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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
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IDMA BULLETIN

Vol. No. 51 **Issue No. 24** **22 to 30 June 2020**

IDMA Comments to Department of Pharmaceuticals (DoP) on Draft EIA Notification 2020

The Association has submitted the following comments on 23rd June 2020 to Mr Mohd Farhan, Technical Consultant (Pharma), Pharma Bureau, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi in response to their email dated 19th June 2020 on the above subject. The said Submission was also made to Secretary, MoEF&CC:

"Greetings from Indian Drug Manufacturers' Association.

At the outset we wish to once again reiterate that in order to increase production of APIs in the country, it is absolutely necessary that the Government does away with the cumbersome archaic guidelines of environmental controls which presently also control manufacturing activities of Active Pharmaceutical Ingredient (API) producers along with the effluent characteristics. Nobody disputes the need to ensure environment is not polluted. But that can be achieved simply by ensuring adequate Common Effluent Treatment Plants (CETPs) are installed so that all discharges from API units are fed to them. Then all that is needed is to just monitor functioning of CETPs and discharge from them, leaving API units to concentrate on manufacturing of drugs.

EIA Notification 2020 continues with the cumbersome procedures and highly technical Guidelines which can be understood by very few. Most MSMEs (who comprise bulk of API manufacture in the country) cannot understand the fine print of the 83 page document. What we need is simplified Guidelines which do away with numerous layers of permissions as presently required before being able to produce the API, and which still continue to be part of the new document. At least for API manufacture, a simplified version is need of the hour. Consent as broad category of "API & Intermediates" with no control over quantity of production, are need of the hour.

In spite of our reservations towards continuation of such a bulky document, as per your request we have made several suggestions which are highlighted in yellow in the attached draft*. They can be broadly classified under following heads chronologically:

1. Few amendments to "Definitions" and addition of Sr. No. (39) for Industries Areas set up prior to 1994/2006 – also additions in Para 14.
2. Some suggestions for Expert Appraisal Committee (EAC) such as age limit for Members, more independent ones, expediting approvals etc (Para 6).
3. Broad basing of SEIAA/UTEIAA and no break in appointment of fresh committee once term of earlier one is over. Suggestions for expediting permission procedures also for SEAC/DEAC (Para 7 & 8).
4. Prior EC/EP – new clause for simplification (Para 10).
5. Scoping – Suggested reduction in timelines to expedite process (Para 12). Amendment in prior EC/EP (Para 18).
6. Optional procedure for EIA Report preparation. Confidential process details not to be part of application (Para 13).
7. Timelines too long. Reduced days suggested for "Public Consultation" (Para 14) and "Appraisal" (Para 15).
8. For grant of Prior-EC, suggested more liberal exemption criteria. Declaration of 'No increase in pollution load' should suffice instead of prior permission (Para 16).
9. Suggestions regarding "Amendment in prior-EC/ EP" (Para 19), and "Monitoring of post project prior EC/EP" for greater flexibility (Para 20).
10. In Schedule for list of Projects needing prior EC/EP" Sr. No. 21, 25 and 27 changes suggested. Mainly inclusion of API manufacture under B2 category irrespective of size of unit.
11. Reduction in timelines as in Appendices 2.3, 2.4 and 3.1.
12. In order to ensure time bound clearances of all applications, wherever time lines are specified, it should be added that "if no decision is taken within that stipulated period then the application will be deemed to have been approved". Thanking you and with warm regards."

*(*Not reproduced here)*

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Processing of Export/Import permits and Route change - Digitalization of issuance of permits and facilitation of smooth trade by permitting route change – IDMA Repn.

IDMA has submitted the following representation on 22nd June 2020 to Shri Anil Kumar Jha, Additional Secretary (Revenue), Department of Revenue, Ministry of Finance, New Delhi with copies to Shri Ritvik R Pandey, IAS, Joint Secretary (Revenue), Department of Revenue, Shri Dinesh Bouddh, Director (Narcotics), Department of Revenue, Ministry of Finance, Shri Rakesh Asthana, IPS, Director General, Narcotics Control Bureau, Shri R N Srivastava, IRS, Deputy Director General (Operations), Narcotics Control Bureau, New Delhi, Shri Gyan Sarvar, IRS, Narcotics Commissioner, Central Bureau of Narcotics, Gwalior, MP on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

IDMA had submitted a representation to Department of Revenue on the aforesaid subject matter on May 8th, 2020 requesting URGENT consideration for streamlining the procedure of application, processing and issuance of export authorization/import licence/NOC and route change and amendment of the NDPS Rules/RCS Order, 2013 to facilitate "Ease of doing business" and digitilisation of the process.

Another representation was made to the Narcotics Commissioner, dated June 1st, 2020 and a copy marked to your kind attention, that due to the continued disruption of international airlines, lockdown in several countries, lockdown in several metro cities of India and non-functioning of administrative functions in Companies, we had requested for continuance with the procedure, as stipulated in the April 1st, 2020 Public Notices, **for a period of 3 months, post complete lifting of Lockdown by the Government of India.** This would also provide necessary time for normalization of business activities, post the lockdown, in various parts of the world and India.

With this letter, we also humbly request that as a result of digitalization of the import/export applications, the processing time under Rule 56 (1) and 59 (1) of the NDPS Rules 1985 & Clause 10 (3) & 11 (3) of the RCS Order, 2013 may also be kindly amended to **10 working days in place of 21 working days**. The processing time in USA and Europe is generally 7 working days. This would enable India to be competitive with the western countries in turning around time or exports, in line with these countries.

The above is an **URGENT** need of the hour and we humbly request a speedy consideration and amendment of the NDPS Rules/RCS Order, 2013 and consideration of our representation to Narcotics Commissioner on extension of the Public notices, for a period of 3 months post the lifting of the lockdown, to facilitate "Ease of doing business" and digitilisation of the process. Thanking you."

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India playing 'Pharmacy of the World' role during Covid-19 crisis: SCO Secretary-General

Vladimir Norov, Secretary General of Shanghai Cooperation Organization (file photo) - Reuters

India is playing the role as the Pharmacy of the world during the Covid-19 pandemic with its vast experience and in-depth knowledge in medicine, setting the tone for many regional and global initiatives, Shanghai Cooperation Organisation Secretary-General Vladimir Norov has said.

India has so far supplied medicines to 133 countries in the fight against Covid-19, which shows India's generosity, although the country's Government has taken urgent measures to prevent and treat the disease on a national scale, Norov told in an interview.

This is a worthy and responsible example of the behaviour of a major power, and at the same time demonstrates the complementarity and mutual support of the SCO member states, he said. India last week overwhelmingly won the election to the United Nations Security Council (UNSC) for a non-permanent seat.

Commenting on India's election to the UNSC, Norov, who visited New Delhi in January this year and held extensive talks with the top Indian leadership, said that the country's entry into the powerful UN organ is more than symbolic.

This is more than symbolic now as India secures its non-permanent membership in the UN Security Council for the period of 2021-2022. I am sure that highly qualified scientists and medical professionals in India will take an active part in the efforts of the world community to study and research the Coronavirus pandemic and develop a vaccine, Norov said.

India plays the role of the 'Pharmacy of the world', and in terms of a pandemic, it is crucial in a global context, he said. Beijing-headquartered SCO is an eight-member economic and security bloc. India and Pakistan were admitted into the grouping in 2017. Its founding members include China, Russia, Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan.

India today sets the tone in many regional and global initiatives. It has a good reason for this: it relies on its vast experience and deep knowledge in the field of medicine and health management, including the production of high quality, affordable medicines, equipment and vaccines, said Norov, the former foreign Minister of Uzbekistan.

India has become the world's largest producer of generic medicines, accounting for 20 percent of the total global production, and meeting 62 percent of the worldwide demand for vaccines, he said. Norov said that taking into account India's commitment to international cooperation and solidarity, as well as its positive contribution to supporting the world's most important institutions of cooperation, he gives it a priority in efforts to reach a consensus on the central role of the UN and the World Health Organization (WHO).

He said that India has also played an active role in assisting many countries, including the SCO member states, in the supply of medicines and essential drugs. With India's accession into the SCO as a full member, new opportunities for further development and deepening of full-scale cooperation have opened up, the Secretary-General of the grouping said.

India's policy and practice in the international arena in the context of the Coronavirus pandemic have fully proved the correctness of the course outlined by Prime Minister Narendra Modi at the Bishkek Summit in 2019 - the priority of cooperation in the field of health, he said. Norov also

made a special mention of Modi's proposals to evolve a common vision for strengthening healthy cooperation in the region.

At the last SCO Summit, Modi made several proposals to activate key areas of interaction. He noted that there should be a common vision of strengthening healthy cooperation in our region.

In his opinion, the letters that add up as the word HEALTH can be a great format for collaboration: H- Healthcare cooperation, E-Economic cooperation, A-Alternative energy sources, L-Literature and culture, T-Terrorism free society, H-Humanitarian cooperation, he said.

India has far-reaching broad plans to increase the role and authority of the SCO in the international arena, Norov added.

Source: PTI Beijing, The Hindu Business Line/Reuters, 21.06.2020

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IDMA applauds donation of 2.50 lakh strips of Vitamin D jointly by FBL-Indchemie to Maharashtra Police

Maharashtra Police had requested for donation of Vitamin D tablets and other Vitamins such as Vitamin C to be provided for Police personnel all over Maharashtra for boosting their immunity during the COVID-19 pandemic. Many IDMA Members responded to the request and donated the Vitamins generously (as reported in *IDMA Bulletin* dated 30 May 2020).

Maharashtra Police requested for more Vitamin D tablets. We are proud to inform that our Members, Fermenta Biotech Ltd (FBL - formerly known as DIL Ltd) and Indchemie Health Specialities Pvt Ltd came forward to manufacture 2.50 lakh strips (2.5 lakh strips X 8 tablets per strip = 20 lakhs tablets) of the brand DV 60K, each strip containing recommended dosage sufficient for two months specially for Maharashtra Police as a joint CSR initiative. Vitamin D has been shown to play an important role in immunity support. The tablets were delivered to Maharashtra Police earlier this month by **Shri Srikant Sharma, Vice-President, Legal and Company Secretary, FBL.** Through this initiative, we join our Members in thanking the Corona Warriors who work tirelessly to protect us in these challenging times.

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Procedure for Transhipment of Export Cargo from Bangladesh to third countries through LCSs to Port/Airport, in containers or closed bodied trucks - reg.

Customs Circular No.29/2020, dated 22nd June, 2020

To
The Principal Chief Commissioner/Chief Commissioner of Customs,
The Principal Commissioners/Commissioner of Customs.

The undersigned is directed to refer to Circular No. 42/2018-Customs dated 02nd November, 2018, which was issued to facilitate exports of Bangladesh to third countries, via transhipment through India. It provides detailed procedure of transhipment, in terms of section 54 of the Customs Act, 1962 (hereinafter referred as the "Act"), from LCS to Port/Aircargo as listed below:

Sr.No.	From (LCS)	To (Port/Aircargo)
1.	LCS Petrapole	By road to: i) Kolkata Port ii) Aircargo complex, Kolkata iii) Nhavasheva Port
2.	i) LCS Petrapole ii) LCS Gede/ Ranaghat	By rail to Nhavasheva Port

Through the aforesaid Circular, transhipment facility was introduced on pilot basis to gain experience and obtain feedback from industry, so as to frame a facilitative regulation with adequate safeguards. The aforesaid Circular has been extended from time to time, and the last extension was granted till 30th June, 2020 vide letter No.550/02/2018-LC dated 5th February, 2020.

After reviewing the utilization and other relevant aspects, and with a view to facilitating trade, Board has decided to continue the facility under Circular No. 42/2018-Customs as below:

3.1 Transhipment of goods from LCS Petrapole to Aircargo complex, Kolkata, shall be continued following the procedure prescribed in the aforesaid Circular, until further direction from the Board.

Other transhipment movements listed in the above table, shall be continued following the procedure prescribed in the aforesaid Circular, until the Sea Cargo Manifest and Transhipment Regulations, 2018 (hereinafter referred to as "SCMTR 2018") is fully implemented, upon which the procedure of SCMTR 2018 shall apply:

It is clarified that regulation 7 of SCMTR 2018 prescribes a form for the purposes of transhipment and transit of goods from a sea port to a land customs station and vice-versa. Hence, the movement of Bangladesh third country export cargo, from land customs stations to sea ports, as specified in the Table at Para 1, shall be guided by SCMTR 2018 from date of its implementation.

Further, attention is drawn to regulation 10 of the SCMTR 2018 which mandates the authorized carrier to provide track and trace facility for locating goods brought for transhipment. Regulation 9 of SCMTR 2018 provides for sealing of cargo meant for transhipment by land route. It is clarified that presently the electronic cargo tracking system (LCTS) and ECTS seals are being provided by M/s Transecur Telematics Private Limited **(www.transecur.com)** under ADB's Pilot Program for monitoring of traffic in transit of Nepal. The authorized carriers have an option to use same for transhipment of goods from Bangladesh, in absence of any other facility.

Difficulties, if any, faced in the implementation of this Circular should be brought to the notice of the Board.

F.No.550/02/2018-LC

Dr Swati Bhanwala, OSD (Land Customs), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

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Electronic Communication of PDF based copies of Shipping Bill & e-Gatepass to Custom Brokers/Exporters – reg.

Customs Circular No.30/2020, dated 22nd June, 2020

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

In its continuing endeavor to promote 'Faceless, Contactless, Paperless Customs' Board has decided to rely upon digital copies of the Shipping Bill and do away with the requirement of taking bulky printouts from the Service Centre or maintenance of voluminous physical dockets in the Custom Houses. This reform will yield immense benefits in terms of saving the time and cost of compliance for the trade, thereby enhancing the ease of doing business, while providing enhanced security features for verification of authenticity and validity of the electronic document.

Board directs that **w.e.f. 22.06.2020** only the digital copy of the Shipping Bill bearing the Final LEO would be electronically transmitted to the exporter and the present practice of printing copies of the said document for the exporters and also for maintaining a docket in the Customs House would stand discontinued. This reform complements the introduction of a digital pdf Out-of-Charge (OOC) copy of the Bill of Entry and Gatepass w.e.f. 15.04.2020 and launch of the 1st Phase of Faceless Assessment at Chennai and Bengaluru w.e.f. 08.06.2020.

The salient features of the secure electronic communication of the Final LEO copy of the Shipping Bill and the Gatepass copy of Shipping Bill are as follows:

3.1. Final Let Export Order (LEO) Copy of Shipping Bill:

3.1.1 After the review of the matter of taking printouts of Shipping Bills in 2016, Board vide Circular No. 55/2016-Customs dated 23.11.2016, had done away with Exchange Control copy of the Shipping Bill and made printing of the Export Promotion copy of the Shipping Bill optional.

3.1.2 Currently, the Shipping Bill is being printed in duplicate, namely Customs Copy and Exporter Copy. Further, it is ascertained that, the Export Promotion copy is also being printed in many instances, based on the request of the exporters. This necessitates the exporter/Customs Broker to take physical printouts in the Service Center and present it to the Customs Officer. In many locations, physical signing of the printouts is also insisted upon.

3.1.3 To promote a paperless environment, Board has decided to do away with the taking the printouts referred to in para 3.1.2 above. Instead, Directorate General of Systems has enabled a functionality of communicating by email, the PDF version of the Final LEO copy of the Shipping Bill to the Customs Broker and exporter, if registered. This electronic Final LEO copy can serve multiple purposes such as being shared with DGFT, Banks etc. This Final LEO copy of the Shipping Bill will have the following features:

a. The PDF version will bear a digitally signed and encrypted QR code which can be scanned to verify the authenticity of the document using Mobile App ICETRAK. The QR code is tamper proof, which is digitally signed by CBIC to ensure the authenticity. Key details like SB No., SB Date, FOB value, Package Details are available in the secured QR Code.

b. A version number is also embedded in the QR code which can be used to ascertain whether the document is indeed the latest version (in case of cancellation of LEO etc.). The same would be verifiable at ICEGATE Enquiry.

3.1.4 Let Export Order (LEO) message shall also be sent to custodians who are integrated with ICEGATE. In this connection, it may be noted that **the SB LEO message is not being received electronically by those custodians who are NOT connected via MFTP.** Field formations are urged to immediately ensure the registration of all custodians with the ICEGATE system. Directorate General of Systems' advisory No.14/2019 dated 06.12.2019 in this regard may be followed.

3.2 e-Gatepass Copy of Shipping Bill:

3.2.1 It is a well-known fact that, the Shipping Bill printout is also being used extensively by the logistics operators during the movement of export goods, including transhipment, by road or rail or during the loading of cargo into vessels, aircrafts etc as a proof of export. This is despite the electronic information existing in the Customs Automated System and Board having made printing and use of Transference copies of Shipping Bill optional. Therefore, taking cognizance of the logistics needs, the Directorate General of Systems would henceforth communicate through email, the eGatepass PDF copy of the Shipping Bill to the Customs Broker and the Exporter, if registered. Accordingly, Board has decided to do away with the printing of Transference copies of Shipping Bill. The following are the features of eGatepass copy of the Shipping Bill:

a. The electronic document provides key summary details like Container/Packages related to logistics movement and facilitates authentic, easy and quick verification by the Custodian, at the point of Entry/Exit.

b. There will be two types of QR codes (i) for entire eGatepass document, and (ii) for each container/ package covered under the eGatepass. This will ensure that only those containers/package move out which are covered under the Gatepass document.

c. In case of packaged and other bulk cargos, the eGatepass copy of the Shipping Bill will be generated during LEO.

d. In case of containerised cargo, the eGatepass copy of the Shipping Bill will be generated after the receipt of the container stuffing information for the SB.

It is re-iterated that for the purposes of exports, all the supporting documents should mandatorily be uploaded in eSanchit and collection of physical dockets shall be dispensed with.

It is possible that there may be scenarios other than those mentioned above, where printouts of Shipping Bills are required. Board desires that such scenarios shall be immediately informed. The respective Principal Commissioners/Commissioners of Customs would take a decision on allowing printouts only in such exceptional situations.

Suitable Trade Notice/Standing Order may be issued to guide the trade and industry. Difficulty, if any, faced in implementation of this Circular may be brought to the notice of Board immediately.

F.No.450/26/2019-Cus. IV

Ananth Rathakrishnan, Deputy Secretary (Customs), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

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Issuance of Preferential Certificate of Origin for India's exports to Vietnam under ASEAN-India FTA - reg.

DGFT Trade Notice No.15/2020-2021, dated 21st June, 2020

To,
All Exporters/Members of Trade,
All Designated Issuing Agencies under FTAs/PTAs.

Reference is invited to Trade Notice No.12/2020-2021 dated 22.05.2020 issued in view of the various representations received from exporters expressing difficulties in obtaining preferential access in Thailand and Vietnam based on the digitally signed electronic Certificates of Origin and manual applications for the said countries was allowed.

The given issue has been taken up and it is decided that one additional copy i.e. electronic copy along with the set of 4 copies shall be generated by the system. The electronic copy shall bear the image signature of the officer and stamp of the issuing agency. Exporters may send the electronic copy to the partner country for any immediate clearance. Where required, the exporter may also collect the other set of printed certificates (in quadruplicate) duly ink-signed by the officer along with the stamp from the designated office for any subsequent submission to the partner country authorities.

The COO applications for exports under ASEAN-India FTA to all ASEAN countries except Thailand should now be submitted through the e-COO Platform by the exporters to the offices of the designated issuing agencies i.e. EIA, MPEDA and Textile Committee. No physical application shall be accepted from 22.06.2020. However, manual applications submitted prior to the given date may be issued.

These agencies (EIA, MPEDA and Textile Committee) will henceforth issue the Certificate of Origin online and provide on request the printed copy of certificate along with stamp and wet-ink signature of the issuing officer to the exporter.

This issues with the approval of the Competent Authority.

File No.01/02/82/AM-19/EDI

Md Moin Afaque, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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Launch of new DGFT platform and Digital delivery of IEC related services – reg.

DGFT Trade Notice No.16/2020-21, dated 25th June 2020

To,
1. All members of Trade/Trade Associations and other stakeholders of DGFT,
2. Regional Authorities (RAs) of DGFT.

1. As part of Digital India programme and for Ease of Doing Business, DGFT has undertaken an initiative to revamp its services delivery mechanisms to promote and facilitate foreign trade. As a step in that direction, the first phase of a new digital platform of DGFT is scheduled to Go-Live on **13th July 2020**. The platform will become accessible through the existing website: **https://www.dgft.gov.in**

2. In the first phase, the website will be catering to the services related to the IEC issuance, modification, amendments etc processes along with a Chatbot (a virtual assistant) catering to queries of users. Other online modules relating to Advance Authorisation, EPCG, and Exports Obligation Discharge which are part of next phase will be rolled out subsequently after the first phase stabilizes.

The following important points may be noted with regard to the new platform design:

i. Access to the services would be through a username and password based system. The first time logins/user ID may be created through a registration process on the new platform.

ii. For user ID creation, registered mobile number/email ids of the IEC holders will be mandatorily required. The same will be authenticated by the process of OTP/ email based authentication process.

iii. Users would have to link their login IDs to their specific IECs. The process of linking would be available post login through Digital Signature/Aadhaar based e-Sign.

iv. **Digital Signature (DSC)/Aadhaar based e-Sign will be required for applying and modifying IEC or adding or updating the IEC-linked users.** Users may take necessary actions for procuring/updating their information etc on the DSC/Aadhaar.

3. The user profile can be then used by the IEC holders to engage with DGFT and its services. This will enable the user to electronically file their application related to IEC, AA, EPCG, including amendments & redemption, monitoring the status of the application, raising queries, replying to the deficiencies etc. among other services related to the Foreign Trade policy.

4.The new platform is also designed for smooth migration of legacy (older) data of DGFT and its stakeholders. The existing data will be used for the online processing of the previous applications henceforth. The users will be able to monitor the status of their applications and the pending obligations thereof. These numerous features should significantly benefit the trade community. Users are requested to familiarize themselves about the new platform and its features.

5. DGFT RAs are directed to intimate the staff/officials about the launch of the new platform. All the staff/officials must have an NIC/GOV email ids with updated mobile numbers. The same will be used in the Back Office (BO) portal of the new platform. RAs are also directed to spread awareness about the new platform among the trade stakeholders. Staff/Officials may also refer to the content about the platform provided to them during the training sessions.

6. It is further informed that for the purposes of go-live of first phase and the required systems configurations, **the IEC applications and modification process would be suspended from 3:00 pm on 10.07.2020 till 13.07.2020**. Stakeholders are requested to plan in advance about the IEC services.

7. In case of any issues/queries you may contact DGFT Helpdesk at 1800-111-550 from 9:00 am to 6:00 pm Monday to Saturday.

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

File No.01/02/29/AM20/EGTF

Tasleem Ahmed, Asst. Director General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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Glenmark, Cipla, Hetero receive DCG(I) approval for COVID-19 treatments

Glenmark launches oral antiviral Favipiravir for treatment of mild to moderate COVID-19

- *Manufacturing and marketing approval granted as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in India.*
- *The approval's restricted use entails responsible medication use where every patient must have signed informed consent before treatment initiation.*
- *Favipiravir shows clinical improvements of up to 88% in COVID-19, with rapid reduction in viral load by 4 days.*
- *Clinical improvement noted across age groups 20 to >90 years, including in patients with co-morbid conditions like diabetes and heart disease suffering from mild to moderate COVID-19.*
- *Glenmark to market the antiviral under the brand name 'FabiFlu®'.*

In a landmark development for COVID-19 patients in India, Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, announced the launch of antiviral drug Favipiravir (brand name FabiFlu®) for the treatment of mild to moderate COVID-19 patients. Glenmark has received manufacturing and marketing approval from India's drug regulator, making FabiFlu® the first oral Favipiravir-approved medication in India for the treatment of COVID-19. Favipiravir is backed by strong clinical evidence showing encouraging results in patients with mild to moderate COVID-19. The antiviral offers broad spectrum RNA virus coverage with clinical improvement noted across age groups 20 to >90 years. Favipiravir can be used in COVID-19 patients with co-morbid conditions such as diabetes and heart disease with mild to moderate COVID-19 symptoms. It offers rapid reduction in viral load within 4 days and provides faster symptomatic and radiological improvement. Of most importance, Favipiravir has shown clinical improvement of up to 88% in COVID-19 mild to moderate COVID-19 cases. Glenmark successfully developed the Active Pharmaceutical Ingredient (API) and the formulation for FabiFlu® through its own in-house R&D team. Glenmark filed the product for Clinical Trial with India's drug regulator DCGI and became the first pharmaceutical company in India to receive approval for conducting phase 3 clinical trial on mild to moderate COVID-19 patients. Commenting on the significance of this development, Mr Glenn Saldanha, Chairman and Managing Director of Glenmark Pharmaceuticals Ltd., said, "This approval comes at a time when cases in India are spiralling like never before, putting a tremendous pressure on our healthcare system. We hope the availability of an effective treatment such as FabiFlu® will considerably help assuage this pressure, and offer patients in India a much needed and timely therapy option."

He added, "FabiFlu® has demonstrated an encouraging response in mild to moderate COVID-19 patients during clinical trials. Moreover, it is orally administered, and so it serves as a more convenient treatment option over other intravenously administered medications. Glenmark will work closely with the Government and medical community to make FabiFlu® quickly accessible to patients across the country". Favipiravir is approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. It has a unique mechanism of action: it is converted into an active phosphoribosylated form (favipiravir-RTP) in cells and recognized as a substrate by viral RNA polymerase, thereby inhibiting RNA polymerase activity. Most patients exhibiting mild to moderate symptoms can benefit from FabiFlu® use. The drug will be available as a prescription-based medication for INR 103/tablet, with recommended dose being 1800 mg twice daily on day 1, followed by 800 mg twice daily up to day 14. Earlier last month, Glenmark also announced that it is conducting another clinical trial to evaluate the efficacy of two antivirals Favipiravir and Umifenovir as a combination therapy in moderate hospitalized adult COVID-19 patients in India.

Source: Glenmark Press Release, 20.06.2020

Cipla launches Remdesivir lyophilised powder for injection 100 mg treatment for patients with severe COVID-19

Cipla Limited (BSE: 500087; NSE: CIPLA EQ, hereinafter referred to as "Cipla"), announced the launch of Remdesivir under its brand name CIPREMI. The US FDA issued an Emergency Use Authorization (EUA) to Gilead Sciences Inc for emergency use of Remdesivir for the treatment of hospitalized 2019 Coronavirus disease (COVID-19) patients. It is the only US FDA approved Emergency Use Authorisation (EUA) treatment for adult and paediatric patients hospitalized with suspected or laboratory confirmed COVID-19 infection. In May, Gilead Sciences Inc extended a voluntary non-exclusive license to Cipla to manufacture and market Cipla's generic version of Remedisvir called CIPREM.

Cipla has been granted regulatory approval by the Drug Controller General of India (DCGI) for restricted emergency use in the country as part of the accelerated approval process considering the urgent and unmet medical need. As part of a risk management plan, Cipla will provide training on use of the drug, informed patient consent documents, conduct post marketing surveillance as well as conduct a Phase IV clinical trial on Indian patients.

According to a preliminary report from the ACTT-1 (Adaptive COVID-19 Treatment Trial 1) study, a randomized clinical trial conducted with Remdesivir in 1063 patients over 60 centres across US, Europe and Asia demonstrated a faster time to clinical recovery in hospitalised patients as compared to placebo. Most of these patients were on oxygen therapy of which some were receiving high flow oxygen or non-invasive ventilation, and some were on a mechanical ventilator. The mortality rates in the study were 7.1% in those given Remdesivir and 11.9% in those who were given placebo. As part of its efforts to enable speedy and equitable access to this treatment and in anticipation of demand, Cipla will be commercializing Remdesivir through its own facilities and partnered sites. The drug will be supplied through Government and open market channels, to ensure equitable distribution. Commenting on the launch, Mr. Umang Vohra (MD and Global CEO, Cipla Limited) said, "Cipla appreciates the strong partnership with Gilead to bring Remdesivir to patients in India. We have been deeply invested in exploring all possible avenues to save millions of lives impacted by COVID-19 pandemic, and this launch is a significant milestone in that direction. We will continue to collaborate with all stakeholders in the healthcare ecosystem towards providing access to such promising treatments in furtherance with our belief that no patient should be denied access to life-saving treatments."

Source: Cipla Press Release, 21.06.2020

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Hetero announces generic Remdesivir for treatment of Covid-19

Hetero, one of India's leading generic pharmaceutical companies, announced that it has received the manufacturing and marketing approval for the investigational antiviral medicine 'Remdesivir' from the Drug Controller General of India (DCGI) for the treatment of Covid-19. Hetero's generic version of Remdesivir will be marketed under the brand name 'COVIFOR' in India. Dr B Partha Saradhi Reddy, Chairman, Hetero Group of Companies, commented: "In the light of increasing COVID-19 cases in India, the approval of 'COVIFOR' (Remdesivir) can prove to be a game-changer given its positive clinical outcomes. Backed by strong backward integration capabilities, we can ensure that the product is immediately made available to patients across the country. We are prepared for ensuring enough stocks required to cater to the present needs. We will continue to work closely with the Government and medical community to make a difference in the fight against COVID-19. This product is made indigenously in line with 'Make in India' campaign as envisioned by our Hon'ble Prime Minister." The drug 'Remdesivir' has been granted approval by DCGI for the treatment of suspected or laboratory-confirmed cases of COVID-19 in adults and children, hospitalized with severe symptoms of the disease. COVIFOR (Remdesivir) will be available in 100 mg vial (Injectable) which has to be administered intravenously in a hospital setting under the supervision of a healthcare practitioner. The product is launched under a licensing agreement with Gilead Sciences Inc to expand access to COVID-19 treatment in low and middle-income countries.

Source: Hetero Press Release, 21.06.2020

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Ministry of Micro, Small and Medium Enterprises (MSMEs) launches another funding scheme to help the distressed MSME sector

The Scheme will provide Rs. 20,000 crore of guarantee cover to two lakh MSMEs.
This is a sub-debt facility to the promoters of those operational MSMEs which are distressed or NPA

Ministry of MSME Press Release dated 24th June 2020

Minister of MSME, Shri Nitin Gadkari launched the Credit Guarantee Scheme for Sub-ordinate Debt (CGSSD) which is also called "Distressed Assets Fund–Sub-ordinate Debt for MSMEs".

As per the Scheme, the guarantee cover worth Rs. 20,000 crores will be provided to the promoters who can take debt from the banks to further invest in their stressed MSMEs as equity.

It was being felt that the biggest challenge for stressed MSMEs was in getting capital either in the form of debt or equity. Therefore, as part of Atmanirbhar Bharat package, on 13th May, 2020, Finance Minister had announced this scheme of sub-ordinate Debt to the promoters of operational but stressed MSMEs. After completion of necessary formalities including approval of CCEA and consultation with Finance Ministry, SIDBI and RBI among others, the scheme was formally launched by Shri Gadkari from Nagpur.

The highlights of the scheme are:

- This Scheme seeks to extend support to the Promoter(s) of the operational MSMEs which are stressed and have become NPA as on 30th April, 2020;
- Promoter(s) of the MSMEs will be given credit equal to 15% of their stake (equity plus debt) or Rs. 75 lakh whichever is lower;
- Promoter(s) in turn will infuse this amount in the MSME unit as equity and thereby enhance the liquidity and maintain debt-equity ratio;
- 90% guarantee coverage for this sub-debt will be given under the Scheme and 10% would come from the concerned promoters;
- There will be a moratorium of 7 years on payment of principal whereas maximum tenor for repayment will be 10 years.

It is expected that this scheme would provide much required support to around 2 lakh MSMEs and will help in reviving the economic activity in and through this sector. It will also help in protecting the livelihoods and jobs of millions of people who depend on them. Promoter(s) of MSMEs meeting the eligibility criteria may approach any Scheduled Commercial Banks to avail benefit under the scheme. The scheme will be operationalised through Credit Guarantee Fund Trust for MSEs (CGTMSE). Necessary Guidelines alongwith answers to possible FAQs have been issued and made public in this regard.

On this occasion, Shri Nitin Gadkari thanked the Prime Minister and Finance Minister for this Scheme. He also thanked the officials of Department of Expenditure, Department of Financial Services and Governor of RBI for supporting this innovative Scheme of the Ministry.

Source: PIB, MoMSME Press Release, 24.06.2020

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Shri Gowda holds meeting with pharmaceutical officers to review various aspects of proposed Bulks drugs and medical device park

Ministry of C&F Press Release dated 24th June 2020

Minister of Chemicals and Fertilisers Shri D V Sadananda Gowda held a meeting with senior officers of Department of Pharmaceuticals to review various aspects of proposed development of three Bulk Drug

Parks and four Medical Device Parks across the country. The meeting was attended by MoS Shri Mansukh Mandaviya, Secretary Pharmaceuticals Dr P D Vaghela, Joint Secretary Shri Navdeep Rinwa and Dr S Eswara Reddy, Joint Drugs Controller.

Shri Gowda and Shri Mandaviya suggested that the modalities of selection of locality of parks as well as of beneficiaries under PLI scheme should be based on some well-defined objective criteria to ensure orderly development of the parks.

Shri Gowda further said that these schemes will increase competitiveness of domestic production of Bulk Drugs and medical devices due to benefits available in clusters in the form of state of art common infrastructure and logistics facilities. Development of these parks will not only reduce our dependency on imports but will also be helpful in making India a major player in global pharma exports. With rising per capita income and increasing prevalence of lifestyle diseases, the out of pocket expenditure on medicines and devices like stent is set to accelerate in future. The vision of the Prime Minister Shri Narendra Modi to make affordable medicines available to every citizen requires that medicines are produced in the country at cheaper rate. These schemes are the need of the hour.

With Prime Minister Modi's thrust on building "Atma Nirbhar Bharat" and strengthening of drug security, the Union Cabinet has approved schemes for supporting development of three Bulk Drugs Parks and four Medical Device Parks on March 21, 2020 in order to reduce dependency on imports and boost local manufacturing and employment.

Under promotion of Bulk Drug Parks, Government of India will give one-time grants-in-aid to three Bulk Drug Parks with a maximum limit of Rs. 1000 Crore per Bulk Drug Park, or 70% (90% in case of hilly States and North Eastern Region) of the project cost of Common Infrastructure Facilities whichever is less. In addition, Government has also approved Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of 53 identified critical KSMs/Drug Intermediates and APIs in the country with outlay of Rs 6,940 crore during the tenure of the scheme from 2020-21 to 2027-28.

Similarly, for promotion of Medical Device Parks, Government of India will give one-time grants-in-aid to four Medical Device Parks with a maximum limit of Rs. 100 Crore per Medical Device Park, or 70% (90% in case of hilly States and North Eastern Region) of the project cost of Common Infrastructure Facilities whichever is less. In addition, Government has also approved Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of medical devices in the country with outlay of Rs 3,420 crore during the tenure of the scheme from 2020-21 to 2025-26.

Secretary, Pharmaceuticals gave a brief on various aspects of bulk drug and medical device parks, and said that the Department is in process of formulating guidelines for implementation of these schemes.

Source: PIB, MoC&F Press Release, 24.06.2020

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Extension of various time limits under Direct Tax & Benami laws

Ministry of Finance Press Release dated 24th June 2020

In view of the challenges faced by taxpayers in meeting the statutory and regulatory compliance requirements across sectors due to the outbreak of Novel Corona Virus (COVID-19), the Government brought the Taxation and Other Laws (Relaxation of Certain Provisions) Ordinance, 2020 [the Ordinance] on 31st March, 2020 which, inter alia, extended various time limits. In order to provide further relief to the taxpayers for making various compliances, the Government has issued a Notification on 24th June, 2020, the salient features of which are as under:

I. The time for filing of original as well as revised income-tax returns for the FY 2018-19 (AY 2019-20) has been extended to **31st July, 2020.**

II. Due date for income tax return for the FY 2019-20 (AY 2020-21) has been extended to 30th November, 2020. Hence, the returns of income which

are required to be filed by 31st July, 2020 and 31st October, 2020 can be filed upto 30th November, 2020. Consequently, the date for furnishing tax audit report has also been extended to 31st October, 2020.

III. In order to provide relief to small and middle class taxpayers, the date for payment of self-assessment tax in the case of a taxpayer whose self-assessment tax liability is upto Rs. 1 lakh has also been extended to 30th November, 2020. However, it is clarified that there will be no extension of date for the payment of self-assessment tax for the taxpayers having self-assessment tax liability exceeding Rs. 1 lakh. In this case, the whole of the self-assessment tax shall be payable by the due dates specified in the Income-tax Act, 1961 (IT Act) and delayed payment would attract interest under section 234A of the IT Act.

IV. The date for making various investment/payment for claiming deduction under Chapter-VIA-B of the IT Act which includes section 80C (LIC, PPF, NSC etc.), 80D (Mediclaim), 80G (Donations) etc has also been further extended to 31st July, 2020. Hence the investment/ payment can be made upto 31st July, 2020 for claiming the deduction under these sections for FY 2019-20.

V. The date for making investment/construction/ purchase for claiming roll over benefit/deduction in respect of capital gains under sections 54 to 54GB of the IT Act has also been further extended to 30th September, 2020. Therefore, the investment/ construction/ purchase made up to 30th September, 2020 shall be eligible for claiming deduction from capital gains.

VI. The date for commencement of operation for the SEZ units for claiming deduction under section 10AA of the IT Act has also been further extended to 30th September, 2020 for the units which received necessary approval by 31st March, 2020.

VII. The furnishing of the TDS/TCS statements and issuance of TDS/TCS certificates being the prerequisite for enabling the taxpayers to prepare their return of income for FY 2019-20, the date for furnishing of TDS/TCS statements and issuance of TDS/ TCS certificates pertaining to the FY 2019-20 has been extended to 31st July, 2020 and 15th August, 2020 respectively.

VIII. The date for passing of order or issuance of notice by the authorities and various compliances under various Direct Taxes & Benami Law which are required to be passed/ issued/ made by 31st December, 2020 has been extended to 31st March, 2021. Consequently, the date for linking of Aadhaar with PAN would also be extended to **31st March, 2021.**

IX. The reduced rate of interest of 9% for delayed payments of taxes, levies etc specified in the Ordinance shall not be applicable for the payments made after **30th June, 2020.**

The Finance Minister has already announced extension of date for making payment without additional amount under the *"Vivad Se Vishwas"* Scheme to 31st December 2020, necessary legislative amendments for which shall be moved in due course of time. The said Notification has extended the date for the completion or compliance of the actions which are required to be completed under the Scheme by 30th December, 2020 to 31st December, 2020. Therefore, the date of furnishing of declaration, passing of order etc under the Scheme stand extended to 31st December, 2020.

Deferment of the implementation of new procedure for approval/ registration/ notification of certain entities u/s 10(23C), 12AA, 35 and 80G of the IT Act has already been announced vide Press Release dated 8th May, 2020 from 1st June, 2020 to 1st October, 2020. It is clarified that the old procedure i.e. pre-amended procedure shall continue to apply during the period from 1st June, 2020 to 30th September, 2020. Necessary legislative amendments in this regard shall be moved in due course of time.

The Finance Minister has already announced reduced rate of TDS for specified non-salaried payments to residents and specified TCS rates by 25% for the period from 14th May, 2020 to 31st March, 2021. The announcement was also followed by the Press Release dated 13th May, 2020. The necessary legislative amendments in this regard shall be moved in due course of time.

Source: PIB, MoF Press Release, 24.06.2020

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Central Goods and Services Tax (Removal of Difficulties) Order, 2020 – reg.

Gazette Notification No.S.O.2064(E), dated 25th June 2020

(No.01/2020-Central Tax)

WHEREAS, sub-section (2) of section 29 of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as the said Act) provides for cancellation of registration by proper officer in situations described in clauses (a) to (e) as under: -

(a): a registered person has contravened such provisions of the Act or the rules made there under as may be prescribed; or

(b): a person paying tax under section 10 has not furnished returns for three consecutive tax periods; or

(c): any registered person, other than a person specified in clause (b), has not furnished returns for a continuous period of six months; or

(d): any person who has taken voluntary registration under sub-section (3) of section 25 has not commenced business within six months from the date of registration; or

(e): registration has been obtained by means of fraud, willful misstatement or suppression of facts:

Provided that the proper officer shall not cancel the registration without giving the person an opportunity of being heard.

AND WHEREAS, sub-section (1) of section 169 of the said Act provides for service of notice (opportunity of being heard); clauses (c) and (d) of said sub-section are as under: -

(c): by sending a communication to his e-mail address provided at the time of registration or as amended from time to time; or

(d): by making it available on the common portal; or

AND WHEREAS, sub-section (1) of section 30 of the said Act provides for application for revocation of cancellation of the registration within thirty days from the date of service of the cancellation order;

AND WHEREAS, sub-section (1) of section 107 of the said Act provides for filing appeal by any person aggrieved by any decision or order passed by an adjudicating authority within three months from the date on which the said decision or order is communicated to such person and sub-section (4) of section 107 of the said Act empowers the Appellate Authority that it may, if he is satisfied that the appellant was prevented by sufficient cause from presenting the appeal within the aforesaid period of three months, allow it to be presented within a further period of one month;

AND WHEREAS, a large number of registrations have been cancelled under sub-section (2) of section 29 of the said Act by the proper officer by serving notices as per clause (c) and clause (d) of sub-section (1) of section 169 of the said Act and the period of thirty days provided for application for revocation of cancellation order in sub-section (1) of section 30 of the said Act, the period for filing appeal under section (1) of section 107 of the said Act and also the period of condoning the delay provided in sub-section (4) of Section 107 of the said Act has elapsed; the registered persons whose registration have been cancelled under clause (b) or clause (c) of sub-section (2) of section 29 of the said Act are unable to get their cancellation of registration revoked despite having fulfilled all the requirements for revocation of cancellation of registration; the said Act being a new Act, these taxpayers could not apply for revocation of cancellation within the specified time period of thirty days from the date of service of the cancellation order, as a result whereof certain difficulties have arisen in giving effects to the provisions of sub-section (1) of section 30 of the said Act;

NOW, THEREFORE, in exercise of the powers conferred by section 172 of the Central Goods and Services Tax Act, 2017, the Central Government, on the recommendations of the Council, hereby makes the following Order, to remove the difficulties, namely: —

1. Short title: This Order may be called **the Central Goods and Services Tax (Removal of Difficulties) Order, 2020.**

2. For the removal of difficulties, it is hereby clarified that for the purpose of calculating the period of thirty days for filing application for revocation of cancellation of registration under sub-section (1) of section 30 of the Act for those registered persons who were served notice under clause (b) or clause (c) of sub-section (2) of section 29 in the manner as provided in clause (c) or clause (d) of sub-section (1) of section 169 and where cancellation order was passed up to 12th June, 2020, the later of the following dates shall be considered:-

a): Date of service of the said cancellation order; or

b): 31st day of August, 2020.

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.

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Government notifies criteria for classifying Micro, Small and Medium Enterprises: Udyam Registration – reg.

Gazette Notification No.S.O.2119(E), dated 26th June 2020

1. In exercise of the powers conferred by sub-section (1) read with sub-section (9) of section 7 and sub-section (2) read with sub-section (3) of section 8, of the Micro, Small and Medium Enterprises Development Act, 2006, (27 of 2006), hereinafter referred to as the said Act, and in supersession of the notifications of the Government of India in the Ministry of Micro, Small and Medium Enterprises Number S.O.1702 (E), dated the 1st June, 2020, S.O.2052(E), dated the 30th June, 2017, S.O.3322(E), dated the 1st November, 2013 and S.O.1722 (E), dated the 5th October, 2006, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (11), except as respects things done or omitted to be done before such supersession, the Central Government, after obtaining the recommendations of the Advisory Committee in this behalf, hereby notifies certain criteria for classifying the enterprises as Micro, Small and Medium Enterprises and specifies the form and procedure for filing the Memorandum (hereafter in this Notification to be known as "Udyam Registration''), with effect from the 1° day of July, 2020, namely:--

1. Classification of enterprises:

An enterprise shall be classified as a Micro, Small or Medium Enterprise on the basis of the following criteria, namely:--

(i) a micro enterprise, where the investment in plant and machinery or equipment does not exceed one crore rupees and turnover does not exceed five crore rupees;

(ii) a small enterprise, where the investment in plant and machinery or equipment does not exceed ten crore rupees and turnover does not exceed fifty crore rupees; and

(iii) a medium enterprise, where the investment in plant and machinery or equipment does not exceed fifty crore rupees and turnover does not exceed two hundred and fifty crore rupees.

2. Becoming a Micro, Small or Medium Enterprise:

(1) Any person who intends to establish a Micro, Small or Medium Enterprise may file Udyam Registration online in the Udyam Registration portal, based on self-declaration with no requirement to upload documents, papers, certificates or proof.

(2) On registration, an enterprise (referred to as "Udyam" in the Udyam Registration portal will be assigned a permanent identity number to be known as "Udyam Registration Number".

(3) An e-certificate, namely, "Udyam Registration Certificate" shall be issued on completion of the registration process.

3. Composite criteria of investment and turnover for classification:

(1) A composite criterion of investment and turnover shall apply for classification of an enterprise as micro, small or medium.

(2) If an enterprise crosses the ceiling limits specified for its present category in either of the two criteria of investment or turnover, it will cease to exist in that category and be placed in the next higher category but no enterprise shall be placed in the lower category unless it goes below the ceiling limits specified for its

present category in both the criteria of investment as well as turnover.

(3) All units with Goods and Services Tax Identification Number (GSTIN) listed against the same Permanent Account Number (PAN) shall be collectively treated as one enterprise and the turnover and investment figures for all of such entities shall be seen together and only the aggregate values will be considered for deciding the category as Micro, Small or Medium Enterprise.

4. Calculation of investment in plant and machinery or equipment.--

(1) The calculation of investment in plant and machinery or equipment will be linked to the Income Tax Return (ITR) of the previous years filed under the Income Tax Act, 1961.

(2) In case of a new enterprise, where no prior ITR is available, the investment will be based on self-declaration of the promoter of the enterprise and such relaxation shall end after the 31st March of the Financial Year in which it files its first ITR.

(3) The expression "plant and Machinery or Equipment" of the enterprise, shall have the same meaning as assigned to the plant and machinery in the Income Tax Rules, 1962 framed under the Income Tax Act, 1961 and shall include all tangible assets (other than land and building, furniture and fittings).

(4) The purchase (invoice) value of a plant and machinery or equipment, whether purchased first hand or second hand, shall be taken into account excluding Goods and Services Tax (GST), on self-disclosure basis, if the enterprise is a new one without any ITR.

(5) The cost of certain items specified in the *Explanation I* to sub-section (1) of section 7 of the Act shall be excluded from the calculation of the amount of investment in plant and machinery.

5. Calculation of turnover:

(1) Exports of goods or services or both, shall be excluded while calculating the turnover of any enterprise whether Micro, Small or Medium, for the purposes of classification.

(2) Information as regards turnover and exports turnover for an enterprise shall be linked to the Income Tax Act or the Central Goods and Services Act (CGST Act) and the GSTIN.

(3) The turnover related figures of such enterprise which do not have PAN will be considered on self-declaration basis for a period up to 31st March, 2021 and thereafter, PAN and GSTIN shall be mandatory.

6. Registration process:

(1) The form for registration shall be as provided in the Udyam Registration portal.

(2) There will be no fee for filing Udyam Registration.

(3) Aadhaar number shall be required for Udyam Registration.

(4) The Aadhaar number shall be of the proprietor in the case of a proprietorship firm, of the Managing Partner in the case of a partnership firm and of a karta in the case of a Hindu Undivided Family (HUF).

(5) In case of a Company or a Limited Liability Partnership or a Cooperative Society or a Society or a Trust, the organisation or its authorised signatory shall provide its GSTIN and PAN along with its Aadhaar number.

(6) In case an enterprise is duly registered as an Udyam with PAN, any deficiency of information for previous years when it did not have PAN shall be filled up on self-declaration basis.

(7) No enterprise shall file more than one Udyam Registration:

Provided that any number of activities including manufacturing or service or both may be specified or added in one Udyam Registration.

(8) Whoever intentionally misrepresents or attempts to suppress the self-declared facts and figures appearing in the Udyam Registration or updation process shall be liable to such penalty as specified under section 27 of the Act.

7. Registration of existing enterprises:

(1) All existing enterprises registered under EM—Part-II or UAM shall register again on the Udyam Registration portal on or after the 1st day of July, 2020.

(2) All enterprises registered till 30th June, 2020, shall be re-classified in accordance with this notification.

(3) The existing enterprises registered prior to 30 June, 2020, shall continue to be valid only for a period up to the 31st day of March, 2021.

(4) An enterprise registered with any other organisation under the Ministry of Micro, Small and Medium Enterprises shall register itself under Udyam Registration.

8. Updation of information and transition period in classification:

(1) An enterprise having Udyam Registration Number shall update its information online in the Udyam Registration portal, including the details of the ITR and the GST Return for the previous financial year and such other additional information as may be required, on self-declaration basis.

(2) Failure to update the relevant information within the period specified in the online Udyam Registration portal will render the enterprise liable for suspension of its status.

(3) Based on the information furnished or gathered from Government's sources including ITR or GST return, the classification of the enterprise will be updated.

(4) In case of graduation (from a lower to a higher category) or reverse-graduation (sliding down to lower category) of an enterprise, a communication will be sent to the enterprise about the change in the status.

(5) In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise will maintain its prevailing status till expiry of one year from the close of the year of registration.

(6) In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place.

9. Facilitation and grievance redressal of enterprises:

(1) The Champions Control Rooms functioning in various institutions and offices of the Ministry of Micro, Small and Medium Enterprises including the Development Institutes (MSME-DI) shall act as Single Window Systems for facilitating the registration process and further handholding the Micro, Small and Medium Enterprises in all possible manner.

(2) The District Industries Centres (DICs) will also act as Single Window facilitation Systems in their Districts.

(3) Any person who is not able to file the Udyam Registration for any reason including for lack of Aadhaar Number, may approach any of the above Single Window Systems for Udyam Registration purposes with his Aadhaar enrolment identity slip or copy of Aadhaar enrolment request or bank photo pass book or voter identity card or passport or driving licence and the Single Window Systems will facilitate the process including getting an Aadhaar number and thereafter in the further process of Udyam Registration.

(4) In case of any discrepancy or complaint, the General Manager of the District Industries Centre of the concerned District shall undertake an enquiry for verification of the details of Udyam Registration submitted by the enterprise and thereafter forward the matter with necessary remarks to the Director or Commissioner or Industry Secretary concerned of the State Government who after issuing a notice to the enterprise and after giving an opportunity to present its case and based on the findings, may amend the details or recommend to the Ministry of Micro, Small or Medium Enterprises, Government of India, for cancellation of the Udyam Registration Certificate.

F.No.21(5)/2019-P&G/Policy-(Pt-IV)

A K Sharma, Secretary, Ministry of Micro, Small and Medium Enterprises, Government of India, New Delhi.

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NEW DEVELOPMENTS

IICT working on repurposing of important drug compounds to develop affordable medicines for COVID-19

The Indian Institute of Chemical Technology (IICT) is working on repurposing of some of the important drug compounds to develop medicines that can be used in the effective treatment of COVID-19 disease spreading like wildfire in India and across the globe.

Dr S Chandrasekhar, Director of IICT, while speaking at a Webinar on the initiatives taken up by the institute to contain the deadly Coronavirus pandemic, informed that a team of scientists from the IICT has been working on developing a new process technology wherein some of the existing potential drug compounds such as Favipiravir, Remdesevir and Umifenovir which are available drugs used in the treatment of other diseases, can be effectively repurposed to treat the prevailing deadly Coronavirus and that too at a very low and affordable cost.

Delivering his speech on the topic of 'Mitigating COVID-19', the IICT Director said that ever since the outbreak of Coronavirus global pandemic, the IICT scientific community has been working tirelessly in extending a helping hand to the Government and the public to mitigate and contain the spread of the deadly virus. "Ever since the COVID-19 outbreak IICT has been intensively involved testing of drugs, vaccines, Personal Protective Equipments (PPEs) and self hygiene solutions. Our team of scientists has been working continuously to a solution in

the form of drugs and protection gear to reach the society at affordable prices," said Dr Chandrasekhar.

Adding further, the IICT Director also informed that the medical grade masks and face shields used in various Government hospitals and by common people in the society are designed and developed after technical approval by the IICT researchers. Principal scientists Dr Prathama S Mainker and Dr Ch Raji Reddy gave important insight of the drug development journey of IICT. They said they are seriously working on the repurposing of important available medicines like Favipiravir, Remedesevir and Umifenovir, which have been found effective in dealing with prevailing Coronavirus. Currently, we are working on developing a process technology so that it will enable to repurpose the available potential drugs so that we can bring out most effective medicines at affordable cost to treat the deadly COVID-19 disease," observed the Principal Scientists from IICT.

Source: A Raju, Pharmabiz, 16.06.2020

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Researchers identify potent antibody cocktail to treat COVID-19

Researchers at the University of Maryland School of Medicine (UMSOM) evaluated several human antibodies to determine the most potent combination to be mixed in a cocktail and used as a promising anti-viral therapy against the virus that causes COVID-19. Their research, conducted in collaboration with scientists at Regeneron Pharmaceuticals, was published in the journal *Science.* The study demonstrates the rapid process of isolating, testing and mass-producing antibody therapies against any infectious disease by using both genetically engineered mice and plasma from recovered COVID-19 patients.

The antibody cocktail evaluated by UMSOM researchers will be used to treat COVID-19 patients in a clinical trial that was launched last week. The study was funded by Regeneron, a biotechnology company based in Tarrytown, New York.

Antibodies are proteins the immune system naturally makes in response to foreign invaders like viruses and bacteria. Antibody therapies were first tried in the late 19th century when researchers used a serum derived from the blood of infected animals to treat diphtheria.To produce the so-called monoclonal antibodies for an antibody cocktail to fight COVID-19, the researchers first needed to identify which antibodies fight the novel Coronavirus most effectively.

This involved determining which antibodies could bind most effectively to the spike protein found on the surface of SARS-CoV-2, the virus that causes COVID-19. The Regeneron team evaluated thousands of human antibodies from plasma donations from recovered COVID-19 patients. They also generated antibodies from mice genetically engineered to produce human antibodies when infected with the virus.

"The ability of the research team to rapidly derive antibodies using these two methods enabled us screen their selected antibodies against live virus to determine which had the strongest anti-viral effects," said study co-author Matthew Frieman, Ph.D.,, Associate Professor of Microbiology and Immunology at the University of Maryland School of Medicine. He has been studying Coronaviruses for the past 16 years and has been carefully studying SARS-CoV-2 in his secure laboratory since February.

Dr Frieman and his UMSOM colleagues evaluated four of the most potent antibodies for to determine the potential of each one to neutralize the SARS-CoV-2 virus. They identified the two that would form the most powerful mix when used in combination.

"An important goal of this research was to evaluate the most potent antibodies that bind to different molecules in the spike protein so they could be mixed together as a treatment," said study co-author Stuart Weston, Ph.D., a post-doctoral research fellow in the Department of Microbiology and Immunology. The cocktail containing the two antibodies is now being tested in a new clinical trial sponsored by Regeneron that will investigate whether the therapy can improve the outcomes of COVID-19 patients (both those who are hospitalized and those who are not). It will also be tested as a preventive therapy in those who are healthy but at high risk of getting sick because they work in a healthcare setting or have been exposed to an infected person.

"Our School of Medicine researchers continue to provide vital advances on all fronts to help fight the COVID-19 pandemic and ultimately save lives," said Dean E Albert Reece, MD, Ph.D., MBA, who is also Executive Vice President for Medical Affairs, UM Baltimore, and the John Z and Akiko K Bowers Distinguished Professor, University of Maryland School of Medicine. "This particular research not only contributes to a potential new therapy against COVID-19 but could have broader implications in terms of the development of monoclonal antibody therapies for other diseases."

Source: University of Maryland School of Medicine, Science Daily/World Pharma News, 16.06.2020 (Excerpts)

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India plans list of substitute Nations for critical imports

The Government is working on a list of alternative countries that could be suppliers of critical components that cannot currently be manufactured domestically, officials said.

"DPIIT (Department for Promotion of Industry and Internal Trade) is working with the industry to line up a list of low-quality imports from China. The next step is to substitute them, internally or externally," a Government official told. "The engagement looks to firm up tariff and non-tariff measures to curb imports of raw, intermediary and finished products from China."

Once DPIIT is ready with the list, the Government will reach out to countries and work out ways to incentivize supply to the Indian market, even as it tries to encourage domestic manufacturing of the goods, officials added.

The move is a part of a large exercise undertaken by the Government to relook the Free Trade Agreements to ensure cheap Chinese products do not flood the Indian market, establish stringent quality controls that would disqualify a host of Chinese imports, and incentivise producers to relocate production to India — boosting manufacturing and exports under likes of the Production-Linked Incentive scheme.

"The Government is cognizant of the fact that dependence on China cannot go away overnight. There is an overall focus on a calibrated effort to discourage imports from that country, by sourcing them from other destinations, even as India tries to ramp up its manufacturing abilities," another official said.

The official added that Southeast Asian countries, along with Japan and South Korea, have emerged as possible destinations, but the comparative price factor vis-à-vis India remains a concern. "For non-critical sectors like textiles, electronics, we should look for new sources in Southeast Asia as there is not much difference in respect to labour cost arbitrage. At the same time, we should take more and more sector-specific measures to make our Small and Medium Enterprises produce them in a competitive manner," said Bipul Chatterjee, Executive Director, CUTS International, a global public policy think-tank promoting consumer welfare through trade, regulations and Governance.

Source: Anandita S Mankotia & Dipanjan Ray Chaudhary, The Economic Times, 26.06.2020

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Ancient Drug brought into Covid Battle

Findings suggest 'clinical benefits'; the drug is available in India, say doctors

A 2,000-year-old medicine might offer hope in the fight against Covid-19. A new study published in the Journal of *American Medical Association* (JAMA) suggested that anti inflammatory drug colchicine, which is prescribed for gout, can provide significant benefit to those hospitalised with Covid-19.

"The findings of the present study suggest a significant clinical benefit from colchicine in patients hospitalised with Covid-19," the study said. Known since ancient times, colchicine was extracted from herbaceous plant Colchicum autumnale. In 1819, French pharmacists isolated a peculiar substance in the roots of Colchicum autumnale. A German pharmacist further analysed it in 1833 and coined the name colchicine.

The drug was tested on 105 Greek patients hospitalised with Covid-19. Besides receiving standard antibiotics and antivirals (but not remdesivir), half of the particapants got daily doses of colchicine for up to three weeks, while the other half did not.

The results suggest a significant clinical benefit from colchicine in patients who are hospitalised with Covid-19. Doctors in India say the drug is commonly available in the

country and is also used in some heart conditions. Dr Anoop Misra, Chairman at Fortis C-DOC (Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology) Hospital, is hopeful. "Simple, low cost and widely available drugs need to be repurposed for Covid-19 treatment. Colchicine seems promising according to this randomised trial, and it must be tested in our population," he said.

Colchicine is available in India under different brand names. The latest data from market research firm AIOCD's tracking solution Pharma Trac shows that Colchicine is sold in India by **Ajanta Pharma as Geton** and by **Inga Labs Pvt Ltd as Goutnil.** The study was published in JAMA Network Open on June 24. "The results of the GRECCO-19 trial suggest that colchicine is "safe" and may improve outcomes in patients with Covid-19," it said.

Adding that data need to be corroborated with larger, longer term studies. The new study also suggests that colchicine has anti-inflammatory and anti-clotting effects that could help limit the cardiovascular damage wreaked by Covid-19. JAMA pointed that the study "provides intriguing initial data on the effect of colchicine on clinical outcomes in patients with Covid-19".

The GRECCO-19 trial was an open-label RCT with 1:1 randomization comparing optimal medical treatment plus colchicine with optimal medical treatment alone (control group) among 105 patients from 16 Greek medical centres.

Source: Teena Thacker, The Economic Times, 26.06.2020

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Cutting China ties not easy, drug imports up 28% since Doklam

India's aspiration to reduce its dependency on China in the pharmaceutical sector has remained on paper so far, show figures. During the 2017 Doklam standoff, Indian manufacturers of Active Pharmaceutical Ingredients (APIs) had called for policies to reduce imports of the key raw material from China and increase their local production. The Government, too, had similar plans.

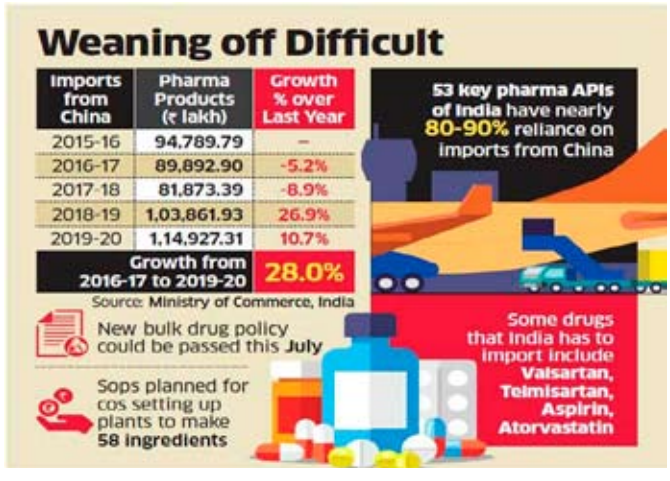
The country's imports of pharmaceutical products from China, however, rose to ₹1,150 crore in 2019-20 from ₹947 crore in 2015-16, a cumulative growth of 28%, according to data from the Commerce Ministry. Imports of miscellaneous pharma products jumped 58% to ₹276 crore in this period. Including pharma ingredients, chemicals and Key Starting Materials that get reported in various other categories, India's imports from China are estimated to be about $2 billion (₹15,250 crore) a year.

Drug makers say that the low cost of importing these items, along with slow movement on the policy front for encouraging the domestic bulk drug industry, led companies to continue relying on Chinese imports.

As tensions rise over the border dispute at the Galwan valley, trade between the two neighbours is under stress, with an increasing call to cut imports from the neighbouring country. As per industry estimates, as much as 70% of India's API requirements, a key starting material required for manufacturing anti-infectives to anti-cancer medication, come from China. For certain products like penicillin and azithromycin, imports account for 80-90%.

The dependence has only increased since the Covid-19 outbreak. While India had bought kits used for antibody tests from China, local pharma companies are paying three times more for procuring bulk drugs, as travel bans and logistical issues pushed up the price of several APIs.

"The Covid pandemic is a wakeup call that we should not be dependent on only one country for our medicine supply," said Sudarshan Jain, the Secretary General of the Indian Pharmaceutical Alliance, a lobby group of the top ten Indian drug manufacturers. Jain said it would take at least two to three years for Indian companies to put up a new bulk drug manufacturing unit. And companies need incentives like cheaper land, power, faster environmental clearances and financial schemes to compete with Chinese manufacturers.



The new API policy floated by the Ministry of Chemicals admits that despite India being the third largest pharma exporter in the world, about two-thirds of its API requirements were met through imports for economic

reasons. The new bulk drug policy that is expected to get passed next month offers incentives for drug manufacturers who are setting up manufacturing plants to produce 58 key drug ingredients that India currently is heavily dependent on imports, especially from China.

For the Indian pharma sector, it is a déjà vu of 2017:

During the Doklam border dispute between India and China, there were similar tensions of a trade war. But within a year India's imports not only returned to normal levels but grew in double digits. In 2017, the Indian Drug Manufacturers' Association, the lobby group of domestic manufacturers, had suggested that India impose higher registration fees on imports from China and increase the inspection of goods coming from the country.

(This story has not been edited by economictimes.com and is auto–generated from a syndicated feed ET subscribe to)

Source: Divya Rajagopal, The Economic Times, 22.06.2020

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Coronavirus: CSIR, Cipla Phase-II trial result on Favipiravir projects 20-30% cheaper drugs

Multi-centre Phase-II drug trial being done by the Council of Scientific and Industrial Research (CSIR) shows that its drug can cost lesser by at least 20-30 per cent of the current price. As per the results, it could lead to a major reduction in the cost of the drug required for the treatment of mild and moderate symptoms of coronavirus.

Barely a day after Indian pharma firm Glenmark Pharmaceuticals launched antiviral drug Favipiravir as "FabiFlu" for Covid-19 patients with mild and moderate symptoms, another multi-centre Phase-II drug trial being done by the Council of Scientific and Industrial Research (CSIR) shows that its drug can cost lesser by at least 20-30 per cent of the current price.

A source aware of the development said, "Our projection is 20-30 per cent lesser than the current price point." As per the results, it could lead to a major reduction in the cost of the drug required for the treatment of mild and moderate symptoms of coronavirus.

The CSIR had done end-to-end synthesis of Favipiravir in April. It is now conducting multi-centre Phase-II trials of the drug with Mumbai-based pharma company Cipla which is due to make public the trial results soon.

In the race to be the first one to unleash a "wonder drug" to cure the novel coronavirus infection in India, several Indian pharma companies have received approvals to produce and market re-purposed drugs after trials they conducted on them showed some positive results.

On Saturday, 20.06.2020, Glenmark Pharmaceuticals said it has launched antiviral drug Favipiravir, under the brand name FabiFlu, for the treatment of patients with mild to moderate Covid-19 at a price of about Rs. 103 per tablet. The drug will be available as a 200 mg tablet at a Maximum Retail Price (MRP) of Rs. 3,500 for a strip of 34 tablets, Glenmark Pharmaceuticals had said.

Based on Phase-3 data, Glenmark obtained approval for the manufacture and marketing of the antiviral drug. The company claimed that Favipiravir shows clinical improvements of up to 88 per cent in Covid-19 patients, with a rapid reduction in viral load by four days.

Meanwhile, several pharma firms have now been granted approvals by Drug Controller General of India (DCGI) to launch Remdesivir as the coronavirus drug in India -- Cipla, Hetero Labs, Jubilant Lifesciences and Mylan. Hetero and Cipla both received approval on Saturday, 20.06.2020.

Cipla is hoping to launch the coronavirus drug by the end of June under the brand name "CIPREMI" and price it between Rs 3,000 and Rs 4,000 per dose in a tie-up with BDR Pharma to manufacture the drug.

Hetero's drug called "COVIFOR" is expected to hit the market in a week and the firm intends to price it between Rs 5,000 and Rs 6,000 per dose.

Source: Milan Sharma, India Today, 22.06.2020

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FSSAI directs authorities to strictly implement RDA for health supplements

The Food Safety and Standards Authority of India (FSSAI) has directed the Central and state licensing authorities to strictly implement the limitation with respect to Recommended Daily Allowance (RDA) prescribed by the Indian Council for Medical Research (ICMR) for nutrients while granting licences to the FBOs for products such as health supplements and nutraceuticals governed under Section 22 of the FSS Act.

The apex food authority has also asked state administrations to take strict action against the FBOs

failing to comply with the recommendations with respect to RDA.

In an order, FSSAI has stated that all Central as well as state licensing authorities are hereby advised to strictly implement the limitation of 'Not More than One RDA' as per Section 22 of the FSS Act and the FSS (Health Supplement, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, while granting the licences to the FBOs except for the food for special medical purpose and food for special dietary use, where use of more than one RDA is permitted.

The state authorities were also directed to undertake a review of the RDAs mentioned by the FBOs in the existing licences issued by their offices for health supplements, nutraceuticals and so on and issue notices to such manufacturers to direct them to undertake necessary modification in compliance with the FSS Act and Regulations thereunder.

The licensing authority needs to ensure that such products need to comply with the RDA limitations and stringent action may be taken against the defaulters," reads the order.

Sushil Khaitan, CEO & Director, Purenutrition.me, says that while India currently is only 2% of the global nutraceuticals market, valued at US$209 billion, it does have tremendous potential for growth in the future. Additionally, the market is still at its nascent stage with a mix of old and new players.

Khaitan said, "Hence, regulations such as these are a welcome move. In our industry, one of the key issues we face is quality control. Brands offering supplements at a lower cost may have artificial additives, which not only affect the efficacy of the products but may also have harmful effects on the user's health. These stringent measures by the FSSAI will ensure that customers only get quality products."

He added, "Additionally, it will also realign manufacturing units and workforce to focus on a patient-first approach, rather than a sales approach; an absolutely essential point as the world faces a healthcare crisis. I also believe that nutraceuticals companies will need to allocate more resources and funds to research and offer innovative solutions to health issues. I believe this move will help the industry prosper and grow in the right manner."

According to FSSAI, it has received several complaints that many FBOs were flouting norms for the RDA and also the licensing authorities were ignoring the requirement under Section 22 and the FSS Regulations for Health Supplement, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food.

Source: Ashwani Maindola, FnBnews.com, 22.06.2020

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Glenmark launches Covid-19 drug at Rs. 103 per tablet

Drug firm Glenmark Pharmaceuticals on Saturday 20.06.2020, said it has launched antiviral drug Favipiravir, under the brand name FabiFlu, for the treatment of patients with mild to moderate Covid-19 at a price of about Rs. 103 per tablet. The drug will be available as a 200 mg tablet at a Maximum Retail Price (MRP) of Rs. 3,500 for a strip of 34 tablets, Glenmark Pharmaceuticals said.

FabiFlu is the first oral favipiravir-approved medication in India for the treatment of Covid-19, it added. It is a prescription-based medication, with recommended dose being 1,800 mg twice daily on day one, followed by 800 mg twice daily up to day 14, the drug firm said. When asked about the company's manufacturing capacity of the drug, the drug firm said: "Considering a minimum of two strips per patient, Glenmark will be able to provide FabiFlu for about 82,500 patients in the 1st month itself. We will be closely monitoring the evolving situation and basis the situation, we will work to scale and meet the healthcare needs of the country".

The company is producing the Active Pharmaceutical Ingredients (API) for the product at its Ankleshwar plant, while the formulation is being manufactured at its Baddi plant. The drug will be available both through hospitals and the retail channel, Glenmark said. When asked if the company is looking for tie-ups with hospitals for supply of the drug, it said: "Our effort right now is to prioritise manufacturing to ensure FabiFlu is accessible to all patients who need it. Glenmark will certainly make a consideration to support private and public healthcare facilities and arrange for other suitable options as per the need and in time".

The Mumbai-based firm had on Friday, 19.06.2020, received the manufacturing and marketing approval from the Drugs Controller General of India (DCGI)."This approval comes at a time when cases in India are spiralling like never before, putting a tremendous pressure on our healthcare system," Glenmark Pharmaceuticals Chairman and MD

Glenn Saldanha said.The company hopes that the availability of an effective treatment such as FabiFlu will considerably help assuage this pressure, and offer patients in India a much needed and timely therapy option, he added.

Glenmark will work closely with the government and medical community to make FabiFlu quickly accessible to patients across the country, Saldanha noted. The company has developed the API and the formulation for FabiFlu through its in-house Research and Development team, Glenmark said.

"We chose to initiate work on Favipiravir, as it has proven *in vitro* activity against SARS CoV2 virus, which is the virus responsible for Covid-19. "Second is it has a wide therapeutic safety margin for Covid-19 at the dose that we administer," Glenmark Pharmaceuticals President India Formulations, Middle East and Africa Sujesh Vasudevan said at an online press conference.

Moreover, it is an oral product and that is a huge benefit especially when the hospital infrastructure is under strain, he added. Manufacturing and marketing consent has been granted as part of an accelerated approval process, considering the emergency situation of Covid-19 outbreak in India, the drugmaker said. The approval's restricted use entails responsible medication usage where every patient must have signed informed consent before treatment initiation, it added.

Favipiravir can be used for coronavirus patients with co-morbid conditions such as diabetes and heart disease with mild to moderate COVID-19 symptoms, Glenmark said. It offers rapid reduction in viral load within four days and provides faster symptomatic and radiological improvement. Favipiravir has shown clinical improvement of up to 88 per cent in mild to moderate COVID-19 cases, it said.

Favipiravir has been approved in Japan since 2014 for the treatment of novel or re-emerging influenza virus infections. Last month, Glenmark also announced that it is conducting another clinical trial to evaluate the efficacy of two antivirals Favipiravir and Umifenovir as a combination therapy in moderate hospitalised adult COVID-19 patients in India. India on Saturday, 20.06.2020, saw another record spike of 14,516 new COVID-19 cases in a single day, pushing the tally to 3,95,048, while the death toll rose to 12,948 with 375 new fatalities, according to Union Health Ministry data.

Source: Susmita Pakrasi, Press Trust of India, Hindustan Times, 21.06.2020

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Ayurvedic manufacturer restrained from using registered trademarks of Franco-Indian Pharmaceuticals

Franco-Indian Pharmaceuticals moved the court after one of its representatives noticed in early June that it's trademark DIAVIT was being used by Green Cross Health Innovation to sell an Ayurvedic formulation through various e-commerce sites.

The Bombay High Court (HC) last week restrained an Ayurvedic manufacturer, Green Cross Health Innovation, from using registered trademarks of Franco-Indian Pharmaceuticals Pvt Ltd; for trying to push the sale of its own products online while taking advantage of the coronavirus disease (Covid-19) induced lockdown restrictions.

Franco-Indian Pharmaceuticals moved the court after one of its representatives noticed in early June that it's trademark DIAVIT -- prescribed as supportive therapy for diabetics -- was being used by Green Cross Health Innovation to sell an Ayurvedic formulation through various e-commerce sites. The company alleged that the duplicate product was not available in the market before the Covid-19 outbreak was reported. The firm informed the court that it has been manufacturing pharmaceutical products over the past six decades and has an estimated annual turnover of Rs. 800 crore. It also stated its strong presence not only in the domestic market, but also in other Asian and African countries. The firm stated that DIAVIT is one of its registered trademarks, which is used for its multivitamin and multi-mineral formulations since 2000, and a brand extension called DIAVIT PLUS was launched in 2009.

Justice Gautam Patel found merit in the company's allegation of infringement of its registered trademark and issued the restraining order. The judge said the trademarks were identical in all respects.

"There's no question about that — there is not just phonetic and linguistic similarity, but the defendant's (Green Cross Health Innovation) adoption is identical in every way to the plaintiff's (Franco-Indian Pharmaceuticals) DIAVIT mark. There's no question, prima facie, of a likelihood of confusion. It's inevitable," he said. "Thus, beyond the commercial considerations of trademark infringement and commercial loss, there's public safety, health, and public law dimension," he added.

Source: Kanchan Chaudhari, Hindustan Times, 22.06.2020

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Maharashtra: High case fatality rate remains a cause for concern for state authorities

The number of deaths due to Covid-19 in Maharashtra has crossed the 6,000-mark even as the Case Fatality Rate (CFR) remained high at 4.67%, much above the national rate of 3.23%. The CFR in Maharashtra has risen over the past few weeks, up from 3.25% on May 25 and 3.37% on May 31, when the state government had vowed to bring it down to below 3%.

The state government's recent exercise of reconciliation last week led to the addition of 1,328 cases on June 16, resulting in a sudden spike in CFR to 4.8%, up from 3.79% the day before.

A total of 862 cases were added in Mumbai alone after the reconciliation, leading to a spurt in the city's CFR, which stood at 5.52% on Sunday, 21.06.2020. Similarly, a few other districts, including Aurangabad, Solapur and Jalgaon, have high CFRs and this has forced the state machinery to concentrate on reducing the rate. Chief Minister Uddhav Thackeray directed district authorities on Friday, 19.06.2020, to constitute task forces of expert doctors from the private sector to keep the CFR in check. The state task force of 11 doctors from leading private hospitals in Mumbai too decided to concentrate on reducing the CFR.

"For the next two weeks, we are concentrating on reducing deaths in the state. We are ready for the rising case load and the health infrastructure has been augmented by the government after the task force insisted upon it. Our decisions of introducing plasma therapy and using tocilizumab medicine have paid off well. Now, we have demanded the use of remdesivir medicine " said Sanjay Oak, who heads the task force of 11 doctors constituted by the government for the clinical management of critically ill patients.

Oak said the task force expects an undulating pattern of cases and there will be ups and downs for the next few days, before the numbers start subsiding.

The state government has been highlighting the improvement in the doubling rate and betterment in the recovery rate, but the rise in CFR has proved worrisome for authorities. "The district collectors and civic authorities have been directed to go in for aggressive tracing of suspected contacts and their testing. They have been asked to concentrate on vulnerable people and their clusters to keep deaths in check. They have been asked to trace more than 10 people against every positive patient to contain the spread," said a state official who declined to be named.

The state recovery rate is currently 49.78%. The doubling rate improved to 25.9 days on June 16, up from 3.5 days on March 31 and 10.2 days on April 30 and 20.1 days on May 31, the state health department said.

Source: Surendra P Gangan, Hindustan Times, 22.06.2020 (Excerpts)

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Pharma API imports from China: India moving towards self-reliance

India is moving towards reducing dependency on the import of Active Pharmaceutical Ingredients (APIs) and drug intermediates from China. "There has been a 4 percent reduction in import of APIs and other raw materials from China in the last one year," R Uday Bhaskar, Director-General, Pharmaceutical Export Promotion Council (Pharmaexcil), told.

About 65 percent of the raw materials for Indian drug makers worth $3.5 billion are being sourced from China

Indigenous production:

There are multiple factors that warrant indigenous production of raw materials. "The geopolitical realities, including tension between India and China, as well unexpected challenges such as Covid-19 work in favour of domestic production," said the MD of a Hyderabad-based listed Pharma company. The import of raw materials from China was halted for over two months due to the global and domestic lockdown and was restored only recently.

The rising cost of APIs being imported is another major concern as it is adversely impacts cost of production as well as the margins of Indian firms. According to a note of the Ministry of Commence, between March and May this year, there has been a 20 percent increase in prices due to the impact of Covid-19. The journey towards self reliance started almost a year back in a significant way. Pharmexcil conducted a study with the support of the Ministry of Commerce & Industry on 'Strategies to Reduce Import Dependence of APIs, KSMs and intermediates', and submitted a Detailed Project Report (DPR) to the Government in January.

Some schemes have also been sanctioned to develop three mega bulk drug parks in partnership with States. The Government is giving grants to States with Rs.1,000 crore for

each bulk drug park. As part of a Production-Linked Incentive Scheme, financial incentives for the eligible manufacturers of 53 critical bulk drugs (26 fermentation-based and 27 chemical synthesis-based bulk drugs) have been provided on their incremental sales over base year 2019-20 for a period of six years at a cost of Rs.6,940 crore.

On their part, drug manufacturers, too, realised the need for local production and have been adopting different strategies. When contacted on the steps being taken, GV Prasad, Co-Chairman and CEO, Dr Reddy's said: "Dr Reddy's is working to increase its backward integration of APIs." It is learnt that few players have also started sourcing them from domestic players, who are now seeing a business proposition in their production.

Source: G Naga Sridhar, The Hindu Business Line, 18.06.2020

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Finance Ministry may impose anti-dumping duty on import of antibacterial drug ciprofloxacin HCL from China

The Union Finance Ministry is likely to impose anti-dumping duty on import of antibacterial drug ciprofloxacin hydrochloride (HCL) from China to provide a level playing field for domestic industry vis-à-vis foreign manufacturers and exporters. China accounts for 97.76% of the total imports of ciprofloxacin HCL in India. The drug is used to treat different types of bacterial infections, including skin infections, bone and joint infections, respiratory or sinus infections, urinary tract infections, and certain types of diarrhoea.

The Directorate General of Trade Remedies (DGTR), an investigation arm of Union Ministry of Commerce and Industry, had initiated anti-dumping probe into import of antibacterial medicine from China in January this year following a complaint filed by Aarti Drugs which has 43 percent share in total domestic production of ciprofloxacin HCL.

The complaint was supported by Godavari Drugs Limited, another producer of the product. Besides Aarti Drugs and Godavari Drugs, Aurobindo Pharma, Dr Reddy's Laboratories, Neuland Laboratories, Emmennar Pharma, Sreepathi Pharmaceuticals and Sun Pharmaceutical Industries are some of the other producers of the antibacterial drug in India. The DGTR has conducted anti-dumping investigation from April 2018 to June 2019.

Over the years, import of the antibacterial drug from China has increased substantially. A total of 117 metric tonnes of ciprofloxacin HCL have been imported from China in 2015-16 followed by 171 metric tonnes in 2016-17, 217 metric tonnes in 2017-18 and 347 metric tonnes during period of investigation i.e. April 2018 to June 2019.

Zhejiang Guobang Pharmaceutical Co Ltd., Zhejiang Jingxin Pharmaceutical Import & Export Co Ltd., Zhejiang Langhua Pharmaceutical Co Ltd., Shangyu Jingxin Pharmaceuticals Co Ltd are some of the major Chinese exporters of ciprofloxacin HCL in India. On the other hand, domestic industry's antibacterial drug sale has declined over the years.

The sale of ciprofloxacin HCL by domestic manufacturers stood at 908 metric tonnes in 2015-16, followed by 810 metric tonnes in 2016-17, 648 metric tonnes in 2017-18 and 1,007 metric tonnes during period of investigation which is an exception.

The DGTR in its preliminary findings recently concluded that the domestic industry has suffered price suppression on account of import of ciprofloxacin HCL from China. It has also led to low capacity utilization and losses of domestic manufacturers. Further, the return on capital employed of the domestic industry has become negative. The imports may impact the ability of the domestic industry to raise capital investments, it added.

With an aim to protect domestic industry, DGTR has recommended imposition of anti-dumping duty ranging from US$ 0.94 per kg to US$ 3.29 per kg in its preliminary findings. While DGTR recommends the duty, the Finance Ministry takes the final call to impose the same.

Commenting on dumping of Chinese ciprofloxacin HCL in India, Indian Drug Manufacturers' Association (IDMA) Executive Director Mr Ashok Madan said, "Anti-dumping duty will eliminate injury caused to the domestic industry by the unfair trade practices of dumping so as to re-establish a situation of open and fair competition in the Indian market, which is in the general interest of the country. Imposition of anti-dumping duty, therefore, would not affect the availability of the product to the consumers. The drug industry which used to import ciprofloxacin HCL from China at cheaper rate will buy it from domestic manufacturers after imposition of anti-dumping duty as there will be hardly any difference in cost of the product."

Source: Laxmi Yadav, Pharmabiz, 20.06.2020

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Stopping China imports may hurt India's edge, exports: telcos, pharma companies

At a time when a sentiment in favour of boycotting Chinese goods is gathering steam, companies across import-dependent sectors such as automobile, pharmaceuticals, electronics, telecommunications, etc have said that any move in this direction could be counter-productive and impact the overall competitiveness of the Indian manufacturing sector.

They attribute two main reasons for this: One, automobile and pharmaceuticals companies have invested deeply in building a supply chain that traces back to China significantly and disrupting that supply chain could adversely affect their competitive situation in the export segments. Two, for companies in the telecommunications and electronics segments, the disruption could come from the lack of domestic manufacturing capabilities and significantly higher input costs.

China accounts for around 14 percent of India's total imports, and major items in the import basket being components for smart-phones and automobile, telecom equipment, plastic and metallic goods, Active Pharmaceutical Ingredients (APIs), and other chemicals.

In telecom, the Department of Telecommunications (DoT) has already asked state-owned operators BSNL and MTNL to keep Chinese vendors out of the scope for their tenders. Advice to private companies to not use China-made equipment in their networks is also being considered now.

"Clearly, this is not something that we would prefer to happen but we have to see what is in the national interest. Huawei makes $122 billion globally, and they make just over $1 billion from India. It's not that if you go after telecom, you'll make a big dent," said Rajan Mathews, Director General, Cellular Operators Association of India (COAI), a body representing the top three private mobile companies.

"What our operators do when they want to purchase any piece of equipment for their network, is create a list of all items that are necessary. No company runs 100 percent on just one vendor, it is an aggregation of multiple vendors. They look at aspects such as a vendor's maintenance facility, support facility, best quality and best price, following which they make a choice. But if you take away some companies from this equation, the choice will be reduced. Obviously, lesser the number of suppliers, the remaining get to have more negotiating power over the Purchaser," Mathews said.

Further, despite having a laid down plan for the electronics manufacturing segment since 2015, much of India's electronic goods are only assembled locally with high dependence on import of parts from China. Gurugram-based Micromax, which was once the top mobile phone maker in India, lost out to Chinese smart-phone companies which came with budget offerings, and now has lined up several new launches. Other Indian companies like Intex and Lava, too, met the same fate, though the latter still has a grip in smaller towns.

"But for Lava too, the original device manufacturer is a Chinese vendor sitting in China with even the design being done there. They might have local semi-knocked down manufacturing facility in India to assemble the phone, but in the end it's all Chinese," the source said.

He underlined that it would not be easy for Indian brands to cash in as they wouldn't be able to achieve the cost benefit Chinese manufacturers have.

According to the Internet and Mobile Association of India (IAMAI), India suffers from several cost disadvantages compared to other countries like China, Vietnam, South Korea and Taiwan. Such disadvantages emanate from challenges like logistics, high cost of debt, lack of utilities like high quality power and water. Countries like China and Vietnam provide incentives to the industry to make domestic manufacturing competitive, according to IAMAI.

Similarly, for the automobile sector, the relations developed with component suppliers in China over decades have provided a shot in the arm to Indian vehicle makers.

An executive at a Pune-based automotive company said there was a need for a coherent strategy on countries and suppliers. "That our company has spent years building a supplier base in China and that they are contributors to our competitiveness, especially external markets such as Africa and South America is key to our business. Even if we import a certain quantity from China, our exports are 15 times that," the executive said.

While it is unclear whether India will implement a ban on imports of ingredients used to make crucial medicines, some industry executives fear rising tensions with China may indirectly create shortages.

"The major problem we are going to face is in imports of intermediates, which we need in huge quantities to convert to Active Pharmaceutical Ingredients (APIs). Many APIs also come from China. There are many examples of medicines like paracetamol, cephalosporin and penicillin, for which we do not currently produce intermediates," said RC Juneja, Chairman of Delhi-headquartered Mankind Pharma.

"If you buy from other countries, the prices of the ingredients will be costlier, but the National Pharmaceutical Pricing Authority (NPPA) may not allow us to increase prices to offset this pressure," Juneja said. Another fear is that, even if India doesn't impose a ban, China may increase prices of the intermediates and APIs in retaliation. "Prices of these ingredients already increased around 10 percent during the initial stages of the outbreak and lockdown in China. Can we say they will not do this again now?" he said.

According to official data, India's pharmaceuticals industry is the third largest in the world in terms of volumes. The country exported around $14.35 billion worth formulations and $3.91 billion worth bulk drugs and intermediates in 2018-19. However, the country also depends heavily on China for various crucial ingredients used to make formulations. Around 68 percent of the $3.56 billion bulk drugs or APIs imported were from China in 2018-19.

Source: Pranav Mukul, Prabha Raghavan & Anuj Bhatia, Indian Express, 20.06.2020

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BIS releases IS 17423:2020 standard for coveralls meant for COVID-19 healthcare workers to ensure quality and patient safety

The Bureau of Indian Standards (BIS) has released standard IS 17423:2020 for coveralls meant for healthcare workers for compliance to quality and patient safety. This standard specifies the requirements for single-use coveralls to meet the urgent need for COVID-19 pandemic.

Coverall is a type of Personal Protective Equipment (PPE) intended to be worn by healthcare personnel for the purpose of isolating all parts of the body from a potential hazard. Coverall for COVID-19 provides protection against various biological agents due to their material sealing arrangements. This standard is based on guidelines issued by Union Health Ministry on rational use of PPEs and has been developed only as interim arrangements, as an emergency temporary measure in larger public interest, to cater to the present crisis due to COVID-19 and is intended to be used for a limited period. By that time it is expected that a full-fledged standard on coverall will be formulated covering all necessary requirements.

As per the standard guidelines, the coverall for COVID-19 shall be made from suitable textile material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard. The fabric used for the manufacturing of coverall shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure with or without coating/lamination engineered to fulfill the functional requirements.

Coverall for COVID-19 consists of an integrated hood with elastic around face opening. It shall be provided with suitable fastening arrangement which shall be covered with a storm flap with provision of self-adhesive sealing. In case of elastic waist, it shall be adhered with glue to minimize the potential entry points. Coverall may also be provided with elastic wrists and ankles for convenience and freedom for movement. It shall also be provided with thumb loop for better and secure fit during overhead work. Coverall shall be joined by sewing, adhesion, thermally/ ultrasonically welding or any other suitable technique. The seams shall be sealed with a tape of suitable material of medical grade of minimum 16 mm width or any other sealing arrangement that ensure that the seam shall pass the same tests as the body specified.

The design of the coverall shall be as per the agreement between the buyer and the seller. Each coverall shall be provided with a pair of shoe covers with an elastic strip to tighten it with the coverall, so that there is no passage for air through it. The coverall shall be manufactured with light colours only, as it is easy to detect possible contamination on light colours. Coveralls shall not be manufactured with black, dark and culturally unacceptable colours. The size of coverall shall be as per agreement between the buyer and the seller.

The coverall shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the coverall shall be conducted under proper hygienic conditions. The coverall shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed between the buyer and the seller.

Packaging of the product shall be such as to maintain the integrity of the product.

The product conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards (BIS) Act, 2016 and the rules and regulations framed there-under, and the product may be marked with the standard mark.

Source: Shardul Nautiyal, Pharmabiz, 16.06.2020

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Pharma MSMEs seek interest subsidy of 7% to expand domestic production of bulk drugs

The Pharma Micro, Small and Medium Enterprises (MSMEs) have urged the Department of Pharmaceuticals (DoP) to provide an interest subsidy of 7 percent for investments in Greenfield critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) projects to encourage API manufacturers to boost domestic production of bulk drugs.

As per draft guidelines for the Rs.6,940 crore Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of 41 critical KSMs/DIs/APIs covering 53 APIs in India, investment threshold for Greenfield/ Brownfield project stands at Rs. 20 crore. MSMEs operating on thin margin are unable to meet threshold investment to manufacture the eligible products post approval to make themselves eligible for the PLI scheme, said Nipun Jain, Chairman of Small and Medium Pharma Manufacturers Association (SMPMA).

Jain said if the Government offers an interest subsidy of 7 percent for investments in Greenfield KSM/DI/API projects, it will help all API units expand their production. Currently, there is 10-11 percent interest for bank loan. The 7 percent difference in interest rate will encourage most of the API units to increase production, he added. There are more than 2,000 MSMEs involved in API and drug intermediate manufacturing in the country, all of them will benefit from the interest subsidy.

The SMPMA Chairman further said in absence of interest subsidy, the DoP needs to evolve mechanism for reservation of MSMEs in the proposed PLI scheme, so that they can avail the scheme. He also suggested lowering investment threshold from Rs.20 crore to make MSMEs eligible for the scheme. The proposed PLI scheme seems investment linked scheme rather than production linked scheme deterring MSMEs from availing it, he added.

The major objective of the PLI scheme is to reduce import dependency and boost the domestic production of bulk drugs. Currently, India imports nearly 68 percent of API, by value, from China. The import of APIs has risen at a CAGR of 8.3 percent from 2012 to 2019 and the bulk drug import reached a value of Rs.249 billion in 2019.

China is also a single supplier for many of the critical intermediaries and APIs including high-burden disease categories such as cardiovascular diseases (for example, digoxin and losartan), diabetes (metformin and glimepiride) and tuberculosis (streptomycin). These are also listed in the National List of Essential Medicines (NLEM). In fact, the current market is largely dependent on China for antibiotic APIs manufactured by the fermentation route such as penicillin, cephalosporins and macrolides.

Of the 41 eligible products for the scheme, there are four fermentation based KSMs/DIs, ten fermentation based KSMs/DIs, four chemical synthesis based KSMs/DIs (with backward integration) and 23 chemical synthesis based KSMs/DIs/ APIs (with backward integration). Rs.20 crore is threshold investment for 23 chemical synthesis based KSMs/DIs/APIs. These include meropenem, atorvastatin, olmesartan, valsartan, losartan, levofloxacin, sulfadiazine, ciprofloxacin, ofloxacin, norfloxacin, artesunate, telmisartan, aspirin, diclofenac sodium, levetiracetam, carbidopa, acyclovir, carbamazepine, oxcarbazepine, vitamin B6, levodopa, ritonavir and lopinavir.

Source: Laxmi Yadav, Pharmabiz, 16.06.2020

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Pharma Cos launch Pharma App to market products and educate doctors about new drugs in the wake of lockdown crisis

On the lines of the medical apps being used by healthcare professionals and chronic patients to avail information on medicines and doctors' services, the pharmaceutical manufacturing companies worldwide have started launching Pharma Apps to educate doctors and hospital administrators about new drugs and promote them in the absence of medical representatives who are kept at bay by medical professionals due to the present pandemic crisis.

It is learnt that the new strategy is implemented to market company products through e-promotion activities. Products will be sent to the doctor or the hospital directly by the manufacturers on placing of orders online.

According to reports from various healthcare industry sources, using mobile technology hundreds of multi-national and other Pharma majors in India are resorting to digital routes to reach out to physicians and hospitals directly to share information on new products. The Pharma Apps rolled out by manufacturers contain information on new products, their efficacy and side-effects related matters and commission offers to doctors and hospitals. This digital form of marketing strategy is adopted by the companies for boosting their marketing in the wake of inability of sales representatives to visit doctors in clinics and hospitals. Manufacturing companies with various therapeutic segments bring out separate apps on each product and share it with doctors who become their 'prospective direct clients' without field staff.

Jiju Malayinkeezhu, a Thiruvananthapuram based medical representative-cum-media worker, said 40 major manufacturing companies have launched their Pharma Apps in Kerala and directly interacting with doctors and hospital administrators, staving off their medical representatives. He said his senior officers in the medical company have collected the contact numbers and email ids of doctors and hospital managers he used to visit, and shared the apps with them. According to him, with this kind of Pharma Apps the manufacturing or marketing firms can directly sell their products without the help of field staff.

Jiju further said once the new digital mode of marketing pharmaceuticals by companies is rolled out everywhere the situation will impact the whole distribution channel and several of the marketing staffs, including medical representatives, and managers of marketing companies, office staffs of C&Fs and super-stockists will lose their jobs. Ultimately, it will affect the business of distributors, wholesalers and the retailers. He said all over India over one lakh medical and sales representatives are working in the field for a livelihood representing various companies.

Reacting to the reports of Pharma Apps in Kerala, N Purushothaman Namputhiri, President of Kerala Drug Manufacturers Association, said so far any of the Kerala drug firms has not yet introduced such an app to attract direct business from hospitals or doctors, but companies from other states might have launched it. He said marketing through mobile technology app is against pharma business ethics.

Meanwhile, Ramesh Sundar, all India President of the Federation of Medical and Sales Representatives Association of India (FMRAI) said e-promotion is not a new mode of marketing in India, it is a strategy prevailing in the market for long. But he added that it would not succeed in India as face-to-face interaction of Pharma marketing is foolproof as the representatives will provide information on efficacy and side effects of the medicines to the doctors in person. He said during lockdown period several companies have made attempts to hold zoom meetings with doctors but many of them showed no interest in participating. It makes the sense that doctors are unwilling to support digital marketing of medicines.

"An overnight shift from the conventional marketing system of medicines to digital mode will not be encouraged by the medical community because they want to be convinced of the medicines launched by a company. For this, they will seek direct or in-person communication of facts about the new drug. Doctors will prescribe a new medicine only after getting solid confirmation of all information about the product. Doctors generally do not encourage digital mode of promotion work, but prefer to get information through medical representatives," Sunder said.

Source: Peethaambaran Kunnathoor, Pharmabiz, 16.06.2020

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Chemists not to sell Remdesivir, only direct supply to hospitals: Drug Controller

After permitting restricted emergency use of antivirals Remdesivir and Favipiravir in COVID-19 patients, the government on Wednesday, 24.06.2020, issued guidance on the manner of supply of drugs to ensure their proper use.

The apex drug regulator said Remdesivir injectable formulations allowed for use in severe COVID-19 patients can't be sold off chemist counters and will only be supplied for use directly to hospitals and institutions.

Favipiravir tablets, approved by Drug Controller General of India (DCGI) for use in mild to moderate COVID-19 cases, will, however, be available at chemist shops.

"Both drugs will be sold only on medical prescription by the treating doctor and in both cases, informed consent of the patient or his representative in a prescribed form are mandatory before initiating treatment," DCGI Dr V G Somani said in an order. Informed consent form requires patients to sign up for: "I have been informed of the possible benefits and well as risks (including side effects) from the usage of the drug by my physician after which I have made an informed choice to take it." In a major development, the government has restricted the stability period for Favipiravir tablets to four months from June to September which means its use will be reviewed after four months.

"The idea is to collect efficacy data on the drug which has been approved for COVID use for the first time in India. The current shelf life of FabiFlu which Glenmark will market is only four months. If the efficacy data is satisfactory the expiry date can be extended. If not, drug use can be modified," a source said. While Remdesivir injectable formulations are expected to be available within 48 hours in hospitals, Favipiravir has already been stocked by chemists. DCGI has allowed Cipla and Hetero Drugs to manufacture and market the generic version of Remdesivir, originally developed by the US-based Gilead Sciences; while Glenmark Pharmaceuticals have been permitted to make Favipiravir, the first oral therapy for COVID-19. Favipiravir has shown rapid reductions in viral load in limited trials.

Source: Aditi Tandon, Tribune News Service, 24.06.2020

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Development of bulk drug, medical device parks to cut India's dependency on imports: Gowda

The development of bulk drug and medical device parks will help in bringing down India's dependency on imports and making the country emerge as a major pharma exporter, the Centre said on Wednesday, 24.06.2020. Union Minister of Chemicals and Fertilisers D V Sadananda Gowda in a meeting reviewed various aspects of proposed development of three bulk drug parks and four medical device parks across the country. Modalities of selection of locality of parks as well as of the beneficiaries under the production linked incentive (PLI) scheme should be based on some well-defined objective criteria to ensure orderly development of the parks, Gowda said.

"These schemes will increase competitiveness of domestic production of bulk drugs and medical devices due to benefits available in clusters in the form of state of art common infrastructure and logistics facilities," he added. "Development of these parks will not only reduce India's dependency on imports but will also be helpful in making it a major player in global pharma exports", Gowda said.

Stating that these schemes are the need of the hour, the minister said that it is necessary that medicines are produced in the country at cheaper rates in line with the vision of Prime Minister Narendra Modi to make affordable medicines available to every citizen.

The Union Cabinet had approved schemes for supporting development of three bulk drug parks and four medical device parks on March 21, 2020 in order to reduce dependency on imports and boost local manufacturing and employment. The meeting was attended by Minister of State for Chemicals and Fertilisers Mansukh Mandaviya, Secretary Pharmaceuticals P D Vaghela, Joint Secretary Navdeep Rinwa and Joint Drugs Controller S Eswara Reddy, the ministry said in a statement.

Source: PTI, Outlook India, 25.06.2020

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Gujarat lends its base to two Covid-19 drugs

Two antiviral drugs -- favipiravir and remdesivir—recently greenlighted for treatment of Covid-19 patients in India have a Gujarat connection. While remdesivir generic version is now being manufactured in Vadodara, the Active Pharmaceutical Ingredient (API) of favipiravir is being made at Ankleshwar in the state.

Cipla has launched generic version of remdesivir — licensed from Gilead Sciences Inc — under cipremi brand for the treatment of hospitalized Covid-19 patients. Glenmark Pharmacueticals has come out with oral antiviral drug favipiravir for the treatment of mild to moderate Covid-19 patients. Both these medications have recently been approved by the Drug Controller General of India (DCGI). "Gujarat's strong manufacturing base is now being utilised in manufacturing of these two approved drugs," said Dr H G Koshia, Commissioner, Gujarat Food and Drug Control Administration (FDCA). Gujarat is among top pharma producing states accounting for 33% of India's total pharmaceutical production.

"Cipla has outsourced manufacturing of generic version of remdesivir to BDR Lifesciences Private Limited, which will make remdesivir lyophilised powder for injection 100mg for Cipla at its plant located in Padra, Vadodara. The licence for the same was issued last Friday, 19.06.2020" Dr Koshia added. When contacted, Cipla spokesperson said, "BDR is among the partnered sites. We have started commercial manufacturing and the product will be available in the next 8-10 days."

Glenmark Pharmaceuticals has also turned to Gujarat for making active pharmaceutical ingredient for favipiravir. "DCGI has given its go-ahead to Glenmark to manufacture API for favipiravir at the company's Ankleshwar plant. While the formulation (tablets) is manufactured at Glenmark's facility in Baddi, Himachal Pradesh, the raw material or API for the drug is manufactured at its facility in Ankleshwar in Gujarat," the commissioner added. When contacted, the company confirmed that it is making API for Favipiravir at its Ankleshwar facility. "The product licence to the company was issued last Saturday, 20.06.2020" Dr Koshia said.

Source: Kalpesh Damor, The Times of India, 25.06.2020

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Indian scientists find coronavirus gene in wastewater, hailed by global community

Scientists in India have for the first time detected genetic material of the SARS CoV- 2 virus in wastewater, a breakthrough that paves the way for using wastewater-based epidemiology (WBE) for real-time surveillance of COVID-19 in the country. The study, led by scientists in IIT-Gandhinagar, found that increased "gene copies" of the virus in Ahmedabad's wastewater matched the incidence of the disease in the city. With this, India "joins the ranks of a handful of countries doing WBE on COVID-19", Andrew Singer, an environmental microbiologist at the UK Centre for Ecology & Hydrology, said on Twitter.

WBE is a promising approach to understand the status of disease outbreak in a certain catchment by monitoring viral load in wastewater. Recent studies had reported that the novel coronavirus (SARS-CoV-2) is present in the faeces of infected individuals. Genetic material (RNA) from the virus has been found in sewage entering treatment plants.

All the three SARS-CoV-2 genes -- ORF1ab, N and S -- were found in the wastewater coming into the treatment plant, said the researchers, who have submitted their study for publication in the international journal 'Science of the Total Environment'. They noted that no gene was spotted in the effluent leaving the plant after treatment. This corresponded broadly with the trajectory of the incidence of the disease. The number of active COVID-19 patients in the Ahmedabad city was two times higher on May 27 than on May 8, they said. According to the scientists, WBE was an effective tool during outbreaks of other viruses such as poliovirus and hepatitis A. The Ahmedabad study aims at assisting concerned authorities and policymakers to formulate or upgrade COVID-19 surveillance to have an explicit picture of the phase of the pandemic, the researchers added.

Kumar cited reports to say a WBE study has indicated the presence of the coronavirus in Italy in December 2019, way before the first confirmed case in the country. "Developing an advanced surveillance system for environmental samples using biotechnological approaches is the need of the hour. This can help us track real time situations not only for the current pandemic but also for seasonal epidemics," Madhvi Joshi, Joint Director of GBRC and one of the authors of the paper, told.

According to the researchers, the number of gene copies was found comparable to that reported in the untreated wastewaters of Australia, China and Turkey, and lower than that of the US, France and Spain. Prosun Bhattacharya of Sweden's KTH Royal Institute of Technology noted that WBE can be unimaginably impactful in the war against COVID-19 with the right information about the catchment and number of people residing in the vicinity. He added that the research by Kumar and his colleagues has put India on the world map pertaining to WBE surveillance. Estimates based on European and North American data suggest that each person infected with SARS-CoV-2 will excrete millions if not billions of viral genomes into wastewater per day, they said. This translates to between 0.15 and 141.5 million viral genomes per litre of wastewater generated, the researchers said. While infectivity of SARS-CoV-2 through wastewater has not yet been reported, the virus potentially enters the wastewater stream from patient excretions and thus can be a great tool for pandemic monitoring, the researchers said.

Using reverse transcription PCR (RT-qPCR) -- a laboratory technique of molecular biology -- researchers should be able to detect the novel coronavirus with high sensitivity, Kumar said. "The findings reported by Kumar and colleagues demonstrate the successful detection of SARSCoV-2 in wastewater -- a highly valuable contribution to global SARS-CoV-2 surveillance research efforts," Kyle Bibby, associate professor and leader of Global Collaboration on WBE, University ofNotre Dame in the US, told.

Because treatment plants collect wastewater across large regions, measuring the level of RNA in untreated wastewater may provide a valuable insight into the percentage of people infected within a region, the researchers said. In the latest study released on June 18, scientists from the Indian Institute of Technology (IIT) in Gandhinagar collaborated with the Gujarat Biotechnology Research Centre (GBRC) and the Gujarat Pollution Control Board (GPCB). They studied samples of wastewater collected on May 8 and May 27 from the Old Pirana Waste Water Treatment Plant (WWTP) in Ahmedabad. Sciences, IITGN, who led the research effort. Bibby heads the WBE global collaboration comprising over 50 institutes and researchers. The group is compiling and sharing all the results obtained through WBE surveillance for the global comparison, according to an article published in the journal Environmental Science & Technology."I would like to congratulate India as one of the elite nations in world-wide efforts in detecting and quantifying SARS-CoV-2 genetic materials in their sewage samples. Kumar and his colleagues showed the capabilities of wastewater-based epidemiology (WBE) in India, the second most populated nation with rapidly growing numbers of COVID-19 confirmed cases," said Keisuke Kuroda, associate professor in Environmental and Civil Engineering at Toyama Prefectural University, Japan.

"This report will surely facilitate a nationwide initiative for detecting the early warning signals of COVID-19 outbreaks in various communities," Kuroda told. Ryo Honda of Japan's Kanazawa University, who is leading a task force on wastewater surveillance in Japan, said the study is an important step for WBE of COVID-19 in India.

Source: oneindia.com, Daily Hunt, 22.06.2020

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INTERNATIONAL NEWS

Human trial of new coronavirus vaccine begins in UK

After China started human trials of its sixth experimental coronavirus vaccine, volunteers began receiving doses of a potential new coronavirus vaccine in the UK. At least 300 people will be administered the vaccine at the Imperial College in London. Oxford University has already started human trials.

According to reports, the vaccine uses synthetic strands of genetic code, called RNA to mirror the virus while training the immune system to identify and fight the virus without developing coronavirus. Another trial of the vaccine is set for October with the product set for distribution in the UK and abroad in early next year.

Meanwhile, the Federal University of Sao Paulo in Brazil said that researchers had begun administering the vaccine developed by Oxford University to volunteers. The vaccine has been developed with pharmaceuticals group AstraZeneca known as ChAdOx1 nCoV-19. The vaccine was administered to high-risk individuals who are likely to come into contact with coronavirus patients namely doctors and nurses. The vaccine is set to be administered to at least 2,000 volunteers in Brazil.

Brazil's acting Health Minister, Eduardo Pazuello, said the country wants to sign a contract for domestic production of the vaccine. Brazil has the second-largest COVID-19 cases after the United States which has 1.3 million infected cases and 1,20,000 deaths.

Amid the race to develop the vaccine, South Africa declared it will also begin trial of coronavirus vaccine this week. The University of Witwatersrand is collaborating with the University of Oxford and the Oxford Jenner Institute on the South African trial. "As we enter winter in South Africa and pressure increases on public hospitals, now more than ever we need a vaccine to prevent infection by COVID-19," University of Witwatersrand (Wits) vaccinology Professor Shabir Madhi said

Source: WION Web Team, 25.06.2020

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India's avoidable import dependence on China

Whether the Government of India would admit or not, it is crystal clear that India is facing a war-like situation with China today

N S Venkataraman

The most important thing that India needs to do now is to convey a firm impression to the Chinese Government that India would not buckle under pressure and military threat. Certainly, this is what many countries in the world, who understand the tactics of China and are concerned about it, expect from India today.

Obviously, India has to confront China on several fronts including trade and economic front. While China has created huge capacities in several industrial and commercial sectors, the fact is that China is excessively dependent on the world market for its industries to operate at the economic capacity utilisation level, by marketing their product internationally. This is the area where China has to be confronted.

US President Trump has understood this and that is why he initiated the trade war with China, which is getting silent approval from several countries. Very few countries criticise the US for its trade war moves, which has made the Chinese economy weaker, though not still weak at an alarming level.

It is high time that India too needs to start a trade war with China. While there is a high level of clamour amongst the cross-section of Indians to ban the import of goods and services from China, some "experts" have been stating that the ban on import of goods from China would nearly paralyze the Indian economy too. This view is certainly not based on facts and not based on a clear understanding of the ground realities in India.

In the year 2019, China's exports to India was $68.3 billion, while India's exports to China was much lower level at $17.1 billion, largely consisting of minerals and natural products. Of these above exports by China to India, drugs and drug intermediates constitute around 65 percent of the total import of bulk drugs and intermediates by India from various countries. Most of these import of bulk drugs and drug intermediates are avoidable, as India has enough capacity. For example, the number of units in India has capacities for the production of several drugs such as Ibuprofen, paracetamol metronidazole, and still India import from China leading to underutilisation of capacity in India.

In the same way, India has adequate installed capacity for several chemicals and even such chemicals are being imported from China. Several examples can be readily pointed out. India imports around 1 lakh tonne per annum of citric acid from China and India was producing citric acid and then closed its plants due to import dumping from China.

Several Indian units such as Hindustan Antibiotics, Torrent Pharmaceuticals, and others were producing Penicillin G earlier and all of them have closed operations due to import dumping from China and now India is largely importing from China.

Why is this situation? The reason needs to be understood and tackled.

India is importing several pharmaceuticals and chemicals from China, not due to lack of production capacity or technological capability but Indian buyers are tempted by low prices offered by Beijing and also because it provides liberal credit terms of as much as six months to the Indian buyers from the date of Bill of Lading, after the Indian buyer would open irrevocable Letter of Credit.

The fact is that China is a nonmarket economy and several hidden subsidies and support are given by the Chinese Government to help the Chinese industries export the products at a low price and there is no transparency in such matters.

What is particularly surprising is that several buyers and traders in India succumb to the temptation of buying products from China due to the low price and liberal credit terms, even if the quality and specification of the Chinese product would be less than that of the product produced in developed countries.

Curbing the import of products from China is now a national necessity to protect India's interests. There are

many non-essential items imported from China such as furniture, bedding, toys, mobile phones, televisions, etc., which India can do without supply from China.

In the case of chemicals, bulk drugs, auto parts etc., the capacity utilisation of Indian industries should be improved and production increased by curbing import from China. There are enough capabilities in India with regard to such products. Even in the case of the renewable energy sector, solar cells are imported from China in large quantities, while solar cell producers in India are languishing. The Government of India should make the price of Chinese goods in India expensive by imposing safeguard duty to protect the Indian industries and national interest. With such protection, Indian industries will have the opportunity to expand capacities, increase production and optimise production cost, which they are unable to do now as they are unable to operate with confidence due to import dumping from China.

India has to learn from the strategy of US President Trump who has imposed tariffs on Chinese products heavily to curb imports from China. China has tried to retaliate by imposing tariffs on US products. In the process, both the countries have not bothered about the regulations of the World Trade Organisation (WTO). China is occupying Indian Territory and has killed Indian soldiers. In such circumstances, India starting a trade war with China is absolutely appropriate. Even as per the WTO rules, safeguard duty can be imposed on the imported product by any country, if the domestic industry would be adversely impacted.

Certainly, a trade war with India would not destabilise the Chinese economy in a big way, but it would cause concern to China. This would make it clear to China about India's determination to confront China and would be a trendsetter for several countries in the world who are equally concerned like India about China's greed, ruthlessness, and territorial expansionist policies.

(Disclaimer: The opinions expressed above are the personal views of the author and do not reflect the views of ZMCL).

Source: WION, 22.06.2020

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The Indian Hand

P B Jayakumar

Whether India develops a Covid-19 vaccine/drug or not, Indian companies will be preferred partners for global Pharma to make and distribute the life-saving drug globally. By Winter. This is the ambitious target set by Scientists to defeat Covid-19.

Regulators, Scientists and Life Sciences companies are working at break-neck speed in what has become the largest and fastest vaccine/drug hunt in human history.

Biotech specialists are using all available platforms or vehicles - dead, artificially engineered and live viruses, apart from DNA - or RNA-based ones - to transport virus-killing antigens into human cells. Big pharmaceutical companies such as Pfizer, Novartis and GlaxoSmithKline are collaborating with each other. They have also opened their patented libraries of drug knowledge to researchers and academia. Governments and philanthropists are pumping in billions of dollars into promising projects. Scientists are attempting hundreds of treatment options from novel plasma and antigen injections to reusing old molecules right from Made in India anti-malarial Hydroxychloroquine to HIV anti-virals to psoriasis or hepatitis drugs. Normally, it takes four-six years to launch a vaccine right from developing a candidate and animal trials to three-stage human trials. The time to bring a drug to market is ten years. Scientists screen lakhs of chemical compounds, identify the candidate and develop it for two-three years before starting clinical trials. Only one or two out of ten candidates reach the human clinical trials stage.

But these are not times. In taming Covid-19, time is of essence. The do-or-die efforts of life sciences companies across the globe have ensured that ten out of 124 vaccine projects on Covid-19 have advanced into the human clinical trials stage within three months. The efforts, whenever and in whatever form they succeed, will see Indian companies and laboratories play an important role in both development and production of these drugs and vaccines.

In India, many leading companies such as Sun Pharma, Biocon and Glenmark are attempting treatments

with known molecules or therapies. At least a dozen Indian companies are also attempting to develop vaccines - from well-known names such as Serum Institute of India (SII), Zydus Cadila, Bharat Biotech, Indian Immunologicals and Hester Biosciences to relatively unknown Mynvax, Neuberg Supratech and Premas Biotech, besides many Government-run labs. India is working on 30 projects by big industry, startups and academia, says the Government. "There are at least eight candidate vaccines, of which four are relatively ahead. Our national science laboratories are working on six candidate vaccines, of which we are very hopeful about two-three," Dr V K Paul, Chairman, Empowered Group - I and Member (Health), NITI Aayog, told the media on May 28. "This is such a huge pandemic that there is no meaning in saying who will come first or second. There is enough room for those going slow and steady also," Dr Paul said when asked about where India stands in the race.

India's generic drug development capability, ability to make finished drugs or vaccines cheaper than anyone else, numerous manufacturing sites in other countries and marketing presence across the globe will force big Pharma and new vaccine/drug developers to rope in Indian partners. That is already happening.

Hunt for Partners:

Take SII, the world's largest vaccine maker in volume terms, and the most promising 'Oxford vaccine', being developed by the Oxford University's Jenner Institute with the Oxford Vaccine Group. The Oxford Research Group is relying on a time-tested way - antigens developed from mild cold causing infections in chimpanzees and containing genetic material of Covid-19 spike proteins that replicate the virus in humans. A section of experts had initially doubted results of trials on monkeys. However, the vaccine is being tested on 1,000 patients in the first two phases. Over 320 people have been given a dose. The results are encouraging.

The group was in discussions with several companies to make the vaccine, including India's SII, but US multinational AstraZeneca licensed the vaccine a few weeks ago. "AstraZeneca is in discussions with Serum Institute of India and other potential partners to increase production and distribution," the company said on May 21. "Our discussions with AstraZeneca are on and we will be able to comment further once the deal is concluded. In addition to this, we are working on multiple vaccine candidates in the US, the UK, Europe, and not relying on one," Adar Poonawala, promoter and CEO of Pune-based SII, told.

The US Government's Biomedical Advanced Research and Development Authority has given AstraZeneca $1 billion for development, production and delivery of the vaccine. The Phase III trial will involve 30,000 participants.

AstraZeneca is taking a big risk. It has signed manufacturing and supply deals for initial 400 million doses and total manufacturing capacity for one billion doses, with first deliveries to begin from September 2020. Pascal Soriot, Chief Executive Officer of AstraZeneca, says more agreements and several parallel supply chains are in the pipeline. Apart from AstraZeneca, SII and US-based vaccine maker Codagenix are also developing a vaccine, in the pre-clinical animal trials stage. SII is also trying a recombinant Bacillus Calmette-Guerin (BCG) vaccine variant for Covid-19 containment.

Novavax, a US-based late-stage vaccine development maker, has an advance candidate vaccine NVX-CoV2373 that is undergoing Phase I human trials in Australia. It has got $388 million from the Coalition for Epidemic Preparedness Innovations to further develop the vaccine. Novavax has chosen an easy way to manufacture the vaccine if its candidate clears human trials. The company acquired SII's unit, Praha Vaccines, at Bohumil in Czech Republic last week in an all-cash transaction for $167 million. Stanley C Erck, President and Chief Executive Officer of Novavax, says this will help them produce more than one billion doses per year. SII will help it augment production at Bohumil by the end of this year. "After acquiring the Czech Republic plant, we had spent an additional $100 million to upgrade it to a world-class facility producing one billion vaccine doses. We have only recovered what we had spent," says Adar Poonawala. He says he decided to sell the plant to focus on own manufacturing efforts in India and also because Serum has another manufacturing plant in Europe, in the Netherlands.

"At least half-a-dozen leading Indian companies such as Serum, Bharat Biotech, Zydus Cadila, Indian Immunologicals, Biological E and Wockhardt have global standard manufacturing capabilities and can supply to different parts of the globe," says Dr R B Smarta, Chairman and Managing Director of Interlink, a pharmaceutical consultancy. Of this group, five are trying to develop own vaccines for Covid-19. Zydus Cadila, which had

developed Indias first tetravalent inactivated Influenza vaccine VaxiFlu-4, is developing two Covid-19 vaccines on its own. Bharat Biotech is also developing two vaccines, with ICMR and overseas universities.

A Helping Hand:

Even if an Indian company is not the first to develop a Covid-19 vaccine, the country has both expertise and capacity to make the vaccines once they are developed, especially for the developing world, considering that it is not easy to start a new vaccine making unit. It requires at least four-five years to commercialise a vaccine plant. India supplies over 60 percent or above 1.25 billion doses of vaccines out of 2.4 billion doses required for the UNICEF's global immunisation programmes. About 70 percent vaccines used globally are made in India. SII alone makes over 1.5 billion doses and supplies to over 150 countries. "We have low manufacturing cost and skilled manpower. However, we now need to focus on development, technology and innovations, and that requires Government support," says Adar Poonawala.

Repurposed Drugs:

Indian firms are also at the forefront of testing and making re-purposed drugs for Covid-19. Sun Pharma is going to test a drug, Nafamostat Mesilate, on Covid-19 patients. It has been approved in Japan for improvement of acute pancreatitis and small blood clots, found in many Covid-19 death cases. "Nafamostat has shown promising results in studies conducted by three independent groups of scientists in Europe, Japan and South Korea, and we believe it holds promise in the treatment," Dilip Shanghvi, Managing Director, Sun Pharma, said in a statement. Sun Pharma has developed the Active Pharmaceutical Ingredient (API) and the finished product in India using technology from its Japanese subsidiary Pola Pharma. Glenmark, the first company to receive approval from the Indian drug regulator to conduct clinical trials of anti-viral drug Favipiravir against Covid-19 in India, is attempting a combination of viral drugs Favipiravir and Umifenovir in hospitalised patients who are showing moderate symptoms of Covid-19 in India. "Combining antiviral agents that have a good safety profile is an effective approach to rapidly suppress initial high viral load," says Monika Tandon, Vice President and Head, Clinical Development, Glenmark Pharmaceuticals. Similarly, Biocon has got permission to use blood purification drug-device CytoSorb to treat Covid-19 patients admitted in intensive care units with confirmed or imminent respiratory failure. It is also working on its psoriasis drug Alzumab to control Covid-19 infections. When US-based Gilead Sciences decided to out-license its new antiviral drug under development, Remdesivir, and modified it for use in Covid-19 patients, it chose three Indian partners - Cipla, Hetero Drugs and Jubilant Life Sciences - to manufacture and supply in 127 countries.

All this is not a coincidence. Experts say India has over 150 US Food and Drug Administration approved plants, the highest outside the US. Most leading Indian manufacturers have multiple plants in almost all geographies, besides marketing setups in most countries, to sell generic drugs. Indian companies, well-versed in making finished formulations, are also now concentrating on developing APIs and the entire value chain in products for treating Covid-19. Above all, Indian companies can make drugs 30-40 percent cheaper than what it costs in the western world. All this will come in handy in quick manufacturing and supply of Covid-19 solutions. "It is a massive opportunity for the Indian Pharma Industry to emerge out of this crisis as a preferred sourcing hub for the world. Being the largest provider of generics globally, India has always been called the pharmacy of the world," says Umang Vohra, Managing Director and Global CEO, Cipla. The Covid-19 crisis showcases the importance of the Indian pharmaceutical industry, says Nilesh Gupta, Managing Director, Lupin. "With more emphasis on global drug supply security, we expect Indian generic majors to benefit by supplying more to the US and the EU by further leveraging our low-cost base, high throughput and quality standards and availability of the required skill set," he says.

However, it is not easy to rule out China, which supplies 40 percent of global API requirements. India is trying to catch up but will require many years to reach the scale of the Chinese API ecosystem. More than that, five out of ten Covid-19 vaccines under human clinical trials are from China. Will they partner with Indian companies? China will not require India's support in manufacturing and considering the current situation, Indian companies will also refrain from dealing with China, says Adar Poonawala, who predicts that China will be able to produce a Covid-19 vaccine. "I really hope they do as all of us are in the race to save lives and produce vaccines for as many people as possible," he says. That is the truth, whether India or China or the US, the aim before humanity is to beat the virus for survival.

Source: Business Today, 28.06.2020 (Excerpts)

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Self-sufficiency in bulk drugs is a must

India cannot afford to continue depending on China for crucial pharma ingredients

Paran Balakrishnan

The Government declared 2015 the Year of the API. That may not sound hugely exciting but the health of the nation depends on them. APIs — or Active Pharmaceutical Ingredients — play a crucial role in our lives as the raw materials that go into making antibiotics, painkillers, and other medicines that people pop every day. The 2015 announcement was followed a year later by the Government fixing a 2020 deadline for when, as Union Minister Ananth Kumar declared, "India is going to become self-reliant (from China in bulk drugs)," calling it a matter of national "health security." Now, guess what? We imported 68 per cent of our APIs or ₹249-billion worth from the Middle Kingdom in 2019, up from ₹193 billion the previous year.

The issue came to the fore in January with the Covid-19 outbreak in Hubei province, China's pharmaceutical heartland, that hit API shipments to India. In February, highlighting India's vulnerability, the Indian Pharmaceutical Alliance, which represents domestic drug producers, described the API inventory situation as "grim."

While supply lines from China have opened up again, the problem of India's dependence on its neighbour has become even more glaring for the country's flagship industry post the deadly hand-to-hand Ladakh border fights. Three decades ago, India was completely self-reliant in APIs. Then, the Chinese built up their own sector with state support and our pharma industry moved up the value-chain to making finished drugs and used low-cost raw materials from China. "We need to examine alternative sources (for APIs) even if they're costlier," says Sudharshan Jain, IPA Director-General.

The Government now says it's serious about breathing life into its promise to make India API self-sufficient. But when it comes to making many things here, India suffers from cost disadvantages, mainly because of expensive power and poor logistics. The government has dusted off 2016 plans to create pharmaceutical clusters where common costs can be shared and also offer fiscal incentives to would-be producers, roughly the same approach it has taken to attract the global electronics giants to India. Incentives are even more important in the case of bulk-drug production because the industry is highly capital intensive and also needs huge tracts of land — of 1,000 to 2,000 acres.

Fund allocation:

The Government has announced it's allocating ₹69.4 billion to push indigenous manufacturing of 53 key APIs such as those required for antibiotics, medicines for heart ailments, diabetes, blood pressure and TB. The government has also approved ₹30 billion to set up three drug parks in the country in tandem with State governments that will feature shared facilities like pollution treatment plants to lower costs for companies.

Just to bring it home, let's look at how dependent we are on Chinese API imports? Well, for blood pressure drugs like losartan and heart drug digoxin, reliance is 100 per cent. For antibiotics like penicillin it's 98.5 per cent and for ciprofloxacin 99 per cent. The numbers are similar for diabetes drugs metformin and glimepiride, according to a KPMG report. The government is also reportedly planning to start sourcing APIs from countries in Europe to diversify.

There's an added disadvantage, though, when it comes to producing bulk drugs: the environmental factor. All pharmaceutical plants are polluting and API production is even more so. The National Green Tribunal (NGT) has insisted that pharmaceutical plants install zero-effluent treatment plants to prevent heavy pollution. This further pushes up the cost of manufacturing APIs.

One report in 2016 had the dramatic headline: 'Hyderabad: A city drowning in pharmaceutical pollution'. (The NGT passed strong strictures against the Telangana Pollution Control Board last November). Hyderabad could be called the first home of the Indian pharmaceuticals industry. API manufacturer Divi, which is headquartered in Hyderabad, is one of the biggest makers in the world of APIs.

The city also has public sector companies like the Indian Drugs and Pharmaceuticals (IDPL) being based there. IDPL and several other companies were large-scale producers of bulk drugs till around the 1990s when the Chinese began to expand their industry. The Chinese systematically looked at what they needed to create — a world-beating industry — and the government offered cheap land, power and finance to would-be producers. Says Jain: "Slowly, they created large plants. The cost of manufacturing was so economical

they became the dominant power." He adds: "We set up a number of committees but nothing has moved."

Which States could be set to become big API-manufacturers? There are only a handful which stand out with existing companies that are already in the game — Gujarat, Maharashtra, Telangana, Andhra Pradesh and Uttarakhand. Of these, Gujarat is reckoned to be the frontrunner — partly because many top decision-makers in the Government are from the State. Andhra Pradesh is the laggard even though it has created small pharmaceutical clusters around Visakhapatnam. Telangana also has put in hard work to be able to offer the incentives to put up a bulk drugs plant.

How long will the government take to decide on which States should put up bulk drug plants? The optimistic estimate is six months. And it will obviously take much more time before any production begins. Says Jain: "If we start now, it will take two-three years." And even that could be the best-case scenario.

Speed up process:

Nobody's suggesting for a moment that we should cut all economic ties with China — even if that was remotely possible. But our top diplomats all concur that, unless peace moves are made very quickly from both sides, this could be a watershed moment. In trade and business terms, what can we do in the short run? It looks like we will have to take Huawei out of the running for major telecom infrastructure deals. And we need to move as quickly as is possible to cut our dependence on China for APIs.

We aren't the only country that's hit the panic button in recent months after realising how heavily dependent we are on the Chinese for APIs. One pharma giant, which has decided that it wants to reduce the pharmaceutical industry's heavy reliance on Chinese APIs, is Paris-based drugmaker Sanofi. It's setting up what it calls a "new industry champion (that) would rank number two globally, with approximately €1 billion in expected sales by 2022." Sanofi aims for the new API company "to help in balancing the industry's heavy reliance on API sourced from the Asian region.

India needs to make sure that this time it lives up to its promise to cut its reliance on Chinese bulk drugs.

Source: The Hindu Business Line, 24.06.2020

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