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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **Centaur Pharmaceuticals launches WOXHeal, a New Chemical Entity for treatment of diabetic foot ulcer** *(Page No. 26)*

★ **DoP to set up 10 Pharma Clusters to equip MSMEs to meet Global Regulatory Standards** *(Page No. 31)*

★ **Industry experts discuss Regulatory Roadmap for Pharmaceutical Industry** *(Page No. 34)*

★ **Researchers at CCMB reveal Coronavirus in India has stable genome and can be effectively cured with vaccine** *(Page No. 33)*

★ **Drug makers, BMGF pledge to strive for Global access to COVID-19 Diagnostics, Therapeutics and Vaccines** *(Page No. 36)*

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IDMA BULLETIN

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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**
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- 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.

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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

GST and Taxation Updates September, 2020

(As on 1st October 2020)

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

Interest on Delayed Payment of GST

Interest on Net Tax Liability for the period 01.07.2017 to 31.08.2020

Notification No. 63/2020 - Central Tax Dated 25.08.2020

GST Wing of CBIC has issued instructions on 18th September, 2020 to all Principle Commissioners / Commissioners to recover interest on Net Tax Liability for the period 01.07.2017 to 31.08.2020.

Wherever SCNs have been issued on Gross tax payable, the same will be kept in call book till retrospective amendment in Section 50 of CGST Act is carried out.

Earlier, The Central Government had appointed 01-09-2020 prescribing that interest in case of delayed furnishing of Section 39 return (e.g. GSTR -3B), shall be levied on that portion of tax that is paid by debiting the electronic cash ledger, i.e., after excluding input tax credit (ITC).

The proviso however excludes situation when such return is furnished after commencement of any proceedings under Section 73 or Section 74.

Compliances: Let us ensure.....

E Invoice System

61/2020-Central Tax dated 30.07.2020

Registered person whose aggregate turnover in a financial year exceeds 500 crore rupees, shall prepare e-invoice w.e.f. 1st October 2020.

We hereby advise to get ready for implementation of E Invoice template in SAP or Accounting platform.

Input tax credit in respect of inward invoices issued in Financial Year 2019-20

- **Section 16(4) of CGST Act, 2017 provides.....**

that Input Tax Credit ('ITC') of any invoice pertaining to Financial Year 2019-20 can be availed till due date of furnishing of the return under Section 39 for the month of September 2020 or annual return for the Financial Year 2019 -20, whichever is earlier.

We should .....

ensure receipt of all invoices/ debit/ credit notes pertaining to Financial Year 2019-20 for timely availment of ITC by 30 September 2020 and avail the same in the GST Return for month of September 2020 within due date, else the same would lapse.

Issuance of Credit notes in respect of invoices issued during Financial Year 2019-20

•Section 34(2) of CGST Act, 2017 prescribes that credit notes against invoices pertaining to Financial Year 2019-20 can be issued only till September 2020 or the annual return for FY 2019-20; whichever is earlier.

•Hence, the credit notes, if any, pertaining to invoices of the Financial Year 2019-20 should be issued by 30 September 2020 and reported in the GSTR 1 return of September 2020.

•If credit notes pertaining to Financial Year 2019-20 are issued beyond September 2020, the same would not be allowed to be adjusted against the output liability of any other months following September 2020.

Issuance of Debit notes in respect of invoices issued during Financial Year 2019-20

Debit notes, if any, pertaining to invoices of the Financial Year 2019-20 should be issued by 30 September 2020 and reported in the GSTR 1 return of September 2020 to enable the customers to claim the credit.

If the debit notes pertaining to the invoices of Financial Year 2019-20 are issued beyond September 2020, your customers would not be able to claim the credit of taxes paid by you in any other months following September 2020.

•Please note that amendment in Section 16(4) vide Finance Act, 2020 relating to delinking the date of debit notes from the date of issuance of invoice is not yet notified.

Rectification of error/ omission in respect of details already furnished in GST return

Proviso to Section 37(3) and Section 39(9) permits -

Rectification of any errors/ omissions in the details furnished in Form GSTR-1 for the Financial Year 2019-20 in the returns to be filed for the subsequent months till furnishing Form GSTR-1 for the month of September 2020 or Annual Return for Financial Year 2019-20, whichever is earlier.

Accordingly, any errors/ omissions in details reported in Form GSTR-1 should be identified and rectified before the aforesaid due date.

GSTR 9 AND GSTR 9C

Last date for submission of GSTR 9 and GSTR 9C is 30.09.2020.

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

We have already requested to authorities for extension of due dates.....

Due dates for submission are expected to be extended to 30.11.2020.

TCS on sale - Section 206C(1H) of Income Tax Act

The Finance Act 2020 has introduced a new Section 206C(1H) to curb and track usage of unaccounted money.

This is effective from 01.10.2020.

- A seller (being a person, whose turnover in the previous financial year exceeds 10 Crores) makes sale of "goods" whose value, either individually or in aggregate exceeds 50 Lakhs, the seller shall collect tax at source at 0.1% on the value of sale consideration exceeding 50 Lakhs from the buyer.

- Deposit the TCS amount within 7 days from the last day of the month in which the tax was collected.

- Every tax collector shall submit quarterly TCS return i.e., Form 27EQ in respect of the tax collected by him in a particular quarter.

- The section states that tax shall be collected on the consideration value exceeding 50 Lakhs only, which means that there is an exemption limit of up to 50 Lakhs (individually or in aggregate on sales during any financial year).

- Export of goods is not covered under TCS on sale of goods.

Indirect Tax: Regulatory Updates

Notification No. 66/2020-CT, dated September 21, 2020

Goods sent / taken out of India on approval or return basis

Section 31(7) of Central Goods and Services Tax Act, 2017 provides that in respect of:

- goods sent or taken on approval for sale or return basis
- invoice to be issued before or at the time of supply or 6 months from the date of removal, whichever is earlier.

Relaxation provided for compliance of Section 31(7):

- *Where the expiry of 6 months from the date of removal is falling between March 20, 2020 to October 30, 2020;*
- *Last date to issue invoice has been extended till October 31, 2020.*

Notification No. 67/2020-CT, dated September 21, 2020

GSTR-4 and GSTR-10 - Reduction of late fees

Late fees for GSTR-4 for the quarters July 2017 to March 2020

- Maximum Late fees: Rs. 500
- Full waiver where tax is nil

GSTR-4 to be submitted during September 22, 2020 to October 31, 2020.

GSTR-4 is a quarterly return for registered person who opted for composition levy.

Notification No. 68/2020-CT, dated September 21, 2020

Late fees for GSTR-10

Maximum Late fees: Rs. 500

GSTR-10 to be submitted during September 22, 2020 to December 31, 2020

GSTR-10 is the final return required to be submitted within 3 months from the date of cancellation or date of order of cancellation of registration, whichever is later.

Notification No. 28/2020-CUSTOMS (ADD)

Provisional anti-dumping duty on imports of Ciprofloxacin Hydrochloride from China PR for a period of six months.

Ministry of Finance has recommended imposition of provisional anti-dumping duty on imports of **Ciprofloxacin Hydrochloride** originating in or exported from China PR for a period of six months.

in order to-

(i) the subject goods have been exported to India from the subject country at dumped prices;

(ii) the domestic industry has suffered material injury;

(iii)the injury to the domestic industry has been caused by the dumped imports;

The provisional anti-dumping duty imposed under this notification shall be effective for a period of six months (unless revoked, amended or superseded earlier) from the date of publication of this notification in the Official Gazette and shall be payable in indian currency.

GST: Important case laws and rulings

CWP No.11474 of 2020 HC - P&H

Petition seeking to quash SCN issued to manufacturers of AUS based sanitizers

- SCNs issued to manufacturers of Ayurvedic/ Unani/ Sidha ('AUS') based sanitizers for discharging GST at rate of 18% instead of 12%
- Petitioner argued that SCNs have been wrongly issued to manufacturers of AUS based sanitizers by misclassifying the same as "alcohol based sanitizer" and that AUS based sanitizer would fall under the 12% GST bracket as against the 18% being argued by the Department
- Petitioner also stated that a comprehensive representation has been already made in this regard to the authorities, however, no action was taken on the same
- The counsel appearing for the tax department informed the court that representation, if already submitted, shall be forwarded to the GST Council.
- The High Court accordingly disposed the petition, however, stating that it is hoped that GST council would take the issue for consideration at the earliest.
- *Relevant to note that recently vide a press note, MoF had clarified that hand sanitizers would attract GST at 18% rate. It was stressed that since, various chemicals, packing materials and input services used in the manufacture of hand sanitisers also attract a GST rate of 18 %, a rate lower than that would lead to an inverted duty structure and put the domestic manufacturers at a disadvantage vis-a-vis importers of hand sanitisers.*

Maharastra AAR in the matter of Tata Motors ltd.

Transportation facility charges recovered by employer not Taxable.....ITC available

Question 1: Whether Input Tax Credit is available on GST charges by service provideron hiring of bus / motor vehicle having seating capacity of more than 13 persons for transportation of employees to & from workplace?

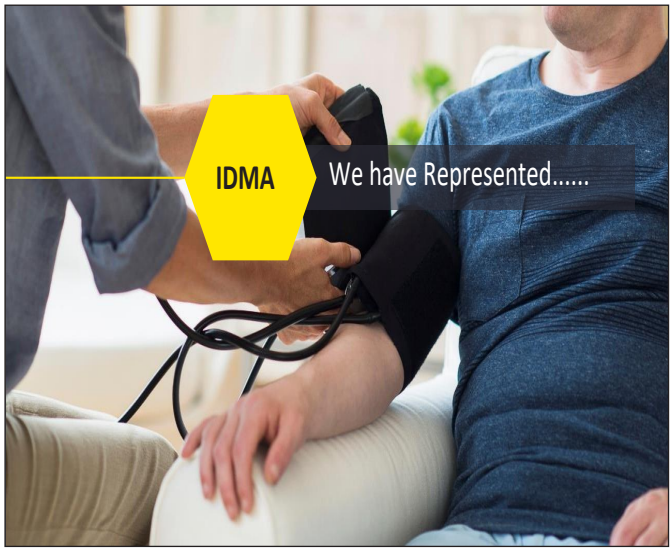
Answer: ITC is available but only after 01.02.2019.

Question 2: Whether GST is applicable on nominal amount recovered by applicant from employees for usage of transportation facilityin non air conditioned bus?

Answer : No.

Other Highlights

GST Council Meeting	**GST Council Meeting is scheduled on 5th October 2020.**
Cost Audit for 2019-20	**In view of the extraordinary disruption caused due to the pandemic, if Cost Audit Report for 2019-20 by the Cost auditor to the board of directors of companies is submitted by 30th November 2020 then the same would not be viewed as violation of Rule 6(5) of companies (cost records and audit) Rules 2014. Consequently, the cost audit report for 2019-20 shall be filed within 30 days from the date of receipt of the copy of the Cost audit report by the company.**
Public Notice 16/2015-2020 -DGFT Track and Trace system	Extension of date of Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments alongwith maintaining the Parent-Child relationship in the levels of packaging and their movement in supply chain **The date for implementation has been extended up to 01 April 2021 for both SSI and Non-SSI manufacturing drugs.**



GST rates for Alcohol based Hand Sanitisers	**We have represented to Ministry of Finance, GST Council and CBIC for considering GST rates @ 12% instead of 18% as forced by them. We should forward a reminder to them before upcoming GST Council.**
Extension of due dates of GSTR 9 and GSTR 9C	**In view of the extraordinary disruption caused due to the pandemic, We have requested GST Council and CBIC for extension of due dates for submission of GSTR 9 and GSTR 9C. Due dates for submission are expected to be extended to 30.11.2020.**
Implementation of E Invoice schema	**We have represented to Ministry of Finance, GST Council and CBIC for extension of date of Implementation of the E Invoice Schema to 01.04.2021. The government has not yet issued any notification in this regard. We hereby advise to gear up for the implementation w.e.f. 01.10.2020.**

Extension of CGST exemption on Services for transportation of Goods by Air/Sea from CSC in India to outside India, by one year: upto 30.09.2021 - reg.

GST-Central Tax (Rate) Notification No.04/2020, dated 30th September, 2020

1. In exercise of the powers conferred by sub-section (3) and (4) of section 9, sub-section (1) of section 11, sub-section (5) of section 15 and section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on being satisfied that it is necessary in the public interest so to do, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.12/2017-Central Tax (Rate), dated the 28th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.691(E), dated the 28th June, 2017, namely:-

In the said notification, in the Table,-

(i) against serial number 19A, in the entry in column (5), for the figures "2020", the figures "2021" shall be substituted;

(ii) against serial number 19B, in the entry in column (5), for the figures "2020", the figures "2021" shall be substituted;

2. This Notification shall come into force with effect from the 1st day of October, 2020.

F.No.354/123/2020-TRU

Pramod Kumar, Director, Department of Revenue, Ministry of Finance, New Delhi

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, vide Notification No.12/2017-Central Tax (Rate), dated the 28th June, 2017, vide number G.S.R.691(E), dated the 28th June, 2017 and was last amended by Notification No.28/2019-Central Tax (Rate), dated the 31st December, 2019 vide number G.S.R.970(E), dated the 31st December, 2019.*

● ● ●

CBIC notifies Special Procedure for taxpayers for issuance of GST e-Invoices till 31.10.2020 - reg.

Notification No.73/2020-Central Tax, dated 1st October, 2020

In exercise of the powers conferred by section 148 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on the recommendations of the Council, hereby notifies the registered persons required to prepare the tax invoice in the manner specified under sub-rule (4) of rule 48 of the Central Goods and Services Tax Rules, 2017, who have prepared tax invoice in a manner other than the said manner, as the class of persons who shall, during the period from the 1st day of October, 2020 to the 31st day of October, 2020, follow the special procedure such that the said persons shall obtain an Invoice Reference Number (IRN) for such invoice by uploading specified particulars in **FORM GST INV-01** on the Common Goods and Services Tax Electronic Portal, within thirty days from the date of such invoice, failing which the same shall not be treated as an invoice.

F.No.CBEC 20/16/09/2019-GST (Part–I)

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

● ● ●

Will the Production Linked Incentive Scheme for Pharmaceuticals deliver?

Y H Gharpure, Chairman and Managing Director, Gharpure Consulting Engineers Pvt Ltd
(former Managing Director, Hindustan Antibiotics Ltd., Pimpri, Pune)

Government central planning means over-riding other people's plans - Thomas Sowell

INTRODUCTION:

China started flooding the Global Markets with Active Pharmaceutical Ingredients (APIs) since 2001, when it entered the WTO. In India, concerns have been raised over last several years about the country's dependence on China for critical APIs, Key Starting Materials (KSMs) and Drug Intermediates (DIs). The Government has now come out with a Production Link Incentive (PLI) Scheme by a Notification dated 27.07.2019, to incentivise Indian industry to invest in manufacture of APIs, KSMs and DIs.

The Notification was preceded by several meetings and deliberations, including three webinars arranged on June 13, 2020 for three different audiences across India.

In spite of the above, there is a need to critically look at the Scheme to ensure investors do not land in the same situation as in the past two decades, when several plants, including 18 fermentation facilities, were forced to shut down, due to their inability to compete.

This paper will examine critically as to why these units had to close down, and whether the PLI Scheme addresses the reasons for the closures.

Closure of Fermentation Facilities:

The PLI scheme has proposed manufacture of many APIs, including fermentation-based ones, but without going into reasons as to why 18 such fermentation facilities closed down over last two decades. Some of these are listed in Table 1.

Table 1: Non-operative API plants in India

API	Producers	Production commenced in
Penicillin G/V*	Alembic, Sarabhai, IDPL, JK, Torrent, Ranbaxy, SPIC	Early 60s
Streptomycin*	Alembic, Sarabhai, IDPL	Early 60s
Tetracycline*	IDPL, Sarabhai, Pfizer	Early 80s
Oxytetracycline*	IDPL, Sarabhai, Pfizer	Early 80s
Kanamycin	Alembic	Early 70s
Erythromycin*	Alembic, Themis, IDPL	Early 80s
Gentamycin	HAL, Themis	Late 80s
Sisomycin	Themis	Late 80s
Vitamin B12	Themis, Alembic, MSD	Early 70s
Cephalosporin C*	Alembic	Early 90s
Pravastatin	Themis, Biocon, Mylan	Late 90s
Griseofulvin	Glaxo	Late 80s
Cyclosporin A	Biocon, Mylan	Late 90s
Bleomycin	Themis	Early 90s
Mitomycin C	Themis	Early 90s
Citric acid	Citurgia, Citric India	Early 80s
Ascorbic acid	Sarabhai, Jayant Vitamin	Early 80s

**denotes the API is in the PLI scheme*

https://www.mycii.in/KmResourceApplication/65793.Indian APIIndustry ReachingthefullpotentialKPMGCII ThoughtLeadershipreport2020.pdf

The closures highlight the fact that there are deep-rooted problems faced by fermentation units. These include:

- Poor quality of strains used – Upgradation of the strain used in fermentation is a continuous process, but India lacks a setup that can undertake strain improvement and testing professionally and efficiently.
- High cost of energy – Energy is a major input for the fermentation industry. Fermenters require power for agitation and aeration, and steam for sterilization. Unfortunately, in India, not only is electricity out of the ambit of GST, but cross-subsidisation of electricity makes it costly for industry.
- High cost of other inputs – The fermentation industry also requires solvents for extraction of the APIs, and these are costlier in India because petroleum products are out of the ambit of GST.

Fermentation is both a science and art, and it is difficulty to practice the art particularly in PSUs. Labour laws in India are on the side of labour and all the more so in public sector.

It would have been better, if the committee had gone into reasons as to why these facilities closed down and given these units a package to restart. After all, it is easier to start an existing closed plant than to set up a new one.

Furthermore, the Government should take extend the PLI Scheme to operating fermentation facilities, so that they do not close down due to the Chinese onslaught. The Indian fermentation industry should also be enabled to compete in the Global Market by matching the assistance given to by the Chinese Government to units in that country (Fig. 1). This is lacking in the Government's PLI Scheme.

Infrastructure support	Cost of utilities & capital	Capacity	Development of ancillary industries for supplies	Investor-friendly labour laws
☛ Land at preferential price ($10/sq.m.) with excellent connectivity to ports and airports. ☛ Located in areas where temperature remains below 22°C for 9-10 months in a year. ☛ Up to 100-MW power plant with steam and dual power transmission lines. ☛ Common effluent treatment plant with 30,000-tpd capacity.	☛ Local currency finance at average interest rate of 5% per annum. ☛ In summer, cost of production may increase 8-9% compared to winter, mainly due to use in utilities to maintain cooler temperature.	☛ Capacity has been created taking into account world demand. Thus, per unit overheads, depreciation and operation costs are lower. ☛ Comparison of Chinese and Indian capacity (10 years ago & now). ☛ 6-APA (14,000/800/Nil); 7-ACA (2,400/NA/Nil); Vitamin C (50,000/NA/NA); Erythromycin (3,000/NA/NA).	☛ Efficient and continuous supply of maize/liquid glucose, which are basic raw materials for fermentation.	☛ Workers can be hired and terminated as per company policy, without interference of local government or labour unions. ☛ Efficiency and company interest are top priorities.

Fig. 1: China's support to fermentation units

Hurdles to PLI Scheme:

While the new PLI Scheme wants entrepreneurs to set up new units for the identified APIs & raw materials, the disbursement of the incentives will be from the second year onwards for chemical APIs and from the third year onwards for fermentation-based ones.

However, setting up a unit in India takes much longer, due delays in getting permissions from pollution control authorities (Table 2), as also other project-related activities (Table 3).

In fact, the PLI Scheme requires few new formalities for starting a new unit including application fee of Rs.1 lakh for fermentation-based products and Rs.50,000 for all others; and bank guarantee for availing the incentive.

Government wants the entrepreneur to bind himself to the investments, capacities and other obligations specified in the order, is the Government willing to give guarantees in respect of following?

- That it will not bring any fiscal measures, which will vitiate profitability of the units being setup;
- Make GST comprehensive by bringing into its fold five petroleum products, electricity, etc. This will eliminate tax on tax.
- Give undertaking that it will not enter into Economic Partnership Agreements and Free Trade Agreements with other countries, enabling producers therein to dump APIs and raw materials into India, even though they are being produced under the PLI Scheme.

Table 2: Approval duration for an API plant

Approval	Duration (Months)
Central Pollution Control Board (CPCB)	9-12
Plant set-up	18-24
Pollution Load Certificate	3-12

Source: Indian API Industry-Reaching the potential, KPMG-CII Report.

Table 3: List of Approvals required and agencies involved (illustrative)

Approvals required	Agencies/stakeholders to be consulted
Allotment of land	State Directorate of Industries (DI), State Industrial Development Corporation (SIDC), Small Scale Industrial Development Corporation (SSIDC)
Permission for land use (in case located outside of an industrial area)	State DI; Department of Town and Country Planning; Local authority/ District Collector
NOC and consent under Water and Air Pollution Control Acts	State Pollution Control Board
Approval of construction activity and building plan	Town and country planning; Municipal and local authorities; Chief Inspector of Factories; Pollution Control Board; Electricity Board
Sanction of power	State Electricity Board
Boiler Inspection Certificate	Chief Inspector of Boilers
Finance	State Financial Corporation/SIDC for term loans; For loans higher than Rs 15-mn, all-India Financial Institutions like IDBI, ICICI, IFCI etc.
Registration under States Sales Tax Act, and Central and State Excise Act	Sales Tax Department; Central and State Excise Department
Code Number for Export and Import	Regional Office of Director General of Foreign Trade

Source: Indian API Industry-Reaching the potential, KPMG-CII Report

China's API onslaught:

China joined the WTO in 2001 after having geared up its manufacturing capabilities, backed by very well-developed infrastructure and Government support. It encouraged industry to put up economic size plants with latest technologies, and made raw materials available at globally competitive prices.

No wonder, Chinese companies started producing APIs (among other products) in larger and larger quantities, and began aggressively exporting them, including to India. Over time, China's share of imports of APIs into India rose – from 23% in 2000, to 52% in 2016,' and to 68% in 2018-19 (Fig. 2).

Worryingly, India is 100% dependent on Chinese suppliers for many critical APIs and their Raw Materials (Table 4).

Table 4: APIs with therapeutic use and India's import dependence

API	Therapeutic use	Dependence on China, %	API	Therapeutic use	Dependence on China, %
Oxytetracycline	Antibiotic	100	Ranitidine	Anti-ulcer	~100
Tetracycline	Antibiotic	100	Ambroxol	Respiratory disease	~100
Azithromycin	Antibiotic	100	Metronidazole	Anti-diarrheal	99
Norfloxacin	Antibiotic	100	Neomycin	Antibiotic	98
Ofloxacin	Antibiotic	100	Ciprofloxacin	Antibiotic	97
Aspirin	Pain	100	Rifampicin	TB	97
Metformin	Anti-diabetic	100	Amoxycillin	Antibiotic	93
Ampicillin	Antibiotic	100	Doxycycline	Antibiotic	91
Levofloxacin	Antibiotic	~100	Paracetamol	Pain	90
Atorvastatin	Cholesterol	~100	Gabapentin	Antibiotic	89
Chloroquine	Anti-malarial	~100	Gentamycin	Antibiotic	86
Montelukast	Asthma	~100	Vitamin C	Nutraceutical	81
Telmisartan	Anti-hypertensive	~100	Chloramphenicol	Antibiotic	78
Cephalosporins	Antibiotic	~100	Vitamin B6	Vitamin	77
Olmesartan	Anti-hypertensive	~100	Vitamin B1	Vitamin	75
Penicillin G	Antibiotic	~100	Ibuprofen	Pain	~75
Streptomycin	Antibiotic	~100	Heparin	Anti-coagulant	72

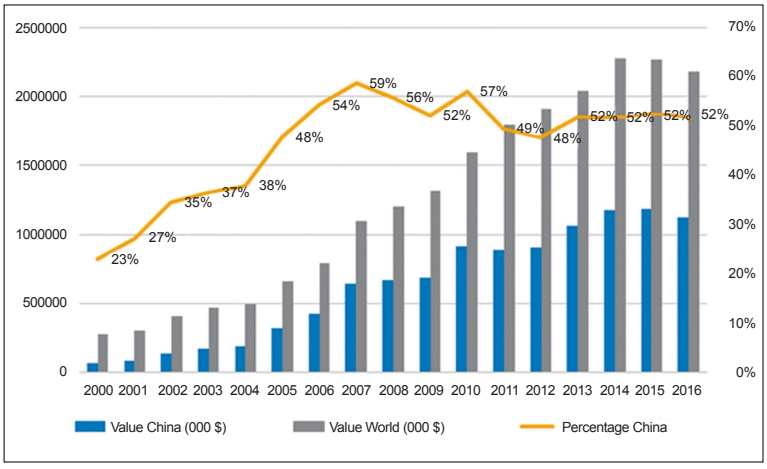


Fig. 2: API imports by India

Source: https://www.orfonline.org/expert-speak/china-india-bulk-drugs-supplier-helplessness-cautious-evolution/

Can PLI Scheme reduce imports?

The total value of manufactured drugs and raw materials of the 41 products covered under the PLI scheme is about Rs.7,831-crore (Table 5). Prices mentioned in this table are approximations drawn from import data over the last few years, but they do provide a measure of the direct benefits that can accrue from the Government Incentives of Rs.6,940-crore earmarked for the PLI Scheme.

At an average import duty of 8%, the investments should be able to support production valued at Rs.8,458-crore, on an import-parity basis.

Over a seven-year period, over which the PLI Scheme will pay out incentives, it can support production of about Rs.47,364-crore (assuming an average capacity utilisation of 80% over this period for the plants). This represents a healthy return on Government investment of Rs.6,940-crore, even without considering the additional tax revenue (direct and indirect, including GST) that will accrue to the Government's coffers.

For the industry, however, the incentives may not be all that significant. The total incentive of Rs.6,940-crore being offered to new units over the seven-year period, works out to about 14.7% of the turnover likely over the seven-year

period – or about 2.1% annually. Considering, the new projects will start to deliver on the investments at a minimum of two years from now, and incentives will be paid out from year 3-10, the amounts will be significantly eroded by inflation. In other words, the incentive will be worth a lot less 5-10 from now, than today! The industry cannot afford to rely on subsidies to ensure competitiveness, but must look to inherent strengths stemming from lowering the project costs, improving timelines of project implementation, reducing operating costs through use of efficient technologies – all of which are under its control.

Table 5: Estimated turnover of drugs under PLI Scheme

	KSM/API/Drug Intermediate	Total capacity, tpa	Price, Rs/kg	Turnover, Rs. Crore
Key fermentation based				
1.	Penicillin G	10,000	650	650
2.	7-ACA	2,000	5,000	1,000
3.	Erythromycin Thiocyanate (TIOC)	1,600	3,200	512
4.	Clavulanic Acid	300	15000	450
Fermentation based niche				
5.	Neomycin	350	1,200	42
6.	Gentamycin	80	7,500	60
7.	Betamethasone	4	70,000	28
8.	Dexamethasone	4	45,000	18
9	Prednisolone	30	16,000	48
10.	Rifampicin	200	6,000	120
11.	Vitamin B1	400	3,000	120
12.	Clindamycin Base	120	12,000	144
13.	Streptomycin	100	1,700	17
14.	Tetracycline	900	1,700	153
Key chemical synthesis based				
15.	1,1 Cyclohexane Diacetic Acid (CDA)	6,000	500	300
16.	2-Methyl-5-NitroImidazole (2-MNI)	3,200	250	80
17.	Dicyandiamide (DCDA)	32,000	120	384
18.	p-Aminophenol	32,000	150	480
Other chemical synthesis based				
19.	Meropenem	40	50,000	200
20.	Atorvastatin	120	13,000	156
21.	Olmesartan	100	15,000	150
22.	Valsartan	100	11,500	115
23.	Losartan	320	5,000	160
24.	Levofloxacin	460	2,500	115
25.	Sulfadiazine	80	1,300	10
26.	Ciprofloxacin	1,200	2,100	252
27.	Ofloxacin	400	2,500	100
28.	Norfloxacin	60	1,800	11
29.	Artesunate	140	7,000	98
30.	Telmisartan	320	4,500	144

31.	Aspirin	11,200	500	560
32.	Diclofenac Sodium	700	625	44
33	Levetiracetam	560	3,500	196
34.	Carbidopa	8	35,000	28
35.	Ritonavir	20	48,000	84
36.	Lopinavir	28	42,000	134
37.	Acyclovir	700	3,000	210
38.	Carbamazepine	260	3,000	78
39.	Oxcarbazepine	260	13,000	338
40.	Vitamin B6	140	2,000	28
41	Levodopa	40	3,500	14
Total		**96,544**		**7,831**

Prices used may not be current; but good approximations

Does India have cost-competitive technologies?

Technology plays a key role in API production and Indian organic chemists are good and have developed cost-effective processes for the chemical synthesis of many molecules. Even then, the API industry depends on China for intermediates. It is difficult to find a synthetic product fully made in India without using imported intermediates or raw materials.

Indian fermentation industry has performed poorly in development of strains and as a result 18 fermentation facilities in India have closed down over last two decades. If fermentation activity is to resume, the PLI Scheme should address the reasons for closure. It is vital that the latest, most cost-effective, and proven strains are developed and used.

Unfortunately, the current status of strain development is not up to Global Standards (Table 6).

Table 6: Issues & technological readiness with respect to production of fermentation-based products

API	Issues	Technology Readiness
Oxytetracycline	Capital intensive, strain development / technology access	Strains research and scale required
Tetracycline	Capital intensive	Strains research and scale required
Ampicillin	Total dependence on 6-APA, a KSM; fermentation based	Strains research and scale required.
Cephalosporins	Large scale fermentation capability, strain development / technology access	Strains research required
Penicillin G	Large scale fermentation capability, strain development / technology access	Strains research required
Streptomycin	Strain development / technology access	Strains research required
Neomycin	Strain development / technology access	Strains research required
Doxycycline	Strain development	Strain research required
Vitamin C	No viable cost-effective technology for KSM manufactured by microbial oxidation	Viable technology for production of KSM, 2-Keto-L-gluconic acid through microbial oxidation to be developed.
Vitamin B12	Strain development	Strains research required
Erythromycin	Non-availability of TIOC technology; large scale fermentation capability, strain development / technology access	Technology for production of TIOC to be developed.
Clarithromycin	Strain development	Strains research required
Meropenem	Local intermediate manufacturers are either small scale or depend on China; Strain development	Strains research required

Clindamycin	Strain development / technology access	Strains research required; viable technology for manufacture of API from KSMs available
Imipenem	Strain development, inferior downstream processing	Strains research required
Doripenem	Strain development, inferior downstream processing	Strains research required
Potassium clavulanate / Clavulanic acid	Large scale fermentation capability, strain development / technology access	Strains research required
Betamethasone	Strain development / technology access	Strains research required
Prednisolone	Strain development/ technology access	Strains research required
Dexamethasone	Strain development / technology access	Strains research required

Source: APIs -Status, Issues, Technology Readiness and Challenges, TIFAC, July 2020

China's pro-industry Policies:

The Chinese Government has encouraged the domestic API and fermentation industry through several measures. These include (Table 7):

- Creation of large Special Economic Zones (10-15x the size of Indian SEZs) in accessible and resource-rich areas;
- Lower borrowing costs – 5-7% vs 11-14% in India;
- Lower logistics costs – 1% of total costs, v/s 3% in India, owing to well-developed transport infrastructure;
- Lower electricity costs – 11 US cents/kWh vs 19 US cents/kWh in India;
- Economies of scale of manufacturing plants;
- Easier availability and lower costs of finance;
- Ease in obtaining regulatory and statutory permissions;
- Availability of world-class physical infrastructure, such as roads, water supply etc.;
- Availability of land at economical rate;
- Fiscal incentives for manufacturing;
- Supportive R&D ecosystem;
- Industry-academia collaboration;
- Overall business environment, enabling speed of execution; and
- Flexible labour policy.

A KMPG/CII study shows that Indian API manufacturers are disadvantaged in all major sectors of manufacturing costs, except in labour costs. As a consequence, Chinese API production costs are about 20% lower than Indian costs (Fig. 3).

India also ranks lower than China in several of the ease of doing business parameters. India's ranking is very low in enforcing contracts and registering properties. Both are key issues not only to investors in India, but more so to foreign companies who want to invest here.

Table 7: Disadvantages faced by Indian API manufacturers vis-à-vis China

	China	India
Borrowing costs	4-5%	12-14%
Raw material costs	x	1.25-1.30x
Power costs	Rs. 7.368 per kWh	Rs. 6.172 per kWh
Logistics infrastructure costs	x-2%	x
Labour costs	1.8x	x
Labour productivity	1.5x	x

Scale of operations	1.3-1.4x	x
Set up and production costs	0.80-0.85x	x
Overall costs	0.7-0.8x	x
Ease of doing business ranking		
• Enforcing contracts	5	163
• Registering property	28	158
• Paying taxes	105	115
• Trading across borders	56	68

Profitability of fermentation-based units:

Knowledgeable people in the fermentation industry have apprehensions as to the viability of the fermentation-based products such as Penicillin G, gentamycin and clavulanic acid.

Based on the strain and technology that may be available to India the profitability of a Penicillin G project is only Rs.31-crore on an investment of Rs.750-crore (Table 8), according to an expert in fermentation.

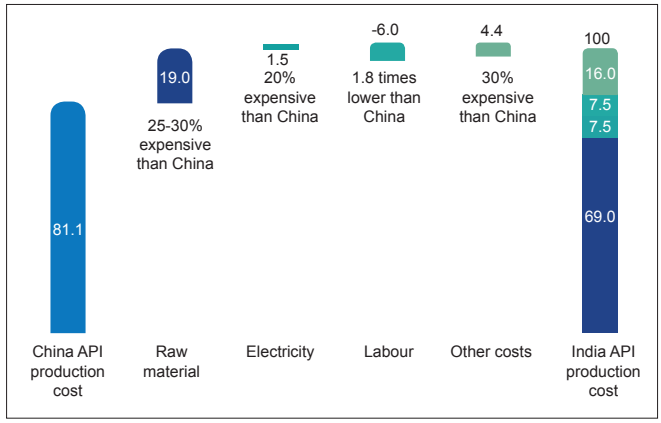


Fig. 3: Comparison of Indian and Chinese API manufacturing costs

Note: Cost of production in India is assumed to be 100 units; Other costs include financing, logistics, production and set-up costs

Source: Indian API Industry-Reaching the potential, KPMG-CII Report

The profitability can, however, change dramatically if more cost-effective strains and technologies are available; technology access is liberalised; capital costs brought down (such as by reviving closed units); and incentives given in line with that provided with other units. Unfortunately, under current policies, the government levies heavy taxes on strains, worsening the commercially viability of a project already marginally so. It is desirable that cutting edge technologies be allowed to be imported free of any duty or taxes.

Table 8: Commercial viability of a Penicillin G unit:

Plant capacity	**8,000 mmu**
Project cost	Rs. 750-crore
Price of Penicillin G	US$6 per Bou
Total turnover	US$48-mn (Rs. 360-crore)
Manufacturing cost for 8,000 MMU	Rs. 301-crore
Interest	Rs. 80-crore
Depreciation	Rs. 48-crore
Total costs	Rs. 429-crore
Incentive from PLI Scheme	Rs. 100-crore (average) (Rs. 120-crore for first four years; Rs. 90-crore for fifth year, and Rs. 30-crore for sixth year)
Total turnover (including PLI)	Rs. 460-crore
Total profit	**Rs. 31-crore (on Rs. 750-crore investment)**

Remedial steps:

Following issues are required to be addressed in order to make the PLI Scheme successful.

Examine reasons for closures:

A quick but serious study should be undertaken as to why many fermentation and API units have closed down and the reasons brought out there from should be quickly addressed so that the new units coming up under the PLI Scheme do not face the same problems.

Permit closed units to avail of Scheme:

Wherever possible, existing units that are closed should be allowed to avail the PLI Scheme. It will not only be faster and easier, but also more economical, as against setting up new grassroot units. For example, Hindustan Antibiotics Ltd. (HAL) can start its fermentation facility at Pimpri, Pune quickly, at much lower cost, without seeking even a rupee from government. A scheme for doing this is ready.

I had already given a proposal in this regard for revival of HAL by converting substantial portion of the land available with the unit into a Biotechnology Park and in the process generating Rs.4,000-crore surplus, which can be ploughed back into HAL, not only to revive, but also to modernize and expand, it.

Permit operating units to avail of Scheme:

The PLI Scheme should also be extended to operating units so that they do not close down. In this connection, we reproduce the opinion of a reputed pharma industry expert: "It is my considered opinion that out of chosen 41 molecules, 27 can be produced by synthetic chemistry route. India's existing API units have idle capacities of around 35-40%. These units, with minor changes, can produce around 20 molecules in just 2-3 months, with least investments. These are the low hanging fruits."

Grant general environmental clearance:

The expert further asserts that instead of the PLI Scheme, "Government should grant a general environment permission to existing API units to produce identified molecules. This should be within the overall pollution loads sanctioned. Chartered Accountants can certify the production and the designated agency can pay the incentive on the incremental turnover of the priority molecules. At the same time, in case of any frauds, there should be stringent penalties."

Cutting edge technologies, such as Zero Liquid Discharge, are now available and they can be leveraged to reduce the pollution load, in spite of the expansion.

Create strain development infrastructure:

A TIFAC report has highlighted the deficiency in respect of availability of latest strains and technologies for fermentation-based units. A laboratory for continuous upgradation and testing of strains needs to be urgently set-up.

It is not for the first time that this issue has been raised. We reproduce below from Hathi Committee report of 1975, i.e. 45 years back!

"There is an urgent need to obtain high yielding strains of microorganisms. One of the units has obtained a high yielding strain of streptomycin and the committee recommends that urgent steps be taken to optimize the production at other public sector units also by making the new high yielding strains at them. It is immediately necessary to acquire high yielding microorganisms for penicillin and tetracycline, and the associated balancing technologies."

In the absence of high quality locally available strains, duty on its imports from abroad should be abolished.

Leave investment decisions to the entrepreneurs:

The minimum capacity and investment requirement should be done away with and left to the entrepreneur's commercial judgement.

Expand ambit of GST:

The ambit of GST should be made more comprehensive by including exempted items like petroleum products, electricity, etc., thereby avoiding double taxation. This will enable the price of electricity – an important input to fermentation units in particular – to come down.

SUMMARY AND CONCLUSION:

Technology will play key a role in success of the PLI scheme. Entrepreneurs who apply under the PLI Scheme must definitely look at the cost-effectiveness of the technology proposed to be used and only then submit proposals.

If cost-effective technologies are not available, proposals may not be received for many fermentation-based products, in particular. If such a situation arises, the government should extend the Scheme to existing units and even

to multinationals who may be having latest technologies and, in extreme cases, if required, further incentives may also be given. They may also be asked to set up the fermentation-based units in SEZs, which may be created solely for the purpose, so that they can not only serve the Indian market, but also export.

There are four ways in which one can respond to situations: Inaction, Reaction, Anticipation and Proactiveness. Unfortunately, most of us in India follow the first two. We never anticipate, and proactiveness is perhaps not in our dictionary.

Although late, it is worthwhile that we have woken up and the government, after considerable deliberations, has come up with PLI Scheme. While doing so, it would have been better if an in-depth study was made as to why several fermentation facilities closed down and why many existing API unit are running at low capacity utilisation.

In this paper, we have identified several reasons for this. They include high cost of input raw materials; high energy cost particularly affecting the fermentation units; inefficient technologies; and delays in setting up new units, amongst others.

In any case, it is a moot point whether industry will be forthcoming with the products at capacities specified and investments requirements just to claim 2.2% Production Linked cash incentive on an annual basis.

Success of this initiative and the more generic, *Atmanirbhar Bharat* campaign will hinge on some key deliverables:

- Basic raw materials must be available at as close as possible to international prices;
- Electricity supply must be made reliable and cost comparable;
- Interest rates have to be brought down to around 4%;
- Land must be made available speedily and at prices projects can bear;
- The process of sanction and realisation of loans needs to be expedited; and
- Cash flow of the Indian industry must be improved. Public sector undertakings can make a contribution here by making payment to their suppliers within a reasonable time (say one month).

In the absence of corrective measures, the PLI Scheme and other initiatives to boost local manufacturing, will fail to deliver on the expected results. Another round of analysis and paralysis will then follow, once again!

Source: Y H Gharpure, Chemical Weekly, 22.09.2020

Comments from **Dr Y K Hamied, Cipla** *(reproduced as received from Mr Gharpure through Email on 28.09.2020)*

"Dear Dr Gharpure,

Congratulations and well done. I found your article on ***"Will the Production Link Incentive Scheme for Pharmaceuticals deliver?"*** *really good. This is most important for India and the World in General. We cannot be totally dependent on China. One or two points missed by you - Steroids intermediates in general dependence on China ARVs intermediates, also Malaria - Natural products, Vitamins, Patented products etc. This problem has to be tackled on a war footing by one and all. Please continue your best efforts. We are all with you in this venture for the sake of our country and it's future progress.*

Warm regards, Yusuf H"

Last date to file GSTR-9 and GSTR-9C for the Financial Year 2018-19 extended to 31 October 2020 - reg.

ATTENTION MEMBERS

The Association had made a representation to CBIC requesting to extend last date for filing of GSTR and GSTR9C. Now CBIC has issued a Notification (as reproduced below) extending the last date to file GSTR-9 and GSTR-9C for the Financial Year 2018-19 to 31 October 2020:

Gazette Notification No. G.S.R. 595(E), dated 30th September, 2020 (No.69/2020)

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 amendment in the notification of 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 words 30th September, 2020, the figures, letters and words **31st October, 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.

Gazette Notification No. G.S.R. 596(E), dated 30th September, 2020 (No.70/2020)

In exercise of the powers conferred by sub-rule (4) of rule 48 of the Central Goods and Services Tax Rules, 2017, the Government, on the recommendations of the Council, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No. 13/2020 – Central Tax, dated the 21st March, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 196(E), dated 21st March, 2020, namely:-

In the said notification, in the first paragraph, -

(i) for the words a financial year, the words and figures any preceding financial year from 2017-18 onwards shall be substituted;

(ii) after the words goods or services or both to a registered person, the words or for exports shall be inserted.

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.*

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CBIC amends Circular No.38/2016-Cus., *re.* Guidelines for Provisional Assessment u/S 18 of the Customs Act 1962

Circular No.42/2020-Customs, dated 29th September, 2020

T*o,*
All Chief Commissioners of Customs/Customs (Prev.),
All Chief Commissioners of GST and Customs,
All Director Generals under CBIC.

1. Reference is drawn to Board's Circular no.38/2016-Customs, dated 22.08.2016 which provides guidelines regarding provisional assessment under section 18 of the Customs Act 1962 and Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020 (hereafter referred to as the CAROTAR, 2020) issued vide Notification No. 81/2020-Customs (N.T.) dated 21st August, 2020.

2. In order to align the Circular no.38/2016-Customs dated 22.08.2016 with CAROTAR, 2020, the entries at Sr.No.1, 2, 5(a) and 5(c) of Table at paragraph 3 of the said Circular are substituted with the entries as below:

1	Imports by Authorised Economic Operators (AEO–T3)	0% (including cases at Sl.No.4 to 6b, except 5(a) and 5(c)).	In terms of Circular No.33/2016-Customs dated 22nd July 2016, as amended.
2	Imports by Authorised Economic Operators (AEO–T1 and AEO–T2) (excluding importers mentioned at Sl.No.3)	(a) 0% (in terms of Sl.No.5 (b), 6(a) and 6(b) (b) 50% (for AEO-T1) or 25% (for AEO-T2) of the applicable bank guarantee or cash deposit specified at Sl.No.4, 6(b)(1).	In terms of Circular No.33/2016-Customs dated 22nd July 2016, as amended.
5 (a)	Cases related to determination of origin under FTAs based on the reasonable belief that the matter involves mis-declaration of origin.	100%	In terms of Rule 5 or Rule 6(1)(b) of CAROTAR, 2020 (Notification No.81/2020 dated 21.08.2020)
5 (c)	Cases related to verification of signatures and seals under FTAs	100%	In terms of Rule 6(1)(a) of CAROTAR, 2020 (Notification No. 81/2020 dated 21.08.2020)

3. With the above amendments, all class of importers, including Authorised Economic Operators (AEO) are required to furnish 100% of differential duty as a security if provisional assessment is requested by the importer when inquiry is initiated in terms of rule 5 or when verification is initiated in terms of rule 6(1)(a) or 6(1)(b) of CAROTAR, 2020.

4. It is requested that the officers under your charge be directed to follow revised guidelines vide amended Circular 38/2016-Customs dated 22.08.2016 while implementing CAROTAR, 2020.

F.No.15021/18/2020 (ICD)

Abhishek Kumar Sharma,
Senior Technical Officer,
Central Board of Indirect Taxes and Customs,
Department of Revenue,
Ministry of Finance,
New Delhi,

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Implementation of S.O.3322(E), dated 25.09.2020 issued by NPPA regarding pricing of Liquid Medical Oxygen and Oxygen Inhalation (Medicinal Gas) in cylinder - reg.

NPPA Gazette Notification No.S.O.3322(E), 25th September, 2020

1. Whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified Paras of the DPCO, 2013, including Para 19 of the said Order to be exercised by the National Pharmaceutical Pricing Authority (NPPA) on behalf of the Central Government.

2. And whereas, Oxygen Inhalation (Medicinal gas) is a scheduled formulation under amended Schedule I of DPCO 2013 and NPPA had notified its ceiling price vide S.O. 5634 (E) dated 02.11.2018. After applying Wholesale Price Index (WPI), the present applicable ceiling price is Rs. 17.49 per cubic meter excluding Goods and Service Tax (GST) which is notified vide S.O. 1213(E) dated 25.03.2020.

3. And whereas, present situation of COVID-19 has resulted in increased demand of Medical Oxygen (MO) in the country. Demand has gone up almost four times, from 750MT/day to approx. 2800MT/day. Currently, during the COVID pandemic, around 50% of the total Liquid Oxygen production is being used for medical purpose in comparison to around 15% usage during the pre-COVID period. Liquid Oxygen is being diverted from industrial use to medicinal use to cope with the additional demand. Many of the States/UTs are dependent on the Medical Oxygen supply from other States/UTs. In order to meet the enhanced requirement, Medical Oxygen is being supplied to remote areas of the country after incurring additional cost on transportation. Due to on-going pandemic of COVID-19, these extra ordinary situations have caused strain at all levels in the value chain of production and supply, especially for distant and interior districts based on terrain and distance.

4. And whereas, Medical Oxygen is not only an essential life saving drug but critical for COVID management. All the clinical protocols world over recognize the role of Medical Oxygen as an essential medical therapy in clinical management of Moderate and Severe cases of COVID-19. Medical Oxygen is not only required for managing the patients of COVID-19 but also for the management of other health emergencies due to Non-COVID causes as well as for elective surgeries and other essential health service. Therefore, ensuring adequate supplies of Medical Oxygen is absolute necessity to save human lives.

5. In view of the COVID-19 pandemic, States/UTs have been advised by the Ministry of Health & Family Welfare (MoHFW) to strengthen the hospital infrastructure accordingly by creating required numbers of Oxygen Supported Beds and ICU Beds. All of these beds will require uninterrupted supply of Medical Oxygen through Medical Oxygen Cylinders and Liquid Medical Oxygen (LMO) Tanks. Without ensuring availability of Oxygen, the dedicated COVID Health Centers and COVID Hospitals can not admit or manage the COVID-19 patients. Therefore, Medical Oxygen is an Essential Public Health Commodity and its uninterrupted availability needs to be ensured.

6. It is informed that due to increase in price of LMO being supplied to filler, the margins for them have been squeezed and are impacting their operational viability. Due to excess demand, delivery through cylinders has increased from 11% pre-COVID to 50% of current oxygen supply. It is therefore, imperative to cap price of LMO to ensure uninterrupted availability of Medical Oxygen though cylinders to the hospitals and consumers.

7. Whereas Empowered Group (EG) 3, now EG2, of the Government of India is *inter-alia*, mandated to ensure availability of Medical Oxygen. EG 2 in its

meeting held on 21.09.2020 noted that currently, Medical Oxygen demand has increased several times due to Covid-19 and Medical Oxygen, both LMO and cylinders are required to be sent to all parts of the country, covering long distances. In view of this, EG2 requested NPPA to look into the ceiling price of medical oxygen, both LMO and cylinders. The State Governments may be required to fix the transport charges under the Disaster Management Act.

8. And whereas, looking at the present situation of COVID-19 and consumption trends of Medical Oxygen in the Country, MoHFW has delegated powers to NPPA to take all necessary steps under clause (l) of subsection (2) of the section 10 of Disaster Management Act, 2005 to immediately regulate the availability and pricing of the LMO & Medical Oxygen Cylinders.

9. And whereas, the inter-ministerial committee constituted by NPPA to monitor prices of APIs and formulations needed for COVID-19 has vide its report dated 22.09.2020 recommended that there is a need to cap the price of LMO and Medical Oxygen in cylinders.

10. The Authority in its meeting on 25.09.2020 examined the issue at length including the recommendations of EG2 and inter-ministerial committee, and decided to cap the price of LMO & Oxygen Inhalation (Medicinal gas) in cylinder.

11. Therefore, in exercise of extra ordinary powers, conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and powers conferred under section 10(2)(l) of Disaster Management Act, 2005 delegated by Ministry of Health and Family Welfare vide Order No. Z-33014/45/2020-RCH/Pt.File-3 dated 23.09.2020, the Authority, in view of extraordinary circumstances as noted above, hereby in public interest, caps and notifies the price as specified in column (4) of the Table below as maximum price (ex-factory) exclusive of Goods and Services Tax (GST) as applicable, in respect of the formulation specified in the corresponding entry in column (2) of the said Table with unit specified respectively in the corresponding entries in columns (3) thereof:

Table

Sr. No.	Name of the Drug	Unit	Maximum Price (ex-factory) Excluding GST (Rs.)
(1)	(2)	(3)	(4)
1	Liquid Medical Oxygen (LMO)	Cubic Meter	15.22
2	Oxygen Inhalation (Medicinal gas) in cylinder	Cubic Meter	25.71*

**Inclusive of inward transportation cost incurred for LMO up to filler.*

Note:

(a) The ex-factory price as specified in column (4) in respect of the drugs mentioned in column (2) shall remain in force up to 31st March 2021 or until further orders, whichever is earlier.

(b) The ex-factory price as specified in column (4) in respect of the drug mentioned at Sr. No. 2 of column (2) is in supersession of price notified at S. No. 610 of S.O. 1213(E) dated 25.03.2020.

(c) Since the new rates are being notified as an emergency measure only for six months, the existing contracts for supply of Medical Oxygen made in accordance with S.O. 1213(E) dated 25.03.2020 may continue to be valid.

(d) The transport cost as fixed by the State/UT Governments would be in addition to price at (a), (b) and (c) above.

(e) The manufacturers not complying with the price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(f) The price as specified in column (4) in respect of the drugs mentioned in column (2) shall be applicable for domestic production and supply.

PN/211/79/2020/

F. No.8(79)/2020/DP/Div-II/NPPA

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

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Import of APIs

Lok Sabha Unstarred Question No.251

Shri Dhanush M Kumar:

Shri C N Annadurai:

Shri Gautham Sigamani Pon:

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

(a): whether Indian Pharmaceutical companies imported more than 70% of the Active Pharmaceutical Ingredients (APIs) used for manufacturing medicines in the country;

(b): if so, the details of the countries from which India imports APIs along with the reasons for high import of APIs;

(c): whether the Government has taken steps to ensure regular supply of APIs in view of Covid-19 by enhancing domestic production and if so, the details thereof;

(d): whether the Government has taken any steps for setting up Bulk Drug Parks in the country especially in Tamil Nadu and if so, the details thereof, State/ UT-wise;

(e): whether Private Sector will also be involved in setting up Bulk Drug Parks, if so, the details thereof and the steps taken in this direction; and

(f): the other steps taken by the Government to create a self-reliant ecosystem in the Pharmaceuticals and Health and Hygiene sector by ramping up domestic production which will help in building an Atma Nirbhar Bharat?

Answered on 15th September 2020

A. (a) & (b): Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2019-20. India imports bulk drugs largely for economic considerations. The following are major countries from which India imported APIs during 2019-20.

S. No.	Country	Percentage share of import
1	CHINA P RP	68.04
2	U S A	3.53
3	ITALY	3.02
4	SINGAPORE	2.88
5	SPAIN	2.17
6	GERMANY	1.85
7	FRANCE	1.56
8	JAPAN	1.53
9	DENMARK	1.26
10	HONG KONG	1.25

GCIS, Kolkata

(c) & (f): 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.

(d) & (e): Under the scheme Promotion of Bulk Drug Parks financial assistance will be provided to the State implementing agencies for creation of common infrastructure facilities in Bulk Drug Parks to be developed by State Governments. Three Bulk Drug parks will be financed under the scheme. States will be selected on the basis of scores obtained by the proposals submitted by the states on a predefined selection criteria (given in the scheme guidelines available on the website of the department under the tab titled 'schemes'). A State Implementing Agency has to be a legal entity set up for the purpose of developing the Bulk Drug Park and having minimum 51% equity of the State Government. No proposal has been submitted by the state Government of Tamil Nadu. States can submit proposals under this scheme within a period of 60 days from the date of issuance of the scheme guidelines (Guidelines were issued on 27th July, 2020).

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

Anti-dumping Duty on Vitamin-C

Lok Sabha Unstarred Question No.275

Shri Manoj Kotak:

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

(a): whether it is true that the Government has lifted anti-dumping duty on Vitamin C;

(b): if so, the reasons therefor;

(c): whether it is also true that approximately 100 Indian units producing vitamin C is affected by this decision of the Government;

(d): if so, the reasons therefor; and

(e): whether the Government has any plan to impose anti-dumping duty on import of Vitamin C from China and if so, the details thereof?

Answered on 15th September 2020

A. (a) & (b): As per information provided by Directorate General of Trade Remedies (DGTR), the Anti-dumping duty was extended on Vitamin-C originating in or exported from China PR on 06.08.2015 for a further period of 5 years vide Department of Revenue's Notification No.38/2015-Customs (ADD) dated 06.08.2015. The anti-dumping duty thereafter expired (got lifted) on 05.08.2020.

(c) & (d): As per the Notification dated 4th September, 2020 issued by Directorate General of Trade Remedies (DGTR) for initiation of Anti-Dumping investigations, there are just 4 Indian Manufacturers which account for 100% production of Vitamin C in India. Therefore, the point that 100 manufacturers got affected does not seem to be true.

(e): Based on the application filed by the domestic industry, Directorate General of Trade Remedies (DGTR) has initiated an anti-dumping investigation concerning imports of "Vitamin C in all its form" from China PR on 04.09.2020. DGTR conducts anti-dumping investigations, under the Customs Tariff Act, 1975 and the rules made there under, and recommends imposition of duty, wherever appropriate, to the Department of Revenue by issuing its preliminary/ final findings. Acting upon such recommendations of the DGTR, the Department of Revenue may impose the provisional or definitive duties.

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

Impact of Lockdown on Companies

Lok Sabha Unstarred Question No.37

Shri Benny Behanan:

Shri Sisir Kumar Adhikari:

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

(a): whether a large number of companies have been affected by the contraction of economy due to the recent lock down in the country;

(b): if so, the details thereof including the number of companies registered and closed down along with the number of unemployment registered during the period from April to August 2020, sector-wise and the State-wise; and

(c): the corrective steps taken/proposed to be taken by the Government in this regard ?

Answered on 14th September 2020

A. (a) & (b): The Government in the Ministry of Corporate Affairs (MCA) administers the provisions of Companies Act, 2013 and LLP Act, 2008. The information regarding contraction of economy due to the recent lock down in the country is not maintained by MCA. Further, information regarding unemployment is also not maintained by MCA.

However, number of Companies registered and closed during April to August 2020 by all Registrar of Companies (ROCs) is as given below:

No of Companies Registered from April to August 2020.	No of Companies Closed (Strike off) From April to August 2020
51807	09 (Applications received prior to Covid period)

(c): MCA has taken steps to provide several incentives/relaxation/concession during Lockdown period so as to reduce the burden of Companies/ LLPs during Covid-19 above said period which includes the following:

(i): Introducing Companies Fresh Start Scheme 2020 (CFSS) vide General Circular No.12/2020 dated 30.03.2020 to enable companies to file documents without additional fees, grating immunity from prosecutions proceeding, etc.

(ii): Introducing LLP Settlement Scheme, 2020 providing similar benefits as CFSS 2020 for the benefits of LLPs.

(iii): Introducing Special Provisions for enabling conduct of Board and General Meetings through Video conferences by Corporates vide General Circular No. 14/2020.

(iv): Introducing Special provisions for filings under section 124 & 125 r/w IEPFA (Accounting, Audit, Transfer and Refund) Rules 2016.

(v): Introducing Special Relaxation in holding of General Meeting by Companies whose Financial Year ended on 31st December 2019 vide General Circular dated 21.04.2020 and holding it through Video conferences vide General Circular No. 20/2020 and 28/2020.

(vi): Allowing Corporates for spending CSR funds for various activities which includes Healthcare, sanitation and disaster management.

(vii): A general extension of 3 months to hold Annual General Meeting for the Financial year 2019-2020 beyond 30.09.2020 has been granted to all about 12 lakhs companies by issue of order by each ROC on 08.09.2020 without any requirement to file any application of the form and without payment of fee.

The Minister of State for Finance and Corporate Affairs (Shri Anurag Singh Thakur)

GST Collections from Companies/ Corporates

Lok Sabha Unstarred Question No.54

Shri Natarajan P R:

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

(a): whether the collection of revenue under the Goods and Services Tax (GST) is achieved as estimated at the time of its inception;

(b): if so, the details of estimated Demand, Collection and Balance (DCB) as on date;

(c): whether there are any arrears of GST collection from any of the Companies/Corporates as on date and if so, the details thereof; Company and Corporate-wise;

(d): the details of refund of cess compensation paid to the State Governments and balance pending during each of the past three years including current year; year-wise and state-wise; and

(e): whether any timeline has been fixed for the clearance of pending payments to the States and the continuance and if so, the details thereof?

Answered on 14th September 2020

A. (a) & (b): The details of Goods & Services Tax (GST) revenue collection and Target (RE/BE) during FY 2017-18, FY 2018-19, FY 2019-20 and FY 2020-21 (April-August) as per Pr.CCA flash figure are tabulated in Annexure-I *(not reproduced here).*

(c): During the COVID induced lockdown to avoid any inconvenience to the taxpayers, Government has extended several relief measures to the taxpayers by way of waiver/reduction of interest, late fee and also extended the return filing dates periodically. It may also be noted that the taxpayers with turnover less than Rs.5 crore continue to enjoy relaxation in filing of returns till September, 2020.

(d) & (e): The details of GST compensation cess collected and compensation released to States is as follows:

(Figures in Rs. Crore)

	2017-18	2018-19	2019-20	2020-21
Compensation Cess collected	62,612	95,081	95,444	21,355 (till July 2020)
Compensation released*	41,146	69,275	1,20,498 (till November 2019)	65,546 (till March 2020)

**State-wise details of GST compensation released in as per Annexure-II (not reproduced here).*

GST compensation cess collected in current FY 2020-21 is not sufficient to pay the admissible GST compensation for period April-July, 2020. Accordingly, to discuss the issue of pending GST compensation and future course of action to meet the GST compensation shortfall has been discussed in 41st GST Council meeting on 27.08.2020 wherein States were given two options to meet their GST compensation shortfall for current FY from market borrowing. Based upon the options exercised by the States, their compensation, borrowing, repayment etc will be dealt as per their individual choice.

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

Web resources bring new insight into COVID-19

Researchers around the world are a step closer to a better understanding of the intricacies of COVID-19 thanks to two new web resources developed by investigators at Baylor College of Medicine and the University of California San Diego. The resources are freely available through the Signaling Pathways Project (Baylor) and the Network Data Exchange (UCSD). They put at researchers' fingertips information about cellular genes whose expression is affected by Coronavirus infection and place these data points in the context of the complex network of host molecular signaling pathways.

Using this resource has the potential to accelerate the development of novel therapeutic strategies. (*The study appears in the journal Scientific Data)*. "Our motivation for developing this resource is to contribute to making research about COVID-19 more accessible to the scientific community. When researchers have open access to each other's work, discoveries move forward more efficiently," said leading author Dr Neil McKenna, Associate Professor of molecular and cellular biology and member of the Dan L Duncan Comprehensive Cancer Center at Baylor.

The Signaling Pathway Project:

For years, the scientific community has been generating and archiving molecular datasets documenting how genes are expressed as cells conduct their normal functions, or in association with disease. However, usually this information is not easily accessible.

In 2019, McKenna and his colleagues developed the Signaling Pathways Project, a web-based platform that integrates molecular datasets published in the scientific literature into consensus regulatory signatures, or what they are calling Consensomes, that rank genes according to their rates of differential expression.

In the current study, the researchers generated Consensomes for genes affected by infection with three major Coronaviruses, Middle East respiratory syndrome Coronavirus (MERS) and severe acute respiratory syndrome Coronaviruses 1 (SARS1) and 2 (SARS2, which causes COVID-19).

McKenna and his colleagues provide a resource that assists researchers in making the most out of Coronavirus' datasets. The resource identifies the genes whose expression is most consistently affected by the infection and integrates those responses with data about the cells' molecular signaling pathways, in a sense getting a better picture of what happens inside a cell infected by Coronavirus and how the cell responds.

"The collaboration with UCSD makes our analyses available as intuitive Cytoscape-style networks," says McKenna. "Because using these resources does not require training in meta-analysis, they greatly lower the barriers to usability by bench researchers."

Providing new insights into COVID-19:

The consensus strategy, the researchers explain, can bring to light previously unrecognized links or provide further support for suspected connections between Coronavirus infection and human signaling pathways, ultimately simplifying the generation of hypotheses to be tested in the laboratory.

For example, the connection between pregnancy and susceptibility to COVID-19 has been difficult to evaluate due to lack of clinical data, but McKenna and colleagues' approach has provided new insights into this puzzle.

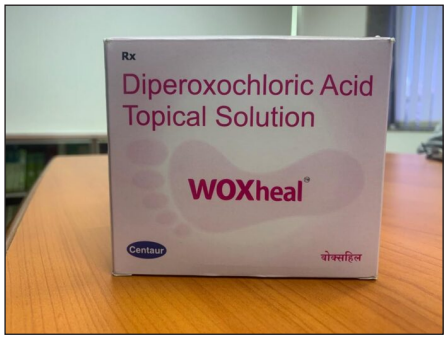
"We found evidence that progesterone receptor signaling antagonizes SARS2-induced inflammatory signaling mediated by interferon in the airway epithelium. This finding suggests the hypothesis that the suppression of the interferon response to SARS2 infection by elevated circulating progesterone during pregnancy may contribute to the asymptomatic clinical course," McKenna said. Consistent with their hypothesis, while this paper was being reviewed, a Clinical Trial was launched to evaluate progesterone as a treatment for COVID-19 in men.

(Scott A. Ochsner at Baylor College of Medicine and Rudolf T. Pillich at the University of California San Diego were also authors of this work. This study was supported by the National Institute of Diabetes, Digestive and Kidney Diseases NIDDK Information Network (DK097748), the National Cancer Institute (CA125123, CA184427) and by the Brockman Medical Research Foundation. The Signaling Pathways Project website is hosted by the Dan L Duncan Comprehensive Cancer Center.)

Source: Baylor College of Medicine, Science Daily, 22.09.2020 (Excerpts)

Centaur Pharmaceuticals launches WOXHeal for treatment of diabetic foot ulcer

Centaur Pharmaceuticals announced the launch of a New Chemical Entity (NCE) – WOXheal. With its dual mechanism of action, WOXheal is a unique product in diabetic foot ulcer treatment. It will save millions of people with diabetes who have to undergo foot amputation globally. WHO predicts that there will be ten crore Indians with diabetes in the next ten years.



Amongst other complications of diabetes; diabetic foot ulcer is the most common complication seen in India. Apart from the fact that diabetic foot ulcers are non-healing, they hamper the Quality of life of the patient and lead to complications such as wet gangrene, cellulitis, abscess, and necrotizing fasciitis, all leading to a total or partial foot amputation.

Data indicates that 25% of people with diabetes will develop a Diabetic Foot Ulcer in their lifetime. 1 in 5 Diabetics hospitalized due to severe foot infection undergo a foot amputation affecting the family's livelihood. Speaking on this occasion, S D Sawant, Chairman and Managing Director of Centaur Pharmaceuticals, said, "We, at Centaur Pharmaceuticals were deeply concerned with the alarming rate of foot amputations in India, and wanted to discover a drug to prevent it.

Fifteen years ago, we collaborated with CytoTools AG, Germany, who had this promising molecule for the treatment of diabetic foot ulcer. We are very happy to offer this ray of hope to people with diabetic foot ulcer in India." A patented product, WOXheal topical solution, is effective in treating diabetic foot ulcers. WOXheal contains the NCE, Diperoxochloric acid, also called as DPOCL. WOXheal has a dual mechanism of action; it has functional antibacterial action against Gram positive and Gram negative bacteria.

It also promotes the growth of fibroblast cells, thereby yielding complete wound closure. Randomized Clinical Trials conducted across India in over 15 Clinical Trial centers on WOXheal elucidated that over 90% of patients with non-healing diabetic foot ulcers showed a reduction in the size of the ulcer, and 75% out of these patients achieved complete healing within 6 to 8 weeks without any safety issue.

The trial's data and outcomes were submitted to the Indian Regulatory Authority, and a manufacturing and marketing approval was granted to Centaur Pharmaceuticals for WOXheal. Dr Mark-Andre Freyberg, the co-innovator of WOXheal and the Chief Executive Officer of CytoTools AG, Germany, said, "WOXheal has completed Phase III Clinical Trials in India and demonstrated rapid and effective wound healing in patients with Diabetic foot ulcers, a condition that is notoriously difficult to treat."

Dr Dirk Kaiser, the co-innovator of WOXheal and the Chief Scientific Officer of CytoTools AG, Germany, said, "WOXheal is a novel drug born out of Indo-German collaboration and it will change the way Diabetic Foot Ulcer management is done and will help prevent amputation." Dr Kaiser also added that Phase III Clinical Trials were ongoing in Europe, and the results from Phase II Clinical Trials were similar to Indian Clinical Trials. This pioneering effort by Centaur Pharmaceuticals, for an unmet medical need, enhances India's stature as a self-reliant nation and a Pharma super-power. WOXheal will be readily available in the entire country by the end of the month.

Source: www.healthtekpak.com, 29.09.2020

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Despite urgency, Pharma Companies committed to Science First Policy on COVID-19 vaccine: Industry Body

In the last nine months since the COVID-19 outbreak, around 170 vaccine candidates have shown promise, with 26 of them entering the human trial stage, Pharmaceutical companies are committed to a "science first" approach in the development of COVID-19 vaccines even as the pressure piles on to end the pandemic, the representative of a Singapore-based industry body has said. Vaccine

development is a complex process, traditionally it takes as long as 20 years, said Ashish Pal, Vice-President of the Singapore Association of Pharmaceutical Industries (SAPI).

"You have pre-discovery phase that can last two to four years. Pre-Clinical and Clinical Trials can take anything between five and 15 years and that does not include regulatory approvals and manufacturing," Channel News Asia reported on Monday, 28.09.2020 quoting Pal. In the last nine months since the COVID-19 outbreak, around 170 vaccine candidates have shown promise, with 26 of them entering the human trial stage, according to the World Health Organization (WHO), which cautions against haste.

"Companies that are developing vaccine candidates are now working on multiple elements of the development process, so (it) is in many ways much more risky, given the fact that a lot is happening much faster, and also in tandem," said Pal, who is also the Managing Director of MSD Pharma Singapore. "More than ever, there is need for urgency but most importantly, without compromising on safety," he told the channel.

Pal said the people could take a great amount of comfort from the joint pledge made by nine American and European vaccine developers. Pfizer, GlaxoSmithKline, AstraZeneca, Johnson & Johnson, Merck & Co, Moderna, Novavax, Sanofi and BioNTech, in a joint statement, has said they would "uphold the integrity of the scientific process as they work towards potential global regulatory filings and approvals of the first COVID-19 vaccines".

"Obviously there's a lot out there about timeframes but the whole process as I've outlined is complex. It's probably too early at this point in time to speculate when a vaccine candidate would be approved," he said. A vaccine has long been awaited to immunise the world against the novel Coronavirus that has claimed over 900,000 lives across the world so far.

Earlier this month, the WHO said it does not expect widespread vaccinations against COVID-19 until the middle of next year. None of the candidate vaccines in advanced clinical trials have demonstrated a ''clear signal" of efficacy at the level of at least 50 percent, the WHO had said. The challenges could be seen when a potential vaccine being developed by British drug maker AstraZeneca and Oxford University hit the pause button last week, following an unexplained illness in a study participant. The WHO's Chief Scientist had called the pause a "wake-up call", urging researchers not to be discouraged. The challenges do not end at development of a vaccine. Manufacturing and distribution will be key areas where global cooperation will be required, Pal said. Given how manufacturing will likely have to be done at "an unprecedented scale", he said, "Companies are probably using a variety of options from expanding manufacturing sites to either refitting or re-purposing their global networks, and identifying additional opportunities to supplement their networks."

Asked about industry collaboration given the lucrative option of a successful vaccine, Pal said, "We are already seeing many examples of industry and academia, as well as industry and industry coming together so I think there are already some very real examples of unique and relevant collaboration today. Distribution of the vaccines will be based on "an equitable distribution that is agnostic to economic tiers", said the SAPI Vice-President. This is being followed by COVID-19 Vaccine Global Access (COVAX) facility, a global allocation plan led by the WHO, the GAVI vaccine alliance and the Coalition for Epidemic Preparedness Innovations, he added.

Launched in late April, the COVAX facility works with vaccine manufacturers to provide countries worldwide with "equitable access to safe and effective vaccines", said the WHO. It aims to deliver at least 2 billion doses of approved vaccines by the end of 2021. For now, it relies on nine experimental vaccines that are across various stages of development and employ a range of different technologies and scientific approaches.

On whether the emerging trend of "vaccine nationalism" could impede the effectiveness of the COVAX facility, Pal said, "I think what countries choose to do is obviously an individual choice. COVAX is a very important platform at this time more than ever before (because) its intent is in line with how best the world can navigate this global pandemic."

Pal stressed that Singapore plays an important role in the global bio-pharmaceutical industry. He pointed to how the industry, which employs more than 24,000 people, remains a bright spot for the Singapore economy despite the current pandemic-fuelled downturn. "We have companies that have significant manufacturing and Research and Development (R&D) presence in Singapore. The range of manufacturing and R&D is varied and what each company is choosing to do is obviously company proprietary," said Pal.

Source: PTI, etnownews.com, 23.09.2020 (Excerpts)

Atma Nirbhar Bharat: Pharma sector in focus right now

Since the violent face-off in the Galwan Valley between India-China, the Indian Government is clamping down on business with China and reducing dependence on China for growing imports. Pharma is one such sector where the Government is seriously looking to curb dependence as India imported close to $3.5 billion worth bulk drugs/drug intermediates from across the world in CY2019, of which, 67% ($2.4 billion) was from China.

Intermediaries and APIs are crucial chemical compounds (raw materials) required to manufacture formulations or medicines. Thus, dependence on a single country for such a crucial thing is not prudent in India's national interest, hence there is a need to diversify the sourcing and develop domestic capacity.

Dependence on China is particularly high for products like Antibiotics/Penicillin, for which, more than 90% of imports are from China. The Indian Pharma industry is the third-largest in the world by volume and 14th largest in terms of value. In order to push local manufacturing, the Government has announced plans to localise the manufacturing of 53 critical APIs and intermediates. It has offered a Rs.6,940 crore Production Linked Incentives between 5%-20% for incremental sales and plans to set up three mega drug parks to drive sustainable cost competitiveness.

Moreover, the Government is considering increasing the import duty on APIs to 20-25% from the current 10%, to help boost local manufacturing of the bulk drugs. The Indian Government's recent incentives to boost domestic manufacturing of APIs and intermediaries would improve backward integration over the next few years and curtail supply-chain disruption risk for Indian drug makers. The incentives should address core issues of pricing competitiveness and funding and make domestic production more competitive.

During the Q1FY21 results, API sales grew 35% Y-o-Y/20% Q-o-Q for healthcare companies. This was largely led by (a) non-inclination to buy from Chinese suppliers, which led to better market share, (b) Covid led higher off-take of medicines, (c) re-stocking to some extent, and (d) favourable pricing. Thus, going ahead, with the inclination to buy from Chinese suppliers reducing, we expect better growth prospects for the API business. After three to five years of the downtrend in P/E, Healthcare is now back to its 10-year average over the past three months.

Strong quarterly results, rising US FDA approval, and favourable Government policies have boosted Pharma stocks. Export-oriented companies witnessed increased demand for their products (API/formulation) across developed as well as ROW markets. The ANDA approvals have been better than previous quarters, implying the smooth functioning of the US FDA. Further, we expect steps taken by the Government to be positive for some of the API players.

We prefer Divis among large caps while we prefer IPCA, Alembic Pharma, Laurus Labs, Alkem Labs, and Granules among mid-caps. Divis is well placed to benefit from its (a) API prospects, and (b) a strong relationship with Innovators for CRAMS (Contract Research and Manufacturing Services). We are positive on IPCA on the back of (a) superior performance in the DF segment, (b) the addition of new APIs as well as increased traction in existing API molecules, (c) product launches under its own label in the UK, and (d) increased backward integration to derive further benefit by improving manufacturing efficiency.

We are positive on Alkem given the healthy ANDA pipeline for the US market and expect the outperformance to continue for chronic therapy in DF and trade generics segment. Laurus Labs: Formulations/Synthesis segment to drive the revenue. Change in regimen and in-house API consumption to affect ARV API segment growth. Update in new molecule additions in API segment. Outlook for ANDA-led Formulations business is a variable to watch. Granules has multiple growth levers, such as (a) the ANDA pipeline for US generics (with some products having limited competition opportunity), which should drive an increase in the share of formulations for developed markets, (b) enhanced reach for core molecules, and (c) reduced operational expenditure through backward integration.

(The writer is the Head, Equity Strategy, Broking & Distribution, at Motilal Oswal Financial Services).

Source: Hemang Jani, Deccan Hearald, 20.09.2020

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Lao PDR offers significant export opportunities for Indian Pharma, Ayurveda and allied sectors

With the Lao People's Democratic Republic (PDR) Government giving highest priority for healthcare, the Pharmaceutical Export Promotion Council of India (Pharmexcil) is planning to take advantage of this

opportunity and taking various initiatives to promote export of low-cost high-quality Indian generics, ayurvedic and other products of medical and healthcare sectors.

As part of this initiative, Pharmexcil in association with the Indian embassy at Vientiane, Lao has decided to organize a webinar on September 30, 2020, facilitating online meeting with members of Indian exporters, and members of regulatory, medical and health and key stakeholders from Lao.

According to Udaya Bhaskar, Director General of Pharmexcil, though Lao is a small country with a very small market for the medical, health and other pharmaceuticals markets, the country offers a significant opportunity for Ayurvedic and herbal products. "As part of our continuous initiative to promote Indian exports, we are planning to organize a webinar online meeting with the members of Indian exporters.

The Indian embassy at Vientiane is expected to coordinate with the stakeholders from Lao for an online meeting. The webinar is also followed by a Business-to-Business meeting wherein the Indian exporters can utilize the opportunity and build a strong export network," informed the Pharmexcil DG.

Apart from Pharmaceuticals, Medical and Surgical, the Lao healthcare markets offer huge potential for the herbals and other traditional medicines. As the Lao Government has recently announced its commitment for prioritizing the healthcare sector, the Indian generic players can easily cash in on the opportunity, as the demand for generic medicines is very high in the country.

"Lao though is a small country, its market offers huge potential for Indian exporters. Moreover, the Government has also come up with offers and incentives for investments in the field of agriculture and Pharma sectors for promoting herbals and traditional medicines," observed the DG.

In addition to explore the available opportunities, the webinar online meeting is also expected to create awareness on the regulatory framework and registration requirements for greater market access for the Indian exporting members. The webinar will also emphasize on strengths of Indian Pharma industry and investment schemes being offered by the Laos Government.

Source: A Raju, Pharmabiz, 23.09.2020

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DCGI asks importers to submit undertaking on product quality to ensure faster clearance from port offices

Aiming at faster clearance of import consignments at ports, the Drugs Controller General of India (DCGI) has asked importers to submit an undertaking along with a bill of entry that packaging of their consignment is not damaged and content of drugs has not deteriorated.

As part of ease of doing business, the DCGI's initiative aims to ensure that importers strictly comply with conditions of import license and maintain integrity of drugs. As per a notice issued by the DCGI recently, in light of doing business and for utilizing fast track system of risk management system, with ICEGATE integration for online clearance of imported drugs and cosmetics, it is proposed that the human interface may be reduced by devising method, while ensuring that the integrity of drug/cosmetics, its packages and seal is intact before the release and out of charge.

Therefore, it is a responsibility of the importer to ensure the same and furnish the undertaking with each integrated declaration or bill of entry that the packaging is not damaged/broken/destroyed and the content of drug/cosmetic has not deteriorated in a prescribed format, it stated. Besides submitting the said undertaking at the time of import, all importers are required to furnish label of respective consignment, certificate of analysis (COA) of release of batch and import license/permission along with bill of entry and other documents as per Drugs and Cosmetics Rules, 1945 at the port office.

Each importer is required to comply with the conditions of the import license or the no objection certificates (NOCs) issued under the D&C Act. Welcoming this, Sahil Munjal, Vice Chairman, Pharmexcil said, "It is a welcome step by the Government to release all import consignments with importer's declaration that package seal is intact and package is not broken/damaged. This will help importers to release import consignments from ports/airports without unnecessary delays. It is a welcoming step by DGCI in ease of doing business."

Said Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association "Importers have been complying with conditions of import license under D&C Act. The DCGI's recent mandate that importers submit requisite documents along with an undertaking that their consignment is intact and is fit for consumption before

the release of imported goods from ports/airports, is in the direction of ensuring importers' strict compliance with provisions of D&C Act. It's a welcome step."

However, an industry insider stated that there are certain unscrupulous importers who manage to import and sell unregistered/prohibited Pharma products in the country by mislabeling and misfiling bill of entry with customs' ICEGATE. They get imported consignments released from ports and airports with tacit support from customs officials without securing NOC from Additional Drugs Controller (ADC). This is posing risk to public health. The DCGI needs to look into the issue and coordinate with customs authority to check the import of unregistered/banned Pharma products in the country, he added.

Source: Laxmi Yadav, Pharmabiz, 25.09.2020

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Health Ministry issues draft Regulatory Guidelines for development of vaccines

The Union Health Ministry has issued draft regulatory Guidelines for development of vaccines with special consideration for COVID-19 vaccine to provide Guidance to the vaccine developers to ensure that vaccines are well-characterized and manufactured consistently.

Unlike chemical drugs, vaccines are complex heterogeneous class of medical products, and hence specific consideration in respect of development of Chemistry, Manufacturing, and Controls (CMC) data, non-clinical data and clinical data will provide clear understanding of regulatory landscape for their development and approval in a scientific manner.

Therefore, these detailed Guidelines and regulatory pathways have been prepared to provide for CMC, nonclinical and Clinical Development of vaccines including COVID-19 vaccines. These Guidelines stipulate that vaccines remain stable at the recommended storage conditions for the duration of Clinical Trial during clinical development stage and throughout its shelf life post approval.

Adequate toxicity data as well as immunogenicity in respect of humoral and/or cell-mediated immune response are generated in nonclinical studies in relevant animal models. It further stipulates that challenge studies in relevant animal species and non-human primates may be conducted concurrently with clinical trials. Adequate clinical data to establish safety and humoral, cell-mediated immunogenicity are generated.

This will also ensure that Post Marketing Surveillance (PMS) including assessment of Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) is carried out to assess vaccine safety in post market scenario. The main objective of development of vaccines is to generate adequate data on quality, safety, immunogenicity and/or efficacy to support application for marketing authorization.

As vaccines are heterogeneous classes of medical products, much of the considerations for their development should be given on a product-specific basis. Requirements may vary depending on the type of vaccine whether it is inactivated or live attenuated microorganisms based or antigen based which is extracted from pathogen or derived from r-DNA technology or by chemical synthesis, or a vaccine containing naked nucleic acid, including plasmids for expressing specific antigens or otherwise, it will also be dependent on manufacturing process, its mechanism of action and the nature of the disease to be prevented as well as target population.

This Guidance provided in these documents will be applicable in general for CMC data, nonclinical and clinical development of any vaccine including COVID-19 vaccines.

Import or manufacture for sale of drugs including vaccines are regulated under Drugs and Cosmetics Act, 1940 and Drugs & cosmetics Rules, 1945 and New Drugs and Clinical Trials Rules, 2019. Detailed requirements and guidelines for conduct of nonclinical and clinical studies and approval of new drugs which includes vaccines are specified in the second schedule of New Drugs and Clinical Trials Rules, 2019.

As per the Rules, products like vaccines, r-DNA derived products, LMO, Stem cell derived products, gene therapeutic products, etc are always considered to be new drugs. For such products manufacturers are required to obtain manufacturing permission from Central Drugs Standard Control Organisation (CDSCO) under the New Drugs and Clinical Trials Rules, 2019 before Licencing the product under the Drugs and Cosmetics Rules,1945.

The Manufacturing Licence for such product is granted after joint evaluation and inspection by the concerned State Licencing Authority and CDSCO. In general, all vaccines including the vaccines against Coronavirus infection manufactured/imported into the country are required to comply with the requirements and Guidelines specified in the Drugs and Cosmetics Rules, 1945 and New Drugs and

Clinical Trials (NDCT) Rules, 2019 and other applicable Guidelines published by CDSCO from time to time in case of manufacturer r-DNA derived vaccines the requirements and Guidelines prescribed by Department of Biotechnology are also required to be complied with.

In general, all vaccines including the vaccines against Coronavirus infection manufactured/imported into the country are required to comply with the requirements and Guidelines for CMC specified in the Drugs and Cosmetics Rules, 1945 and NDCT Rules, 2019 and other applicable Guidelines published by CDSCO from time to time. All vaccines are required to be characterized and manufactured in compliance with the Good Manufacturing Practices (GMP) as prescribed in the Rules.

Source: Shardul Nautiyal, Pharmabiz, 22.09.2020

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DoP to set up 10 Pharma clusters to equip MSMEs to meet Global Regulatory Standards

In a bid to encourage Pharma MSMEs to equip themselves to meet the regulatory requirements of Pharmaceutical Inspection Cooperation Scheme (PICS), the Department of Pharmaceuticals (DoP) is planning to set up 10 clusters in the country under its cluster development scheme with a grant-in-aid of Rs.20 crore for each cluster.

The interest subvention of five percent will also be offered under the scheme. Navdeep Rinwa, Joint Secretary, DoP made this announcement recently while addressing a video conference organized by PHD Chamber of Commerce and Industry (PHDCCI) on "The Future of Pharma Industry" to showcase the potential of Haryana attracting the investors to the state. The cluster development programme for Pharma sector (CDS-PS) was launched by the DoP on June 17, 2015 to provide support to Pharma SMEs to enhance their quality, productivity and innovative capabilities.

The aim of the scheme is to increase competitiveness, easy access to standard testing facilities and value addition in the domestic Pharma industry especially to SMEs through creation of common world class facilities such as common testing facilities, training centre, R&D centres, effluent treatment plant common logistics centre.

It will help industry meet the requirements of standards of environment at a reduced cost through innovative methods of common waste management system. The cost of production will be reduced by 20% in the clusters leading to better availability and affordability medicines in the domestic market.

Said Rinwa, India is taking steps to join PICS which will benefit the drug industry. For this, the drug units are required to upgrade/set up plants complying with global regulatory requirements and central and state drug regulators need to be trained along with upgradation of research facilities. The PICS membership offers a slew of benefits including reduced duplication of inspections, cost savings, export facilitation and enhanced market access. Currently 52 regulatory bodies from across the globe including US FDA, MHRA, PDMA are members of PICS.

The Joint Secretary, DoP said to make Indian drug industry competitive vis-a-vis China which is able to produce economically because of high scale of production, the Government is giving preference to high scale and high quality manufacturing. The Government has approved four schemes, two each for bulk drugs and medical devices parks. He exhorted the industry and the states to come forward and participate in these schemes.

He said that the Production Linked Incentive (PLI) schemes for promoting domestic manufacturing of KSMs, DIs and APIs and medical devices will go a long way in boosting domestic manufacturing of 53 bulk drugs for which India is critically dependent on imports. Speaking on the occasion, Sham Singla, Chairman, Haryana Pharma Committee, PHDCCI said Pharma is a thrust sector for most of the state Governments and also for the central Government. The Haryana Government has come forward in terms of formulating lucrative industrial policies for new investors. He added that the upcoming Pharma cluster in Karnal and API Park in Panipat would go a long way in making Haryana a preferred Pharma hub.

Anurag Aggarwal, MD, HSIIDC informed that Haryana will bid for the Pharmaceutical parks with full force and put forward the best proposals. He said that Haryana is ideal for setting up of the pharmaceutical parks due to its strategic advantage as Haryana surrounds Delhi from three sides providing access to nearly 11 percent of the domestic market. It has excellent road and air connectivity because 15 national highways are present in Haryana with four of them passing through Delhi-NCR region and has international airports in its vicinity at Delhi and Chandigarh.

B R Sikri, Vice President, Bulk Drugs Manufacturers Association of India stressed that transparency, ease of

doing business, location of all concerned offices in the park, single window system and deemed approval, competitive land cost etc will go a long way in success of proposed Pharmaceutical parks in Haryana.

Source: Laxmi Yadav, Pharmabiz, 22.09.2020

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Big opportunity for Indian exporters as Mexico faces severe shortage of cancer drugs

The oncology drug makers in India have a tremendous opportunity in Mexico which has witnessed one third of deaths due to cancer and is facing shortage of oncology products. In a bid to overcome the shortage of oncology drugs, Jalisco, one of the 32 states in Mexico, is looking to procure medicines directly from Indian companies. The Jalisco Government has proposed to the Indian Embassy in Mexico that they are interested in buying medicines directly from Indian firms, starting with oncological medicines which they would like to procure as soon as possible considering the shortage in the state.

The list of products required by the Jalisco Government includes bevacizumab, pertuzumab, cyclophosphamide monohydrate, trastuzumab, doxorubicin hydrochloride, ifosfamide, mitomycin, etoposide, rituximab, palonosetron, rituximab, carboplatin, docetaxel, dacarbazine, cytarabine, daunorubicin hydrochloride, ondansetron, imatinib mesylate, filgrastrim, thalidomide, lenalidomide, letrozole, fluorouracil, nilutamide, granisetron, eribulin mesylate, etc.

The manufacturers of oncology products having sanitary registration/approval of COFEPRIS (Mexico) or any other approvals such as Swiss Agency for Therapeutic Products (Swissmed), European Commission, US Food and Drug Administration, Ministry of Health of Canada, Therapeutic Products Administration of Australia, Regulatory Agency of reference of WHO/PAHO and regulatory agencies who are members of the Pharmaceutical Inspection Cooperation Scheme, can export them to Jalisco.

The oncology drugs prequalified by the prequalification program for medicines and vaccines of the World Health Organization are also eligible for the export to the Latin American country. Considering that this may be a big opportunity for the Indian companies, Pharmexcil has requested the member companies which can provide the said medicines in the list and have the sanitary registration/ approval of COFEPRIS (Mexico) or any other approvals as mentioned above to submit the details to it. It is advisable to analyze the overall need for a single import, because once the medicine has entered, it is mandatory to apply for health registration within 5 days for future imports (only the first entry of goods into the country is exempt from health registration). The entry must be by complete batches, no separate vials or unidose are allowed. From the amount entered into the country, 4 to 5% is taken to show compliance with national and international standards in regulation of good practices in the elaboration of medicines.

In Jalisco, public hospitals are affected by the shortage of cancer medicines. They buy the drugs from distributors certified by the Government who bring them from abroad, which is very costly, sources said, adding that the prices of oncology products have soared because of the shortages

Source: Laxmi Yadav, Pharmabiz, 26.09.2020

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Dassault Systèmes' 3D EXPERIENCE platform to accelerate Pharma manufacturing under Make in India Programme

In order to accelerate Pharma manufacturing under the Make in India programme, Dassault Systèmes is chipping in its expertise in frugal production techniques using digital technology. This according to the company will see India's workforce to be productive with the use of their 3D EXPERIENCE platform which will enable them in designing, engineering and manufacturing products in the country.

"What we are seeing now is a trade war between US and China. Here many companies are choosing to leave China to localize production in India. This is extremely important for this country which has started the 'Make in India' programme because it allows its manufacturers to become efficient and pursue excellence in plant engineering', said Bernard Charles, Vice Chairman, CEO, Dassault Systèmes.

Today, Pharmaceutical companies look for procedure execution with data and metadata capture with full instrument integration. A case in point is the IPCA Laboratories which recently installed Dassault's 'One Lab' platform that allows research, development, analytical and QC laboratories to become paperless support end-to-end systems.

At a recently held 'Dassault Systèmes, the 3D EXPERIENCE Forum India 2020', Charles said, "India by itself is a gigantic market with gigantic needs and a gigantic potential of talent. Hence, India is an important country for us because we have a lot to offer. There was a time when China was preferred for low cost and high quality production. But this is changing as Vietnam, Indonesia and India are becoming the destination of choice in Asia."

Stating that 60 percent of global Clinical Trials for COVID-19 vaccines are done on Dassault platform, Charles said this has enabled to speed up much of the human studies. Our Synthetic Control Arms platform is based on the data of 20 years of experiences to create virtual groups of certain population characterization and then compare with real group of people on the Clinical Trial.

"We are making huge progress with this because the Clinical Trials are targeting the right population and evaluating the risk quickly as well as the efficacy of the therapeutics," he said. According to Florence Verzelen, EVP, industry, marketing, global affairs, workforce of the future, Dassault Systèmes, "In India, we have seen dynamism across its universities to adopt the digital technologies and create curricular competency centres to train the new generation and make them agile with this kind of techniques. Only digital technologies can enable large output of production at an economical cost. This country is ideally positioned to play that card. It is here with education and the innovation centres, we can work along with different state Governments to use the 3D EXPERIENCE platform." A priority of Dassault Systemes is to partner with universities to create Centres of Excellence and provide experience based learning. Besides we will enable companies to collaborate with our Centre of Innovation, she added.

Source: Nandita Vijay, Pharmabiz, 26.09.2020

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Researchers at CCMB reveal Coronavirus in India has stable genome & can be effectively cured with vaccine

A team of researchers at Centre for Cellular and Molecular Biology (CCMB) in Hyderabad who have been working on identifying the true genetic characteristics of SARS-Cov-2 virus have revealed that the prevailing virus strain in India is having a highly stable genome and is showing a very slow genetic drift making it more suitable for a vaccine to cure it effectively.

According to Rakesh Mishra, Director of CCMB, a worldwide research has been taken up to study and identify how often the SARS CoV-2 virus is mutating. As part of this research, the Hyderabad based CCMB scientists have also taken up a genetic research on the COVID-19 virus and analyzed more than 2000 SARS-CoV-2 genomes secured from various parts of India and found that the virus unlike in its earlier days is hardly mutating and is found to be highly stable with a very low genetic biodiversity. "Unlike earlier days, the SARS-CoV-2 virus which is widely spreading across the world is now found to be hardly mutating. This is a positive sign, because viruses which have a stable genome can be easily cured by administering vaccine," informed the CCMB Director.

Revealing more on the genetic research on the SARS-Cov-2 virus, apart from CCMB research, similar research work was also carried out by genetic scientists in USA, wherein they have also conducted detailed genetic studies on 27977 SARS-Cov-2 virus sequences secured from 84 countries and studied its characteristics and tried to track its evolution since its origin. The US scientists have published the genetic study analysis of the same in the Proceedings of the National Academy of Sciences (PNAS) of USA. "Both the studies conducted at CCMB and those conducted by scientists in USA have shown common indication that the SARS-Cov-2 virus has a slow genetic mutation and is having a highly stable genome, making it suitable to be cured by a vaccine," revealed the Mishra.

It is learnt that a vaccine or viral drug can act effectively on a virus when and only when the genetic characteristics of that disease causing agent is stable. The CCMB Director said that continuous research on the novel Coronavirus will be on because to develop a drug or a vaccine knowing its characteristics is very important, or else it will impede the development of a broadly protective vaccine.

Source: A Raju, Pharmabiz, 26.09.2020

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Bring the Public Health Bill

The unprecedented healthcare crisis arising out of the COVID-19 pandemic has exposed the glaring gaps in the country's domestic laws in dealing with a pandemic of this scale which has infected around 50 lakh people in the country, and counting. When the pandemic raised its ugly head in the country in March this year, the Central Government was left with no other option but to direct

the state governments to invoke the Epidemic Diseases Act (EDA) of 1897 as there was no rationally structured domestic legislation to fall back on to tackle a pandemic like COVID-19 which was fast spreading its tentacles in the entire nook and corner of the country.

But, the fact is that the 123-year-old colonial law is hopelessly inadequate to deal with a pandemic like COVID-19 as it does not even define what a disease is, let alone an epidemic or a pandemic. It has proved to be a law which has outdated scope to handle emergencies of this scale and complexity. It was clear from the fact that most of the steps that the Central Government had taken to deal with the emerging situation were based on mainly administrative orders as there was no proper legislation which can handle a healthcare crisis of this magnitude.

The EDA, which is India's solitary law that has been historically used as a framework for containing the spread of various diseases including cholera and malaria, was drafted by the British Administration and came into effect on February 4, 1897, amidst the outbreak of the bubonic plague in Bombay. But, even that time the law proved to be inadequate, and the plague soon spread to Bangalore and other parts of India. It is sad to note that even after 123 years of its existence, the country is still depending on a colonial-era Act, the battered Section 144 of the IPC, which prohibits public gatherings, and the Disaster Management Act of 2005 to deal with a pandemic.

In contrast, democratic countries such as the US, UK, Australia, Canada, etc have in place more comprehensive and updated legislations to deal with public health emergencies such as the ongoing pandemic. These countries continuously adapt their existing laws to contemporary needs, enabling them to customise their responses to evolving emergencies.

It is under this background, healthcare professionals, activists and even politicians have urged the Government to study and introduce the lapsed Public Health Bill 2017 in the ongoing session of Parliament and refurbish it to meet the current requirements. Apart from several healthcare professionals and activists, senior Congress leader M Veerappa Moily also wrote a letter to Prime Minister Narendra Modi on April 9 this year, when the pandemic was at its nascent stage in the country, urging him to revive the lapsed Bill by promulgating an Ordinance which would give special powers to the Centre and States to deal with the COVID-19 crisis. In February 2017, the Union Health Ministry had come out with a draft Public Health (Prevention, Control and Management of Epidemics, Bioterrorism and Disasters) Bill which proposed to empower State and local authorities to take appropriate actions to tackle public health emergencies like epidemics and bioterrorism. It had clear-cut definitions for the terms epidemic, isolation, quarantine, social distancing, public health emergency, public health emergency of international concern, ground crossing, disinfection, decontamination, etc.

The Bill listed 33 epidemic-prone diseases which include anthrax, bird flu, dengue, HIV/AIDS, yellow fever, rabies, plague, measles, kala-azar, Ebola, Japanese Encephalitis among others. It also provided for repealing the Epidemic Diseases Act of 1897. However, the Bill did not get adequate support as concerns were raised over the sweeping powers it envisaged for the state to subject a person to compulsory treatment even without consent.

Hence it could not see the light of the day and lapsed. The COVID-19 pandemic has exposed the deep vulnerabilities and glaring gaps in the country's healthcare system and domestic laws pertaining to epidemics. The Government should now refurbish and re-introduce the lapsed Public Health Bill to meet the present day requirements. That is the need of the hour.

Source: Ramesh Shankar, Pharmabiz-Editorial, 23.09.2020

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Industry experts discuss regulatory roadmap for Pharma industry

There is a need for clear cut Research and Development policies in the Indian regulatory system, said Dr Eswara Reddy, Joint Drug Controller General of India, participating in this discussion, at a panel virtual on 'Regulatory roadmap to promote competitiveness & investments', held as part of CII Life Sciences Conclave 2020. During the discussion, he spoke on the challenges in the regulatory system and indicated that there is a need for revision in the legislation to address concerns in emerging areas.

He also informed about several challenges such as lack of research on regulatory science, the dearth of Guidance document availability, lack of a system to update the skill and knowledge of regulators etc. He also stressed that there is a need for a clear cut policy on paediatric drugs, FDCs, orphan drugs, etc, as well as a suitable mechanism to ensure confidentiality of submissions. He spoke about the proposed regulatory road map which will benefit the industry as well.

He informed that timelines are fixed for disposal of various applications and it has also initiated the deemed

approval concept. He indicated that the authorities are restructuring permission and mechanism for drug discovery, promoting drug discovery and innovation, streamlining and simplifying of various activities related to the approval process and also streamlining the regulatory process at the state level. The CDSCO is also proposing to have a centre for research excellence.

"Since the launch of Sugam portal, 60-70 percent activities are managed online and we are aiming to adopt complete paperless office," said Reddy. He also mentioned that with the authority intends to prepare policies on FDCs, vaccines, orphan drugs, paediatric drugs with international collaboration which will help the industry in complying with the global standards. Summing up, he said that moving forward, the industry wants to be a manufacturer of innovative products and the regulators are playing a facilitator's role to help the industry achieve this vision. He also stressed that there is a need for the regulatory authority to become more stringent. His fellow panel members also shared their viewpoints on the Government announced schemes and regulatory mechanism and shared a few suggestions.

Mr Mahesh Doshi, National President, IDMA requested that there should not be frequent changes in the regulatory system, its impact on the industry is adverse. Mr B R Sikri, Chairman, FOPE, and VP, BDMA suggested that there should be a time-bound scheme for existing chemical synthesis API manufacturers. He said that there are nearly a dozen of products where actual incentive works out to less than four percent as against 10 percent being claimed by the Government. So, again these products will not be manufactured and the basic purpose will get defeated.

He stated, "With regards to existing manufacturers who have the capacity to produce, we have given a list of the products which we can start tomorrow, then why can the Government not consider some incentive because otherwise, it is not viable to produce these products." He also urged that whatever commitments are being made by state Governments, it should have validity for a specific period to maintain or augment their rank of ease of doing business. V V Krishna Reddy, National President, Bulk Drug Manufacturers Association highlighted that the time taken for environment clearance is considerably longer than expected, the process should be speeded up by the authorities to encourage single-window clearance mechanism.

Vikrant Shrotriya, MD and Corporate Vice President, Novo Nordisk suggested waiving off the phase IV Clinical Trial for rare disease. He also made suggestions in the area of FDI and how advanced regulatory mechanisms can benefit the sector. Mahesh Bhalgat, COO, Syngene International added that for innovation in India, the industry needs support from the Government on all fronts. He also added that COVID–19 brought speed to the approval process in the Indian regulatory system which should be continued in the future too. He was the moderator of this panel discussion.

Source: Usha Sharma, Express Pharma, 01.10.2020

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As domestic sales decline, drug makers focus on exports to sustain growth

Exports are helping Pharmaceutical (Pharma) companies sustain the growth momentum as they launch new products and tap newer markets. While sales in the domestic market declined 4.2 percent during the April-July period, exports grew steadily at 9.5 percent during the same period. "Exports to South Africa and the UK (which are the No.2 and No.3 markets for Indian Pharma) have recovered after a decline in 2019-20. Exports to the US are growing steadily. Indian companies are also tapping new opportunities in Latin America. Earlier in the month, we signed an agreement with the state of Hidalgo in Mexico to promote exports and investment in that country. Mexico is still a small market for us, but was the fastest growing export destination in the April-July period.

Currently, the country largely depends on the US and Europe for its medicines. Indian companies are looking to grow their share by supplying antibiotics, antivirals, and chronic therapy drugs," said Ravi Uday Bhaskar, Director General of Pharmaceuticals Export Promotion Council of India (Pharmexcil). During April-July, drug makers exported products worth $7.4 billion — a growth of 9.5 percent year-on-year (YoY). While the export of formulations and biologicals rose 16.7 percent, the export of bulk drugs and intermediates fell 7.2 percent. Vaccine exports, too, were lower by 19 percent YoY as immunisation programmes took a back seat due to the Covid-19 pandemic.

"Our key markets — the US and South Africa — are driving growth for us. We have had meaningful launches like the first generic version of Albuterol (bronchodilator) in April and have a strong product pipeline in the US, especially in the respiratory segment. With fewer elective surgeries, we have been able to grow fast in both the markets because of new products and commercial excellence," said Kedar

Upadhye, Global Chief Financial Officer, Cipla. Drugmaker Lupin expects its exports to stabilise to pre-Covid levels in the next two quarters, with the launch of new products in Europe and the US. These include biosimilar Etanercept in Europe and Albuterol in the US. The company has also reintroduced key anti-diabetic drugs like Glumetza and Fortamet in the US, following a voluntary recall earlier this year. Rating agency CRISIL expects Indian Pharma exports to grow at 11-12 percent in the current financial year and outpace the domestic market, which is estimated to grow 5-6 percent. This would result in 8-9 percent overall growth for the industry. According to CRISIL, growth in exports to regulated markets like the US and Europe will be supported by a steady increase in new product launches from compliant plants, lower pricing pressure on existing generics, and a visible easing in scrutiny by the US Food and Drug Administration in recent months. Tanvi Shah, Associate Director, CRISIL Ratings, said, "Higher exports should offset some of the reduction in domestic formulation sales because of pandemic-led disruptions, especially in the acute therapies segment (around 60 percent of domestic formulation sales)."

Source: Business Standard, 28.09.2020 (Excerpts)

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INTERNATIONAL NEWS

Drug makers, BMGF pledge to strive for Global access to COVID-19 Diagnostics, Therapeutics and Vaccines

Several Global Life Sciences Companies and the Bill & Melinda Gates Foundation have pledged and committed to expand Global access for COVID-19 diagnostics, therapeutics, and vaccines. In a collective statement, they informed, "COVID-19's existence anywhere poses a threat to communities everywhere. The health, social and economic impacts can only be addressed through the collective actions of stakeholders across private, public, and philanthropic sectors in partnership with civil society.

As organisations dedicated to improving and protecting global health, with our varied skills, roles, and resources, we remain committed to doing our part in ending this pandemic worldwide." The statement said, "Earlier this year AstraZeneca; Bayer; bioMérieux; Boehringer Ingelheim; Bristol Myers Squibb; Eisai; Eli Lilly; Gilead; GSK; Johnson & Johnson; Merck & Co (known as MSD outside the US and Canada); Merck KGaA, Darmstadt, Germany; Novartis; Pfizer; Roche; and Sanofi together with the Bill & Melinda Gates Foundation each pledged ourselves to the fight against COVID-19."

The companies and BMGF said that through partnerships with other stakeholders they will strive to ensure global access to diagnostics, therapeutics, and vaccines that will help to accelerate the end of the pandemic. To accomplish this critical goal, they promised to:

Develop innovations for patients worldwide:

"We will continue advancing the Research and Development of COVID-19 diagnostics, therapeutics, and vaccines that are suitable to meet the needs of populations around the world. To do so, we will work to expand Clinical Trials to account for diverse representation including lower-income settings and endeavour to address the specific product characteristics needed for use in lower-income settings even after new innovations are brought forward," assured the companies through a statement.

Strive for timely availability:

"By scaling up manufacturing at unprecedented speed and much earlier than usual, we will bring large quantities of safe and effective innovations to countries around the world for broad distribution as early as possible, no matter their income level. Mechanisms for rapidly escalating supply must be aligned with the specific context of a rapid pandemic response and tailored to each product, with options including early voluntary licensing and appropriate approaches to peer-to-peer innovator company manufacturing agreements," they pledged.

Enable affordability for lower income countries:

The companies said, "We will pursue a range of approaches to make products we are developing or supporting affordable in lower-income countries. These approaches will be independently determined by each supplier in response to the pandemic to address the significant affordability challenges, including approaches such as donations,

not-for-profit supply, or equity-based tiered pricing based on countries' needs and capabilities."

Support effective and equitable distribution of these innovations globally:

"We will strive towards equitable allocation of our products and support global mechanisms like COVAX, recognising the most effective approach to equitable access will vary across vaccines, therapeutics, and diagnostics. We also will use our collective voice alongside other global health stakeholders to advocate for the strengthening of health systems and distribution networks so crucial innovations reach everyone who needs them. In doing so, we support evidence-based prioritisation so that healthcare workers, high-risk individuals, and other priority groups identified by WHO and other health authorities are protected for the duration of the pandemic, regardless of the country they live in. We will advocate for equitable distribution, recognizing that sovereign nations have final decision-making authority," they stated.

Maintain public confidence in our innovations:

"We will continue making the safety of individuals who receive products we are developing or supporting the highest priority. Adherence to the strictest scientific and ethical standards in product development and in manufacturing processes will remain the top priority over speed or politics," guaranteed the drug makers.

The Collaboration has also called upon Governments, multilateral institutions, companies, NGOs, and others to:

- Provide sufficient, dedicated, sustainable, and timely funding for the procurement and delivery of the tools necessary to end the COVID-19 pandemic.
- Diversify representation in critical decision-making and coordination bodies with special emphasis on voices representing low-income and lower-middle-income countries.
- Continue quickly developing and communicating clear Guidance on product needs in lower resource settings as early as possible as our understanding of COVID-19 and the tools to combat it evolve.
- Advance fit-for-purpose regulatory and liability processes for all stakeholders involved, which prioritize safety while not slowing down access to critical new tools.
- Build and maintain public confidence in the approval mechanisms for diagnostics, therapeutics, and vaccines by ensuring robust safety and efficacy reviews and removing unwarranted political considerations from these discussions and the approval process.
- Enhance country readiness and in-country delivery systems by ensuring adequate expertise and resources are in place for effective country planning, distribution, and follow-up for new diagnostics, therapeutics, and vaccines.

Source: Express Pharma, 01.10.2020 (Excerpts)

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