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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 Issue No. 41 01 to 07 November 2020

MBA-STYLE INTERNATIONAL EDUCATIONAL PROGRAM FOR POTENTIAL LEADERS

Empowerment
Through Education
Living A Dream,
Building A Future

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021

For further information / queries, please open the below links on our website www.idma-assn.org:

Circular / Covering Note | NSF Presentation | WHY APPQM? By Mr S M Mudda | APPQM 5 Modules | APPQM Series 1 FEEDBACK | REGISTRATION FORM

APPQM FOR DEVELOPING CHANGE AGENTS FOR QUALITY EXCELLENCE

APPQM - Program Modules

1. **Pharmaceutical Quality Management Systems – Best Industry Practices**
   (How to ensure your QMS drives business improvements)
2. **Managing Change: Change Control and Deviations**
   (Advanced problem solving, deviation management, report writing and change management)
3. **Human Factors – Getting people to follow the rules**
   (How to improve performance, reduce human error, embed a quality mind-set & keep your people)
4. **Transforming Data into Information – the Practical Application of Statistics to Transform your Business**
   (The practical application of statistics to transform your business)
5. **Quality by Design, Process Validation and Technology Transfer**
   (Building a foundation for Product Quality and Knowledge Management)

Advantages of NSF's Virtual Training

- NSF's virtual training combines live instructor-led virtual classrooms and self-paced learning online (easy to navigate e-learning) to provide participants with an interactive and engaging learning experience.
- Enhanced Virtual Interactivity – such as polls, etc.
- Virtually managed Break-out rooms - These are as good as physical break out groups
- Use of Team works – specially smaller group sizes
- Use of Tasks and Case Studies
- Courses managed Brilliantly by NSF - Each course is managed on NSF Learning Management System (LMS), with electronic course material
- Time for self-study each day.
- Guest Speakers (including MHRA, US FDA ex-regulators) enhance the modules and motivate the delegates

Additional Benefits:

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees **(from £8000 to £3300)**
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Why APPQM in INDIA?*

When launching the first series of the APPQM, we at IDMA along with NSF, UK reflected on the perceived trust deficit with international regulators despite being regarded as a 'Pharmacy of the World' and offered a global education program APPQM, in collaboration with NSF Health Sciences, UK, as a collective proactive response from the industry. We boldly stated APPQM would be Unique, World-Class and transform the operation efficiency of companies attending. Well, did series one live up to expectations?

Over 40 delegates attended series one.

This is what they thought:

"Transformative", "world-class", "best business investment we've ever made", "life changing", "worth every penny and more", "my company will be sending more delegates to series two", "has helped transform our quality culture" are just some examples of the feedback we've received from APPQM delegates.

Nearly 30 'work placement projects' have been completed by APPQM delegates.These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

*Please visit IDMA website for details of benefits

Current Challenges & APPQM

In this challenging times, the pharmaceutical industry will become competitive only if the 3 factors - **Legacy & Reputation** (License to Operate), **Profit & Efficiency** (Cost Control) and **Customer service** are balanced and managed well.

The COVID-19 pandemic has created unique challenges as well as opportunities for the industry. In the absence of any regulatory inspections happening until quarter III of 2021 and reduced physical oversight by the corporate QA functions, the external interventions on the site will be reduced. There is an urgent need to use this time for building a strong leadership at the site for quality and compliance.

We recommend the virtual APPQM for the site teams for keeping themselves updated with the changing regulatory expectations in the post COVID-19 phase, once the physical inspections start.

The need of the hour is to focus on long term preventive measures aimed at achieving continual improvements rather than short term Compliance-Oriented approach.

Please don't get left behind and register for the second series of APPQM to have a competitive edge in the global market and to be future ready.

REGISTRATION FEE FOR SERIES TWO

The Registration Fee for **APPQM SERIES 2** is restructured at

Rs.3,15,000/- (Rupees Three Lakh Fifteen Thousand Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the Registration Form and send it to

Melvin Rodrigues actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

For further information / queries :

You may also contact **Mr. S. M. Mudda**, @ **mudda.someshwar@gmail.com** / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M MUDDA Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**MAHESH H DOSHI** National President, IDMA	**DR. GEORGE A PATANI** Hon. General Secretary & Vice Chairman, Industry Institution Interaction Committee, IDMA	**DAARA B PATEL** Secretary – General, IDMA

IDMA Representation to DoP on Revised Guidelines for the Production Linked Incentive Scheme (PLI) dated 29th October, 2020 – reg.

The Association has submitted the following representation on 3rd November 2020 to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, New Delhi with copies to Dr V K Saraswat, Member, NITI Aayog and Ms Shubhrata Prakash, Director, NITI Aayog on the above subject:

"At the outset we wish to thank you for the revised PLI Guidelines incorporating industry suggestions. Removal of the minimum investment criteria and the condition of domestic sales should encourage a greater number of applicants to take advantage of the Scheme. As regards 'Brownfield units' we are sending a separate note for flexibility in present environmental regulations for better utilisation of surplus capacity. At the same time we still feel if they can be covered under the PLI Scheme, the country can see expeditious production of eligible products.

Further, we wish to bring to your kind notice our following suggestions:

1. Reasonable time limits for grant of various permissions for additional production from Pollution Control authorities needed for timely implementation of the project, and ultimate success of the PLI Scheme.
2. Many of the eligible products are "Intermediates" or require intermediates to be developed to achieve value addition. Although, Para 5(f) of EIA 2006 Notification mentions "API & Intermediates" but the recent relaxation in EC rules by MoEF&CC wide Notification No.S.O.3636(E) dated 15.10.2020 for treating all Bulk Drug Projects as B2 category has omitted word "Intermediates". Even the draft 2020 EIA Notification (yet to be notified) also mentions under para 5(f) "APIs & Intermediates". **Unless included intermediates' production under PLI Scheme will get delayed, as EC will be insisted upon.**
3. Point at 12.5 (iii): mentions "Base Line (if applicable)". Base Line is not defined in the revised PLI. We request for clarification of this term.
4. Change of location may be permitted as long as the committed investment is achieved.
5. Clause 4.2.6 – Suggest rethinking. Carry forward of unused incentive amount be allowed as in the 1st year it may not be possible to achieve 100% production due to teething problems.
6. Finally, since the criteria of "minimum investment" is now removed in the revised Guidelines, some of the wordings **(in Bold)** as shown below are no longer relevant or need minor alterations, which you may wish to look into **as there is no longer an investment criteria.**

2.18. **However, the investment already made in the ancillary facilities shall not qualify for the purpose of the committed investment to be made under the scheme.**

2.21.3 **Expenditure on land shall not be considered.** Similarly **Guest House, Recreation building, office building residential accommodation etc shall not be considered as threshold investment.**

6.11 **Investment as defined in the Guidelines shall be considered for determining the eligibility.**

6.1.6 **The applicant shall submit a certificate by Chartered Engineer to be appointed by PMA for committed investment by the applicant and shall be relied upon by PMA.** Looking forward to your favourable consideration".

● ● ●

Scheme for grant of ex-gratia payment of difference between compound interest and simple interest for six months to borrowers in specified loan accounts (01.03.2020 to 31.08.2020) – reg.

DFS Notification Ref.F.No.2/12/2020-BOA.I, dated 23rd October 2020

1. *State Bank of India (SBI),*
2. *All India Financial Institutions (AIFIS),*
3. *All Nationalised Banks,*
4. *All Banking Companies, Urban Co-operative Banks, and Non-Banking Financial Companies (NBFCs) registered with RBI [through RBI}),*
5. *All NBFC–Micro Finance Institutions (NBFC-MFIS) that are members of an RBI-recognised Self-Regulatory Organisation [through Micro Finance Institutions Network (MFIN) and Sa-Dhan],*
6. *All State Co-operative Banks, District Central Co-operative Banks and Regional Rural Banks (RRBs) [through the rural banking system supervisor {National Bank for Agriculture and Rural Development (NABARD)},*
7. *All Housing Finance Companies (HFCs) registered with the National Housing Bank (NHB) [through the supervisor of HFCs (National Housing Bank)],*

1. The undersigned is directed to convey that in view of the unprecedented and extreme COVID-19 situation, the Central Government has approved "Scheme for grant of *ex-gratia* payment of difference between compound interest and simple interest for six months to borrowers in specified loan accounts (01.03.2020 to 31.08.2020)". Benefits under the scheme would be routed through lending institutions. Operational Guidelines for the scheme are attached*****.

2. Eligibility criteria for *ex-gratia* payment under the scheme are as follows:

(a):: Borrowers in the following segments/classes of loans, who have loan accounts having sanctioned limits and outstanding amount of not exceeding Rs.2 crore [aggregate of all facilities with lending institutions] as on 29.02.2020, shall be eligible under the Scheme:

(i): MSME loans;

(ii): Education loans;

(iii): Housing loans;

(iv): Consumer durable loans;

(v): Credit card dues;

(vi): Automobile loans;

(vii): Personal loans to professionals;

(viii): Consumption loans.

Any borrower whose aggregate of all facilities with lending institutions is more than Rs.2 crore (sanctioned limits or outstanding amount) will not be eligible for *ex-gratia* payment under this scheme.

(b):: The aforesaid eligibility shall be subject to the following further conditions and stipulations:

(i): Account should be standard as on 29.02.2020, i.e., loan should not be a Non-Performing Asset (NPA) as on 29.02.2020.

(ii): Lending institution must be either a banking company, or a Public Sector Bank, or a Co-operative Bank [j.e., an Urban Co-operative Bank or a State Co-operative Bank or a District Central Co-operative Bank], or a Regional Rural Bank, or an All India Financial Institution, or a Non-Banking Financial Company or a Housing Finance Company registered with RBI or National Housing Bank as the case may be. A Non-Banking Financial Company, Micro Finance Institution should be a member of a Self-Regulatory Organisation (SRO) recognised by RBI.

(iii): The *ex-gratia* payment under this scheme shall be admissible irrespective of whether the borrower in sub-clause (1) had fully availed or partially availed or not availed of the Moratorium on repayment announced by RBI vide its circular DOR. No.BP.BC.47/21.04.048/2019-20, dated 27.03.2020 and extended on 23.05.2020.

3. The period to be reckoned for crediting of difference between compound interest and simple interest by the lending institutions mentioned in paragraph 2(b)(ii) above to eligible borrowers as per paragraph 2 above would be from 01.03.2020 to 31.08.2020 (six months/184 days). For accounts closed during the said period, the period for crediting would be from 01.03.2020 and restricted to the date of closure of such account.

4. The benchmarks and modalities for *ex-gratia* payment of difference between compound interest and simple interest under the scheme would be as detailed in the attached operational Guidelines. The rate of interest would be as prevailing on 29.02.2020, i.e.,incasethe rate of interest has changed thereafter, it shall not be reckoned for the purposes of this computation. The payable *ex-gratia* amount shall have to be credited to the account of the borrower by the respective lending institutions as *ex-gratia* payment under the scheme.

5. The aforesaid exercise of crediting the amount as stated above in the respective accounts of the eligible borrowers described in paragraph 2 above by the respective lending institution shall be completed on or before 05.11.2020.

6. After the exercise mentioned in paragraph 5 above has been completed, lending institutions can lodge their claim for reimbursement latest by 15.12.2020.

   Claims shall be submitted to designated officer(s)/ cell at the State Bank of India (SBI). SBI is advised to appropriately equip its designated officer(s)/cell for processing such claims in a timely manner, and to notify details of the same on its website.

7. Issues and concerns relating to claims submitted by the lending institutions shall be handled through the designated cell at SBI in consultation with Government of India. Each lending institution shall put in place a grievance redressal mechanism for the eligible borrowers for redressal of their grievances arising out of the present scheme within one week from the date of issuance of these Scheme Guidelines, at appropriate level(s). While putting in place such grievance redressal mechanism, lending institutions can keep in mind the communication dated 01.10.2020 issued by the Indian Banks' Association in respect of resolution framework for COVID-19 related stress for Guidance. Grievances, if any, of the lending institutions shall be resolved through the designated cell at SBI in consultation with the Ministry of Finance, Government of India.

8. In case of any issues/queries relating to interpretation of this scheme, the decision of Government of India shall be final.

A K Ghosh,
Under Secretary,
Department of Financial Services,
Ministry of Finance, New Delhi.

(*Operational Guidelines not reproduced here. Members-interested to have the same may kindly write to IDMA Secretariat at email: admin@idmaindia.com for getting a soft copy of the same through email).

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DGFT MATTERS

Discontinuation of Extension Counter RA Goa - reg.

Joint DGFT Trade Notice No.01, dated 29th October 2020

To All Concerned;

Attention of the Trade is invited to the discontinuation of Extension Counter RA Goa with immediate effect as per the instructions received from Director General of Foreign Trade (Hqrs.) vide letter no.01/69/12/33/2018-O&M (Pt.) dated 6th October, 2020 and in continuation of O&M Instruction No.05/2018 dated 6th September, 2018 and earlier Trade Notice No.03 dated 10th September, 2018.

All the Trade & Industry in Goa are hereby requested to file all the applications and correspondence henceforth in RA Mumbai by using the Office Code 03 instead of Office Code 17 which was used for erstwhile Goa Office.

A K Choudhary, Additional Director General of Foreign Trade, Office of The Additional Director General of Foreign Trade, Mumbai.

● ● ●

CBIC further amends Notification No.16/2017 to provide exemption to Specified Medicines under certain Patient Assistance Programmes (PAPs) run by Pharmaceutical Companies - reg.

Notification No.41/2020-Customs, dated 29th October, 2020

In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.16/2017-Customs, dated the 20th April, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.394(E), dated the 20th April, 2017, namely:

In the said notification, in the Table, for the entries in column (3) and column (4) at the serial numbers given in column (1) of the Table below, the corresponding entries at column (2) and column (3) of the Table below shall be substituted, namely:

Table

(1)	(2)	(3)
17.	"Win for Patients - Cancer Care/Umaang	Novartis Healthcare Private Limited
18.	Win for Patients - Cancer Care/Umaang	Novartis Healthcare Private Limited
19.	Win for Patients - Cancer Care/Umaang	Novartis Healthcare Private Limited
20.	Win for Patients - Cancer Care/Umaang	Sandoz India Private Limited
21.	Win for Patients - Cancer Care/Umaang	Novartis Healthcare Private Limited
22.	Win for Patients - Cancer Care/Umaang	Novartis Healthcare Private Limited
43.	Sutent Patient Assistance Programme - STAR	Pfizer Products India Private Limited
44.	Crizalk Patient Assistance Programme - STAR	Pfizer Products India Private Limited
45.	Inlyta Patient Assistance Programme - STAR	Pfizer Products India Private Limited
46.	Palbace Patient Assistance Programme - PRERNA	Pfizer Products India Private Limited
47.	Enbrel Patient Assistance Programme	Pfizer Limited
48.	Xeljanz Patient Assistance Programme	Pfizer Limited
49.	Genotropin Patient Assistance Programme	Pfizer Products India Private Limited
50.	Atgam Patient Assistance Programme	Pfizer Products India Private Limited
51.	Aromasin Patient Assistance Programme	Pfizer Products India Private Limited
52.	Campto Patient Assistance Programme	Pfizer Products India Private Limited".

F.No.332/24/2010-TRU (Pt.III)

Gaurav Singh, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi.

Note: *The Principal Notification No.16/2017-Customs, dated the 20th April,2017 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.394(E), dated the 20th April, 2017, and was last amended by Notification No.83/2017-Customs, dated the 31st October, 2017 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.1356(E), dated the 31st October, 2017.*

Manufacturing and other operations undertaken in bonded warehouses under Section 65 of the Customs Act, 1962 - reg.

Circular No.48/2020-Customs, dated 27th October, 2020

To,
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),
All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,
All Principal Commissioners/Commissioners of Customs/ Customs (Preventive),
All Principal Commissioners/Commissioners of Customs & Central tax,
All Principal Director Generals/Director Generals under CBIC.

1. Section 65 of the Customs Act, 1962 provides that the owner of any warehoused goods may carry on any manufacturing process or other operations in the warehouse in relation to such goods, with the permission of the Principal Commissioner of Customs or Commissioner of Customs and subject to such conditions as may be prescribed. Manufacture and Other Operations in Warehouse (No.2) Regulations 2019, were issued vide Notification No.69/2019-Customs (N.T.) dated 01.10.2019, hereinafter referred to as, "MOOWR, 2019" prescribing the procedure, documentation and compliances to be followed under Section 65 of the Customs Act, 1962.

2. Board has from time to time received suggestions and requests from members of the trade and industry on the scheme of Manufacturing and other Operations in a Warehouse under Section 65 of the Customs Act, 1962. The requests revolve around making the scheme more investor friendly and seeking more clarity with regard to certain aspects. A Committee was therefore constituted by the Board to study the provisions of Section 65 of the Customs Act, 1962 and the regulations issued there under and make recommendations for consideration of the Board. The committee has since submitted its report.

3. The issues raised by the trade and the recommendations of the Committee have been examined. To bring in greater regulatory clarity and certainty for investors, Board has decided to clarify the following issues:

(i) Job work for a Section 65 unit: Trade has sought clarity on the goods eligible to be sent for job work and the procedure to be followed for removal of goods for job work by a Section 65 unit.

Clarification: Circular No.34/2019-Customs dated 1st October 2019 had provided, in Annexure B (Form to be maintained by a unit operating under section 65 of the Customs Act, 1962 for the receipt, processing and removal of goods) for removal of goods from a Section 65 unit for job work and receipt after job work, as part of the manufacture or other operations. Thus, only inputs are allowed to be sent out from a Section 65 unit for job work. The capital goods can be sent outside the Section 65 unit for repair, with the permission of the bond officer.

The job work shall be subject to the following conditions:

(i) The goods upon import should be first deposited in the Section 65 premises and duly accounted for before the same is sent for job work.

(ii) It should be possible to establish the identity/correlate the goods after job work with those sent for job work.

(iii) On completion of the job work, the goods can be brought back to the Section 65 unit or exported/ cleared to DTA from the job worker's premises. In case the goods are exported/cleared to DTA from the job worker's premises, the procedure as per Regulations 14 and 15 of MOOWR 2019, as applicable shall be followed and the date of removal from job workers premise shall be deemed to be the date of removal from the warehouse.

(iv) Scrap, waste or remnants generated during the job work shall be either returned to the Section 65 unit or cleared from job-worker's premises on payment of applicable duties.

(v) The procedure and timeline for the return of goods sent for job work under Section 65 unit will be in line with GST provisions, as the Section 65 Unit is also a GST registrant.

(vi) The account to be maintained under Circular No.34/2019-Customs dated 1st October 2019 will be kept updated as regards job work at all times.

Trade has also requested that moulds, jigs, tools, fixtures, tackles, instruments, hangers, patterns and drawings be allowed to be sent to the job workers premises for use in the job work. Considering the nature of goods sought to be removed from a Section 65 unit for the purposes of job work, Board has decided to allow the said goods viz moulds, jigs, tools, fixtures, tackles, instruments, hangers, patterns and drawings to be sent to the premises of a job worker, subject to due accounting of the goods by the Section 65 unit in the account specified. Such goods will be used by the job worker exclusively for the concerned Section 65 unit. The procedure and timeline will be in line with the GST provisions.

It may also be noted that the bond to be executed by a Section 65 unit, prescribed through the aforementioned circular, stays in full force notwithstanding the removal of goods for job work from a Section 65 unit.

In case of violation of any of the above provisions, the goods shall be deemed to be cleared for home consumption on the date of clearance of the goods for job work. The applicable duties, interest and penalties shall be reckoned accordingly.

(ii) Job work for others by a Section 65 unit: Trade has sought clarity on whether the Section 65 unit can itself carry out job work for other units and the procedure to be followed for the same.

Clarification: The issue has been examined with a view to enhance capacity utilization and acknowledging the realities of manufacturing environment where various units support each other in producing the final product. It is clarified that a Section 65 unit being a GST registered unit, can perform job work operations and shall maintain due accounting of such job work as per the provisions of GST law.

In case any imported inputs which are warehoused are consumed during the job work process, duty shall be paid on such goods (i.e. the warehoused goods) by filing Ex-Bond Bill of Entry, when such job worked goods are returned to the principal/owner. In case the goods after job work are exported from the premises of the Section 65 unit, the import duty on the warehoused goods used for the job work need not be paid as per section 69 of the Customs Act, 1962.

(iii) Whether a Section 65 unit can procure goods from FTWZ: Circular 34/2019-Customs dated 1st October 2020, does not explicitly mention sourcing of goods from FTWZ. Hence there is apprehension on whether such sourcing is allowed.

Clarification: Vide para 14 of Circular No. 34/2019-Customs dated 1st October 2020, Board has clarified that the objective of Section 65 is to enable manufacture and other operations in customs bonded warehouses. For this purpose, the units should be able to procure required raw materials, consumables, capital goods etc., imported or procured from domestic market.

There are no restrictions imposed on sourcing of goods by units operating under Section 65. Moreover,the units are GST registrants, which are also allowed to procure goods from SEZ/ FTWZs. In view of the foregoing, it is clarified that a Section 65 unit may source capital goods or inputs from a SEZ/FTWZ, following the applicable procedures.

4. The above provisions may be given wide publicity through issue of Public Notices.

5. Any difficulties faced in the implementation of this Circular may please be brought to the notice of Board.

F.No:473/03/2015-LC

Temsunaro Jamir,
Additional Commissioner(ICD),
Central Board of Indirect Taxes & Customs,
Department of Revenue,
Ministry of Finance,
New Delhi.

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CBIC notifies New Exchange Rates w.e.f. 16th October 2020 - reg.

Notification No.99/2020-Customs (N.T.), dated 15th October, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.95/2020-Customs(N.T.), dated 1st October, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 16th October, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	53.55	51.25
2.	Bahraini Dinar	200.95	188.60
3.	Canadian Dollar	56.85	54.85
4.	Chinese Yuan	11.10	10.75
5.	Danish Kroner	11.80	11.35
6.	EURO	87.80	84.70
7.	Hong Kong Dollar	9.65	9.30
8.	Kuwaiti Dinar	247.80	232.35
9.	New Zealand Dollar	50.10	47.85
10.	Norwegian Kroner	8.05	7.80
11.	Pound Sterling	97.15	93.85
12.	Qatari Riyal	20.80	19.55
13.	Saudi Arabian Riyal	20.20	18.95
14.	Singapore Dollar	55.00	53.10
15.	South African Rand	4.55	4.30
16.	Swedish Kroner	8.45	8.15
17.	Swiss Franc	82.00	78.75
18.	Turkish Lira	9.55	9.00
19.	UAE Dirham	20.65	19.35
20.	US Dollar	74.25	72.55

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	71.05	68.40
2.	Korean Won	6.60	6.20

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

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

CBIC extends due date of return under Section 44 till 31.12.2020 - reg.

GST-Central Tax Notification No.80/2020, dated 28th October, 2020

(Central Tax)

In exercise of the powers conferred by sub-section (1) of section 44 of the Central Goods and Services Tax Act, 2017 (12 of 2017), read with rule 80 of the Central Goods and Services Tax Rules, 2017, the Commissioner, on the recommendations of the Council, hereby makes the following further amendment in the Notification of the Government of India in the Ministry of Finance (Department of Revenue), No.41/2020-Central Tax, dated the 5th May, 2020 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 275(E), dated the 5th May, 2020, namely:-

In the said notification, for the figures, letters and word "31st October, 2020", the figures, letters and word **"31st December, 2020"** shall be substituted.

F.No.CBEC-20/06/09/2019-GST

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

Note: *The Principal Notification No.41/2020-Central Tax, dated the 5th May, 2020, was published in the Gazette of India, Extraordinary, vide number G.S.R.275(E), dated the 5th May,2020 and was last amended vide Notification No.69/2020–Central Tax dated the 30th September, 2020, published vide number G.S.R.595(E), dated the 30th September, 2020.*

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Ban on Chinese Products

Lok Sabha Unstarred Question No.482
Prof Saugata Ray:
Shri Gopal Chinnaya Shetty:

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

(a): whether Union Government has achieved success in banning the import of Chinese products on the basis of rules;

(b): if so, the details thereof;

(c): whether the Industrial Sector of the country has been benefitted with this decision; and

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

(e): whether banning the import of China products helps Atmanirbhar Bharat Abhiyan and if so, the details thereof?

Answered on 16th September 2020

A. (a) to (e): The Government regularly reviews the country's import policy, based on emerging trade and economic factors. Decisions to regulate imports are taken based on the assessment in national and public interest. At present, approximately 550 tariff lines are under the 'Restricted'/'Prohibited' category for imports under the Foreign Trade Policy, imports of which are restricted from all countries including China. To support and expand domestic capacities, Government has also implemented policies to promote the domestic manufacturing through ease of doing business and Production Linked Incentives (PLSs), including in the field of mobile phones and electronics components and bulk drugs and medical devices, in line with the vision of Atmanirbhar Bharat. The full impact of the promotional measures on the industry will be discernible as the global economy recovers.

The Minister in the Ministry of Commerce & Industry (Shri Piyush Goyal)

Export of Medical Items

Lok Sabha Unstarred Question No.503
Shri Kuruva Gorantla Madhav:
Shri Lavu Sri Krishna Devarayalu:
Shri Pocha Brahmananda Reddy:

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

(a): whether the Government has removed the ban on exports for diagnostic kits, PPEs, sanitizers, Hydroxychloroquine and other medical items;

(b): if so, the details thereof;

(c): whether after the ban on exports of said items, the indigenous production of the above items has increased drastically; and

(d): if so, the details thereof?

Answered on 16th September 2020

A. (a) and (b): The prohibition on export of various medical items such as PPE Coveralls, 2/3 Ply masks, Face Shields, Sanitizers (except when exported in containers with dispenser pumps), Hydroxychloroquine API and its formulations, 13 other Pharmaceutical APIs and its formulations and Ventilators has been removed. While export of Diagnostic Kits, N-95/FFP2 masks is currently restricted, their export is allowed subject to a monthly quota.

(c) & (d): The prohibition on export of medical items was imposed to ensure domestic availability of these items to fight COVID-19. These have been relaxed based on an assessment, from time to time, of the domestic requirement, production capacity and surplus available for export. Prior to 20th March, 2020, the requirement for PPE Coveralls was largely met through imports as there was very limited domestic production suitable for COVID-19 requirements.The export ban on PPE Coveralls was removed when the domestic production of PPE Coveralls subsequently reached 1.5 crore units per month. The availability of Alcohol based Hand Sanitizers was 10 lakh litres per

annum. This manufacturing capacity subsequently increased to 38 Lakh litres per day, enabling the prohibition on the export of Alcohol based hand sanitizers (except when exported in containers with dispenser pumps) to be removed. Ventilators production in country, which was negligible prior to January 2020, was ramped up to enable export of domestically manufactured ventilators today.

The Minister in the Ministry of Commerce & Industry (Shri Piyush Goyal)

Misclassification of Export Items

Lok Sabha Unstarred Question No.516

Shri Ravneet Singh Bittu:

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

(a): whether it is a fact that there are increasing cases of misclassification of items by the importers as 'Others';

(b): if so, the details thereof, sector-wise and the action taken against the defaulting importers;

(c): whether the Government is planning to curb import of uncategorised items and impose requirement of special licences for them and take other related measures;

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

(e): if not, the reasons therefor?

Answered on 16th September 2020

A. (a) to (e): About one fourth of India's total imports are under the 'Others' category of Indian Trade Classification (Harmonized System) [ITC (HS)], 2017, Schedule–I (Import Policy). Accordingly, Government has initiated a review of the imports under 'Others' category and advised Trade and Industry to accurately mention the specific ITC (HS) code of the item sought to be imported while filing the Bill of Entry. In addition to efforts being made by the Government, trade advisories were issued requesting importers to propose separate new ITC (HS) codes where no such codes exists for a specific item. As part of this initiative, the Finance (No.2) Act, 2019 dated 1st August, 2019 created new specific ITC (HS) codes for a number of items, which were earlier in the 'Others' category. Matters related to misclassification of export-import items are dealt with by the Customs Authorities under the relevant provisions of law.

The Minister in the Ministry of Commerce & Industry (Shri Piyush Goyal)

In Rajya Sabha

Raw materials for making drugs

Rajya Sabha Unstarred Question No.691

Smt Phulo Devi Netam:

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

(a): whether it is a fact that our dependency on China in the matters of medicine is increasing, if so, the details of import of medicines during the last six months;

(b): whether it is also a fact that the supply of raw materials for drugs from China has declined during the spread of Coronavirus infection;

(c): whether it is also a fact that China has overcharged for raw material used for making drugs, the details thereof; and

(d): the efforts being made by Government to make India self-reliant in the field of medicine, the details thereof?

Answered on 18th September 2020

A. (a): Many APIs are imported from China, for manufacturing of medicine. As per available data from the various Port Offices of CDSCO, the details of import of such APIs during the last six months are under:

S. No.	Months	Quantity in MTS	Value in Crore
1	March,2020	4448.9	795.02669
2	April, 2020	5341.7	897.57950
3	May, 2020	3961.4	949.42975
4	June, 2020	3634.1	973.63478
5	July, 2020	4812.1	1094.8240
6	August,2020	4023.5	804.81575

Source: DCGI, CDSCO

(b): The supply of raw material from China got impacted for short time. However, the major Indian pharmaceutical companies had adequate stocks which were monitored by the Department. The supply was restored once the factories opened after the lockdown period in China.

(c): No complaints/references regarding over charging for raw material used for making drugs has been received.

(d): With a view to attain self-reliance and reduce import dependence in APIs/Bulk drugs, the Department of Pharmaceuticals has rolled two schemes viz (i) "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" and (ii) "Promotion of Bulk Drug Parks". The Guidelines of both the schemes were released on 27th July, 2020.

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

Export opportunities for Pharmaceutical companies

Rajya Sabha Unstarred Question No.696

Shri Vaiko:

Shri K R Suresh Reddy:

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

(a): whether there are ample export opportunities for Pharmaceutical companies in India to export to Eastern Europe and Russia;

(b): if so, the efforts made by Government to facilitate Pharma companies; and

(c): whether Government would offer incentives and concessions to encourage exports in Pharma sector in view of higher potential in exports, the details thereof?

Answered on 18th September 2020

A. (a): The market size of Eastern Europe (excluding Russia) is relatively small as compared to the European Union, offering relatively smaller business opportunity for Indian pharmaceutical exports. However, Russia is an important destination for Indian pharmaceutical exports and it is the fourth largest importer of pharmaceutical products from India, worth USD 552.41 million, which grew at 14% and contributed 2% of the total Pharma exports from India. Other than Russia, countries such as Poland, Greece, Ukraine, Romania, Slovenia, Uzbekistan and Hungary are the other markets in the Eastern Europe which have business potential for India, from the perspective of generics market.

(b): Export promotion is a continuous process. Government of India, through various institutional dialogue mechanisms such as Joint Working Groups, regularly engages with the respective country's Health and Commerce Ministries and other concerned Government agencies to promote our Pharma trade interests. Cooperation agreements/ MoUs are also entered into for closer engagement as per the requirement. Various issues faced by the Indian companies including market access concerns are regularly taken up with the concerned agencies of these countries at appropriate levels.

(c): Government, through its schemes, encourages the Indian industry to explore new markets, register more products, show case their products in major International fairs including participating in Buyer Seller Meetings, all of which help in maintaining our competitiveness in the international markets. The Government, with effect from January 2019, has increased the financial assistance under the MAI (Market Access Initiative) from Rs.50 lakhs to Rs.2 crore per company per year, and also introduced Rs.25 lakhs for implementation of bar-coding to MSME units. These measures are expected to facilitate enhanced market access for Indian Pharma.

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

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Inhaled antibody drug for COVID-19 clears Coronavirus in animals

Aridis Pharmaceutical has developed an inhalable COVID-19 antibody that successfully eradicated signs of the novel Coronavirus in infected hamsters. (pixabay)

Monoclonal antibodies for COVID-19 recently took center stage as Regeneron's ex-perimental cocktail was used to treat President Donald Trump, who went on to rave about it. But that therapy, as is typical for antibody drugs, needs to be injected into the body.

Aridis Pharmaceuticals is working on an inhaled neutralizing antibody for COVID-19 dubbed AR-711, which was discovered using samples from patients who had recovered from COVID-19. The drug successfully cleared signs of SARS-CoV-2 virus from infected hamsters at a far lower dose compared with other experimental monoclonal antibodies, according to results published on preprint site bioRxiv.

Encouraged by the preclinical results, Aridis plans to start testing AR-711 in non-hospitalized mild-to-moderate COVID-19 patients in the first half of next year. If the drug eventually succeeds in human trials, the company could offer a self-administered option for COVID-19, saving patients the need to travel to healthcare facilities for infusions that could take hours to complete.

"Over 90% COVID-19 symptomatic patients are home-bound, under quarantine, and often not treated. While these patients wait, their health can deteriorate, and they could infect those around them," Aridis CEO Vu Truong, Ph.D., said in a statement. "Having a convenient way to self-medicate with the simplicity of an asthma inhaler where the drug is delivered directly to the infection site can have a transformative impact on patients' lives, expand treatment coverage, and ultimately reduce global transmissibility."

Most antibodies and vaccines that are being developed by drug companies target the Receptor-Binding Domain (RBD) of the novel Coronavirus's spike protein. This small part plays an important role in viral infection, as it docks to the ACE2 receptors on human cells to gain entry.

A team of scientists from the University of Alabama at Birmingham and the Texas Biomedical Research Institute isolated RBD-specific B cells from recovered patients to produce monoclonal antibodies that can neutralize SARS-CoV-2, the virus that causes COVID-19. One candidate, 1212C2, emerged with potent inhibition of RBD binding to ACE2.

Recent research has shown hamsters to be a good model for COVID-19-related research. So the researchers injected the antibody into hamsters' abdomens before challenging the animals with SARS-CoV-2.

While control hamsters developed live virus in their nasal cavities and lungs, animals that got 1212C2 before the challenge showed a meaningful viral load reduction after two days, and three of four animals eradicated the virus after four days. The treated hamsters also experienced significantly less lung disease compared with control rodents.

The scientists further modified 1212C2 to increase its half-life and used a proprietary technology to stabilize it to allow for delivery with a nebulizer. In hamsters, the inhaled version cleared COVID-19 in the lungs of all animals after four days, while all control hamsters had detectable virus in their lungs at that time point. Lung lesions were also significantly decreased in 1212C2-treated hamsters compared with those in the control group.

Injection is the typical approach for administering monoclonal antibodies, but usually less than 0.1% of the injected dose makes it into the fluid lining the lung. That makes it an inefficient delivery vehicle for respiratory infections such as COVID-19, the researchers argue.

Several other teams are exploring inhaled drugs to treat COVID-19. A team led by scientists at the University of Pittsburgh School of Medicine recently developed a drug that's based on an antibody component 10 times smaller than a full-sized antibody. The drug blocked SARS-CoV-2 in hamsters, and a startup called Abound Bio is looking to move the candidate into clinical trials as an inhaled therapy.

UK biotech Synairgen, meanwhile, recently said its inhaled formulation of inter feronbeta, called SNG001, cut the risk of developing severe COVID-19 by 79% compared to placebo among patients in a double-blind trial. Patients who got the drug were also more than twice as likely to recover from COVID-19.

Gilead Sciences is also testing an inhalable form of its COVID-19 drug remdesivir after the infused version showed it could cut recovery time for hospitalized patients. The hope is that the inhaled formulation could reach less severely ill patients outside the hospital setting.

One potential advantage of Aridis' drug is its dosing. The lowest dose that cleared the virus in hamsters corresponded to an estimated human equivalent strength of 2mg to 6mg. "This compares very favorably to other clinical stage COVID-19 mAbs, where up to 8,000 mg are being studied to achieve clinical benefit," Hasan Jafri, M.D., Chief Medical Officer of Aridis, noted in a statement.

"The exceedingly low drug dose that achieved therapeutic efficacy is particularly exciting, as it provides a unique opportunity to meaningfully reduce treatment costs and hospitalization burden at a potential magnitude not previously achievable with mAbtherapies," Truong said.

The company is also pairing AR-711 with another antibody in a cocktail dubbed AR-701, which is being developed as an intravenous treatment for moderate-to-severe hospitalized COVID-19 patients.

Source: fiercebiotech.com, 22.10.2020 (Excerpts)

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Johns Hopkins researchers publish COVID-19 'prediction model'

Using a combination of demographic and clinical data gathered from seven weeks of COVID-19 patient care early in the Coronavirus pandemic, Johns Hopkins researchers today published a "prediction model" they say can help other hospitals care for COVID-19 patients - and make important decisions about planning and resource allocations. Brian Garibaldi, MD, Associate Professor of Medicine at the Johns Hopkins University School of Medicine, led a team that published in the Annals of Internal Medicine the article that shares important lessons learned in the care of COVID-19 patients between March 4 and April 24, 2020, at five Johns Hopkins hospitals in Maryland and Washington, DC.

During those 52 days, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Suburban Hospital and Sibley Memorial Hospital admitted a combined 827 people age 18 or older - 336 Black, 264 white, 135 Hispanic, 48 Asian, 2 Native American and 42 multiracial - who tested positive for the Coronavirus and had symptoms of COVID-19. From the data those patients generated, the researchers developed a prediction model using a set of risk factors known to be associated with COVID-19 to forecast how likely a patient's disease is to worsen while being treated in a hospital and at what point in their care that might happen. Among the risk factors researchers considered as part of the model were a patient's age, Body Mass Index (BMI), lung health and chronic disease, as well as vital signs and the severity of a patient's COVID-19 symptoms at the time of admission.

The model, called the "COVID Inpatient Risk Calculator (CIRC)," is available online. Garibaldi says the calculator is meant to help hospital physicians and other health care providers assess the risk of a patient's condition worsening. "This is some of what we've learned in the months since we started seeing patients with COVID-19 at our hospitals," says Garibaldi. "As we continue to grapple with high numbers of COVID-19 infections across the United States, it's important to share knowledge with our colleagues at other hospitals."

Among the highlights of the study was the rapidity with which the disease can progress from mild or moderate to severe, particularly if a patient had all or some of the risk factors associated with the disease. Forty-five of the patients in the study had severe COVID-19 when they

were admitted to the hospital. But 120 patients developed severe disease or died within 12 hours of being admitted. Of the 302 patients in the study who developed severe disease or died, the median time of disease progression was 1.1 days.

"Rapid progression of disease following admission [to the hospital] provides a narrow window to intervene," Garibaldi writes in the article. "Different combinations of risk factors appear to predict severe disease or death, with probabilities ranging from over 90% to as little as 5%." For example, using the CIRC, Garibaldi and his colleagues estimate that a 60-year-old white woman with a BMI of 28, no chronic disease and no fever who is hospitalized for COVID-19 has a 10% chance of her disease worsening by day two of her hospital stay. The longer she's in the hospital, the greater that chance becomes, at 15% after four days and 16% after a week.

Conversely, the researchers considered an 81-year-old Black woman admitted to the hospital with COVID-19. The hypothetical patient has a BMI of 35, diabetes, hypertension and a fever. CIRC forecasts her probability of progressing to severe disease or even death by just the second day of her hospital stay is 89%. That percentage increases to higher than 95% by days four and seven. By June 24, 694 of the patients in the study had been discharged from the hospital, 131 had died and seven were still hospitalized with severe COVID-19.

"We identified a few readily measurable demographic and clinical factors that, when assessed on admission to the hospital, can predict if someone has a 5% or a 90% risk of developing severe disease or dying from COVID-19," says Amita Gupta, MD, Professor of Medicine at the Johns Hopkins University School of Medicine, who directs the Center for Clinical Global Health Education and is a co-author of the study. "This is incredibly useful information to have when communicating with patients and their families, as well as for informing resource allocation in the hospital."

The study's data comes from a registry of all patients treated for the novel Coronavirus infection at hospitals in the Johns Hopkins system. Known as "JH-CROWN," the registry - which is funded by InHealth, the institution's precision medicine initiative - offers demographics, diagnoses, procedures, social histories and other data points relevant to caring for COVID-19 patients.

"The JH-CROWN data registry embodies the same teamwork and dedication that went into the care of more than 3,000 COVID-19 patients admitted to Johns Hopkins hospitals since the start of the pandemic," Garibaldi says. "We hope it can teach us more about the nature of COVID-19 and improve both patient care and research as we prepare for a second wave of infections in the fall."

Source: World Pharma News, 23.09.2020 (Excerpts)

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Strong activation of anti-bacterial T cells linked to severe COVID-19

A type of anti-bacterial T cells, so-called MAIT cells, are strongly activated in people with moderate to severe COVID-19 disease, according to a study by researchers at Karolinska Institutet in Sweden that is published in the journal Science Immunology. The findings contribute to increased understanding about how our immune system responds against COVID-19 infection. "To find potential treatments against COVID-19, it is important to understand in detail how our immune system reacts and, in some cases, perhaps contribute to worsening the disease," says Johan Sandberg, Professor at the Department of Medicine, Huddinge, at Karolinska Institutet and the study's corresponding author.

T cells are a type of white blood cells that are specialized in recognizing infected cells, and are an essential part of the immune system. About 1 to 5 percent of T cells in the blood of healthy people consist of so-called MAIT cells (mucosa-associated invariant T cells), which are primarily important for controlling bacteria but can also be recruited by the immune system to fight some viral infections. In this study, the researchers wanted to find out which role MAIT cells play in COVID-19 disease pathogenesis. They examined the presence and character of MAIT cells in blood samples from 24 patients admitted to Karolinska University Hospital with moderate to severe COVID-19 disease and compared these with blood samples from 14 healthy controls and 45 individuals who had recovered from COVID-19. Four of the patients died in the hospital.

The results show that the number of MAIT cells in the blood decline sharply in patients with moderate or severe COVID-19 and that the remaining cells in circulation are highly activated, which suggests they are engaged in the immune response against SARS-CoV-2. This pattern of reduced number and activation in the blood is stronger for MAIT cells than for other T cells. The researchers also

noted that pro-inflammatory MAIT cells accumulated in the airways of COVID-19 patients to a larger degree than in healthy people.

"Taken together, these analyses indicate that the reduced number of MAIT cells in the blood of COVID-19 patients is at least partly due increased accumulation in the airways," Johan Sandberg says. In convalescent patients, the number of MAIT cells in the blood recovered at least partially in the weeks after disease, which can be important for managing bacterial infections in individuals who have had COVID-19, according to the researchers. In the patients who died, the researchers noted that the MAIT cells tended to be extremely activated with lower expression of the receptor CXCR3 than in those who survived.

"The findings of our study show that the MAIT cells are highly engaged in the immunological response against COVID-19," Johan Sandberg says. "A likely interpretation is that the characteristics of MAIT cells make them engaged early on in both the systemic immune response and in the local immune response in the airways to which they are recruited from the blood by inflammatory signals. There, they are likely to contribute to the fast, innate immune response against the virus. In some people with COVID-19, the activation of MAIT cells becomes excessive and this correlates with severe disease."

Source: Karolinska Institutet, Science Daily, 28.09.2020

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Researchers uncover clues for COVID-19 treatment

By examining preexisting research for other conditions, researchers at the University of Cincinnati have found a potential treatment that could be applied to COVID-19. The findings, published in the Journal of Biological Chemistry, established that a lipid found in the human body could be used to prevent or treat infections with SARS-CoV-2, the virus that causes COVID-19. That lipid, called sphingosine, is a natural element taken from the body and is important in the lipid metabolism of all cells and the local immune defense in epithelial cells, a type of cell that lines the surfaces of the body including skin, blood vessels, urinary tract and organs. They serve as a barrier between the inside and outside of your body and protect it from viruses.

"We investigated whether a specific lipid is able to interfere with the binding of SARS-CoV-2 to human epithelial cells," says corresponding author Erich Gulbins, MD, a visiting Professor in UC's Department of Surgery. He is also Chair of the Department of Molecular Biology at the University of Duisburg-Essen, Germany. "Sphingosine has been shown in past studies to prevent and eliminate bacterial infections of the respiratory tract, but it is unknown if it can be used to prevent viral infections. The Coronavirus needs to bind to specific molecules on the surface of human cells as a prerequisite to infect them," Gulbins says.

"This is similar to the key and lock principle of a door: To open the door you must insert the key into the lock. We show that the lipid sphingosine binds into the cellular 'lock,' the receptor ACE2, for SARS-CoV-2 and thereby prevents binding of the virus to and infection of human cells."

Researchers in this study analyzed the use of this lipid in regulating infection in cultured human cells with SARS-CoV-2 particles added. "We showed that sphingosine prevented cellular infection in these cultures, and pretreatment of cultured cells or freshly obtained human nasal epithelial cells with low concentrations of sphingosine prevented adhesion of and infection with the virus," says Gulbins. "These findings indicate that sphingosine prevents at least some viral infection by interfering with the interaction of the virus with its receptor; it could be used as a nasal spray to prevent or treat infections with SARS-CoV-2," he adds. "The nasal spray must be developed, but sphingosine is a natural product. More research is needed to see if this could be a treatment for COVID-19."

Co-author Syed Ahmad, MD, Co-Director of the UC Cancer Center, Professor and chief of the division of surgical oncology at UC and a UC Health surgeon, says this collaboration is particularly fascinating because it takes medical research from other areas of study and applies it to a timely public health issue. "The ACE2 receptor has been studied and identified as a treatment target in pancreatic cancer," says Ahmad, the Hayden Family Endowed Chair for Cancer Research. "This is an example of taking existing research and applying it to COVID-19 science in order to make progress in the field. This is how translational science works."

Source: World Pharma News, 29.09.2020 (Excerpts)

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New drug candidate for the treatment of COVID-19

Researchers from the University of Kent, the Goethe-University in Frankfurt am Main (Germany), and the Hannover Medical School (Germany) have identified a drug with the potential to provide a treatment for COVID-19.

The international team led by Professor Martin Michaelis, Dr Mark Wass (both School of Biosciences, University of Kent), and Professor Jindrich Cinatl (Institute of Medical Virology, Goethe-University) found that the approved protease inhibitor aprotinin displayed activity against SARS-CoV-2, the Coronavirus that causes COVID-19, in concentrations that are achieved in patients. Aprotinin inhibits the entry of SARS-CoV-2 into host cells and may compensate for the loss of host cell protease inhibitors that are down regulated upon SARS-CoV-2 infection.

Aprotinin aerosols are approved in Russia for the treatment of influenza and could be readily tested for the treatment of COVID-19.

Professor Martin Michaelis said: "The aprotinin aerosol has been reported to be tolerated extremely well in influenza patients. Hence, it may have a particular potential to prevent severe COVID-19 disease when applied early after diagnosis.

Source: World Pharma News, 30.10.2020 (Excerpts)

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SCTIMST develops OralScan handheld device for detecting oral cancer

The Sascan Meditech, a startup incubated at TiMED, a technology business incubator of the Sree Chitra Tirunal Institute for Medical Science and Technology (SCTIMST), Thiruvananthapuram has developed OralScan, a hand held imaging device for screening, detection and biopsy guidance of oral cancer.

OralScan is a Make-in-India initiative with seed funding from the scheme National Initiative for Developing and Harnessing Innovations (NIDHI) of Department of Science and Technology (DST). Oral scan was designed and developed entirely in India and supported by the biotechnology ignition grant of Biotechnology Industry Research Assistance Council (BIRAC), INVENT (DST), and Kerala Start-Up Mission. The company recently received investment from Unicorn India Ventures, said the release.

"Kerala Government plans to compile a registry of cancer patients in the state as part of efforts to codify its various initiatives against the deadly disease. These kind of innovations have come forward to brace this change and also appreciating the efforts of Business incubator TIMED-SCTIMST at this time," Kerala State Health Minister K K Shailaja said.

According to Dr Subhash Narayanan, CEO of Sascan, oral cancer is a growing concern in India with more than 80,000 fresh cases reported each year. The disease has a high mortality rate because of the delay in detection. Current practice relies on oral examinations using a torch light to detect early stage cancers of the oral cavity. Varies studies have demonstrated that this screening technique is not very reliable and often Oral Potentially Malignant Lesions (OPMLs) go undetected in the early stages.

"This device is expected to have good demand in general dentistry, oral medicine, oral/maxillofacial pathology and surgery," said Balram, Engineer, CEO of the incubator Sree Chitra. Varies studies have demonstrated that this screening technique is not very reliable and often Oral Potentially Malignant Lesions (OPMLs) go undetected in the early stages. Even experienced clinicians find it difficult to locate the optimal site for a biopsy based on conventional oral examination. This leads to multiple biopsies, increased expenditure and false negative reports which can delay diagnosis and outcome. The device will be marketed at a price of Rs.5.9 lakhs. This will be a onetime investment for hospitals and laboratories without any additional costs of consumables, said the statement issued by the SCTIMST.

Source: Pharmabiz, 31.10.2020

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Health Ministry to review 4-point PSAIIF recommendations to improve Healthcare Services in the Country

The Union Health Ministry will now closely review the recommendations of the Patient Safety and Access Initiative of India Foundation (PSAIIF) to improve healthcare services in the country. The Government sees the need to improve the healthcare delivery as COVID-19 pandemic has brought out the disparities in the system.

The Foundation, which completes ten years of its existence, has put forth a four-point recommendation to the Government where it insists people should have cost-effective choices at the Health and Wellness Centres (H&WC), CGHS and ESIC approved medical centres, besides hospitals managed by the state and Central Governments without any discrimination and bias.

In a virtual dialogue with PSAIIF members, Rajesh Bhushan, Secretary, Ministry of Health & Family Welfare said that every effort will be made to look into the suggestions to handle the issues confronting medical care for quality and affordable access.

"We are looking to develop a multi-stakeholder consultation module in order to effectively facilitate implementation of the various schemes across 11 Ministries: Health, Commerce, Chemicals & Fertilizers among others in the interest of the patients. The initiative emerges from the lessons learnt from ongoing COVID-19 pandemic, Bhushan said.

In its proposals, PSAIF first sees the need to engage with patient groups and expand Ayushman Bharat to cover all vulnerable and senior citizens irrespective of their economic profile and digitize patient records with total data privacy.

Secondly, it mandates a multimedia campaign and a citizen portal similar to Jago Grahak Jago to build a robust awareness and education initiative for patients and care givers to access safe, credible and quality information to make an informed choice in medical consultation. It sees the need to control misleading, deceptive claims promised by the manufacturers and healthcare service providers to curb the menace of spurious and not-of-standard medicines and devices. There is a need to discourage self-medication, irrational use of antibiotics, medicines, diagnostics by linking with several schemes managed by the Pharmacovigilance Programme of India, Haemovigilance Programme of India, Materiovigilance Programme of India, Consumer Awareness & Publicity and Price Monitoring and others.

Thirdly, for Universal Health Coverage to take, we see digital technology as a key enabler. The Government must consider increasing healthcare spends from 1 to 5% and increase subsequently to 7% of GDP, investing at least 5% of the GDP in healthcare. There should be focus on innovation, R&D and use of modern technology. People must be able to access healthcare without facing financial hardships, said Bejon Misra, founder, PSAIIF.

In the National Digital Health Mission, e-pharmacy would be a vital tool and therefore Government should notify the same at the earliest, said Dr B R Jagashetty, former National Adviser (Drugs Control) to MoHFW & CDSCO, even the prescriptions should have the brief diagnosis based on which medicines are prescribed to have proper prescription audit.

The OTC drugs must be defined and listed with the Guidelines. The order of direction U/s 33P issued to all State Licensing Authorities not to grant licenses to brands but only generic names needs to be withdrawn or modified suitably to have proper index of all medicines produced/ imported, he added.

The fourth agenda is to build a common platform to promote quality healthcare bringing in all stakeholders with various Ministries working in the interest of the patients, said Misra.

Source: Nandita Vijay, Pharmabiz, 02.11.2020

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DoP introduces revised PLI scheme for Bulk Drugs & Medical Devices Removing Minimum Investment limit

In a bid to ensure effective participation of the industry, the Department of Pharmaceuticals has introduced revised Production Linked Incentive (PLI) scheme guidelines for promoting domestic manufacturing of key starting materials (KSMs), Drug Intermediates (DIs), Active Pharmaceutical Ingredients (APIs) and medical devices, removing minimum investment criteria and incorporating export and sale-based production criteria following an appeal by drug and medical device industries.

As per the revised Guidelines of PLI scheme for boosting indigenous production of 41 products which cover all the identified 53 APIs for which India is critically dependent on China, the criteria of 'minimum threshold' investment have been replaced by 'committed investment' by the selected applicant. The change has been made to encourage efficient use of productive capital as the amount of investment required to achieve a particular level of production depends upon choice of technology and it also varies from product to product.

The provision for verification of the actual investment made by the selected applicant for the purpose of giving incentives under the scheme continues. The provision which restricts the sales of eligible products to domestic sales only for the purpose of eligibility of receiving incentives has been deleted, bringing the scheme in line with other PLI schemes and encouraging market diversification.

A change has been made in the minimum annual production capacity for 10 products viz tetracycline, neomycin, para amino phenol (PAP), meropenem, artesunate, losartan, telmisartan, acyclovir, ciprofloxacin and aspirin. Minimum annual production capacity is a part of eligibility criteria under the scheme. The last date for receiving applications under the scheme is now extended by a week to November 30, 2020.

The Guidelines of the scheme were originally issued on July 27, 2020 which has now been superseded by revised Guidelines issued by the department on October 29, 2020.

The revised Guidelines were approved by NITI Aayog Chairman led empowered committee of the scheme following recommendation of technical committee set up under the scheme which received suggestions from the DoP. Industry associations such as IDMA, BDMA, SMPMA etc have made representations to the department seeking removal of threshold investment criteria and inclusion of export and sale based production criteria in the PLI scheme to encourage participation of more manufacturers.

Welcoming the revised Guidelines of the PLI scheme, Yogin Majmudar, Chairman of Bulk Drug Committee, IDMA said, "The removal of minimum investment criteria is a welcome step. The threshold investment requirement was a constraint for the manufacturers who can make minimum investment to produce identified products considering they already have common surplus utilities available to them."

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

Majmudar also hailed inclusion of export criteria in the revised PLI scheme, saying that this will increase the number of the applicants in the scheme.

If there are more than four applicants for 27 chemical synthesised products and more than two applicants for 14 fermentation based products, selection of applicants for the incentive will be done on the basis of marks obtained by them in the evaluation criteria which include committed annual production capacity and quoted sale price etc.

It is learned that so far DoP has received around 125 applications for manufacturing of bulk drugs under the PLI scheme. The Pharmaceutical Industry is still in the wait-and-watch mode on making investment in manufacturing identified bulk drugs as there are chances of a steep decline in prices of Chinese APIs, once Indian manufacturers commence production of these bulk drugs, said an industry expert.

It will take around two years to commence operation of Greenfield projects of identified KSMs, DIs, APIs. China could reduce prices of these products to discourage their local production by then, he said.

In the past, there were instances of Chinese API makers reducing prices of raw materials to sabotage the local manufacturing of bulk drugs. The Government had also not come forward to support the manufacturers of fermentation based products grappling with dumping of low priced Chinese products, he added.

With the minimum investment criteria has been done away with, the provision of committed investment mentioning that using ancillary facilities of existing plants will not qualify for committed investment to be made under the scheme is a little bit confusing to manufacturers. The provision should have been removed, said another industry expert.

Hailing the revised PLI scheme Guidelines, Nipun Jain, Chairman of Small and Medium Pharma Manufacturers Association said replacement of the criteria of threshold investment with committed investment is a great relief. It will encourage MSME manufacturers to participate in the PLI scheme in large numbers. This will make the country self-reliant in the production of APIs in the long run. Currently, India is known as the Pharmacy of the World.

Besides this, it supplies APIs across the world whenever needed. The revised Guidelines will make it a worldwide leader in APIs."

Similarly, there is replacement of the criteria of 'minimum threshold' investment with 'committed investment' by the selected applicant in the revised PLI scheme Guidelines of medical devices.

Besides this, the eligibility criteria of minimum sales threshold has been amended in line with projected demand, technology trend and market development, for the purpose of availing incentive under the scheme.

The tenure of the scheme has been extended by one year considering the capital expense expected to be borne by the selected applicants in FY 2021-22. Accordingly, the sales for the purpose of availing incentives will be accounted for 5 years starting from FY 2022-2023 instead of FY 2021-2022. The last date for receiving applications under the scheme has also been extended by a week to November 30, 2020.

Source: Laxmi Yadav, Pharmabiz, 02.11.2020

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Health Ministry amends D&C Rules to bring Tapentadol under Schedule H1 to curb its abuse

The Union Ministry of Health and Family Welfare has notified a draft amendment to the Drugs and Cosmetics Rules, 1945 that would bring Tapentadol, a synthetic opioid analgesic under Schedule H1 to regulate its sale, distribution and prevent its abuse. Schedule H1 stipulates that the drug can be sold only on prescription. According to the draft amendment issued by the Ministry on October 20, 2020, in the Drugs and Cosmetics Rules, 1945, in Schedule H1, after serial number 47 and entry relating thereto, the following serial number and entry shall be inserted, namely — 48. Tapentadol.

The Central Drug Standard Control Organisation (CDSCO) approved Tapentadol Immediate-Release (IR) preparations (50, 75 and 100 mg) for moderate to severe acute pain and Extended-Release (ER) preparations (50,100,150 and 200 mg) for severe acute pain in April 2011 and December 2013 respectively.

Tapentadol which has been available in India since 2011 is widely abused due to its easy and cheap availability. The packaging of the drug does not indicate that it is a schedule H, H1 or X drug and is thus available more or less over the counter. Taking serious note of widespread abuse of Tapentadol, psychiatrists have appealed to drug control authorities to consider regulation of the drug.

According to a study carried out by Centre for Addiction Medicine, Department of Psychiatry, National Institute of Mental Health and Neurosciences, Bangalore last year to assess Tapentadol abuse and dependence in India, injection drug abuse of Tapentadol is emerging rapidly and is associated with high rates of Hepatitis C infection in southern India. A possible reason is easy and cheap availability of tablets that can be easily repurposed for injection, stated the study.

Analysis of internet search data also shows that Tapentadol is receiving attention from internet users in India and this interest is maximum in northern states like Punjab, Jammu & Kashmir, Himachal Pradesh with a high prevalence of current opioid use.

Said Diptadhi Mukherjee, MD, Senior Resident, Centre for Addiction Medicine, Department of Psychiatry, National Institute of Mental Health and Neurosciences, Bangalore, who is among eight authors of the study, "Urgent regulatory measures were required to curb Tapentadol abuse. The increase in the number of cases at our centre last year shows that Tapentadol is attaining notoriety as an easily and cheaply available drug of abuse. In India, prescription opioids have contributed more to opioid abuse than illicit opioids in the past as well as present."

It has been eight and a half years since Tapentadol entered the Indian market. There are no drug safety alerts or advisories from the Pharmacovigilance Programme of India (Indian Pharmacopoeia Commission, 2019), and the current drug label does not indicate that Tapentadol is a Schedule H or H1 drug, Dr Mukherjee pointed out.

Abusers mostly take Tapentadol through an intravenous route which is very dangerous. Unlike Tramadol, parenteral preparations of Tapentadol are not available, and there is minimal safety data for intravenous use. This is important as the bioavailability of oral Tapentadol is only 32%, due to extensive first-pass metabolism, added the senior resident doctor.

Regulatory systems take a long time to respond to the abuse of new drugs. For example, doctors reported that widespread tampering and injecting of dextropropoxyphene in northeastern states was causing high morbidity and mortality as early as 2005. It was banned much later in 2013, only to be reintroduced in 2017 with strict

regulations. Similarly, Tramadol received approval in 1993 and was brought under Schedule H1 in 2013 followed by being classified as a psychotropic drug under Narcotic Drugs and Psychotropic Substances (NDPS) Act in 2018.

"We aver that initially allowing unregulated sale of a new opioid medication and responding later with excessive regulations constitutes double jeopardy. During the initial period several users get addicted and when there is decreased availability due to regulation, they switch to other opioids," Dr Mukherjee stated.

Source: Laxmi Yadav, Phamabiz, 31.10.2020

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Medical Device Companies ask DoP to reduce threshold investment limit to Rs.75 to 90 crore from Rs.180 crore under PLI Scheme

Medical device manufacturers have urged the Department of Pharmaceuticals (DoP) to consider reducing threshold investment limit in range of Rs.75 to Rs.90 crore from Rs.180 crore for domestic manufacturers in the Production Linked Incentive (PLI) Scheme for promoting domestic manufacturing of medical devices. This, according to the Association of Indian Medical Device Industry (AiMeD), will also widen the scope of eligibility to cover COVID-19 utility medical devices.

The Government of India through its flagship "Make in India" initiative relied heavily on the Indian manufacturers to meet the rising demand of essential healthcare equipment for the country pushing the Indian medical devices sector to become self-reliant especially for essential 39 COVID-19 medical devices. DoP had notified PLI Scheme for promoting domestic manufacturing of medical devices through a Gazette Notification dated July 21, 2020. Total financial outlay of the Scheme is Rs.3,420 crore.

According to Rajiv Nath, Forum Coordinator, AiMeD, "The threshold investment limit of Rs.180 crore over 3 years is palatable for those manufacturers with turnovers of over Rs.800 to Rs.1,000 crore which hardly anyone can bear. That is why, we have sought DoP to consider reducing this in the range of Rs.75 crore to Rs.90 crore for domestic manufacturers.

As per the PLI Scheme for medical devices, the incentive per company will be applicable on incremental sales of manufactured goods over base year subject to ceilings as decided by the Empowered Committee (EC). This has been done to address disability in manufacturing of medical devices in India *vis-à-vis* other major manufacturing economies.

AiMeD has worked with Quality Council of India (QCI) to expedite finalization of Indian Certification for Medical Devices (ICMED) Scheme Plus Certification as well as with consultants consortium to provide online training on Quality Management System (QMS) certification to new entrepreneurs who had ventured into medical devices manufacturing towards capacity building to meet QCIs ICMED certification and regulatory compliance so that they could develop confidence to seek global certification of CE and US FDA compliance for enabling global competitiveness.

Under the PLI scheme, financial incentives shall be given to selected companies based on threshold investment and incremental sales (over Base Year) of medical devices covered under target segments. Under the Scheme, financial incentive shall be given to selected companies at the rate of 5% of incremental sales (over Base Year) of goods manufactured in India and covered under Target segments, for a period of five years i.e. from FY 2021-22 to FY 2025-26. The PLI scheme, however, is applicable only for Greenfield projects. Financial incentive under the scheme shall be provided only to companies engaged in manufacturing of goods covered under target segments in India.

Eligibility shall be subject to thresholds of investment and incremental sales of manufactured goods (covered under Target Segments) over Base Year. An applicant must meet all the threshold conditions to be eligible for disbursement of incentive. Eligibility under Production Linked Incentive scheme shall not affect eligibility under any other Scheme and VICE-VERsa. The tenure of the scheme is from FY 2020-21 to FY 2026-27.

The application window for receiving the applications shall be 120 days. Financial Year 2019-20 shall be treated as the base year for computation of incremental sales of manufactured goods. Assessment of threshold investment and incremental sales of manufactured goods shall be based on details furnished to the departments/ministries/ agencies and statutory auditor certificates. Application under the Scheme can be made by any company registered in India

Source: Shardul Nautiyal, Pharmabiz, 30.10.2020

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CBIC assures of no delay in Customs Clearance of imported consignments at ports due to implementation of Faceless Assessment

The Central Board of Indirect Taxes and Customs (CBIC) has assured the Federation of Custom Brokers' Association in India that there will be no delay in inbound shipment clearance at ports in the country after the next couple of weeks due to the implementation of faceless assessment for customs clearance.

The faceless assessment for customs clearance introduced by CBIC across the country in the first week of September 2020 in a phased manner, has led to 15-20 days delay in shipment clearance at ports as against 2-3 days before the implementation of faceless assessment. The first phase of the faceless assessment has started in Chennai and Bengaluru ports with an aim to bring transparency and remove red tape. It has now been introduced at other ports in the country as well.

The CBIC has decided to roll out nationwide faceless assessment for imports at all ports by October 31, 2020 whereby assessing officers physically located in a particular jurisdiction will assess bills of entry of imports of a different customs station or port, which will be assigned to them through an automatic system. The processing will be done without any direct interaction between the importer and customs authorities.

Now the delay in customs clearance of imported consignments has reduced to 4-5 days which will be ended over next couple of weeks, stated Parthiv Dave, founder, Federation of Custom Brokers' Association in India. The CBIC has assured Dave led Federation of reducing delay in customs clearance of imported consignments in 15 days.

Earlier the Federation had written to Prime Minister Narendra Modi informing about the difficulties faced by customs brokers since implementation of faceless assessment which led to rise in numerous hidden costs.

"After the implementation of faceless assessment the dwell time of assessment has increased due to which the transaction cost has increased. This has caused a slowdown in the manufacturing process and also the economy of India. The shipping companies are charging EXIM rate in foreign currencies in a haphazard manner," stated the trade association in the letter.

"The concept of introduction of faceless assessment was to bring an end to cut down the physical appearance and illegal gratification whereas the results are quite different. The officers even do not know how to assess the Bill of Entry (knowingly/unknowingly) and have started giving multiple means of queries, giving unnecessary examination orders, etc. The Bill of entry is idle for several days unattended by the assessing officer at different faceless assessment locations.

The status of the Bill of Entry is untraceable at the faceless assessment point. The customs brokers are forced to appoint middle-men to look after their assessment work at other ports resulting in additional costs on the customs broker, which is indirectly passed on to the importer. It may kindly be noted that the illegal gratification has not been stopped, whereas, it has grown enormously. Hence, the importers are left with no choice but to surrender the assessing officers just to save their business.

The goods are required at the factory for the production purpose of the importer. The traders who have sold their goods in advance are also suffering in this situation. It appears that ease of doing business does not prevail," stated the letter.

Hence, it has suggested to the authority that instead of implementing fully faceless assessment the focus should be on a Risk Management System (RMS). In the last 10 years, the percentage of RMS clearance of Bill of Entry has gradually increased and that is the best option for ensuring uniformity in assessment across the country, said Dave.

Source: Laxmi Yadav, Pharmabiz, 29.10.2020

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Serbia throws up opportunities for Indian drug exporters

The southeast European country, Serbia which is referred to as the crossroad of Europe due to its position in the central Balkan Peninsula, has thrown up opportunities for Indian pharmaceutical companies. About 32 Serbian drug firms are looking for business collaboration with Indian drug makers. These companies are Uni-Chem, Farmix d.o.o, SB Trade, Zdravlje Actavis (part of Teva Group - Israel), Hemofarm (STADA Group - Germany), Galenika (NC Group - Brasil), Phoenix Pharma (German Company), Salveo, PharmaS, Interlab exim, AbelaPharm, ADOC, Dimidijus Pharm, Dragis pharm, Esensa, EcotradeBG, Innventa pharm, Inpharm, Vemax Pharma, Vemax Pharma,

R&B Medical Company, Slaviamed, Sanomed, El Pharma, UTI, Oktal Pharma, Unifarm Medicom, Eurofarm, Proton System, Sibex Line, and Group International.

Some of these companies also assist in product registrations as required in Serbia. Serbia could prove to be a stepping stone for Indian drug companies to boost their exports to EU, EFTA, CEFTA, EAEU regions, Turkey, Australia, Japan and USA since the country has free trade agreements with them.

According to Rados Gazdic, Director at the Development Agency of Serbia, a skilled workforce, prime geographic location, financial incentives and tremendous support from the Government are a few factors that make Serbia a hotspot for foreign investments. A 10-year Corporate Profit Tax Holiday is available for investors who hire more than 100 employees and invest more than €8.5 million. The Tax holiday begins once the company starts making a profit.

Further more, investors can benefit from 14 free zones in Serbia that provide exemption from the payment of VAT and custom duties, said Gazdic. Serbia has imported organic chemicals worth US$ 3,9954.9 and medicinal and pharmaceutical products worth US$ 6,487.7 from India in FY 2019.

The medicinal and pharmaceutical products which are imported from India include vitamins and their derivatives, Intermixtures of provitamins and vitamins, streptomycins and their derivatives; salts thereof, chloramphenicol and its derivatives; salts thereof, erythromycin and its derivatives; salts thereof, antibiotics, Ephedrines and their salts, Theophylline and aminophylline and their derivatives; salts thereof, steroidal hormones, their derivatives and structural analogues, glycosides and their derivatives, antisera and other blood fractions and modified immunological products, Sterile suture materials and sterile surgical catgut, adhesive dressings and other articles having an adhesive layer, dental cements and other dental fillings etc.

Serbia has offered immense opportunities for Indian Pharma industry considering total imports and Indian share in the Serbian market. Considering this, the embassy of India, Belgrade has written to the Pharmaceutical Export Promotion Council of India (Pharmexcil) throwing light on business opportunities for India Pharma industry in Serbia.

Said Uday Bhaskar, Director General, Pharmexcil, "We have received communication from the embassy of India, Belgrade towards promotion of Indian pharmaceutical products in Serbia. The market offers tremendous opportunities for Indian drug makers considering total imports and the share of Indian drug companies in the Serbian market."

He said "We have requested member companies to avail this opportunity and contact the Serbian companies directly for business collaborations. The member companies can also send a proposal to the embassy of India, Belgrade which will further introduce them to the Serbian companies and concerned authorities for further correspondence on the subject."

The Pharmexcil proposed to mount a trade delegation to Belgrade, Serbia during the first quarter of 2020. The delegation was however postponed due to time constraints and comparatively less participation interest from the member companies, added Bhaskar.

Source: Laxmi Yadav, Pharmabiz, 26.10.2020

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Indian Pharma industry calls on US FDA to conduct virtual inspections in the wake of COVID-19 pandemic: Dr Sandhu

Indian pharmaceutical industry has called on the US FDA to consider conducting virtual inspections of their plants and facilities in the wake of COVID-19 pandemic. The shift from physical to virtual inspections would certainly ease the challenges and smoothen the continued availability of life-saving medicines, which would involve a significant transition which, when made possible, would be a giant step in embracing the post-COVID-19 scenario, stated Dr Gurpreet Sandhu, President, Council for Healthcare and Pharma & Founder Reva Pharma.

The virtual inspection can be slightly more challenging for the highly toxic products manufactured in contained facilities due to limited visibility of internal infrastructure used despite having windows in place. The additional physical inspection may be added for ensuring the safety of products, but this may delay the approval and launch of life-saving drugs. With COVID-19-enforced imperative to protect its personnel, the US FDA had suspended physical inspections in March and indicated towards late July that it was looking to restart domestic inspections.

In view of the sheer severity of the ongoing pandemic, the US FDA has proposed a series of alternative tools of inspection such as product sampling at borders,

summoning of records in advance, examination of a company's compliance history and even making use of information shared by other Governments as part of mutual recognition and confidentiality agreements.

Dr Sandhu added that unlike the physical surveillance inspection in which trained drug inspectors make a physical visit to plants, virtual inspections would involve deploying advanced IT, internet, and video technologies for an inspector to make an assessment. India has not only traditionally been one of the largest suppliers to the US meeting 40% of the latter's generic demand, it has emerged as a critical source for COVID-related medications.

Even assuming that the US FDA would have the best technology options available at its end, the Indian plants and facilities – some of them located in the remote areas of the country – would need an upgrade so that the two systems are able to communicate and engage with each other seamlessly for an immaculate inspection, stated Dr Sandhu.

"Since COVID-19 came unexpectedly, there has been no prior technological arrangement between the US FDA and the designated manufacturing plants, putting in place a remote inspection and assessment architecture. The alignment of technologies, platforms and standards along with data protection and confidentiality measures must be speeded up because of the efficiencies and rigour that this arrangement can potentially achieve", added Dr Sandhu.

The appeal by the Indian Pharmaceutical industry may be worth exploring at this juncture because of the substantial improvement and upgradation of infrastructure achieved by it in the last decade. Dr Sandhu added that the integrity of the whole process would in the end be contingent on the integrity and the intent of the Pharma manufacturers whose plants are under inspection. As a result, the credibility of a virtual inspection is likely to depend on the veracity of a few random physical inspections so that the transition to the new process can be embedded as a norm for posterity.

Source: Yash Ved, Pharmabiz, 26.10.2020

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Container shortage affects Pharma exports, industry seeks solution

Due to the shortages of containers, exporters are facing 50-60 percent hike in the freight charges

Exporters across the country are facing a shortage of containers along with the rise in freight charges which is affecting business activities. To overcome these challenges, the Pharma industry is urging the Government to resolve the issue on a priority.

Reportedly, exporters are facing 50-60 percent hike in freight charges, which is affecting the business significantly. Recently, the Pharmexcil communicated to its members that they are in receipt of a communication from the Logistics Division of the Commerce Department informing that the division has several representations regarding the shortage of empty containers for exports. The Division has interacted with the Container Shipping Lines Association (CSLA) and the stakeholders on the subject matter. It is, therefore, requested that the industry should give the projection of the requirements of containers for the next two months.

According to an industry source, the Ministry of Shipping has informed that there are huge chunks of unclaimed containers lying at the docks unclaimed for months, which is also resulting in the shortage of containers.

To deal with the situation, Piyush Goyal, Commerce and Industry Minister, has requested Mansukh L Mandaviya, Minister of State for Road Transport and Highways, Shipping and Chemicals and Fertilizers to auction such cargo and also invite non-cartel shipping lines to give preferential berthing to cartelised lines who have berths leading to 40-60 percent increase in freight, which will increase competition, lessen monopoly in the market and ultimately benefit the exporters.

Responding to this, Dr Dinesh Dua, Chairman, Pharmexcil, said, "If the Ministry of Shipping can break the cartel of shipping lines who have increased freight charges by 49-60 percent by inviting other shipping lines who do not have berthing space to get preferential space and their rates are reasonable it'll do a world of good to all exporters, including Pharma."

Expressing concerns, Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association (SMPMA) commented, "There is a need for the higher authorities to intervene in this matter, as the shortage of containers and increase in freight charges are not only affecting the Pharma industry in India but our Pharma products supply which goes to nearly 200 plus countries, is also likely to have a severe impact due to this hurdle. We are facing back to back challenges, which is ultimately slowing down the growth momentum of the Indian Pharma industry. Therefore, we urge the authority to take up this matter on a priority."

Mr S V Veerramani, Chairman and Managing Director, Fourrts (India) Laboratories and Past National President, IDMA expressed, "Off-late, there has been a shortage of containers for exports. Vessel availability and container availability have become serious concerns. With the result, exports are suffering heavily. We understand that this is because of a reduction in imports, which has resulted in the availability of containers for exports."

He elaborated, "Because of this, there are efforts to even get paid empty containers into India, which will certainly add to the cost of freight in exports. Already the carriers have indicated that the freight will go up substantially in the coming months. For example, a 20Ft container with a freight cost of $628 to Tanzania is likely to be revised to $1200 from December 1, 2020. Same way, the freight to Ghana for a 20Ft container costing $1987 is likely to be increased to $3943 from December 1, 2020. Therefore, the increase in freight will certainly result in reducing the margins for exporters."

Anwar Daud, MD, Zim Laboratories informed, "There is an acute shortage of containers. It is partly due to the tendency of exporters including Pharma to ensure security and safe passage of their smaller (LCL) consignments also by dispatching them in full, sealed containers. Receipt of goods is damaged or partly missing condition has been more frequently noticed due to mishandling in transit during COVID-19 and exporters have found that exports in full containers reduce human handling and errors."

He added that Central India has huge seasonal exports of rice, oranges, etc and the post-harvest grain and fruit export season has picked up, which is causing further pressure on containers."

Source: Usha Sharma, Express Pharma, 02.11.2020

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Boosting domestic APIs crucial for India to sustain its Global stronghold as Generic Supplier: Experts

With India receiving the double whammy of widely spreading COVID-19 pandemic and the sudden cutting down of API imports from China due to the border disputes and other currently prevailing issues, it has been clearly understood that the Indian Pharmaceutical Industry which is boasting of its global stronghold as a lead generic supplier to the world is highly vulnerable and cannot sustain for long, unless and until the Indian Government and its policy makers do not take urgent corrective steps to save the industry, according to industry experts.

According to Dr P V Appaji, former Director General of Pharmexcil, although India is known as the "Pharmacy of the World", as it contributes 20 percent of the world generics and 60 percent of the total vaccines in the global market, it is a matter of great concern that even today India is depending on a single country like China for sourcing its APIs, Key Starting Materials (KSMs) and other intermediates.

"Even though Indian Pharma industry has made long strides and succeeded to rule the roosts of global markets in supplying high quality low cost generics, the recent COVID-19 pandemic and the border disputes with China have really opened up our eyes and made us understand that whatever we have achieved is not going to stay sustained for longer, unless and until we take concrete steps to boost our domestic API sector," opined Dr Appaji.

Despite the fact that India is among the few countries in the world which has 665 US FDA approved plants outside US and has 44 percent global ANDAs, the country's dependence on China to source its Pharmaceutical raw materials will make all these achievements demean if the Indian Pharma sector is not self reliant in producing its own APIs.

If one looks at how the recent prevailing COVID-19 has impacted the policy decisions of central Government with regard to changes in import-export policies, the DGFT (Directorate General of Foreign Trade) during the month of March this year has made changes in their export policy and they banned several formulations. Later, on 25th March 2020 again, this export policy was changed and the "wonder drug" Hydroxychloroquine, considered for treatment of COVID-19, too was included in the list.

All this was done because the API which is used in the manufacturing of these formulations is imported from the global market especially from China and due to COVID-19 the import of these APIs was badly affected, as these APIs were in short supply. In view of this, it can be clearly observed how COVID-19 pandemic has gravely impacted India's policy decision making machinery. Taking lessons from this, it is high time the Indian Government and its policy makers take urgent initiatives to boost India's API capabilities, or else Indian Pharma sector will become vulnerable not just due to global pandemics like COVID-19, but also will be compelled to dance to the tunes of countries like China and may even lose India's stronghold

as a global generic supplier to the world market," warned S V Krishna Prasad, CEO and Managing Director of Cito Healthcare.

However, despite COVID-19 pandemic created havoc in India, the one thing that is hailed all over is Indian bulk drug industry's growth rate. While during the period 2016-20 the industry has witnessed its growth between 8-9 percent, even during the COVID-19 pandemic ruining all kinds of businesses and giving a shocker to the economy, the Indian Pharmaceutical sector is still hovering around 8-9 growth rate which is a positive sign even during the period of healthcare uncertainty in India, observed industry experts.

Source: A Raju, Pharmabiz, 24.10.2020

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Government expands PLI scheme: India seeks to cull China reliance with latest move to boost bulk drug manufacturing

The latest amendments to the Centre's PLI scheme come on the heels of several complaints received by the DoP claiming that the scheme was too restrictive

- *India's pharma industry is, reportedly, the 3rd largest in the world by Volume, and the 14th largest in terms of Value.*
- *Indian pharmaceutical companies rely on Chinese API imports for roughly 70 percent of their total bulk drugs requirement.*
- *According to reports, as of October 8, the Department of Pharmaceuticals (DoP) had received as many as 29 applications to the PLI scheme from India's pharma companies.*

The central Government, on Thursday, 29.10.2020 decided to remove the criteria of 'minimum investment' and 'barring exports' in the Production-Linked Incentive scheme aimed to strengthen India's indigenous production of pharmaceutical raw materials. The move is specifically geared to further encourage increased production of Active Pharmaceutical Ingredients (APIs) required in the manufacture of medicines.

In late July this year, the Government notified the PLI scheme as India's Pharmaceutical industry reeled from major supply-chain disruptions encountered due to the COVID-19 outbreak in China, and the stringent lockdown measures imposed. India's Pharma industry is, reportedly, the 3rd largest in the world by volume, and the 14th largest in terms of value.

Yet, although it contributes approximately 3.5 percent of total drugs and medicines exported across the world, its import dependency on China for APIs has been much cautioned against. Bulk drugs, or APIs, are the raw materials required to make formulations or medicines. China, reportedly, controls 55 percent of the global API space. Indian pharmaceutical companies rely on Chinese API imports for roughly 70 percent of their total bulk drugs requirement.

The Government's approval of the PLI scheme in March was aimed to address this over-dependency which has been brutally exposed by the COVID-19 pandemic. Under the scheme, which runs for 6 years starting with the base year of FY 2019-20, financial incentives will be provided based on the sales of Pharma manufacturers for 41 products covering all of India's required 53 APIs. Applicable only for Greenfield projects, the total financial outlay for the scheme is Rs.6,940 crore.

According to reports, as of October 8, the Department of Pharmaceuticals (DoP) had received as many as 29 applications to the PLI scheme from India's Pharma companies. However, several bulk drug manufacturers had complained that the scheme was too restrictive.

The DoP had received several recommendations from Pharma manufacturers to amend the scheme by removing the minimum investment limit of Rs.400 crore for the manufacturing of four fermentation-based bulk drugs, and Rs.20-50 crore for the manufacturing of 37 other bulk drugs. With the latest relaxations on the minimum investment criterion, it appears that the DoP has paid heed to the concerns of India's Pharma manufacturers.

While the PLI scheme is indeed a significant step forward toward enabling the Pharma industry to become 'aatmanirbhar,' several challenges do remain. Industry experts have noted that the production of cost of APIs in China are a staggering 20 to 30 percent less than they are in India.

As per some reports, a substantial chunk of India's API units run at just 30 percent capacity compared to China's capacity utilisation of 70 percent. It is widely acknowledged that the last three decades has seen India cede its production advantage in the Pharma manufacturing space to China. As such, further infrastructural incentives and tax

benefits may be required if India is to truly transform its Pharma industry into one characterised by self-reliance.

Source: etnownews.com, 31.10.2020

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Pharma exports soar 15% in first half of FY21

Pharmaceuticals exports from the country is on course to cross $23b for the first time this fiscal after growing 14.85% y-o-y at $11.78b in the first half, a Senior Commerce Ministry official said.

"Going by the indications of demand for our pharma products across the globe, India is likely to maintain similar growth in pharmaceutical exports during the second half of the fiscal as well to close the fiscal with exports of at least $23b and may even touch $24b," said Ravi Uday Bhaskar, DG, Pharmexcil.

The growth is driven by drug formulations and biologicals, shipment of which grew a record 21.85% year-on-year at $8.99 billion in the April-September period as countries across the globe turned to India to meet a spike in demand amid the Covid-19 pandemic that caused lockdowns and production disruptions in many parts of the world.

For the first time in the history of Indian pharmaceutical exports, formulations and biologicals accounted for 76.3% of the total pharma exports this first half, up from around 72% a year ago.

India had exported pharmaceuticals worth $20.58 billion last fiscal.

"We had projected India to report $22 billion of pharmaceutical exports last fiscal but we fell short and ended up at $20.58 billion, owing to disruptions in logistics and lockdowns in various importing countries during Covid-19 pandemic in last quarter of fiscal ended March 2020," Uday Bhaskar told.

Besides formulations and biologicals, herbal products also saw a record growth of 20.77% year-on-year in the first half at $168.87 million. Herbal products account for less than 1.5% of Indian pharma exports.

Exports of bulk drugs, drug intermediates, Ayush, vaccines and surgicals declined marginally in the first half, owing to change in immediate healthcare focus of nations across the globe towards handling Covid-19 pandemic. Bulk drugs and drug intermediates reported a fall of 4.5% at $1.87 billion during this first half, down from $1.96 billion last fiscal. "The fall in bulk drugs and drug intermediate exports can also be seen as a positive development since most Indian companies have used them for value addition to make high-margin and high-value formulations, adding to the overall growth of Indian pharmaceutical exports," Uday Bhaskar said.

Exports of vaccines dipped 7.27% in the first half at $359.05 million while exports of surgicals and Ayush products remained almost flat, slipping 0.11% at $317.07 million and by 0.65% at $72.1 million, respectively.

"India exports vaccines mostly to meet the scheduled immunisation programmes to children by various countries and with the change in healthcare focus of these countries towards addressing Covid-19 pandemic, India saw a fall in vaccine exports," said Uday Bhaskar.

However, the country "may see a significant surge in export of vaccines this fiscal if it succeeds in introducing Covid-19 vaccine before the fiscal end", he added.

Source: C R Sukumar, ET Bureau, The Economic Times, 03.11.2020

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INTERNATIONAL NEWS

Virus-hunting trio win Nobel for medicine on Hepatitis C discovery

Two Americans and a Briton won the 2020 Nobel Prize for Medicine on Monday, 05.10.2020 for identifying the Hepatitis C virus, in work spanning decades that has helped to limit the spread of the fatal disease and develop drugs to cure it. The discoveries by Harvey Alter, Charles Rice and Briton Michael Houghton mean there is now a chance of eradicating the Hepatitis C virus – a goal the World Health Organization wants to achieve in the next decade.

"It's so other-worldly – it's something you don't think will ever happen," Alter, 85, said after picking up the phone only after a third pre-dawn call from Stockholm. The trio-share the 10 million Swedish crown ($1.1 million) award for discovering and proving that a blood-borne virus

causes Hepatitis C, which afflicts 70 million people and causes 400,000 deaths each year.

"(To) go from basically the beginning-part of this discovery to when it can be successfully treated – this is kind of a rare treat for a basic scientist," Rice, 68, told reporters on a Zoom call.

Nominations for this year's award preceded the Global spread of the new Coronavirus pandemic, but the choice of winners recognises the importance of identifying a virus as the first step in winning the battle against a new disease.

Rice said advances in gene sequencing would make it possible today for researchers to achieve "spectacular" progress towards developing treatments and vaccines for COVID-19. Nearly 3 million Hepatitis C sufferers are co-infected with the Human Immune deficiency Virus (HIV) that causes AIDS, according to the WHO.

Three Steps:

The shared prize recognizes research dating back to the 1960s when Alter, at the US National Institutes of Health (NIH), found that a liver disease that was not Hepatitis A or B could be spread through blood transfusions. A team led by Houghton, then working for the pharmaceuticals firm Chiron, created a clone of a new virus in the mid-1980s from fragments found in the blood of an infected chimpanzee.

The disease it causes was named Hepatitis C. It's identification made it possible to develop tests to screen blood bank supplies and greatly reduce the spread of the disease, which can cause cirrhosis and liver cancer. "We thought it would be solved quickly, but it actually took seven years to find," Houghton told a news conference on Zoom. "I thought I was going mad."

The final piece of the jigsaw puzzle came when Rice, now at Rockefeller University in New York, was able to genetically engineer a version of the Hepatitis C virus and demonstrate that it alone could cause symptoms in a chimpanzee comparable to an infection in humans.

But Rice told Reuters that the WHO was unlikely to be able to eradicate the virus by 2030, in part because a broadly effective and widely available vaccine was still years away, and also because many countries have banned research on chimpanzees, which was more powerful than studies on rodents.

Houghton, 69, is a Professor of Virology at Canada's University of Alberta. He told reporters the award validated his team's work on a Hepatitis C vaccine, which is now in Clinical Trials.

Costly Treatment:

While effective antiviral treatments are now available, a course can cost $30,000 in the United States. "In well-resourced countries that have the political will to do it, we are seeing huge progress," said Graham Cooke, NIHR Professor of Infectious Diseases at Imperial College, London.

In poorer countries, he said, "there are lots of challenges to overcome, but I think it is a realistic ambition". Rice said manufacturers were now attempting to lower the price, in part by granting production rights in poorer countries. "I would have been much happier had it been more rapid," he said.

Because of the Coronavirus pandemic, the Nobel Foundation has cancelled the banquet that traditionally forms the centre piece of the award ceremonies in Stockholm in December, and will present medals and diplomas in a televised event instead.

Source: Reuters News Service/Cyprus-mail.com, 07.10.2020

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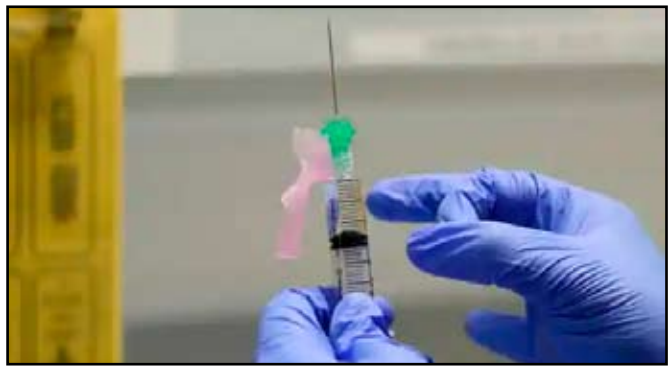
When we can get a Covid Vaccine? Crucial results coming over next few weeks



Some developers of Covid vaccines may release interim data from their final stage trials over the next few weeks. There is no approved COVID-19 vaccine yet, but several are in advanced trials, including from Pfizer Inc, Johnson & Johnson, AstraZeneca-Oxford University, Novavax and Moderna.

Pfizer and its partner BioNTech could have late-stage Clinical data as soon as the end of October, the vaccine

makers had said earlier. "Based on current infection rates, the companies continue to expect that a conclusive readout on efficacy is likely by the end of October," Pfizer said earlier this month while seeking US regulator's approval to expand its trial to 44,000 participants.

Data from Moderna is also expected soon after. Johnson & Johnson and Novavax have also recently begun their own late-stage trials and could have data over next few months.

Meanwhile, a top Russian scientist behind its Sputnik V Covid vaccine told Reuters that Moscow plans to publish interim results based on the first 42 days of monitoring volunteers. If Russia is able to publish interim data from final-stage trials it has a high chance of becoming the first worldwide to announce any data from a final-stage trial.

The first of 5,000 volunteers in Russia was vaccinated on September 9, which means interim results could be issued some time after October 21. Russia's sovereign wealth fund, which has invested in the vaccine's roll-out, has said it expects interim results to be published in October or November. Several Western developers are conducting final-stage trials that have already been going on for more than 42 days but have not published any interim results. Their early-stage trial results were peer-reviewed and published in The Lancet. Russia had approved a Covid vaccine in August even before the final-stage trials.

The head of the Food and Drug Administration office that oversees vaccines said drug makers developing Covid-19 shots are aware of the data that will be required to gain an emergency-use authorization, regardless of whether the agency provides formal guidance.

"The companies know what we're expecting," said Peter Marks, Director of the FDA's biologics office, at an event recently. The US agency has scheduled a meeting of outside experts to discuss a vaccine. The Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session, to discuss, in general, the development, authorization and/or licensure of vaccines to prevent COVID-19. No specific application will be discussed at this meeting.

Source: Live Mint (With Agency Inputs), 30.09.2020 (Excerpts)

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FEATURE

COVID-19 vaccine delivery: Prepping for challenge extraordinaire

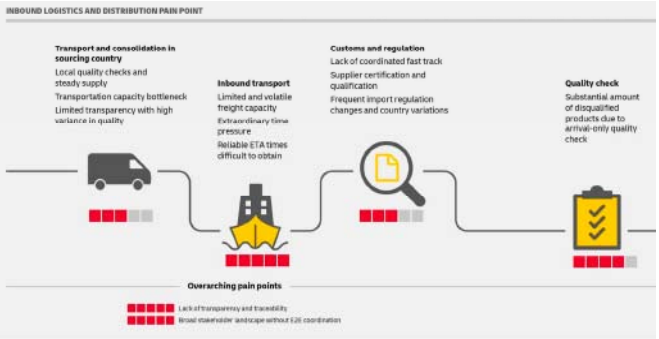
Lakshmipriya Nair

India will have a very strategic role to play in ensuring universal access to COVID-19 vaccines. All stakeholders must step up their game and eliminate chinks in their supply chain and successfully execute this critical task

COVID-19 vaccines are likely to be a reality very soon, and the world lives in the belief that it will help vanquish the Coronavirus. Yet, as experts rightly point out, ensuring universal access to these vaccines will be a very crucial aspect in the battle strategy against the wily virus which has disrupted lives and livelihoods worldwide. And, supplying billions of COVID-19 vaccine doses efficiently across the globally, with utmost care for their efficacy, when they are approved and available for distribution is going to be the ultimate logistics challenge witnessed until now.

A few weeks earlier, DHL along with McKinsey, published a white paper on 'Delivering Pandemic Resilience', which highlights, "To provide global coverage of COVID-19 vaccines, up to ~200,000 pallet shipments and ~15 million deliveries in cooling boxes as well as ~15,000 flights will be required across the various supply chain set-ups." The DHL-McKinsey whitepaper also identifies

key hurdles in COVID-19 vaccine logistics. Take a look at some of the pain points that the report highlights.



Hence, Express Pharma spoke to a few players in the Pharma logistics space to gain more insights into the three biggest challenges that the logistics sector will be faced with and the preparations underway to tackle them. Because after all, aren't we only as strong as our weakest link?

Ultra-low transport and storage temperatures:

Generally, vaccines are stored and transported between the temperatures of 2°C to 8°C range. However, with over 250 vaccines are being developed and tested across the world, the temperature requirements for at least some of them are likely to be considerably lower. And, as the development of most of these vaccines has been fast-tracked looking at their urgent need to control and end the pandemic, experts also feel that more rigorous procedures will be imposed to maintain and protect their efficacy during transportation and storage. This may necessitate temperature-controlled transport and warehouses at ultra-low temperatures (up to -80°C).

While India does have considerable expertise in vaccine production and distribution, the scale and scope of COVID-19 vaccines could pose a serious problem. So, how are the Indian players in this sphere optimizing and ramping their capacities before the COVID-19 vaccines become available? Vikash Khatri, Co-Founder, Aviral Consulting informs, "Indian logistics players have already started preparations to handle the volume surge. Since this demand is not permanent, companies are looking for coordinated efforts to ramp up short term competencies." He adds, "For surface transportation and storage, we don't foresee a major gap in the available infrastructure and the required infrastructure. A large quantum of infra will be used out of the existing setup, for which logistics companies are getting ready with necessary upgrades for the Pharma industry." The flurry of measures on varied fronts by the different players corroborates Khatri's views.

To cite a few examples;

DHL opened its first temperature-controlled facility in India in July near the Hyderabad airport for Pharma shipments. The company informed that the new facility offers "conditioning of packaging materials in different chambers for varying temperatures up to -20°C." The facility offers online temperature monitoring and SMS alerts with all data available for download from a cloud-hosted service as well.

Similarly, Kool-ex, a Pharma cold chain logistics service provider has partnered with IndoSpace, a Developer and Manager of industrial real estate and warehousing in India, to build GDP/GWP compliant, temperature-controlled, Pharma distribution centres across the country. They plan to jointly design and set up three warehouses with 42,000 pallet positions in each warehouse, in the first phase by 2021 near Mumbai, Delhi and Bengaluru. Koolex also intends to set-up 10-11 warehouses by 2023. These also include cold room facilities which will offer -20°C, if required for COVID-19 vaccines.

Blue Dart, an express logistics provider and part of the Deutsche Post DHL Group (DPDHL) is also ramping up its infrastructure with its pre-existing specialized Temperature-Controlled Logistics (TCL) to transport critical shipments such as vaccines, medical samples and more. The company informed through a statement that it can handle various temperature requirements be it frozen: (-80°C to -20°C), deep chilled (2°C to (8°C) or ambient (15°C to 25°C)

"With an agile response team overseeing the up scaling of our current capabilities, a strong fleet of dedicated Boeing 757 aircraft and robust infrastructure for our temperature-controlled logistics solutions, we are capable and prepared to meet any immediate large-scale demand," informs Ketan Kulkarni, CMO & Head – Business Development, Blue Dart through a statement.

A few players also suggest that the cold chain facilities which are used to transport cell and gene therapies, as well as the capabilities in the food and agro-based industries, can also be redeployed with suitable upgrades to undertake and successfully execute this huge task. This could be a good idea but given how vital is the endeavour and the implications it will have on the wellbeing of populations across the country, putting strict protocols in place and ensuring that they are adhered to will be paramount.

Airfreight capabilities:

The air cargo industry will obviously have a very pivotal role to play in the whole vaccine delivery chain given the nature of the cargo, need for speedy delivery with temperature compliance for safety and efficacy, handling capability of the stakeholders and operational specialization etc. But, this would translate into mammoth capabilities. Recently, IATA, an airline industry body had said that transporting the COVID-19 vaccines will be the "largest transport challenge ever" and the equivalent of 8,000 Boeing 747s will be needed to execute this mammoth task assuming that each person will require only one dose of the vaccine.

Giving more understanding about the scenario, Khatri points out, "COVID-19 vaccine will be required for each human being leading to the overall requirement of 7.8 billion units of doses, while the overall estimated market of vaccines was 3.5 billion doses, in 2018. Once we include booster doses for COVID-19 vaccines, this requirement will be double than this. Air cargo plays a key role in the supply chain of vaccines in normal times and it has a well-established global time-and-temperature- sensitive network to cater to routine requirement. But such a high volume requires extraordinary capabilities."

"Even if we consider that 25 percent of volume can be connected by surface mode in and around manufacturing countries, the demand of air cargo capacity will be approximately 12000 large freighters for primary and booster dose of vaccines," he adds. Bharat Thakkar, Co-Founder & Joint MD, Zeus Air Services admits, "Air cargo will be the primary initial solution that Governments and Pharma companies will engage to deliver the vaccines. Therefore, yes, the demand for vaccine deliveries will overtake the demand for regular cargo by quite a margin."

Giving some more clarity into the whole issue, Rajiv Hariramani, VP–Air Freight, Skyways Air Services informs that in the months since the onset of COVID-19, air cargo from India has touched about 65000 tonnes per month of which 70 percent is Pharma exports. This is only likely to increase once the vaccines become available. However, both, Thakkar and Hariramani are upbeat about India's air cargo sector's abilities to handle exports of COVID-19 vaccine delivery because they believe that there is ample untapped capacity that could be galvanized to deal with a spurt in demand.

Thakkar updates, "Currently, AAI and private airport operators are building capacity and implementing solutions which should be ready by the time vaccines are approved. It is also pertinent to point out that a lot of passenger aircraft have been drafted into carrying cargo, which will increase carrying capacity and therefore reduce delays in shipping." He says that our airports already have a certain amount of infrastructure which can be upgraded to create short-term competencies. To explain his point, he informs that per month 20000 tonnes of cargo is flown from only Mumbai, and since the time a new facility was launched in January 2020, the capacities have doubled. The Mumbai airport can keep almost 100 pallets at any given time on any given day.

Likewise, all major cities have air cargo terminals with cold storage facilities, be it Mumbai's Cargo Service Centre and Air India's APEDA; Delhi Cargo Service Centre and Celebi Delhi Cargo Terminal Management in Delhi; AISATS and Menzies Aviation Bobba (Bangalore) in Bengaluru or GMR Hyderabad Air Cargo in Hyderabad. These terminals can customise to meet ultra-low storage requirements.

Moreover, he promises, "Indian cargo agents will be ready to meet the increased demand for vis-à-vis transport from factories and onwards. Cargo agents, such as ourselves, have had experience in moving mission-critical cargos across the world for aid in times of natural disasters, famines and even in times of war. He discloses that he is also working to optimize the processes to make them more efficient and cost-effective with the existing resources. Hariramani also assures, "Most important aspect is the air capacity. We are working to create enough air cargo capacity to handle large volumes of vaccine with the type of service that would be required – active/ passive along with the provision for end-to-end tracking of the shipment."

He explains, "Warehouses being a dominant aspect, we have partnered with reputed organisations having exclusive facilities pan India for various temperature ranges, besides our warehouse close to the cargo terminal in Delhi which serves packing stations, temperature zones, dangerous goods handling arena, general and courier screening as well as storage zones." He updates that Skyways' warehouse in Delhi has a cold room of 20 cubic metres and they are currently constructing a cold room in their warehouse in Bangalore of the same capacity. In Mumbai and Hyderabad too, the company is working to expanding its GDP-compliant warehousing capabilities.

"Understanding the need for reefer transportation, we have joined hands with a few reputed GDP/ISO certified

vendors who can cater to Pan India transportation with their dedicated fleets. Besides, our subsidiary Phantom Express owns a fleet of 35 trucks in Delhi NCR and we are further mapping across South and West of India," adds Hariramani. "Considering the various aspects involved in vaccine handling, we have appointed a dedicated team that has been trained by GDP certified authorities and will act as a central control tower," he apprises. The industry stakeholders also share the belief that vaccine delivery will be carried out in phases and not as a one-time activity since the vaccines need to be produced in massive quantities.

Another report from PwC Health Research Institute, titled, 'Developing a COVID-19 vaccine may not be enough,' also states that "vaccination is likely to occur in waves as the federal and state governments make decisions about which groups should be the highest priority and how the criteria for vaccine recipients are broadened as more doses become available." While the report refers to the US scenario, it stands true for India as well. The stakeholders hope that this, in turn, will help them to plan out a more co-ordinated approach, thereby avoiding sudden spikes and unanticipated glitches.

Last-mile delivery:

Ensuring that the COVID-19 vaccines reach every nook and corner of India, no matter how far-flung and remote they are, will require a robust infrastructure for a green corridor to transport COVID-19 vaccines, along with a large number of trained personnel and monitoring capabilities. Combining all this to create a blueprint that is fail-safe will require all our famed ingenuity and expertise gained as one of the major global exporters of Pharma products. A Herculean task indeed! Thakkar points out, "The challenges will be in proper planning of the movement of the vaccines, which will need to be synchronised between Pharma companies, logistics solutions provider, airlines and distribution channels."

"It will be prudent for Pharma companies to work with their cargo handlers to define daily production capabilities. The cargo handlers, in turn, can build capacity (if need be) and also advise their respective clients as to cold chain solutions required to move the cargo from their factories to the airport and onwards to their eventual distribution channels," advises Thakkar. Khatri outlines, "Creation of capability for short term demand is one of the key challenges, where logistics players can't justify huge CAPEX. To mitigate this risk, the industry is adopting a two-way strategy. First is around mobilization of resources from other pre-existing setups for short term and second is about improving operating efficiency, so that same infra can handle more volumes with faster turnaround."

So, all stakeholders of the supply chain are stepping up their game and getting ready to collaborate on a level unseen before. For instance, Rahul Agarwal, Director, Kool-ex Warehousing, enlightens that the private sector is not sure to what extent the Government will control the supply and distribution of the vaccines and price-control of these vaccines are also likely. So, they are slightly wary of making huge investments at their end which might not get utilised and are looking for partners in this exercise.

He says that several Pharma companies are talking to Kool-ex to create end-to-end supply capabilities. After discussions with these players, the company has worked out a per vial costing, which ranges between Rs.10 to Rs.25 for end-to-end distribution based on different scenarios and conditions. This includes two legs of warehousing and three legs of transportation. "We are not giving them (Pharma companies) a Capex model, but a pay-per-use rental model. It will be viable for them because it will help them benchmark an end-to-end cost, right from the beginning," explains Agarwal.

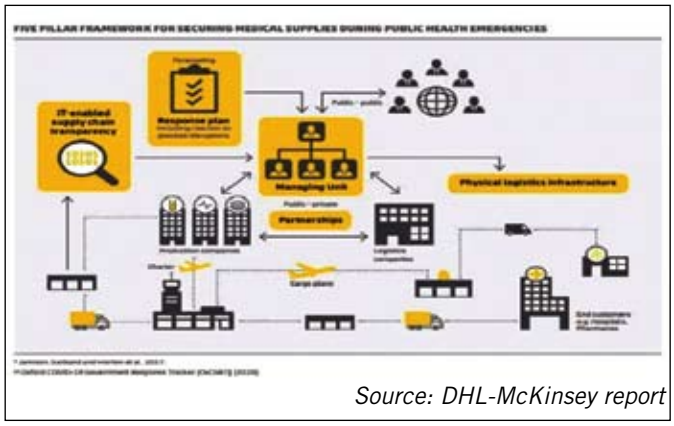
So the company is building portable storages which can be rented. Once the need is over, these storage facilities can be put to other uses. Khatri also states, "Industry is working with Government agencies, freight forwarders, port operators for quick turnaround of aircraft and speedy border clearances." At the same time, industry players like Hariramani emphasise on the huge role that the Government will have to play in this whole exercise. He points out that as the private players plan and prepare for this massive endeavour, the Government will have to be in the forefront of facilitating a smooth path for the supply and distribution of these vaccines to all nook and corners of the country as well as worldwide.

"Governments of vaccine producing nations have been requested by world bodies to take the lead in facilitating seamless logistics across borders whilst providing security since this will be a highly valuable commodity," reminds Thakkar as well.

To explain his point, he calls attention to a snag in the current scenario that needs to be smoothened and states, "Another challenge that has come to the fore recently is the fact that Ministry of Civil Aviation has announced a change in the rule of open sky policy of 1990. The new rules have restricted non-schedule freighter operators to

operate from six metro airports rather than operating pan India. This will lead to delays in the transportation of the vaccines. Due to this policy, we will need to move cargo on scheduled operators from non-metro locations and load it on to a cargo plane of non-scheduled operators in metros. This will have to be reviewed for vaccines movement and other exports to cut down on lead times."

The DHL-McKinsey whitepaper also outlines the most important measures that the Government should take to ensure adequate supplies. The paper highlights that these aspects will form the "pillars of successful crisis response management" and "will be key to meeting the supply chain challenges of future global health emergencies". They are as follows:



Source: DHL-McKinsey report

(1): Developing and disseminating a clear and pre-defined emergency response plan.

(2): Building a partnership network of both public-private and public-public partnerships.

(3): Identifying and ensuring access to required physical logistics infrastructure.

(4): Establishing IT-enabled supply chain transparency.

(5): Creating organisational structures and allocating resources to institutionalize and coordinate the entire response management including plan, partners, infrastructure and IT.

The stakes are very high and the margin for error is very low. The Indian Government must consider the recommendations by industry stakeholders while formulating its blueprint.

On a hopeful note, Dr Harsh Vardhan, Union Minister of Health and Family Welfare, recently informed that the Centre is also working on plans for building capacities in HR, training, supervision etc., on a massive scale and roughly estimates to receive and utilise 400-500 million doses covering approximately 20-25 crore people by July 2021.

He said that there is a high-level committee headed by Dr V K Paul, Member (Health), Niti Aayog is drawing up the entire process. Vaccine procurement is being done centrally and each consignment will be tracked real-time until delivery to ensure it reaches those who need it most. He added that these Committees are working on understanding the timelines of availability of various vaccines in the country, obtaining commitments from vaccine manufacturers to make available maximum number of doses for India inventory and supply chain management and also on prioritisation of high-risk groups. States are being closely guided to submit details about cold chain facilities and other related infrastructure which will be required down to the block level.

Impact and implications:

Thus, preparations are on in full swing but their result will be seen only in the days to come. However, it is to be hoped that this entire venture will not only be successful in ending this pandemic but also be instrumental in creating a structure which will bring in better efficiencies in the supply chain and fasten access to medicines and vaccines.

Source: Express Pharma, 22.10.2020 (Excerpts)

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Indian Pharma is being squeezed – and it's bad news for drug access in developing countries

Thankom Arun, *Professor of Global Development and Accountability, University of Essex and*
Reji K Joseph, *Associate Professor of Economics, Institute for Studies in Industrial Development*

India's Pharmaceutical industry is renowned for selling medicines to the world at reasonable prices, especially developing countries. This has helped Africa in its fight against HIV/Aids, for instance. Such endeavours have earned India a reputation as the "Pharmacy of the World".

Now, the advantages that have enabled India to play this role are in danger of being eroded. Not only would this be bad news for India's economy, it could make it harder for developing countries to access the medicines they need – threatening the UN Sustainable Development Goals in the process.

India's challenges:

India is the World Leader in generic medicines, which contain the same ingredients as the originator version, and go on the market after the original Patent has expired. India's top Pharma firms include Cipla, Aurobindo Pharma, Lupin, Dr Reddy's Laboratories and Sun Pharmaceutical Industries Ltd.

One challenge is coming from China, which has increasingly been exporting Active Pharmaceutical Ingredients in recent years. Indian companies have managed to turn this into an opportunity by using these ingredients to supply medicines at reasonable prices while reducing their production costs and R&D spend.

But China is also expanding into drug formulations. By our calculations, China's global share of formulations exports trebled from 0.4% in 2009 to 1.2% in 2018, while India's doubled over the same period from 1.5% to 3.6%. Remarkably, 36% of China's exports are to the EU and North America, where regulations are the most stringent, compared to 19% in 2009. Beijing's "Made in China 2025" policy has identified Pharmaceuticals as one of its strategic industries.

China's rising share of formulations has been aided by improved standards that appear to be making the world less apprehensive about Chinese medicine quality. Notably, the China Food and Drug Administration issued Guidelines in 2013 to make generic medicines bioequivalent to the originals, and in 2016, the Government made them mandatory.

Chinese Pharma has also placed much emphasis on using AI and genetics for developing new drugs. This enables firms like XtalPi to identify thousands of molecules which could be used to treat a disease with fewer resources and time.

One silver lining is that China is proposing a new regulation that would give its firms exclusive control over their clinical test data. This sort of rule is favoured by the "innovator" Pharma industries that we see in the west, and is opposed by generic Pharma industries like India's. It indicates where Chinese Pharma might be headed, and may drive up its production costs for formulations – thus potentially benefiting India.

Another challenge to India is wealthy countries protecting their Pharma industries to ensure drug security. In August, President Trump issued an executive order that called for the elimination of drug imports, both as Active Ingredients and Formulations. France and Germany look to be heading in a similar direction.

If the US order is strictly adhered to, it will heavily affect Indian Pharma. More than half of India's Pharma sales are from exports, and by our calculations, the US has bought 37% of them over the past three years.

Access to the US market is also critical for leading firms to maintain profit margins. For example, when Dr Reddy's secured 180-day exclusivity in the US for selling the antidepressant fluoxetine 40mg in 2001-02, it increased the company's annual sales of generic drugs by 81% and operating profits by 50%.

The COVID dimension:

COVID-19 underlines India's importance to developing countries when it comes to drug access. The Serum Institute of India (SII), the world's largest vaccines producer, is collaborating with the World Health Organization, the COVAX facility of Global Alliance for Vaccines and Immunisation (GAVI), and the Coalition for Epidemic Preparedness Innovations (CEPI) to produce and supply 100 million doses of a COVID-19 vaccine at a maximum cost of US$ 3 per dose.

This is the lowest quoted price in the world for a COVID vaccine, and will see them distributed in low-and-middle-income countries. By comparison, German biotech firm BioNTech's deal with US involves a price of US$ 19.50 per dose, while the Moderna/US deal is set at between US$ 32 and US$ 37 per dose.

SII separately has a manufacturing agreement with AstraZeneca to produce one billion doses of the Covishield vaccine, which the UK company is developing with the University of Oxford. The drug is in phase III trials in India at the moment.

SII is also partnering with US firm Novavax to develop and distribute the NVX-CoV2373 vaccine in collaboration with CEPI and COVAX. Again, this involves a minimum of one billion doses for India and other low to middle income countries.

Several other COVID vaccine candidates are being developed by Indian Pharma firms: Covaxin, being developed jointly by Bharat Biotech and the Indian Council of Medical Research, has just entered phase III; and ZyCoV-D, by Zudus Cadila, is in phase II. These too are likely to be much cheaper than western equivalents.

Besides vaccines, Indian firms are developing drugs for treating COVID conditions. Baladol, developed by PNB Vesper Life Sciences, has become the first new drug for treating COVID to enter phase II Clinical Trials around the world. Studies so far have shown that it reduces death rates by 80% – whereas WHO-approved medication dexamethasone reduces them by 20%.

Despite India's contribution to global access to medicines, the Government has never tried to use this as an instrument of foreign policy. All decisions on export destinations and pricing have been made by the firms.

Contrast this with China, which is reportedly using its own vaccine projects as a commercial negotiating tool with countries who stand to benefit. This threatens to put pressure on countries whose leverage was limited already. It is another reason why India's position as Pharmacy of the World has a value far beyond its borders.

(Disclosure statement: The authors do not work for, consult, own shares in or receive funding from any company or organisation that would benefit from this article, and have disclosed no relevant affiliations beyond their academic appointment).

Source: The Conversation, 31.10.2020 (Excerpts)

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Reducing API dependence: Have we got the strategy right?

***Reji K Joseph,** Associate Professor, Institute for Studies in Industrial Development, New Delhi explains that the PLI scheme has some gaps that need to be plugged for it to be truly successful*

The Government of India launched two schemes in July this year for the promotion of indigenous manufacturing of Active Pharmaceutical Ingredients (APIs), Drug Intermediaries (DIs) and Key Starting Materials (KSMs). The Production Linked Incentive (PLI) scheme exclusively focuses on those APIs, which the Drug Security Committee constituted by the Department of Pharmaceuticals (DoP) has identified as heavily import-dependent on China. The API Parks scheme, on the other hand, has the objective of enhancing the competitiveness of Indian API industry by providing easy access to common utilities such as steam, waste management, etc in three selected API Parks. The industry response to these schemes, however, has been lukewarm especially the PLI scheme. A closer examination shows that the design of these two schemes has some major flaws which may result in much less than the expected outcome in terms of elimination of import-dependence on China.

The history of Indian pharma industry shows that the focus of the private sector has always been on the formulations and not APIs. The Hathi Committee (1975), the recommendations of which laid the foundation of a vibrant generic pharma industry in India, had looked into this issue and found that the capital invested to turnover ratio was much higher in APIs as compared to formulations. It was coercion in the form of marketing approval of formulations tied to the indigenous production of APIs that made the Indian private sector invest in the production of APIs. Withdrawal of this coercion and removal of restrictions on imports through economic reforms in the 1990s again made the private sector to shun indigenous production of APIs.

Another interesting aspect of the dynamics of the Indian pharma industry is that the Small and Medium Enterprises (SME) have an important role, especially in the production of APIs. It is reported that they account for 70-80 per cent of the APIs produced in India in terms of quantity. This may sound defying logic, small fellows producing more capital-intensive segment of the pharma industry. But, as APIs are sold in their chemical name, without branding, large firms have no interest in the production of APIs and their focus is on branded formulations. Their production of APIs, if at all, is largely for captive consumption. The SMEs, which are not in a position to establish brands, focus on APIs.

Interestingly, the focus of the PLI scheme is on large firms which are not interested in the manufacture of APIs. In the antibiotics area, where more than half of the budget for the scheme is allocated, each of the beneficiaries is required to incur a minimum investment of Rs. 400 crores.

This huge amount of investment is required in each of the four antibiotics APIs/DIs/KSMs. Only large companies can afford investments at this scale.

Secondly, the PLI scheme doesn't consider the option of utilising those API manufacturing facilities which are lying idle. It requires all likely beneficiaries to make fresh investments in the manufacturing facility, irrespective of whether or not they have the idle capacity to produce the same product. There are many firms which used to produce APIs but closed down operations due to cheaper imports from China. It doesn't make any business sense for a firm which has unused API manufacturing capacity to invest afresh for creation of new additional capacity. The report of the Drug Security Committee provides a list of more than 30 firms including Biocon, Torrent, Alembic, Hindustan Antibiotics Ltd (HAL) and Indian Drugs and Pharmaceuticals Ltd (IDPL) that have wound up production of fermentation-based APIs.

Thirdly, and most importantly, the PLI scheme doesn't have a technology component. Without appropriate technology, API manufacturers in India would not be in a position to beat their Chinese counterparts in pricing. There are four key areas where Chinese firms have an edge over Indian firms – the cost of raw materials, cost of electricity, cost of steam and effluent treatment and size of operations. The only advantage that Indian API manufacturers enjoy vis-a-vis their Chinese counterparts is in the cost of labour. As a result, the import of APIs is 35-40 per cent cheaper as compared to the cost of indigenously produced APIs. It is not possible to overcome some of the disadvantages India is having like the size of operations. Therefore, only technology can compensate for the disadvantages and make the production of APIs a profitable business.

The API Parks scheme may help in reducing the cost of inputs like electricity and steam and the cost of effluent treatment. As this scheme is open to all APIs, it is likely that producers of those APIs in which India has a comparative advantage will shift their operations to the Parks. It is not that India is only importing APIs, it is, in fact, a major exporter in the case of certain APIs. Many APIs are categorised under Indian Trade Classification (Harmonised System) chapter 29.42 (other organic compounds), which includes APIs of Cefadroxil, Ibuprofen, Cimetidine, Famotidine, etc.

Export from India of this category in 2019 accounted for 71 per cent of global exports. It is reported that the DoP has given the go-ahead to governments of Andhra Pradesh, Himachal Pradesh and Telangana in establishing the API parks. The API parks scheme may not be of much use in reducing the import-dependence and ensuring drug security.

What should be done, then? It seems this is the high time for leaving the private sector to focus on their area of interest – formulations. Unless the formulations segment is well taken care of, it may also face the fate of the API industry and the 'Pharmacy of the World' tag may become a thing of the past.

The Indian pharma industry has undergone a major transformation since the 1990s and now more than half of the turnover is coming from exports. China is considerably enhancing its presence in the global generic drug market, a challenge to the Indian pharma industry. During the last ten years, from 2009 to 2018, the share of China in the global export of formulations (as captured by ITC HS codes 3003, 3004 and 300220), has grown at a Compound Annual Growth Rate of 15 per cent as compared to 11 per cent of India. While the share of India in global exports of formulations doubled during this period to reach 3.6 per cent, the share of China increased three times and reached 1.2 per cent. What is more significant is that China has managed to export more than one-third of its exports to the regulated markets of EU and North America, where the regulations are most stringent. The share of these destinations in China's exports increased from 19 per cent to 36 per cent during the same period.

This shows that after placing its foot firmly in APIs, China is focusing on formulations.

Who then should produce the APIs? The task of manufacturing of those APIs in which the private sector has no interest should be entrusted with the Public Sector Enterprises (PSEs). There are five central PSEs in the pharma sector, which had played an important role in establishing the API manufacturing capability in India during the 1970s and 80s. PSEs such as HAL and IDPL have huge capacities for the production of APIs which are kept idle. Instead of treating PSEs as a liability, they need to be strategically utilised. It comes out that API dependence can only be eliminated with the involvement of PSEs unless the Government is willing to whip the private sector.

The International Monetary Fund (IMF), which generally promotes privatisation, has recently (Fiscal Monitor, April 2020) highlighted the significant role played by State-Owned Enterprises (SOEs) in the development of industrial sectors, especially in developing countries. It points out that such strategic use of SOEs is justified as measures to correct market failures.

Simultaneously, the public sector research laboratories under the CSIR network should be tasked with the development of new green and cost-effective technologies for the production of APIs. Production of APIs and intermediates from wasted vegetables and food grains need to be explored as tonnes of vegetables and grains are wasted in India. A process technology developed at the University of Calicut for the production of Penicillin from waste fruits shows that the cost of production can be reduced by one-third as compared to conventional fermentation technologies. Such technologies developed at our academic institutions need to be identified and assimilated to API manufacturing efforts. Unless the public sector enterprises and laboratories are integrated into the strategy, the objective of reducing import dependence on China may remain a distant dream.

Source: Express Pharma, 03.11.2020

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