Objectionable Advertisement), Act, 1954 and Drugs & Cosmetics Rules, 1945, said the statement issued by the Ministry of Ayush.

Whereas the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs & Cosmetics Rules, 1945 have prescribed provisions for prohibition of misleading advertisements and claims of ASU drugs along with penalty provisions for the defaulters. Till date ASU drugs defined under Section 3(a) of the Drugs & Cosmetics Act, 1940 are manufactured for sale under license in accordance with the formulae described in the authoritative books specified in the First Schedule to the Act and are widely consumed by the public due to their tradition of use and time-tested effectiveness.

Source: Neethikrishna, Pharmabiz, 22.01.2021

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Government needs to formulate Policy to lower cost of production to attract more investors into API sector: Expert

Stressing that the Central Government needs to formulate an appropriate industrial policy to lower the cost of production and provide more incentives to attract investors into the Active Pharmaceutical Ingredient (API) manufacturing sector, a leading API industry analyst Shashikanth Mishra felt that the Central Government is trying to wash off its hands from its responsibilities by providing few short term incentives for API entrepreneurs.

While speaking to Pharmabiz, Mishra said, "If we want Indian Pharma firms not to depend excessively on China for some of the important APIs and Key Starting Materials (KSM), it is very important for the Government to act in the right time at the right place. Even though the Central Government had taken some steps since 2015 onwards to improve the API sector in India, even though 6 years have gone past, nothing concrete has been emerged out of those initiatives as the Pharma sector is still depending on China for its APIs and KSMs even today," observed Mishra.

Citing the statistics, Mishra said that India imports about $3.5 billion worth of APIs from China which comprises more than 70 percent of its requirements. Though the Government policy makers in India viewed that such a high dependence on imports of APIs would have strategic dimensions and undermine public health, despite such a grave concern India still imported APIs worth of Rs.17,400 crore during the financial year 2019.

"The most worrying thing is that India's dependence on China for some of the life-saving antibiotics like cephalosporins, azithromycin and penicillin is more than 90 percent. Therefore it is very important for our policy makers to think on those lines and must ensure at least these life-saving medicines are manufactured in India, which would otherwise jeopardize the entire public health system if the supply of such medicines is suddenly stopped due to any kind of untoward incidents between these two countries," opined Mishra.

In view of the above, Mishra suggested that the Central Government must formulate an appropriate industrial policy which aims to lower the cost of production in areas with a strong export potential (such as APIs) for the pharmaceuticals sector. He also advised that the Government must create common infrastructure facilities for the API sector which can reduce the operational costs for the industry. The industry expert also felt that although a new bulk drug scheme has been announced but the need of the hour is a single window clearance to expedite its implementation. He suggested that India needs to step up manufacturing APIs for its own captive use, for which Government needs to provide adequate subsidies for Greenfield investment in the API sector. It is also felt that government has offered production linked tax incentives for firms to make the API space to be more competitive. If there is lower cost of capital, it will assist the firms operating in the Indian API and intermediates space, opined Mishra, giving his perspective on API sector in India.

Source: A Raju, Pharmabiz, 21.01.2021

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IPC rolls out sensitization programme for medical device companies on causality assessment & post market recall

To effectively report Serious Adverse Events (SAEs) due to faulty medical devices, the Indian Pharmacopoeia Commission (IPC) on behalf of the Materiovigilance Programme of India (MvPI) has rolled out sensitization programmes for manufacturers on causality assessment and post market recall to ensure safety of medical devices.

The latest in the series of such programmes conducted pan-India benefited manufacturers associated with Association of Indian Medical Device Industry (AiMeD). The participants were given a low down on capacity building in terms of compliance to reporting adverse events due to a medical device with reference to new Medical Device Rules (MDR)–2017 for effective regulatory regime.

As of today, there are 50 Medical Device Adverse Event (MDAE) reporting centres in the country which are working on causality assessment, baseline methodology and post market recall to ensure safety of medical devices. To report adverse events effectively and systematically, IPC launched MDAE reporting form to generate independent and evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

The reporting form includes adverse event details, severity of the event, date, location, device category, model of the device available with the organisation, its use after the event, name of medical device, manufacturer, brand name, model number, serial number and batch number among others. Union Health Ministry has also recommended that all non-serious, known or unknown, frequent or rare SAEs need to be reported on war footing. Duly filled in Medical Device Adverse Event Reporting (MDAER) Form can be sent to the nearest Medical Device Adverse Event Monitoring Centre (MDMC) or directly to NCC for MvPI through helpline number or mail.

Sensitization programmes are also being conducted to do capacity building of MDMCs in the country for effective medical device adverse event reporting. The IPC had earlier sent circulars to MDAE reporting centres in the country to keep a check on SAEs due to faulty ventilators or Personal Protective Equipment (PPE) used by the healthcare staff and patients to tackle Covid-19. It also sent circulars across all the Indian Council of Medical Research (ICMR) labs conducting IVD tests to report SAEs to tackle Covid-19 effectively.

In order to help IPC facilitate baseline study of products available with medical devices companies in India and assure patient safety, the Union Health Ministry has also directed medical device manufacturers to register at medical devices information sharing portal through **hyperlink-www.mvpi.co.in.** This portal which would serve the purpose as an India specific tool has been developed in consultation with Central Drugs Standard Control Organisation (CDSCO) to ensure that safe medical devices are available in the country.

Union Health Ministry is also planning to create a Registry of High Risk Medical Devices to effectively study and follow MDAE. The registry would track usage of high risk medical devices in India mandatorily. The same would be worked out taking reference of international scenarios so that SAEs can be prevented soon before it arises from the manufacturer's end.

Source: Shardul Nautiyal, Pharmabiz, 20.01.2021

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Time to Move On

On January 16, Prime Minister Narendra Modi launched the mother of all vaccination drives in the world when he inaugurated India's massive Covid-19 vaccination drive for which the country has been waiting with a bated breath. Since the pandemic hit India in early 2020, over one crore and 5 lakh people have been infected with the deadly disease, while more than 1.52 lakh have lost their precious lives. Over the next six to eight months, nearly three crore high-risk people, including healthcare and frontline workers, will be inoculated during the initial phase of Covid-19 vaccination drive in the country. For this world's largest inoculation exercise against the novel Coronavirus, the Indian drug authorities had recently approved two made in India vaccines - 'Covishield' and 'Covaxin'. Covishield, developed by the University of Oxford and British-Swedish pharmaceutical company AstraZeneca, is being manufactured by an Indian company, the Serum Institute of India. The company has claimed that the vaccine would be 90 to 95 percent effective if one just keeps a two-to-three months' gap between dose 1 and dose 2. Covishield, which is being touted as one of the most promising vaccines for India where cost and logistics play a big role, can be kept stable for six months at standard refrigerator temperatures. The second vaccine, Covaxin was developed by an Indian biotechnology company Bharat Biotech in collaboration with the country's highest clinical

research body, the Indian Council of Medical Research (ICMR). Though the vaccine has demonstrated the ability to produce antibody against Coronavirus in phase 1 and phase 2 Clinical Trials, the clinical efficacy of Covaxin is yet to be established and it is being studied in phase 3 Clinical Trials. That in its wake brought a lot of misinformation and rumours about the safety and efficacy of these Indian made vaccines. It is a fact that usually it takes many years to develop a vaccine. But two 'Made in India' vaccines were developed in such a short span of time that it triggered the propaganda against the efficacy of these vaccines. Earlier in December last year, Serum Institute and Bharat Biotech had sought emergency use approval from India's drug regulator, the Drugs Controller General of India (DCGI), for their Covid-19 vaccines which were still under trials. Subsequently, the DCGI waved the green flag for these vaccines for restricted use in emergency situation in public interest. The DCGI's decision was based on a provision in 'New Drugs and Clinical Trials Rules, 2019' which Governs Clinical Trials of new drugs and vaccines, and their approvals in India. There are no two opinions about the fact that presently we are facing an absolutely abnormal healthcare crisis, and the entire world is looking for an efficacious and safe vaccine. For such a situation, there is a provision in 'New Drugs and Clinical Trials Rules, 2019' for granting approval to a drug that is still in Clinical Trials, "provided there is a prima facie case of the product being of meaningful therapeutic benefit".

After all, the DCGI gave his seal of approval for these vaccines for restricted use in emergency situation after the Subject Expert Committee of the Central Drugs Standard Control Organisation (CDSCO) gave its recommendation on similar lines. Now, it is time to stop making irresponsible statements and defaming the Indian scientific community and casting aspersions on its integrity by making the politicized statements doubting the research in the field of Covid-19 vaccines. Such reprehensible statements may cause a huge credibility crisis for the Indian scientific community who has devoted themselves and their lifetime to make India a name to reckon with in the export of vaccines all over the world. Now that the mega vaccination drive has started in right earnest in the country, we should not cast aspersions on our scientific fraternity who has been burning the proverbial midnight oil for the last several months to save the humanity from this once-in-a-century healthcare crisis.

Source: Ramesh Shankar, Pharmabiz-Editorial, 20.01.2021

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Mahamana Declarations launches portal for consumers in India & Abroad to access info on traditional medicine

In a major effort to strengthen the credibility of information backed by science in Ayurveda, Siddha, Unani and Homoeopathy, the Mahamana Declarations on Ayush (MDOA) is now accelerating the access to reliable data. This is where its Hamara Ayush portal is conceived as a platform for the consumers in India and globally to access information on traditional healthcare.

Hamara Ayush portal has been made available with support from International Alliance for Patients' Organisations (IAPO), which has official relationship with World Health Organisation. The portal is managed by Consumer Online Foundation, an affiliate member of IAPO and a recognised Consumer Organisation in India by Government of India. All information made available in the portal is from the Ministry of Ayush, state Governments and other recognized institutions and experts on the subject that is made accessible in the manner the citizens understand without compromising on the safety, quality and efficacy of the products and services related to such traditional practices and other healthcare related activities.

This portal shall empower consumers with credible and scientific information on the products and services to enable each one of them to make an informed choice. Our portal also provides scientific papers on various practices of Ayush published by various journals and institutions in a simple and easy-to-understand language. We also share information of providers who are accredited or certified by authorized accredited bodies and mandated institutions as part of the existing laws of India and other regulatory bodies, said Prof Bejon Kumar Misra, the brain behind Mahamana Declarations on Ayush and adviser-consultant, IMS, BHU who also leads the patient groups of the country.

MDOA, which is an independent initiative, has been devised to give a fillip to Ayurveda, Unani, Siddha and Homoeopathy systems of medicine. Faculty of Ayurveda Institute of Medical Sciences (IMS) at the Banarus Hindu University (BHU), Quality Council of India (QCI), FICCI and Patient Safety and Access Initiative, its effort is to expand the reach and use of this Indian traditional medicine. Though the Ministry of Ayush has nothing to do with it, we are in regular touch with them and the nine Special Interest Groups (SIGs) created for the purpose', he added.

This is a one stop portal in the interest of the consumers, supported by all like-minded bodies that are committed to making Ayush a global band in the interest of people to stay healthy, seek medical treatment and access quality healthcare as part of Universal Health Coverage objectives under Ayushman Bharat, promoted and managed by the National Health Authority, Ministry of Health & Family Welfare.

Source: Nandita Vijay, Pharmabiz, 20.01.2021

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NEW DEVELOPMENTS

Obesity, impaired metabolic health and COVID-19

In a Nature Reviews Endocrinology article authors from the German Center for Diabetes Research (DZD) highlight the interconnection of obesity and impaired metabolic health with the severity of COVID-19. First, they provide information about the independent relationships of obesity, disproportionate fat distribution and impaired metabolic health with the severity of COVID-19. Then they discuss mechanisms for a complicated course of COVID-19 and how this disease may impact on the global obesity and cardiometabolic pandemics. Finally, they provide recommendations for prevention and treatment in clinical practice and in the public health sector to combat these global pandemics. Norbert Stefan, Andreas Birkenfeld and Matthias Schulze summarize and discuss data from large and well-performed studies that investigated independent relationships of obesity with the severity of COVID-19. Thereby, they can disentangle the contribution of obesity, visceral fatness and impaired metabolic health for the course of COVID-19. In this respect they found convincing evidence that obesity and overt diabetes, but also visceral obesity and even mild hyperglycemia, represent important risk factors for the disease course. Thus, these risk factors most probably may have an additive effect on the severity of COVID-19.

Then they discuss the impact of the SARS-CoV-2 infection on organ function, focusing on the cardiometabolically relevant tissues and organs as the vessel wall, heart, kidneys, liver, gut and pancreas. Thereby, they address both, the immediate damage of COVID-19 to the organs and the long-term effects of the disease, most probably boosting the development of obesity and cardiometabolic diseases. Thus, obesity and cardiometabolic diseases do not only trigger a more severe course of COVID-19, the SARS-CoV-2 infection does promote the development of these conditions.

The authors further highlight how treatment of obesity and impaired cardiometabolic health helps to avert a severe COVID-19 in patients infected with SARS-CoV-2. In this respect health professionals and politicians should now, more than ever, promote the health benefits of physical activity and support efforts to implement programmes and policies to facilitate increased physical activity and to promote a healthy diet. This might not only be relevant to directly reduce the burden of COVID-19 related morbidity and mortality among those infected, but may also be important in the context of SARS-CoV-2 vaccination, where response should be carefully evaluated in patients with obesity and/or diabetes mellitus, because of a potentially reduced or shortened response.

Source: World Pharma News, 21.01.2021 (Excerpts)

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INTERNATIONAL NEWS

Big Pharma has reinforced its saviour image

Arguably, the most-hated industry in the world is the pharmaceutical industry. Since dying people will pay anything, the normal price resistance of consumers disappears. So, profit margins for new patented drugs can be humongous. When anti-AIDS drug cocktails were invented in the 1990s, US drug companies charged a whopping $15,000 per year. This created an uproar. To mollify critics, major US companies offered the drug "at cost" to poor countries — just $1,500, they said.

But Cipla, an Indian company, was already exporting the drugs at just $800. Cipla was lambasted by US companies as a "pirate" violating patents. Cipla retorted that the US companies were the real robbers and pirates. US President Bill Clinton ultimately sided with the activists. Production shifted massively to countries like India, and prices kept falling. By 2010, the cost was just $200.

Covid shows that we need new systems of government support for Medical Research

No wonder activists denounced US drug companies as killers. Yet, ironically, these very companies had created the cures and saved millions.

The hated drug industry has just performed a miracle, producing several different vaccines against Covid in a few months. It had proved impossible to develop any vaccine at all for several viruses, including AIDS. When Covid struck, sober specialists noted that new vaccines took at least five years to be created, tested and approved. Bill Gates said we would be lucky to get an anti-Covid vaccine in 18 months. Yet in less than a year, vaccines galore have emerged. Russia and China were among the first to create and approve their own vaccines. Western experts cautioned that these countries had not followed all the usual safety protocols. However, it can make sense to shorten test procedures to expedite a vaccine that could save millions of lives.

Pfizer and Moderna in the US have produced vaccines following the usual protocols and are ready for mass vaccination. AstraZeneca and Oxford University have developed a different vaccine which — at the insistence of Oxford University— will be sold at just $3-4 per dose in poor countries.

This vaccine can be stored at 2 to 7 degrees Celsius in ordinary refrigerators, making it suitable for poor countries like India lacking the super-cooling facilities required by the Pfizer and Moderna vaccines. May be half the population of most countries will be vaccinated by late 2021, slashing further transmission of Covid. Gradually, people will resume travel, office meetings, social gatherings and tourism. What lessons now from this? First, the Pharma industry is a saviour, not a killer. The international patent system is seriously flawed.

To make up for huge R&D losses on drugs that fail tests, companies make enormous profits on the few that work. This can sound odious. But remember, the drug companies are the saviours that have doubled life expectancy in the last century, curing dozens of diseases once incurable, relieving the world of immense misery and death. People have shown that they will happily give up their entire life savings for another year or two of life. By that standard, the life-extending services of drug companies make them among the greatest saviours in history.

What the Covid example shows is that Government guarantees can make a huge difference. R&D is expensive. If Governments are serious about health, they should offer significant funding for basic research, research on diseases of specific local interest, and for Clinical Trials. For tackling tropical diseases, developing countries as well as aid consortia and institutions like the world Bank should guarantee to buy a large quantity of promising drugs even before expensive testing begins.

This can be linked to price caps for drugs that clear testing. In theory, all medical R&D could be done by Governments and offered patent-free to all. However, the historical experience in this has been dismal. The Soviet Union and its Red empire stretching across Eastern Europe and Cuba boasted of good and free healthcare but failed to produce significant new drugs. Virtually all the hundreds of new medicines that saved millions of lives were created by profit-motivated R&D by drug companies.

The social motivation of public sector research proved insufficient. Drug companies have been found guilty of many sins: of cartelization to raise prices or diminish competition; of fudging Clinical Trials; of promoting unsuitable or even bogus drugs; of bribing doctors to promote their particular medicines; of encouraging addictive opioids; and of enormous profits on some drugs. Yet the very same sinners have saved millions of lives through R&D. We must harness their skills while reducing the odium of super-profits on a few drugs.

Covid shows that we need new systems of Government support for medical research. Public health is a public good that Governments have a duty to improve. This does not mean just price controls and hospital subsidies but guarantees and funding for relevant R&D on diseases.

(Disclaimer: The opinions expressed in this column are that of the writer. The facts and opinions expressed here do not reect the views of www.economictimes.com)

Source: The Economic Times, 05.01.2021

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US officials plead for more use of languishing antibody drugs

US Health officials are pleading for more use of Covid-19 antibody therapies from Eli Lilly and Co and Regeneron Pharmaceuticals Inc that have been plagued by logistical issues, lack of efficacy data and insufficient reimbursement.

The antibody treatments, touted by President Donald Trump and once feared to be subject to rationing because of demand, have instead been underused. As little as 5% of the supply available was being used in some areas in December, and utilization is now about 20% to 25% of regimens distributed to states, according to a Health and Human Services Department spokesperson.

The US has more than $4.2 billion in supply agreements for millions of doses of antibody therapies for Covid-19, including a $2.6 billion deal with Regeneron clinched this week. Frustrated health officials seek wider use of the drugs that, like Covid vaccines, were developed at top speed in hopes of keeping patients out of hospitals and potentially preventing the severely ill from overwhelming the nation's health system.

"We don't have the kind of evidence people are used to," Janet Woodcock, a long-time Food and Drug Administration official who serves as therapeutics lead for Operation Warp Speed, said Thursday, 14.01.2021 in a briefing. Still, she said, the evidence that the drugs can keep people off hospital wards "is very convincing."

Worth the Effort:

Woodcock, who's likely to play a role in President-elect Joe Biden's administration, urged hospitals and health centers to make the investments to administer the drugs.

"We really feel it is worth it to go to the effort, set up the infusion centers, have as many infusions to high-risk people as possible and decrease the burden to the health-care system," she said at the briefing.

The Lilly and Regeneron antibody treatments mimic proteins that are typically produced by the body to fend off the virus. Trump received Regeneron's antibody therapy after he was diagnosed with Covid last year and heralded the drug's benefits.

Emergency FDA clearances in November made them the first drugs authorized for use in non-hospitalized patients. They're intended specifically for older individuals or those with chronic medical conditions, who are at high risk of progressing to severe Covid-19. But the authorizations were based on small, early-stage trials, a point of contention for Clinicians who say insufficient data makes it difficult to recommend the drugs to patients.

Just over 641,000 doses of the antibody treatment had been administered as of January 6, according to US Government figures. US patients currently hospitalized with Covid numbered almost 130,000 as of January 10, according to the Covid Tracking Project.

Logistical Hurdles:

Getting the drugs to patients is rife with complexity. The antibody therapies must be infused early in a Covid-19 illness, when patients are infectious, so common treatment sites like hospital wards are risky. Further, the Government's distribution plan relies on hospitals. The Government's distribution plan to date has relied heavily on hospitals. Beset by the pandemic, they are not yet getting paid for performing infusions of the Government-supplied drugs because of delays in Medicare reimbursement and payment from commercial health insurers.

"It is a problem at a time when hospitals are financially strapped, as are many others in health care," Nancy Foster, the American Hospital Association's Vice President of quality and patient safety policy, said in an interview. "It needs to be resolved quickly."

An even tougher issue is identifying patients early after infection and getting them timely treatment, Foster said. Many patients aren't tested at hospitals, and the institutions can't always determine who's eligible for antibody treatment, Foster said.

Health-care companies are providing some assistance. Pharmacy chain CVS Health Corp has funding from the US to pinpoint viable recipients and administer antibodies in patients' homes and long-term care facilities. Insurer United Health Group Inc is following as many as half a million patients in a real-world study in partnership with Lilly to help clarify how well the drugs work.

Bolstering Uptake:

Already this year, Lilly is seeing a significant improvement in uptake of its antibody, called bamlanivimab, over last year, according to Chief Financial Officer Joshua Smiley. Some states are "running out of drugs, and are trying to get more, while other states, they're in that 20% or less utilization range," Smiley said in an interview.

Regeneron declined to comment:

Patients and doctors would benefit from more information about where to find the monoclonal antibodies, he said. But the companies can't advertise their products, which lack full approval that's required to do outreach. Absence of a coordinated, federal response is also an

obstacle, creating a void of information about how and where to get the treatment.

"I get friends of friends of friends who say, 'My dad is sick. I know about Lilly's drug, but how do I get it?'" he said.

Belated Website:

The Government has launched a website outlining which hospitals have received antibody therapies. As of Thursday, 14.01.2021 about 23 states lacked any identified infusion sites. Officials say they are working on updating the platform, and that all sites will be required to have their locations listed.

The National Infusion Center Association, an industry group, has also launched a treatment locator. The US has also expanded distribution of antibody therapies to other settings like nursing homes, with hopes of doing so in urgent cares as well, Woodcock said Thursday, 14.01.2021.

The AHA has urged the Government to consider sites like separate infusion clinics run by public health or home health agencies, or converting ambulatory surgery centers into infusion sites. Rural areas are looking at using mobile units, which federal officials have expressed support for, according to Mark Howell, Senior Associate Director of Policy for the AHA. Smiley said he's optimistic that more patients will get access to its antibody therapy. The company will likely invest another $300 million to $400 million this year to ramp up supply and even develop a more easily administered version, after spending about $450 million on its Covid program in 2020.

"We should be able to make a bigger impact than we are making, and certainly we'll be able to make a bigger impact in February and January and so on," Smiley said. "Hopefully by the second half of this year it's not as big of an issue because we're getting the vaccine."

Source: Bloomberg/Hindustan Times, 16.01.2021

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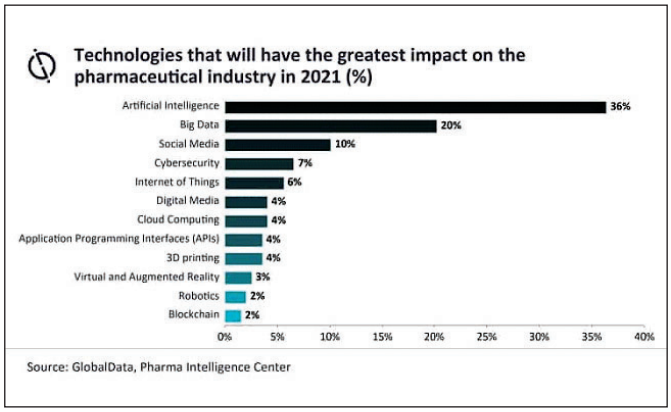
AI to be most disruptive technology across Pharma Industry in 2021 and beyond

Artificial Intelligence (AI) will transform the Pharma industry in the coming years by delivering productivity improvements and efficiencies across the entire Pharma value chain, says Global Data. Global Data's latest report, 'The State of the Biopharmaceutical Industry 2021', reveals that AI is expected to be the emerging technology that will have the greatest impact on the pharmaceutical industry in 2021, as indicated by 36 percent of 198 surveyed pharmaceutical industry professionals.



Kitty Whitney, Director of Thematic Research, comments, "Compared to other industries, Pharma has generally been slow to adopt this technology. However, the AI ecosystem in Pharma has grown significantly over the past number of years, with this trend expected to continue as the benefits of the technology are realized. The urgent need for COVID-19 vaccines and treatments is thought to have hastened the adoption of AI in drug discovery and repurposing, and could be a tipping point for the widespread adoption of the technology across the Pharma industry."

In drug discovery, many Parma companies have partnered with AI vendors or start-ups to take advantage of their technology and expertise. Examples of leading AI vendors operating in this space include Exscientia, Atomwise, Recursion Pharma, Insilico Medicine, and Benevolent AI.

Pharma companies are also beginning to set up more in-house capabilities, as seen by GSK and Novartis. Additionally, in February 2020, Eli Lilly's Olumiant (baricitinib) was identified in just three days by UK-based start-up Benevolent AI as having the potential to treat COVID-19, and it received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) in November.

A recent analysis by Global Data identified almost 100 partnerships between AI vendors and large Pharma companies for drug discovery since 2015, with increasing numbers witnessed in recent years. Analysis shows that four partnerships were forged in 2015, which rose to 27 by 2020, an increase of 575 per cent in just six years.

Whitney adds, "The Pharma industry is under increasing pressure, with rising costs of drug development, manufacturing, and marketing eroding profit margins. As well as drug discovery, AI can be applied across a wide range of other functions, allowing for improved Clinical Trial design and recruitment, smarter and more efficient supply chains, and targeted sales and marketing."

Source: EP News Bureau, Express Pharma, 24.01.2021 (Excerpts)

Factbox: Vaccine Dosing Intervals - What Countries are doing around the World

John Miller

ZURICH: As the world races to contain rising COVID-19 infections fuelled by new Coronavirus variants, some countries are seeking to counter low vaccine supplies with dosing patterns or volumes that stray from how the shots were tested in Clinical Trials. There are differences over the merits of alternative dosing strategies, with some arguing the urgency of the pandemic requires flexibility, while others oppose abandoning data-driven approaches for the sake of expediency. Here is a list of what countries are doing:

UNITED STATES: The US Food and Drug Administration has said that altering the authorised dosing or interval schedules of COVID-19 vaccines is premature and not supported by science, while acknowledging that such questions may be "reasonable" to consider. It is calling for 21 days between doses of Pfizer and BioNTech's shot, and 28 days for Moderna's vaccine.

BRITAIN: In Britain, regulators have said shots can be administered up to 12 weeks apart for vaccines with emergency approval from AstraZeneca and its partner Oxford University, as well as Pfizer/BioNTech. During trials of the Oxford/AstraZeneca shot, the median dosing interval varied between countries, with 10 weeks in British trials and six weeks in Brazil. But Pfizer says its shot has only been properly evaluated with a 21-day interval between doses and there is no data to show that protection is sustained beyond 21 days after the first dose. Britain has also said it will allow people to be given shots of different COVID-19 vaccines on rare occasions, despite acknowledging there "is no evidence on the interchange ability of the COVID-19 vaccines".

EUROPEAN UNION: The European Medicines Agency (EMA) has said there should be a maximum interval of 42 days between the first and the second shot of the Pfizer-BioNTech vaccine that it has approved, based on a study where shots were given 19 to 42 days apart with full protection achieved seven days after the booster.

DENMARK: Denmark has approved an interval of up to six weeks between the first and second Pfizer/BioNTech shots, in line with EU guidance. It has also said the original Guidelines of waiting only three to four weeks should be followed whenever possible.

GERMANY: Germany is considering whether to allow a delay, seeking an independent vaccination commission's Guidance on whether to push a second shot beyond the current 42-day maximum limit amid frustration and criticism within the country over what some see as a sluggish launch.

BELGIUM: The Health Ministry in Belgium says it is planning to follow EMA recommendations for COVID-19 vaccine doses. Ultimately, regional authorities in Belgium typically decide on vaccination plans, but there are no indications there will be differentiated approaches across the nation, a spokeswoman said.

NETHERLANDS: The Dutch Health Minister says the nation is considering waiting longer with a second shot.

IRELAND: The Irish Immunisation Advisory Committee has recommended continued administering of two doses of the Pfizer-BioNTech vaccine in the period indicated by its manufacturers.

SPAIN: The Central Health Authority will continue to recommend administering two doses of the Pfizer-BioNTech vaccine in the period indicated by its manufacturers, Health Minister Salvador Illa said.

SWITZERLAND: Switzerland, which as a non-EU country has its own drugs regulator called Swiss medic that has approved Pfizer/BioNTech's shot, is not planning at this time to deviate from the label of vaccines in order to stretch doses, the Swiss Federal Health Ministry said.

INDIA: Regulators who approved the Oxford/AstraZeneca vaccine, to be made in the country by the Serum Institute of India, have recommended it be administered eight to 10 weeks apart.

Source: The Thomson Reuters Trust Principles/www.News18.com, 06.01.2021 (Excerpts)

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Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 30.01.2021

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.**