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IDMA BULLETIN

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We wish all our Members and Readers
"Happy Independence Day"
15th August

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS


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IDMA BULLETIN

Vol. No. 51 **Issue No. 30** **08 to 14 August 2020**

IDMA ACTIVITIES:

CUSTOMS MATTERS:

SPECIAL REPORT:

NEW DEVELOPEMENTS:

NATIONAL NEWS:

INTERNATIONAL NEWS:

FEATURE:

IDMA Submission on QR-Code/Barcode implementation

The Association has submitted the following representation on 4th August 2020 to Dr Mandeep K Bhandari, IAS, Joint Secretary, Ministry of Health & Family Welfare, New Delhi in continuation of the Video Conference of the Inter-Departmental Committee with stakeholders on the issue of implementation of Barcode/QR code on packaging of drugs (including medical devices) on 31 July 2020:

"Greetings from Indian Drug Manufacturers' Association.

We sincerely thank you for inviting us to the Inter-Departmental Committee meeting as referred above and providing us an opportunity for submitting our views and suggestions on QR-Code/Barcode implementation. Dr Viranchi Shah, Senior Vice-President, IDMA had represented us at the meeting.

We wish to submit as below:

We are with the Government in their efforts in using technology for weeding out the spurious drugs.

A simple, patient & doctor friendly system, based on a technology that is efficient (detection of falsified – spurious drugs), affordable (capex and opex) and industry friendly (ease of application and minimum impact on productivity) is required to be identified and studied. It must also be ensured that it would serve the ultimate purpose of identifying spurious units of drugs at the user's end.

QR Code on API label:

- We believe implementation of affixing QR code on API labels is not necessary.
- Manufacturers of formulations are expected to qualify their vendors, and thereby spurious APIs can be detected.
- Manufacturers of formulation are also supposed to test each lot of API.
- Affixing QR Code may not add any value in detecting spurious APIs.

Track and Trace for Exports:

- India is the only country in the world to have implemented Track and Trace through Barcoding on drug formulation packs for export purposes.
- Even after serious efforts jointly by the Government and the industry for almost a decade, there is very little success. The system seems to have operational issues in implementation. Again, in the absence of infrastructure at the importing country's end, this system does not help to achieve the ultimate purpose, which is to detect fake products in the market place.
- It does not serve the ultimate purpose of identifying spurious drugs as the supply chain infrastructure in importing countries is not capable of reading our codes in the formats used by us.
- Success of Track and Trace requires end to end supply chain (manufacturer to retail pharmacy/ hospital) with the same technology that can read the Indian format of 2D barcodes and validate against our data base. Most countries have not even been approached by India to start working on those lines. For the 200 importing nations to accept this system and change their supply chain system may not be realistic or even feasible. They will be importing from other countries and also making some products locally. Hence they may not agree to reorient their supply chain to read our codes.
- Track and Trace reduces productivity of Indian players against competitors like China, Vietnam, Bangladesh and others, who have not mandated such systems for exports.
- Track and Trace increases unnecessary burden of additional capital investment (Every unit will spend at least 1.5 Crore per unit for SME and several Crores for larger units) on exporters, and also operational costs (15-20 Ps per impression).
- The success of this system is totally dependent on the importing country's readiness with technology to scan the codes in the Indian format and validate them. Until that happens it may not work. Not a single country in the world has adopted a system to scan and interpret the Indian system of Track and Trace.

- Hence we request that being the Pharmacy of the world, we must wait until the global consensus on Barcoding/QR coding emerges. Till such time the Indian system must be implemented only on optional basis.
- We urge that the Ministry of Commerce immediately issue a Notification to make the implementation of the system optional till further orders.

QR Code for domestic market - Top 300 brands:

- Since the ultimate purpose is to easily and efficiently identify and remove spurious drugs from the market, Track and Trace may not be the right solution in the Indian context.
- QR Codes are also not practical for some evident reasons - They are difficult to be scanned from aluminum foil surface of a blister pack giving large number of false results on scanning defeating the purpose; they cannot be printed on small packs such as injection ampoules, eye drops etc. Globally the countries who have full dose packs (10's/14's/ 30's etc) have been able to put some form of codes, supported by tamper proof sealed box packs, thereby making the system full proof. Hence we might have to migrate from secondary pack system to mono-cartons or dose based packs with tamper evident packing to reach to that level. Currently the packs in India are secondary packs such as 10x10's.
- We therefore need to find a solution that is suitable for the special needs of India.
- A simple technology that is patient/doctor friendly (e.g. SMS based or any similar) may be preferred.
- The technology must be efficient in identifying fakes, and should be difficult to copy.
- The technology must be industry friendly within ease of application, minimum capital investment and minimum cost of operation, and should have minimum impact on productivity.
- When considering the technology for implementation, the Government must make provision to reimburse the capital costs to the industry to avoid additional impact on the prices of drugs. Further, the additional operational costs must be allowed to be transferred to the cost of product by allowing increase in MRP of the products.
- Due to the disruption cause by the current pandemic, the entire industry and supply chain is already badly impacted. Last year, industry had to change its labeling due to change in labeling rules. This proposed change that affects labeling may have another disruptive impact on productivity and availability.
- Since the industry is already under stress, and it will take at least up to the end of 2021 for the industry to cope up with the effects of the pandemic, we urge that this move must be postponed till the end of 2021. The issue may be reviewed in the year 2022 and deliberated further through a consensus of all stake holders.

Whenever Track and Trace is being taken up, a single authentication code may be considered, instead of different recommendations like barcode, QR Code etc by various Departments/Ministries.

We earnestly request that Track and Track be evaluated only when the technology and the ecosystem for adopting the same has matured and is robust or else it will result in failure again.

We seek your indulgence in this matter and look forward to your co-operation. Thanking You".

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RBI reply to IDMA representation to allow import of Palladium and other precious metals on Advance Payment used in production of Drugs and Pharmaceuticals

The Association had made a representation on 10 July 2020 to **Shri Shaktikanta Das, IAS,** Governor of Reserve Bank of India (RBI) to allow import of Palladium and other precious metals on Advance Payment used in production of Drugs and Pharmaceuticals (*Please see IDMA Bulletin dated 30 July 2020 Page No. 4)*. RBI replied on 30 July

2020 seeking specific details of the cases that have been declined by RBI referred in our letter. We immediately submitted the same.

We have now received a reply on 7 August 2020 from **Jyoti Sayankrit,** AGM Trade, Foreign Exchange Department, Central Office, Reserve Bank of India, Mumbai Email: jyotisayankrit@rbi.org.in advising Members as below:

"We advise you to inform your members to approach the Regional Offices concerned of RBI through their respective AD banks with such requests."

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Web portals for Production Linked Incentive Schemes

The Department of Pharmaceuticals has informed us (vide E-mail on 11 August 2020) as below:

Reference is invited to the Guidelines of Production Linked Incentive (PLI) Schemes issued by the Department of Pharmaceuticals (DoP) on 27.07.2020 [The Guidelines can be downloaded from DoP website: **https://pharmaceuticals.gov.in/]**

This is to inform that IFCI Ltd has been selected as the Project Management Agency (PMA) for smooth implementation of the Scheme. IFCI Ltd has created web portals and email IDs for each of the PLI Schemes as under:

Scheme	Web Portal	Email ID
PLI Scheme for promotion of domestic manufacturing of critical KSM/Drug Intermediates and APIs	**http://plibulkdrugs.ifciltd.com/**	**bdpli@ifciltd.com**
PLI Scheme for promoting domestic manufacturing of medical devices	**plimedicaldevices.ifciltd.com**	**mdpli@ifciltd.com**

The web portal contains relevant information about the Schemes, Application Forms and contact details, in case of any query of the applicant. The Associations are requested to advise their members to refer the said portals of the IFCI Ltd.

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Transhipment of Cargo to Nepal under Electronic Cargo Tracking System Regulations, 2019 amended (1st Amendment of 2020) - reg.

Notification No.64/2020-Customs (N.T.), dated 31st July, 2020

In exercise of the powers conferred by section 157 read with sub-section (1) of section 54 and section 143AA of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations, to amend the Transhipment of Cargo to Nepal under Electronic Cargo Tracking System Regulations, 2019, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Transhipment of Cargo to Nepal under Electronic Cargo Tracking System (Amendment) Regulations, 2020.**

(2) They shall come into force on the day of their publication in the Official Gazette.

2. In the Transhipment of Cargo to Nepal under Electronic Cargo Tracking System Regulations, 2019,-

(i) in the sub-regulation (1) of regulation 2, for clause (b), the following clauses shall be substituted, namely:-

"(b) "authorised carrier" means an authorised sea carrier, authorised train operator or custodian, registered under regulation 3A;

(ba) "authorised sea carrier" means the master of the vessel carrying imported goods, export goods and coastal goods or his agent or any other person notified by the Central Government in terms of sub-section (1) of section 30 of the Act, in the case of a vessel;

(bb) "authorised train operator" means the train operator carrying imported goods and export goods;

(bc) "custodian" means a person approved by the Principal Commissioner or Commissioner of Customs, for the purposes of section 45 of the Act;";

(ii) after regulation 3, the following regulation shall be inserted, namely:–

"3A. Registration:

(1) The authorised carrier shall apply to the jurisdictional Principal Commissioner or Commissioner of Customs for registration in the Form-II, appended to these regulations.

(2) Where the jurisdictional Principal Commissioner or Commissioner of Customs is satisfied with the information provided by the applicant in Form-II, he shall approve the registration of such applicant for transacting business under these regulations for a period of three years from the date of issue of such registration.

(3) The jurisdictional Principal Commissioner or Commissioner of Customs shall review the registration before the expiry of the initial period of registration of three years and may extend such registration to a further period of five years at a time and in case of an authorised economic operator for a period of ten years.

(4) An authorised carrier registered under regulation 3 of the Sea Cargo Manifest and Transhipment Regulations, 2018, shall be deemed to be registered under these regulations."

(iii) in the regulation 4, for clause (a), the following shall be substituted, namely:–

"(a) declare the cargo destined to Nepal and the port of final discharge in Nepal in the arrival manifest, if he is required to do so as per the Sea Cargo Manifest and Transhipment Regulations, 2018;"

(iv) the "Form", shall be numbered as "Form-I", and after Form-I as so numbered, the following "Form-II" shall be inserted, namely:-

"FORM–II

(See Regulation 3A)

Application for Registration

1. Name of applicant with details of Permanent Account Number (PAN):-

   (In case the applicant is a firm or a company, the name of each of the partners of the firm or the directors of the company as the case may be)

2. Category of the applicant (authorised sea carrier, authorised train operator, shipping line or custodian):-

3. Contact details:-

   Phone number:-

   Email address:-

4. Full address of the applicant:-

   (In case the applicant is a firm or a company, the full address of each of the partners of the firm or the directors of the company as the case may be)

5. The name(s) and address of the authorised person:-

   (In case the applicant is a firm or a company, the name(s) of its partner or partners or director or directors or duly authorised employees who will actually be engaged in the work of filing Declaration of Transhipment).

6. Educational qualification of each of the persons who will actually be engaged in the filing of Declaration of Transhipment:-

7 Details of cases booked under Customs Act against the applicant, if any:-

8. The enclosures:-

   (a) Copy of contract, or

   (b) Memorandum of understanding, or

   (c) Agreement entered into with the foreign authorising agent.

I/We hereby declare that the contents of the above paragraphs are true to the best of my/our knowledge.

Date:-

Place:- Signature of the applicant(s)"

F.No.554/02/2014-LC

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

***Note:** The Principal Notification No.68/2019-Customs (N.T.) was published in the Gazette of India, Extraordinary, vide G.S. R.704(E), dated the 30th September, 2019.*

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Customs notifies 2nd phase of All India roll-out of Faceless Assessment - reg.

Circular No.34/2020-Customs, dated 30th July, 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,

1. Kind reference is invited to Board Circular No.28/2020-Customs and Instruction No.09/2020, both dated 05.06.2020 on the 1st phase of All India roll-out of Faceless Assessment under the umbrella of the **Turant Customs** programme. The 1st phase was begun from 08.06.2020 at Bengaluru and Chennai Customs Zones for items of import primarily covered by Chapters 84 and 85 of the Customs Tariff Act, 1975. As earlier informed, the 1st phase marked the beginning of the pan India roll out of Faceless Assessment, in different phases covering other ports and items of import, leading upto this mode of Customs assessment becoming the norm across the country from 01.01.2021.

2. Board has reviewed the 1st phase of Faceless Assessment at Bengaluru and Chennai and resolved few technical and administrative issues that arose. Board also noted that on expected lines the Faceless Assessment ushered in a smooth and faster clearance process with uniformity in assessment. Accordingly, **Board has decided to begin the 2nd phase of All India roll-out of Faceless Assessment w.e.f. 03.08.2020 by including Delhi and Mumbai Customs Zones and extending the scope of Faceless Assessment at Chennai and Bangalore Customs Zones.** It is clarified that the Customs Zones and the imports already covered under the 1st Phase would continue and be treated as subsumed under the 2nd phase. Thus, the 2nd phase of Faceless Assessment will cover the following specified Customs Zones and the imports primarily under the specified Chapters of the Customs Tariff Act, 1975:-

Sr. No.	Chapter(s) of the Customs Tariff Act, 1975	Appraise-ment Group	Customs Zones	Remarks
1.	84	5	Bengaluru, Chennai, and Delhi	Bengaluru and Chennai Zones were covered in 1st phase. Delhi Zone is newly covered.
2.	85	5A	Bengaluru, Chennai, and Delhi	
3.	89 to 92	5B	Bengaluru, Chennai, and Delhi	Pilot programme has been running in Delhi Zone since September 2019 and now Bengaluru and Chennai are newly covered.
4.	50 to 71	3	Bengaluru, Chennai, and Delhi	Pilot programme has been running in Chennai Zone since September 2019 and now Bengaluru and Delhi are newly covered.
5.	29	2A	Mumbai I, Mumbai II and Mumbai III	Newly introduced Zones

3. Further, for monitoring and ensuring speedy and uniform assessments in the Customs Zones at Sr.Nos.1 to 4 of the above table, in regard to Bills of Entry assigned by the Customs Automated System to the officers of the Faceless Assessment Groups, Board hereby nominates the following officers as Nodal Commissioners:-

Sr. No.	Designation
1.	Principal Commissioner/Commissioner of Customs, Bengaluru City, Bengaluru
2.	Principal Commissioner/Commissioner of Customs, Airport and Air Cargo Complex, Bengaluru
3.	Principal Commissioner/Commissioner of Customs (II), Chennai
4.	Principal Commissioner/Commissioner of Customs (VII), Air Cargo Complex Chennai
5.	Principal Commissioner/Commissioner of Customs, ICD Tughlakabad, Import.
6.	Principal Commissioner/Commissioner of Customs, Air Cargo Import, Delhi.

3.1 For the Customs Zones at Sr.No.5 of the table in para 2 above, Board hereby nominates the Principal Commissioner/Commissioner of Customs, Import-II, New Custom House, Mumbai, the Principal Commissioner/Commissioner of Customs, Nhava Sheva-I, Jawaharlal Nehru Customs House, Mumbai and the Principal Commissioner/Commissioner of Customs(III), Import, Air Cargo Complex, Sahar,

Mumbai as Nodal Commissioners who shall be administratively responsible for monitoring and ensuring speedy and uniform assessments in the three Customs Zones, in regard to Bills of Entry assigned by the Customs Automated System to the officers of the Faceless Assessment Groups.

4. Further, Notification No.63/2020-Customs (N.T.) dated 30.07.2020 is issued for the purpose of empowering the jurisdictional Commissioners of Customs (Appeals) at Bengaluru, Chennai, Delhi and Mumbai to take up appeals filed in respect of Faceless Assessments pertaining to imports made in their jurisdictions even though the assessing officer may be located at the other Customs station. To illustrate, Commissioners of Customs (Appeals) at Bengaluru would decide appeals filed for imports at Bengaluru though the assessing officer is located at Delhi. Similarly, Commissioners of Customs (Appeals) at Mumbai-I would decide appeals filed for imports at Mumbai-I even though the assessing officer is located at Mumbai-II.

5. All other clarifications and guidelines on Faceless Assessment, as provided vide Circular No.28/2020-Customs and Instruction No.09/2020-Customs, both dated 05.06.2020 may be kindly referred to.

6. The concerned Principal Chief Commissioners/Chief Commissioners are requested to issue Public Notices and guide the trade suitably to ensure the smooth roll out of Phase 2 of Faceless Assessment.

7. Any difficulties faced in the implementation may please be brought to the notice of the Board.

F.No.450/26/2019-Cus IV(Pt.)

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

● ● ●

Sea Cargo Manifest and Transhipment Regulations, 2018 amended (2nd Amendment of 2020) - reg.

Notification No.66/2020-Customs (N.T.), dated 31st July, 2020

In exercise of the powers conferred by section 157, read with sections 30, 30A, 41, 41A, 53, 54, 56, sub-section (3) of section 98 and sub-section (2) of section 158 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following regulations further to amend the Sea Cargo Manifest and Transhipment Regulations, 2018, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Sea Cargo Manifest and Transhipment (Second Amendment) Regulations, 2020.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Sea Cargo Manifest and Transhipment Regulations, 2018, in regulation 15:

a. in sub-regulation (1), for the expression, "from 15th May, 2020 till 1st August, 2020", the expression, "from 15th May, 2020 till 30th September, 2020" shall be substituted;

b. in sub-regulation (2), for the words, figures and letters "till 1st August, 2020" the words, figures and letters "till 30th September, 2020" shall be substituted.

F.No.450/58/2015-Cus-IV

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

Note: *The Principal regulations were published in the Gazette of India, Extraordinary, Part II, Section 3 Sub-section (i) vide number G.S.R.448(E), dated the 11th May, 2018 and were last amended vide Notification No.14/2020-Customs (N.T) dated the 14th February, 2020 vide number G.S.R.121(E), dated the 14th February, 2020.*

● ● ●

Executive Order signed by President of USA Mr Donald Trump

On Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are made in the United States

Issued on August 6, 2020 by the White House

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy:

The United States must protect our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and Chemical, Biological, Radiological, and Nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base with resilient domestic supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States. These domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID-19. It is critical that we reduce our dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation's Public Health Industrial Base to respond to these threats. It is therefore the policy of the United States to:

(a) accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(b) ensure long-term demand for Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States;

(c) create, maintain, and maximize domestic production capabilities for Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense; and

(d) combat the trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third-party online sellers involved in the government procurement process.

I am therefore directing each executive department and agency involved in the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs (agency) to consider a variety of actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, and to identify vulnerabilities in our Nation's supply chains for these products. Under this order, agencies will have the necessary flexibility to increase their domestic procurement in appropriate and responsible ways, while protecting our Nation's service members, veterans, and their families from increases in drug prices and without interfering with our Nation's ability to respond to the spread of COVID-19.

Section 2. Maximizing Domestic Production in Procurement:

(a) Agencies shall, as appropriate, to the maximum extent permitted by applicable law, and in consultation with the Commissioner of Food and Drugs (FDA Commissioner) with respect to Critical Inputs, use their respective authorities under section 2304(c) of title 10, United States Code; section 3304(a) of title 41, United States Code; and subpart 6.3 of the Federal Acquisition Regulation, title 48, Code of Federal Regulations, to conduct the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs by:

(i) using procedures to limit competition to only those Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States; and

(ii) dividing procurement requirements among two or more manufacturers located in the United States, as appropriate.

(b) Within 90 days of the date of this order, the Director of the Office of Management and Budget (OMB), in consultation with appropriate agency heads, shall:

(i) review the authority of each agency to limit the online procurement of Essential Medicines and Medical Countermeasures to e-commerce platforms that have:

(A) adopted, and certified their compliance with, the applicable best practices published by the Department of Homeland Security in its Report to the President on "Combating Trafficking in Counterfeit and Pirated Goods," dated January 24, 2020; and

(B) agreed to permit the Department of Homeland Security's National Intellectual Property Rights Coordination Center to evaluate and confirm their compliance with such best practices; and

(ii) report its findings to the President.

(c) Within 90 days of the date of this order, the head of each agency shall, in consultation with the FDA Commissioner, develop and implement procurement strategies, including long-term contracts, consistent with law, to strengthen and mobilize the Public Health Industrial Base in order to increase the manufacture of Essential Medicines, Medical Countermeasures, and Critical Inputs in the United States.

(d) No later than 30 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, the United States Trade Representative shall, to the extent permitted by law, take all appropriate action to modify United States Federal procurement product coverage under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of Essential Medicines, Medical Countermeasures, and Critical Inputs. The United States Trade Representative shall further modify United States Federal procurement product coverage, as appropriate, to reflectupdates by the FDA Commissioner. After the modifications to United States Federal procurement coverage take effect, the United States Trade Representative shall make any necessary, corresponding modifications of existing waivers under section 301 of the Trade Agreements Act of 1979. The United States Trade Representative shall notify the President, through the Director of OMB, once it has taken the actions described in this subsection.

(e) No later than 60 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, and notwithstanding the public interest exception in subsection (f)(i)(1) of this section, the Secretary of Defense shall, to the maximum extent permitted by applicable law, use his authority under section 225.872-1(c) of the Defense Federal Acquisition Regulation Supplement to restrict the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs to domestic sources and to reject otherwise acceptable offers of such products from sources in Qualifying Countries in instances where considered necessary for national defense reasons.

(f) Subsections (a), (d), and (e) of this section shall not apply:

(i) where the head of the agency determines in writing, with respect to a specific contract or order, that (1) their application would be inconsistent with the public interest; (2) the relevant Essential Medicines, Medical Countermeasures, and Critical Inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or (3) their application would cause the cost of the procurement to increase by more than 25 percent, unless applicable law requires a higher percentage, in which case such higher percentage shall apply;

(ii) with respect to the procurement of items that are necessary to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.).

(g) To the maximum extent permitted by law, any public interest determination made pursuant to section 2(f)(i)(1) of this order shall be construed to maximize the procurement and use of Essential Medicines and Medical Countermeasures produced in the United States.

(h) The head of an agency who makes any determination pursuant to section 2(f)(i) of this order shall submit an annual report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, describing the justification for each such determination.

Section 3. I dentifying Vulnerabilities in Supply Chains:

(a) Within 180 days of the date of this order, the Secretary of Health and Human Services, through the FDA Commissioner and in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs and to mitigate those vulnerabilities, including by:

(i) considering proposing regulations or revising guidance on the collection of the following information from manufacturers of Essential Medicines and Medical Countermeasures as part of the application and regulatory approval process:

(A) the sources of Finished Drug Products, Finished Devices, and Critical Inputs;

(B) the use of any scarce Critical Inputs; and

(C) the date of the last FDA inspection of the manufacturer's regulated facilities and the results of such inspection;

(ii) entering into written agreements, pursuant to section 20.85 of title 21, Code of Federal Regulations, with the National Security Council, Department of State, Department of Defense, Department of Veterans Affairs, and other interested agencies, as appropriate, to disclose records regarding the security and vulnerabilities of the supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) recommending to the President any changes in applicable law that may be necessary to accomplish the objectives of this subsection; and

(iv) reviewing FDA regulations to determine whether any of those regulations may be a barrier to domestic production of Essential Medicines, Medical Countermeasures, and Critical Inputs, and by advising the President whether such regulations should be repealed or amended.

(b) The Secretary of Health and Human Services, through the FDA Commissioner, shall take all appropriate action, consistent with applicable law, to:

(i) accelerate FDA approval or clearance, as appropriate, for domestic producers of Essential Medicines, Medical Countermeasures, and Critical Inputs, including those needed for infectious disease and CBRN threat preparedness and response;

(ii) issue guidance with recommendations regarding the development of Advanced Manufacturing techniques;

(iii) negotiate with countries to increase site inspections and increase the number of unannounced inspections of regulated facilities manufacturing Essential Medicines, Medical Countermeasures, and Critical Inputs; and

(iv) refuse admission, as appropriate, to imports of Essential Medicines, Medical Countermeasures, and Critical Inputs if the facilities in which they are produced refuse or unreasonably delay an inspection.

(c) Within 90 days of the date of this order, and periodically updated as appropriate, the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.

(d) Within 180 days of the date of this order, the Secretary of Defense, in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs necessary to meet the unique needs of the United States Armed Forces and to mitigate the vulnerabilities identified in subsection (a) of this section. The Secretary of Defense shall provide to the Secretary of Health and Human Services, the FDA Commissioner, the Director of OMB, and the Director of the Office of Trade and Manufacturing Policy a list of defense-specific Essential Medicines, Medical Countermeasures, and Critical Inputs that are medically necessary to have available for defense use in adequate amounts and in appropriate dosage forms. The Secretary of Defense shall, as appropriate, periodically update this list.

Section 4. S treamlining Regulatory Requirements:

Consistent with law, the Administrator of the Environmental Protection Agency shall take all appropriate action to identify relevant requirements and guidance documents that can be streamlined to provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of Critical Inputs, including by accelerating siting and permitting approvals.

Section 5. Priorities and Allocation of Essential Medicines, Medical Countermeasures, and Critical Inputs:

The Secretary of Health and Human Services shall, as appropriate and in accordance with the delegation of authority under Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness), use the authority under section 101 of the Defense Production Act of 1950, as amended (50 U.S.C. 4511), to prioritize the performance of Federal Government contracts or orders for Essential Medicines, Medical Countermeasures, or Critical Inputs over performance of any other contracts or orders, and to allocate such materials, services, and facilities as the Secretary deems necessary or appropriate to promote the national defense.

Section 6. Reporting:

(a) No later than December 15, 2021, and annually thereafter, the head of each agency shall submit a report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, detailing, for the preceding three fiscal years:

(i) the Essential Medicines, Medical Countermeasures, and Critical Inputs procured by the agency;

(ii) the agency's annual itemized and aggregated expenditures for all Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) the sources of these products and inputs; and

(iv) the agency's plan to support domestic production of such products and inputs in the next fiscal year.

(b) Within 180 days of the date of this order, the Secretary of Commerce shall submit a report to the Director of OMB, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

(c) To the maximum extent permitted by law, and with the redaction of any information protected by law from disclosure, each agency's report shall be published in the Federal Register and on each agency's official website.

Section 7. Definitions. As used in this order:

(a) "Active Pharmaceutical Ingredient" has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(b) "Advanced Manufacturing" means any new medical product manufacturing technology that can improve drug quality, address shortages of medicines, and speed time to market, including continuous manufacturing and 3D printing.

(c) "API Starting Material" means a raw or intermediate material that is used in the manufacturing of an API, that is incorporated as a significant structural fragment into the structure of the API, and that is determined by the FDA Commissioner to be relevant in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(d) "Critical Inputs" means API, API Starting Material, and other ingredients of drugs and components

of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(e) "Essential Medicines" are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of this order.

(f) "Finished Device" has the meaning set forth in section 820.3(l) of title 21, Code of Federal Regulations.

(g) "Finished Drug Product" has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(h) "Healthcare and Public Health Sector" means the critical infrastructure sector identified in Presidential Policy Directive 21 of February 12, 2013 (Critical Infrastructure Security and Resilience), and the National Infrastructure Protection Plan of 2013.

(i) An Essential Medicine or Medical Countermeasure is "produced in the United States" if the Critical Inputs used to produce the Essential Medicine or Medical Countermeasures are produced in the United States and if the Finished Drug Product or Finished Device, are manufactured, prepared, propagated, compounded, or processed, as those terms are defined in section 360(a)(1) of title 21, United States Code, in the United States.

(j) "Medical Countermeasures" means items that meet the definition of "qualified countermeasure" in section 247d 6a(a)(2)(A) of title 42, United States Code; "qualified pandemic or epidemic product" in section 247d–6d(i)(7) of title 42, United States Code; "security countermeasure" in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations.

(k) "Public Health Industrial Base" means the facilities and associated workforces within the United States, including Research and Development facilities, that help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare and Public Health Sector.

(l) "Qualifying Countries" has the meaning set forth in section 225.003, Defense Federal Acquisition Regulation Supplement.

Section 8. Rule of Construction:

Nothing in this order shall be construed to impair or otherwise affect:

(a) the ability of State, local, tribal, or territorial governments to timely procure necessary resources to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.);

(b) the ability or authority of any agency to respond to the spread of COVID-19; or

(c) the authority of the Secretary of Veterans Affairs to take all necessary steps, including those necessary to implement the policy set forth in section 1 of this order, to ensure that service members, veterans, and their families continue to have full access to Essential Medicines at reasonable and affordable prices.

Section 9. Severability:

If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

Section 10. General Provisions:

(a) Nothing in this order shall be construed to impair or otherwise affect:

  (i) the authority granted by law to an executive department or agency, or the head thereof; or

  (ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

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COVID-19: Immune system derails

Contrary to what has been generally assumed so far, a severe course of COVID-19 does not solely result in a strong immune reaction - rather, the immune response is caught in a continuous loop of activation and inhibition. Experts from Charité - Universitätsmedizin Berlin, the University of Bonn, the German Center for Neurodegenerative Diseases (DZNE), the Helmholtz Centre for Infection Research (HZI) and the German Center for Infection Research (DZIF), along with colleagues from a nationwide research network, present these findings in the scientific journal Cell.

Most patients infected with the Coronavirus SARS-CoV-2 show mild or even no symptoms. However, 10 to 20 percent of those affected develop pneumonia during the course of COVID-19 disease, some of them with life-threatening effects. "There is still not very much known about the causes of these severe courses of the disease. The high inflammation levels measured in those affected actually indicate a strong immune response. Clinical findings, however, rather tend to indicate an ineffective immune response. This is a contradiction," says Joachim Schultze, Professor at the University of Bonn and research group leader at the DZNE. "We therefore assume that although immune cells are produced in large quantities, their function is defective. That is why we examined the blood of patients with varying degrees of COVID-19 severity," explains Leif Erik Sander, Professor of Infection Immunology and Senior Physician Charité's Medical Department, Division of Infectious Diseases and Respiratory Medicine.

High-precision methods:

The study was carried out within the framework of a nationwide consortium - the "German COVID-19 OMICS Initiative" (DeCOI) - resulting in the analysis and interpretation of the data being spread across various teams and sites. Joachim Schultze was significantly involved in coordinating the project. The blood samples came from a total of 53 men and women with COVID-19 from Berlin and Bonn, whose course of disease was classified as mild or severe according to the World Health Organization classification. Blood samples from patients with other viral respiratory tract infections as well as from healthy individuals served as important controls.

The investigations involved the use of single-cell OMICs technologies, a collective term for modern laboratory methods that can be used to determine, for example, the gene activity and the amount of proteins on the level of single, individual cells - thus with very high resolution. Using this data, the scientists characterized the properties of immune cells circulating in the blood-so-called white blood cells. "By applying bioinformatics methods on this extremely comprehensive data collection of the gene activity of each individual cell, we could gain a comprehensive insight of the ongoing processes in the white blood cells," explains Yang Li, Professor at the Centre for Individualized Infection Medicine (CiiM) and Helmholtz Centre for Infection Research (HZI) in Hannover. "In combination with the observation of important proteins on the surface of immune cells, we were able to decipher the changes in the immune system of patients with COVID-19," adds Birgit Sawitzki, Professor at the Institute of Medical Immunology on Campus Virchow-Klinikum.

"Immature" cells:

The human immune system comprises a broad arsenal of cells and other defense mechanisms that interact with each other. In the current study, the focus was on so-called myeloid cells, which include neutrophils and monocytes. These are immune cells that are at the very front of the immune response chain, i.e. they are mobilized at a very early stage to defend against infections. They also influence the later formation of antibodies and other cells that contribute to immunity. This gives the myeloid cells a key position.

"With the so-called neutrophils and the monocytes we have found that these immune cells are activated, i.e. ready to defend the patient against COVID-19 in the case of mild disease courses. They are also programmed to activate the rest of the immune system. This ultimately leads to an effective immune response against the virus," explains Antoine-Emmanuel Saliba, head of a research group at the Helmholtz Institute for RNA-based Infection Research (HIRI) in Würzburg.

But the situation is different in severe cases of COVID-19, explains Sawitzki: "Here, neutrophils and monocytes are only partially activated and they do not function properly. We find considerably more immature cells that have a rather inhibitory effect on the immune response." Sander adds: "The phenomenon can also be observed in other severe infections, although the reason for this is unclear. Many indications suggest that the

immune system stands in its own way during severe courses of COVID-19. This could possibly lead to an insufficient immune response against the Coronavirus, with a simultaneous severe inflammation in the lung tissue."

Approaches to therapy?

The current findings could point to new therapeutic options, says Anna Aschenbrenner from the LIMES Institute at the University of Bonn: "Our data suggest that in severe cases of COVID-19, strategies should be considered that go beyond the treatment of other viral diseases." The Bonn researcher says that in the case of viral infections one does not actually want to suppress the immune system. "If, however, there are too many dysfunctional immune cells, as our study shows, then one would very much like to suppress or reprogram such cells." Jacob Nattermann, Professor at the Medical Clinic I of the University Hospital Bonn and head of a research group at the DZIF, further explains: "Drugs that act on the immune system might be able to help. But this is a delicate balancing act. After all, it's not a matter of shutting down the immune system completely, but only those cells that slow down themselves, so to speak. In this case these are the immature cells. Possibly we can learn from cancer research. There is experience with therapies that target these cells."

Nationwide team effort:

In view of the many people involved, Schultze emphasizes the cooperation within the research consortium: "As far as we know, this study is one of the most comprehensive studies to date on the immune response in COVID-19 based on single cell data. The parallel analysis of two independent patient cohorts is one of the strengths of our study. We analyzed patient cohorts from two different sites using different methods and were thus able to validate our findings directly. This is only possible if research data is openly shared and cooperation is based on trust. This is extremely important, especially in the current crisis situation."

Source: DZNE - German Center for Neurodegenerative Diseases, Science Daily, 06.08.2020

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New Approach to Treating Osteoarthritis Advances

Injections of a natural "energy" molecule prompted regrowth of almost half of the cartilage lost with aging in knees, a new study in rodents shows.

The study results revolve around the long-established idea that machines within animal and human cells turn the sugars, fats, and proteins we eat into energy used by the body's millions of cells. The molecule most used to store that energy is called adenosine triphosphate, or ATP. Along with this central role in metabolism, adenosine also helps signal other cells and serves as a building block of genetic material, and so is central to the growth of human tissue.

Previous research had shown that maintaining supplies of adenosine, known to nourish the chondrocyte cells that make cartilage, also prevented osteoarthritis in similar animal models of the disease.

In the new NYU Grossman School of Medicine–led study, researchers injected adenosine into the joints of rodents whose limbs had been damaged by inflammation resulting from either traumatic injury, such as a torn ligament, or from massive weight gain placing pressure on joints. The biological damage in these cases is similar, researchers say, to that sustained in human osteoarthritis.

Published online in the journal Scientific Reports on August 10, the study rodents received 8 weekly injections of adenosine, which prompted regrowth rates of cartilage tissue between 50 percent and 35 percent as measured by standard laboratory scores.

"Our latest study shows that replenishing adenosine stores by injection works well as a treatment for osteoarthritis in animal models of the disease, and with no apparent side effects," says lead study author Carmen Corciulo, Ph.D., a postdoctoral fellow at NYU Langone.

Dr. Corciulo says it is too soon to use this experimental model as a therapy in people. Clinical trials must await a test drug that can be safely stored for days if not weeks, and experiments in larger mammals.

Study senior investigator Bruce N Cronstein, MD, the Dr Paul R. Esserman Professor of Medicine at NYU

Langone Health, says the team's research is important because the few existing drug therapies for osteoarthritis such as acetaminophen and COX-2 inhibitor drugs, including naproxen and ibuprofen, only numb joint pain, or like hyaluronic acid just lubricate its tissues. None stall disease progression or reverse the damage. Painkillers, such as opioids, are often prescribed, but are also highly addictive, he cautions.

"People with osteoarthritis desperately need more treatment options with fewer side effects, and our research advances that effort," says Dr Cronstein, who also serves as the Director of NYU Langone's Clinical and Translational Science Institute. He notes that other experimental medications are being developed elsewhere, including parathyroid hormone to stimulate bone growth, WNT inhibitor drugs to block the bone and cartilage degradation, and growth factor chemicals to promote cartilage growth.

Dr Cronstein, Dr Corciulo, and NYU Grossman School of Medicine have a patent application pending for the use of adenosine and other agents that help with its binding to chondrocytes, called A2A receptor agonists, for the treatment of osteoarthritis.

Among the study's other key findings was that a cell-signaling pathway, known as transforming growth factor beta (TGF-beta) and involved in many forms of tissue growth, death, and differentiation, was highly active in cartilage tissue damaged by osteoarthritis, as well as in cartilage tissue undergoing repair after being treated with adenosine. Additional testing in lab-grown chondrocytes from people with osteoarthritis showed different chemical profiles of TGF-beta signaling during breakdown than during growth, providing the first evidence that the pathway switched function in the presence of adenosine (from assisting in cartilage breakdown to encouraging its repair.)

Developing treatments to halt or slow the disease is important, Dr Cronstein says, because well over 100 million people worldwide are estimated to have osteoarthritis, which is tied to aging, especially in women. This figure, he says, is only expected to grow as more people live longer and obesity rates climb.

"Right now, the only way to stop osteoarthritis is to have affected joints surgically replaced, which not only comes with pain and risk of infection, but is also quite costly," says Dr Cronstein. "If new therapies can delay or prevent disease onset and progression, then fewer joint replacements will save people from a lot of pain and expense."

The study was funded by National Institutes of Health grants R01 AR056672 and R01 AR068593, NYU-HHC Clinical and Translational Science Institute grant UL1 TR000038, and the Arthritis Foundation.

Dr. Corciulo and Dr. Cronstein have a patent for the methods and compositions for treating osteoarthritis and promoting cartilage formation (U.S. Patent 10,441,541), which has been assigned to NYU Grossman School of Medicine. They are cofounders of Regenosine Inc., a company that is developing new treatments for osteoarthritis, and in which they hold a financial interest. Dr Cronstein has consulted for Eli Lilly, Horizon Pharmaceuticals, Bristol Myers Squibb, and Astrazeneca. He also has grants from Arcus Biopharma. All relationships are being managed in accordance with the policies and practices of NYU Langone. Besides Dr. Cronstein and Dr. Corciulo, other NYU Langone investigators involved in this study are Cristina Castro, MD; Thomas Coughlin, PhD; Samson Jacob, MS; David Fenyo, Ph.D.; Daniel B. Rifkin, Ph.D.; and Oran Kennedy, Ph.D.

Source: David March, NYU Langone News, 11.08.2020

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Dr Harsh Vardhan presides over signing of MoU between CSIR and FSSAI

FSSAI awarded the Food Systems Vision Prize for its 'Eat Right India' movement

Web Admin

Dr Harsh Vardhan, Union Minister for Health and Family Welfare presided the signing of MoU between Food Safety and Standards Authority of India (FSSAI) under Ministry of Health & Family Welfare and Council of Scientific & Industrial Research (CSIR) under Ministry of Science & Technology, in the presence of Shri Ashwini K Choubey, Minister of State (HFW).

The MOU aims towards collaborative research and information dissemination in the area of food and nutrition. Congratulating both FSSAI and CSIR for this innovative step that will merge the potential and faculties of both the premier organizations, Dr Harsh Vardhan stated that this MOU will enable identification of technologies and programs to be developed in the area of food safety and nutrition research, along with recognition of innovative technologies available with CSIR for deployment by the Indian businesses and/or for regulating compliances.

It will also seek collection of data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, identification of emerging risks, their mitigation strategies and introduction of rapid alert system. The two organisations will collaborate towards strengthening the quality assurance of laboratory network across the country aimed at development and validation of methods for reliable reporting on quality and safety of food products, he stated.

Speaking on the MoU signed between FSSAI and CSIR, Dr Harsh Vardhan said "The MoU is a very significant step that will create a brighter future for India seeking collaborative research and information dissemination in the area of food & nutrition, and food and consumer safety solutions in India. The collaboration between these two premier institutions of India will contribute in fulfilling the vision of New Food System 2050." Dr Harsh Vardhan also congratulated FSSAI on being selected as one of the ten global organizations for the award by Rockefeller Foundation, SecondMuse, and OpenIDEO for the 'Eat Right India' movement.

The award recognizes organisations that have developed an inspiring vision of the regenerative and nourishing food system that they aspire to create by the year 2050. Dr Harsh Vardhan stated that the award is a strong recognition of FSSAI's holistic and path breaking approach towards food safety and nutrition. It also provides the vision for its growth path, he added.

He said that "the vision of Health for All can be achieved through the twin measures of ensuring physical exercise and choosing nutritious food in our daily lives. The 'Eat Right India' vision is about creating a culture of safe, healthy and sustainable food involving all stakeholders and leveraging technology in food production, processing, distribution, quality and traceability and to empower consumers to adopt right eating practices".

Dr Harsh Vardhan highlighted that the envisioned new food system of 2050 will see a surge in demand for healthy, nutritious, plant-based, local, seasonal and indigenous foods, produced organically. He said it will also see an enhanced focus on climate-friendly food production systems, conservation of land and water resources, reduction in food loss and food wastage across the value chain, increase in small scale production units for self-sustaining local economies, use of environment friendly packaging alternatives, repurposing of waste.

Shri Ashwini Kumar Choubey congratulated the recipients of the highly respected Rockefeller Award. He said "The movement envisioned by India will lead to a revival of traditional Ayurvedic wisdom in ancient food practices, a variety of new employment opportunities to bring these measures into practice and support local and

rural economies, particularly for women bringing about economic growth and gender equity."

The MoU with CSIR will enable FSSAI to identify existing and novel technologies and programs, collect data regarding food consumption, incidence and prevalence of existing emerging risks, develop a rapid alert system and strengthen the quality assurance laboratory network for this purpose", he added. Shri Shekhar C Mande, DG-CSIR, Shri Arun Singhal, CEO, FSSAI and other senior officials of FSSAI and CSIR were also present at the occasion.

Dr Amulya K Panda, Dr Sudesh Kumar Yadav of Center of Innovative and Applied Bioprocessing (CIAB, Mohali), an autonomous body under DBT, Dr Addanki Vamsi Krishna, Scientist, DBT; and Directors of CSIR labs; Shri KMKS Raghava Rao, Director, Central Food Technological Research Institute (CFTRI, Mysore), Dr Alok Dhawan, Director, Indian Institute of Toxicology Research (IITR, Lucknow), Dr Sanjay Kumar, Director, Institute of Himalayan Bioresource Technology (IHBT, Palampur), Dr Ayyappanpillai Ajayaghosh, Director, National Institute for Interdisciplinary Science and Technology (NIIST, Thiruvananthapuram), and Dr Narahari Sastry, Director, North East Institute of Science and Technology (NEIST, Jorhat) joined the meet digitally.

Source: https://www.5dariyanews.com, 08.08.2020

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Prices of Remdesivir and Favipiravir being monitored in India, says report

Regulatory bodies in India are tracking the cost of Remdesivir and Favipiravir amid the COVID-19 pandemic but should consider price caps, a report has suggested. According to a new report, regulatory bodies in India are keeping a close eye on Remdesivir and Favipiravir amid the COVID-19 pandemic to safeguard patients' interest around pricing. The report, from Globaldata, says that the National Pharmaceutical Pricing Authority (NPPA) and the Drug Controller General of India (DCGI) are among the organisations monitoring the prices.

Also, the Indian Council of Medical Research (ICMR) has recently proposed price cap for Remdesivir, whereas Glenmark's Fabiflu (favipiravir) was under scrutiny by the DCGI for both pricing and claims made. Both Remdesivir and Favipiravir have seen a sharp decline in price since the availability of the first generic in India.

According to the report, Hetero was the first company to launch the Remdesivir generic Covifor in India at INR5,400 ($72) per vial. Cipla's Remdesivir generic Cipremi was priced at INR4,000 ($53.4), and is the cheapest version. As organisations are digitally transforming their operations, data integrity remains an extremely important aspect of laboratory processes and software functionality. Laboratories need to promote and ensure that regulatory guidances are being followed and that data is of the highest integrity.

This one-hour session taking place on 29 September at 15:00 BST will focus on industry issues, solutions, trends and how LIMS can enable laboratories to accelerate science and drive productivity, while ensuring regulatory compliance. Similarly, Glenmark's Fabiflu (favipiravir) was priced at INR103 ($1.38) per 200mg tablet, which was reduced to INR75 ($1) owing to benefits gained from higher yields and better scale. Following the launch of other favipiravir generics in India, Favivent by Jenburkt Pharmaceuticals is the cheapest version available at INR39 ($0.52) per 200mg tablet.

Cipla's Ciplenza is priced at INR68 ($0.91) whereas Brinton Pharmaceuticals' Faviton and Hetero Labs Favivir have priced same at INR59 ($0.79) per tablet, says the report. Prashant Khadayate, Pharma Analyst at GlobalData, commented: "Considering the wide variation and fluctuations in the pricing of Remdesivir and Favipiravir, the NPPA should invoke paragraph 19 of the Drug Price Control Order of 2013 which allows fixing the prices of drugs which are of public interest. The NPPA is already considering a proposal for a Remdesivir price cap; however, a price cap for favipiravir should also be considered. During these unprecedented times, regulatory bodies should ensure that companies are not thinking too much about profit."

The report suggests that even though Glenmark has clarified the pricing and claims related issues to the DCGI, there should be more transparency in pricing – especially during this emergency situation. Primarily, cost analysis of the bulk drug used in the generic formulation should be evaluated by the regulatory bodies from the pricing perspective.

"It is very important that the Remdesivir and Favipiravir prices be made as affordable as possible, which is in the best interest of patients and healthcare providers. The NPPA should quickly make a decision on the pricing regulation irrespective of Remdesivir and Favipiravir falling outside the purview of the NPPA as both are considered experimental therapies for COVID-19 and not approved as a drug," Khadayate concluded.

Source: Victoria Rees, European Pharmaceutical Review, 08.08.2020

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Rockefeller Foundation selects FSSAI as finalist for Food System Vision Prize

Food Safety and Standards Authority of India (FSSAI) has been adjudged among the top ten finalists for the Food System Vision Prize by the US-based Rockefeller Foundation. It was declared among the ten finalists for its Eat Right India initiative, from among a pool of more than 1,300 applicants from 110 countries.

Each of the ten finalists will receive a prize of $200,000 and includes Hyderabad-based non-profit organisation Naandi Foundation.

In a statement, the Rockefeller Foundation said the FSSAI's vision behind Eat Right India "looks to create a national movement towards healthier diets through a systems-based approach of reducing food waste; improving hygiene and sanitation across the value chain; and increasing access to and affordability of healthy foods." The Food System Vision Prize focuses on encouraging organizations across the globe to develop a "vision of the regenerative and nourishing food system" that they aspire to create by the year 2050.

Pawan Agarwal, former CEO of FSSAI, who had led the team that submitted the application for the prize last year, said, the food safety authority's Eat Right India initiative has received a global endorsement and the vision which focuses on better food for better lives in the country is "ambitious but achievable."

Agarwal, who is currently serving as Special Secretary (Logistics) at the Commerce Ministry added that it is "heartening to see the commitment of the new leadership at FSSAI towards the Eat Right India" programme.

FSSAI launched the initiative in July 2018 and focuses on empowering citizens to make the right food choices. It is also working on "nudging" food businesses to reformulate their products, provide better nutritional information to consumers and step up investments on healthy food products. Last month, FSSAI CEO Arun Singhal had told BusinessLine, that the food safety authority plans to scale up the Eat Right Campus programme (part of the Eat Right India initiative) over the next two years. Eat Right Campus aims to promote healthy and safe food across educational institutes, corporate offices, hospitals and government offices.

Source: The Hindu BusinessLine, 08.08.2020

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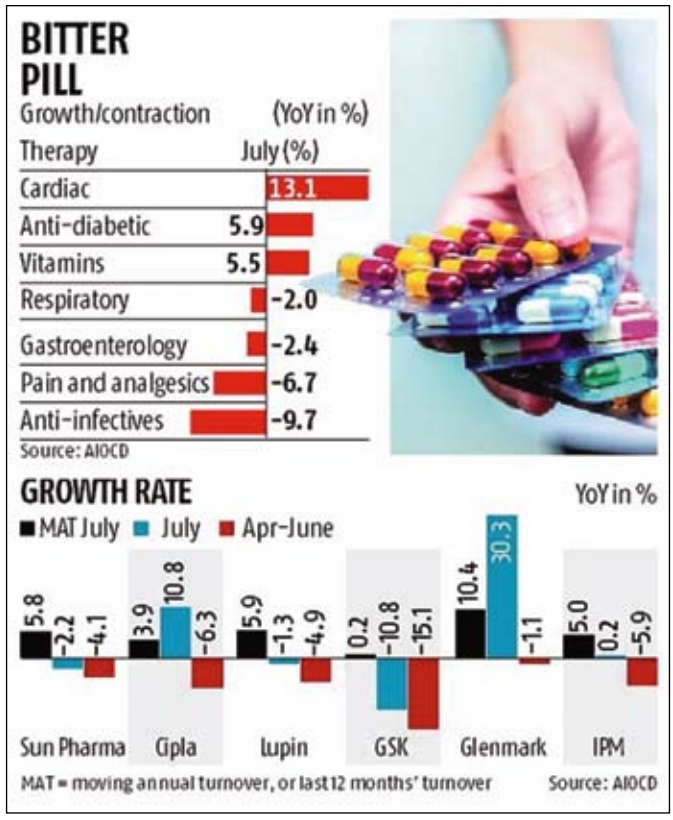
After showing signs of recovery in June, domestic pharma sales dip in July

Data shows that the Covid-19 crisis impacted the growth rate of the domestic market

The domestic pharmaceutical industry clocked negligible growth of 0.2 per cent in July after showing signs of recovery in June. Most therapy areas posted a drop in sales growth rate. Growth has been under pressure since the lockdowns related to Covid-19 started and fresh prescription generations slowed. In May, the Indian pharma market contracted 9 per cent after declining 11 per cent in April. June, however, saw some recovery with the growth coming back at 2.4 per cent.

According to the data from market research firm AIOCD AWACS, the Covid-19 pandemic impacted the growth rate of the domestic market. However, some therapies continued to post growth in July.



Chronic therapy areas (that usually see stickiness from patients) continued to post growth. Cardiac therapy, for example, clocked a 13.1 per cent growth rate, while anti-diabetic grew 5.9 per cent. Respiratory medicine sales, however, shrank 2 per cent. Even after the relaxation of the lockdown, sales of anti-infectives fell 10.2 per cent

in July. Anti-infective (primarily antibiotics) sales usually grow during the monsoons as cold- and fever-related illnesses rise.

Vitamin sales bounced back and grew 5.5 per cent in July as consumer interest in over-the-counter immunity-boosting medicines grew. Several companies have either launched or renewed focus on such brands — Dr Reddy's Laboratories, for example, has launched nutraceutical brands, similarly Zuventus Healthcare's zinc supplement Zinconia has seen traction in the market. The growth in June was also partly due to the low base as monsoons were slightly delayed last year, according to Ameesh Masurekar, director of AIOCD AWACS. "In comparison, this year the monsoons are early. This typically pushes up sales of categories like anti-infectives," he said. Credit rating agency ICRA recently said that it expected the domestic pharma industry to clock 4-6.

Source: Sohini Das, Business Standard, 09.08.2020

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Zydus Cadila gets tentative nod from US FDA to market Parkinson's disease drug

Drug firm Zydus Cadila said it has received tentative nod from the US health regulator to market Carbidopa and Levodopa extended-release capsules, used for the treatment of symptoms of Parkinson's disease, in the US market.

The company has received tentative approval from the United States Food and Drug Administration (US FDA) to market the capsules in the strengths of 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg, Zydus Cadila said in a statement.

The drug will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad, it added. This medication is used to treat the symptoms of Parkinson's disease such as shakiness, stiffness, difficulty moving or Parkinson-like conditions, Zydus Cadila said.

The group now has 295 approvals and has so far filed over 390 Abbreviated New Drug Applications (ANDAs) since the commencement of its filing process, it added.

Source: PTI, ET-Health World, 01.08.2020 (Excerpts)

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As Centre readies new R&D Policy, Pharma and Biotech industries hope for fast approvals, funding

With the Union Government set to come out with a dedicated R&D policy, the country's Pharma and Biotech industries are eager to spur innovation in a transformed regulatory environment where approvals are in sync with the current and advanced technologies.

The much anticipated policy, which mandates globally benchmarking the R&D ecosystem to get rid of archaic laws and strengthen industry-academia linkage, is a positive move, noted Dr Praveen Kumar Vemula, Associate Professor, DBT-Institute for Stem Cell Science and Regenerative Medicine (inStem).

These changes are imperative and will have a great impact on strengthening the internal ecosystem. If the policy reduces dependency on imports of key pharmaceutical ingredients, it will strengthen domestic manufacture, Dr Vemula told.

According to Dr Mahesh Bhalgat, Chief Operating Officer, Syngene International, "As a full spectrum and evolved Contract Research Organization, we recognize this as a positive revision of Guidelines that will result in dramatically scaling up Research and Development and move India higher in the innovation space. Coming close on the heels of the Government's support through the API-PLI initiative, it prepares India to build its own pipeline of innovative therapies. We are positive that modified Guidelines will benefit educational and scientific institutions, resulting in high quality, scalable scientific breakthroughs".

"As a science-led biopharmaceutical company, we understand the importance of benchmarking our research to the global research ecosystem. It will give a fillip to new drugs and devices to treat and manage the country's disease burden. We hope the revised Guidelines will result in research data being accepted nationally and internationally and reduce the time to market," said Dr Anil Kukreja, Vice President, Medical Affairs & Regulatory, AstraZeneca India.

According to Dr Suresh Saravdekar, Vice Chairman, Hospital Pharmacy Division, Indian Pharmaceutical Association and Honorary Consultant (Medication Management) Institute of Medical Sciences, Benares Hindu

University, research from a global perspective in the last five decades indicates that US, Japan, Germany, France and the UK account for two-thirds in value of all medicines produced. Hence, all drugs researched are for global and not for our local needs, he added.

In India too, there are no effective medicines for the 450 orphan diseases, or even Kala Azar and Japanese Encephalitis, malaria, tuberculosis, leprosy, chickunguniya, leptospirosis and dengue.

Quoting a US FDA study, Dr Saravdekar said of the total drugs entering the market, only 14% were innovative and the rest are a modification of the basic chemical of the original drug like for instance the multiple medicines under the proton pump inhibitor category like omeprazole, pantoprazole, lansoprozole, rabeprazole, esomaprozole.

"Further, there is inadequate research for new formulations especially under the paediatric dosage forms like antibiotics, antiviral, anti-tuberculosis, antipyretics and NSAIDs. Therefore, the new R&D policy should incentivise innovation in these areas," he noted.

Dr HV Raghunandan, a Pharma Consultant, pointed out that funding is critical for research. Hence the policy should highlight the financial component to enable the private sector and a consortium of researchers to put up a research and innovation facility. India needs R&D incubators to measure the tangible outcome of innovation.

Moreover, if the Government allocates land, research entrepreneurs will be keen to invest backed by Government and private funding. However, here the project approval processes need to be fast and easy. There is considerable talent in India with expertise in Pharma, Biopharma and medical devices. Hence funding, commercialization, tax holiday, market exclusivity and patent policy are vital components to this R&D policy, said Dr Raghunandan

Source: Nandita Vijay, Pharmabiz, 08.08.2020

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Indian pharma industry expected to be stable this year, says credit rating agency

The Indian pharmaceutical industry is expected to register a growth of 14.2 percent in the second quarter of the current financial year contrary to 4.8 percent in the first quarter, a study by Information and Credit Rating Agency (ICRA) has found. The growth could be attributed to the outbreak of many diseases in many parts aiding the growth of the anti-infective segment.

Gaurav Jain, Vice President and Co-head of ICRA, said the global demand scenario is largely expected to remain stable for Indian pharmaceutical industry owing to inelastic nature of prescription drugs though some impact on volume growth will be felt owing to lockdown (lesser OPDs/Elective surgeries) and lower economic growth. "The impact of lower demand will be felt more in less developed countries which are additionally negatively impacted owing to low crude oil prices," he said.

Overall, ICRA expects the domestic pharmaceutical industry to grow at 4 to 6 percent in the financial year 2021 owing to Coronavirus impact. As per ICRA research, the post-onset of Covid-19 manufacturing activity has gradually started in China with shipments/air cargo arriving in India for key starting materials.

This has led to production continuation for Indian players though the capacity utilisation across plants is yet to reach pre-Covid-19 levels. The lower capacity utilisation is largely contributed by restricted movement of personnel and availability of non-critical raw material (like packaging material) during the lockdown period in India. Indian players hold two to four months of inventory (raw material and finished goods) and similar levels in the distribution channel (finished goods) which will largely suffice demand in the near term till the situation normalises. The domestic pharmaceutical industry is highly dependent on imports, with more than 60 percent of its Active Pharmaceutical Ingredients (API) requirement being imported, and in some, specific APIs like cephalosporins, azithromycin and penicillin, the dependence is as high as 80 percent to 90 percent. Of the total imports of APIs and intermediates into India, China accounts for 65 percent to 70 percent.

"The recent introduction of Rs 10,000 crore bulk drugs park and production linked incentives for API manufacturers by the Union Government will lead to reduced dependence for the domestic formulators on imports from China and augurs well in the long run to manage supply disruptions. The incentive scheme covers 53 APIs which are critical from import dependence on China with few API/KSM being entirely imported," states the ICRA study.

Source: Kiran Tare, India Today, 05.08.2020

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Centre to soon come up with an exclusive R&D Policy for Pharma sector: Official

Observing that scientists who achieve breakthrough innovations should also be rewarded, Secretary of Department of Pharmaceuticals, P D Vaghela on Wednesday, 05.08.2020 said the Centre will soon come up with an exclusive policy for Research and Development in the sector. Vaghela said the Government is planning to set up three National Centres of Excellences (CoE) for drugs, medical devices in the country while the National Institute of Pharmaceutical Education and Research (NIPER) here will house one CoE for drug discovery.

"We should be ready that our scientists also become millionaires. If they (scientists) can invent good products and do some research, why not? That is happening in Europe and the US. Why not in India? Even if a scientist in a Government institute invent something good and it is converted into a commercial product, we should reward him," Vaghela said. He was speaking at the 77th Foundation day of CSIR-Indian Institute of Chemical Technology here through video conference.

"We are working (on the R&D policy). Our R&D policy is more on this, so our department has taken the initiative through industry academia interaction for framing this policy and we are likely to finalise it shortly," the official said. According to Vaghela, Indian pharmaceutical Industry is the third largest in the world by volume and 14th in terms of value even as it contributes 3.5 percent of the total medicines exported globally.

The total size of Pharma and related industry including medical devices in the country was at USD 51 billion in 2019-20, of which 75 percent is contributed by pharmaceutical products alone, he said. Noting that India faces three challenges in the Pharma and medical devices sectors, the official said 86 percent of the total requirement of medical devices including surgical, cardiac stents and electronic gadgets are currently being imported due to cost advantage.

The other two challenges are import dependence for drug intermediates and Active Pharmaceutical Ingredients (API) while the third was R&D in the healthcare and pharmaceutical sector and skilling. He said the central Government was proposing to set up three bulk drug parks, for which it provides Rs 1,000 crore to each. The selection of states, where these parks would come up, would be based on the infrastructure they provide.

(This story has not been edited by Outlook Staff and is auto-generated from news agency feeds)

Source: PTI, Outlook - The News Scroll, 05.08.2020

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Pharma exports grow 7% in Q1

India's Pharma exports rose more than 7% year-on-year to $5,412.12 million in the quarter ended June 30, a growth that came in the backdrop of the lockdown for COVID-19 and associated challenges, especially on the logistics front.

As per Pharmaceuticals Export Promotion Council of India Director General Ravi Udaya Bhaskar drug formulations and biologicals powered the growth with a 15.1% increase to $4,138.97 million. It was the only category where growth was registered and contributed to 76.48% of the total exports.

Bulk drugs and drug intermediates, the other major category, declined 8.38% to $895.77 million. This happened amid mounting uncertainty on raw material availability from China and India restricting for export a clutch of APIs and formulations made from them. Initially, there were also fears that the raw material inventory available with the Pharma companies would barely be enough for 2-3 months.

Surgicals and vaccines, two promising categories, also reported a decline in export, Mr. Bhaskar said. The decline in exports of surgicals was 15.83% to $130.02 million, while those of vaccines dropped 30.49% to $147.46 million. Besides a drop in demand for various products as countries battled the pandemic, a key factor that came in the way of smooth flow of trade were issues concerning movement of goods. A combination of factors pushed up the freight cost for the companies, Mr Bhaskar said.

Dr Reddy's Laboratories President and CFO Saumen Chakraborty, a few days ago, had also referred to how higher freight cost due to shortage of carriers for shipping the goods from India to other countries due to COVID-19-related disruptions led to an increase in the expenses for the company.

The challenges faced by the exporters and the time to normalcy are also reflected from the month-wise export numbers. In April, the Pharma exports actually declined

0.84% to $1514.04 million as against the quick estimates shared earlier that reported a negligible increase.

As the situation on the ground improved and restrictions were relaxed, the exports in May increased 14.30% to $1928.20 million. According to Mr Bhaskar, in June the exports were $1969.88 million or 7.26% higher than $1836.52 million of the corresponding period in 2019.

Source: N Ravi Kumar, The Hindu, 31.07.2020

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Indian Pharma & Healthcare sectors need to innovate for less expensive & effective drug formulations: Experts

Innovation is crucial in healthcare since effective formulations and new drug compositions that are less expensive are needed for universal healthcare. In order to achieve this, there is a need for a constant engagement by the Government with the pharmaceutical industry, stated experts.

The two aspects of healthcare are capability and affordability. COVID-19 has shown us that healthcare expenditure for preventive and curative measures across the population is imperative. Therefore, we need to address healthcare from the standpoint of resources, ageing population and high out-of-pocket expenses. Good healthcare has a positive impact on the population in terms of employability and access to equitable healthcare, said Christiane Hamacher, CEO, Biocon Biologics India.

Sharad Goswami, Senior Director, Corporate Affairs, Pfizer, noted at a recently concluded CII PharmaCon2020 online event that during this current COVID-19 pandemic, a renewed focus on innovation is evident to tackle the challenges. This is where a 6 'P' formula: Policy, Products, Pricing, Production, Preventive and Patents is needed along with an industry-government interface.

The country needs to modernise its current policies. Product innovation can increase productivity and profitability. Pricing innovation is the only way to sustain a business model. Currently, it is a sledge & hammer approach. We need to look at more sophisticated ways to enhance affordability. Indian Pharma needs outcome-based pricing. There is also a need for innovation in production.

Further, innovation in preventive health like a mandatory adult immunisation programme to stall some of the illnesses is much desired. During this COVID-19 phase, many of the Indian companies have invested in innovation. Therefore, we need to make use of this opportunity to strengthen our IP ecosystem to be on par globally, he added.

According to Sanjay Murdeshwar, Country President, Novartis India, affordability and accessibility from an India stand point has already taken long strides towards improving healthcare indicators in the last 30 years. But the fact remains that, we are still far away from the desired health outcomes. Our doctor-nurse population ratio is one of the lowest in the world.

We require 88,000 specialists but have just about 8,000 specialists. Access to hospital beds in rural areas is a challenge. Unless the Government plays a proactive role this cannot be achieved. There is also a need to understand the new valuation of services by using healthcare economics to drive outcome-based treatments.

A small virus has brought down the value of the global economy by $10 trillion. One can imagine its impact on the healthcare system. Therefore, we need innovation to come out with the best medicine or procedure model, said the Novartis India Chief. Umang Chaturvedi, Head of Policy, India & Emerging Markets, Mylan Laboratories, said there is a need to augment healthcare infrastructure. In pharmaceuticals, the country has proved its mettle in the area of anti retroviral drugs like in the case of HIV. Now we need the regulatory system to be streamlined for the sector to grow even further.

Source: Nandita Vijay, Pharmabiz, 05.08.2020

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DCGI approves 471 FDCs of vitamin, mineral and micronutrient, asks manufacturers to get licence from SLAs

The Drugs Controller General of India (DCGI) has directed the State Drug Controllers (DCs) to ask drug makers to get manufacturing licenses of 471 new Fixed Dose Combinations (FDCs) related to vitamins, minerals and micronutrients declared as rational by Prof Kokate Committee and approved by DCGI. This has brought cheers to drug makers manufacturing vitamins, minerals and micronutrients.

This is in continuation to the DCGI letter to state DCs on December 12, 2018 and January 8, 2020 whereby all

the State Licensing Authorities (SLAs) were requested to ask the concerned manufacturers to follow the procedure for obtaining manufacturing licenses directly from SLAs. The list comprising of 1,681 FDCs and 450 FDCs declared rational by Prof Kokate committee were already forwarded with the said letter to the SLAs.

In continuation to the said letter, it may be noted that apart from these 1,681 FDCs and 450 FDCs, further there are 471 more FDCs related to vitamins, minerals, micronutrients etc which have been declared as rational by the committee and report of the committee has been accepted by the Union Health Ministry.

Accordingly with approval of the Health Ministry, it has been now decided to follow a specific pathway for grant of product licenses by the SLAs for these FDCs. Applicants shall submit the requisite fees preferably through Bharatkosh for each FDC to CDSCO as specified under Drugs and Cosmetic (D&C) Act, 1940 and existing Rules thereunder. The applicant shall submit application to the concerned SLA for grant of product manufacturing license giving the details of FDC, serial number of the FDC in the list, stability studies data (6 months accelerated), test specification of the FDC along with method of analysis as well as label and other documents as required for grant of product license under D&C Rules.

The SLA shall grant the product license of such FDCs without seeking NOC from DCGI, if other conditions of license under the D&C Rules, which need to be verified by SLA, are found to have been fulfilled. The SLAs shall verify the quality of such FDCs of each applicant or manufacturer before grant of license. DCGI further stated that every manufacturer permitted to manufacture these FDCs shall submit the Periodic Safety Update Reports (PSURs) as per New Drugs and Clinical Trial Rules - 2019 to the Central Licensing Authority as defined in Rule 3 i.e. DCGI. Failure to submit the PSURs shall be considered as contravention of these Rules.

On September 16, 2014, a committee was set up by the Health Ministry under the Chairmanship of Prof C K Kokate, former Vice-Chancellor, KLE University, Karnataka to look into safety and efficacy of unapproved FDCs which were licensed by the SLAs without approval of DCGI. The committee, after holding a series of meetings had submitted its second assessment report to the Health Ministry on May 27, 2016, categorizing FDCs into four categories -- irrational (category 'a'), requiring further deliberation (category 'b'), rational (category 'c'), and FDCs requiring generation of data (category 'd').

Hailing 471 more FDCs declared rational by Prof Kokate panel and approved by DCGI, Amit Chawla, General Secretary of Madhya Pradesh Small Scale Drug Manufacturers Association said "It will be beneficial for the drug makers in Madhya Pradesh. A large number of FDCs have been in the market for almost a couple of decades and no serious side effects or adverse reactions have been noted."

However, he expressed concern over licence fees of Rs one lakh for each FDC for MSMEs. "COVID-19 pandemic has severely impacted MSMEs as they have limited financial resources and borrowing capacity. Considering financial challenges faced by MSMEs due to Coronavirus pandemic, MSMEs should be allowed to pay licence fees of Rs.15,000 for a FDC instead of Rs one lakh. In 2019 the manufacturers were required to pay registration fees of Rs.15,000 to CDSCO for a FDC along with application and obtain license from SLAs," said Chawla. As per DCGI circular in December last year, MSMEs are required to pay only half of the Rs.2 lakh fees for a FDC declared rational by Prof Kokate committee and approved by DCGI in accordance with provision of New Drugs and Clinical Trials Rules 2019.

Source: Laxmi Yadav, Pharmabiz, 05.08.2020

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Government may hike customs duty on import of APIs by 10-15% to boost local production

With the Centre pushing for India's self-reliance in several industries, the Department of Pharmaceuticals (DoP) is planning to hike customs duty on imported Active Pharmaceutical Ingredients (APIs) by 10-15 percent.

The Government is considering an import duty of 20-25 percent on APIs, against the current 10 percent to boost local manufacturing of bulk drugs, according to a report by the Economic Times. Currently, India imports 68 percent APIs and more than 90 percent antibiotics from China. The country's pharmaceutical industry is the world's third-largest in terms of volume. Even critical APIs, many of which are included in India's National List of Essential Medicines (NLEM), are being imported from China. APIs are important compounds that are used in the manufacturing

of pharmaceutical products. Last month, the DoP notified two key policies -- Production Linked Incentive (PLI) scheme to promote domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) and a scheme for promotion of bulk drug parks.

Incentives of Rs.10 crore were also announced for Indian companies to set up plants to produce 41 products, including 53 crucial APIs which we are currently heavily dependent on China. These incentives were part of the Rs.10,000-crore Production-Linked Incentive scheme approved by the cabinet in March to speed up the manufacturing of critical bulk drugs and APIs in India.

Source: Business Today, 01.08.2020

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Industry hails CDSCO's Sugam portal in expediting licensing process for ease of doing business

The pharmaceutical industry in the country has hailed the Central Drugs Standard Control Organisation (CDSCO)'s online Sugam portal in expediting licensing process for ease of doing business as it has given more than one lakh approvals to manufacturers related to drugs and medical devices in the past five years since its inception.

Launched on November 14, 2015 by CDSCO in association with Centre for Development of Advanced Computing (C-DAC), Sugam portal has been able to approve 119,937 applications out of the 135,389 applications received related to import and registration of drugs, medical device and diagnostics, test license, biologicals, veterinary, BA/BE for export, global Clinical Trial, new drug, investigational new drugs and Fixed Dose Combinations (FDCs) among others.

According to Regulatory Consultant Anupam H Bendre, "Before the Sugam portal was introduced, applications were made in hard copy dossier format to various divisions in CDSCO. The timelines for granting permissions or approvals for applications were almost three times more than what we have in current scenario. The to and fro of queries, documents and other issues in the submitted dossier led to the delay in permissions or approvals.

The Sugam online account registration is one time process. Once the registration process is completed, applications can be made based upon the requirements." SUGAM application is a three step process beginning from online submission, review and final permission or approval.

"Sugam web portal has served as an online single window interface for industry professionals to not only apply for NOCs, licenses, registration certificates but has also been responsive to queries," Bendre added.

While giving industry perspective, Mr Ashok Kumar Madan, Executive Director, Indian Drug Manufacturers' Association (IDMA Delhi Office) said, "Sugam portal is user-friendly and IDMA has conducted a series of workshops during the period of January to March 2020 with CDSCO for manufacturers on the use of Sugam portal. C-DAC officials who have developed this portal were also part of the team answering and explaining the industry during the workshops conducted throughout the country".

C-DAC is an Indian autonomous scientific society, operating under the Ministry of Electronics and Information Technology (MeitY). Earlier the fees for applications were made in the respective bank and then the copy of challan/ receipt was submitted to CDSCO office.

But now in Sugam portal, fee is calculated according to the applications and can be paid online on same portal in bharatkosh.gov.in. The receipt for payment is available on the portal which can be downloaded and submitted in the application.

Due to the introduction of Sugam portal, India is now in the state to compete with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) regions. Yet, there are some challenges faced by the medical device industry.

A separate medical device online portal was also started in line with new Medical Device Rules-2017 (MDR-2017) for applications related to medical devices and *in vitro* diagnostics (IVDs). According to Rajiv Nath, Forum Coordinator, Association of Indian Medical Devices Industry (AiMeD), "The Sugam portal for medical devices is relatively new as compared to Sugam portal for pharmaceuticals and however has teething problems."

He further elaborated, "Following problems have been faced while registering the medical device on the online portal. There is no option available to preview the application before final submission. There is no option of editing after save and continue option.

A file number is generated even prior to final submission, every time a change or correction is attempted a new file number is generated. There is no option available as to how to delete the files which have been generated prior to final submission. There is no option available to add multiple devices, i.e. only one device can be entered in file. Finally, there is no option available to upload details of medical device in the format specified in GSR 102(E) - Rule 19 B(2)(ii) of Medical Device Rules.

Uploading of data on Sugam portal is a mandatory exercise. State licensing authorities are sending out notices to the pharmaceutical companies for not uploading data or for uploading incomplete data on Sugam portal.

While speaking at the Annual General Meeting (AGM) of IDMA in Mumbai recently, Dr Mandeep Bhandari, Joint Secretary, Union Health Ministry had stated, "We are working with CDSCO to build capacities for effective accountability, transparency and digitisation in the pharmaceutical industry."

Source: Shardul Nautiyal, Pharmabiz, 04.08.2020

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Indian excipients industry should get Government support to become self-reliant: Experts

The Indian excipient industry is steering towards harmonisation of standards and supply chain security. The industry also needs to focus on research to widen its scope to develop quality products and processes in production. The sector has not seen the kind of investments like that of generics and API because of paucity of investors and incentives. This, according to the International Pharmaceutical Excipients Council of India (IPEC-India), is the key factor that hinders the growth of this industry in the country.

According to Ravleen Singh Khurana, CEO, Nikita Pharma, a key reason for this is that not many companies are engaged in excipient research. The industry is capital intensive, the margins are not high and hence the focus has been on volumes only. These factors perhaps could deter the future growth of the sector.

When India has positioned itself as the largest exporter of formulations, excipients account for a miniscule share which is a mere one percent to the global market. Under the *Atma Nirbhar* programme, the domestic excipient industry needs to take on the challenge, Khurana added. According to the IPEC-India, the excipient sector has not received the required attention because it has not caught the eyeball of investors. "We also need to encourage all our pharmacy colleges to focus on topics like excipient research and manufacture by students during their research projects. There is also need to include a dedicated subject on excipients in the pharmacy curriculum," according to the IPEC-India.

Here Khurana added, "This would create the required quality workforce for the excipient industry which is known for its sophisticated technology including application labs."

At a webinar on 'Excipients: Mitigation of Supply Chain, Quality & Regulatory Challenges' which was moderated by Subodh Priolkar, CEO, Wincoat Colours & Coating and Vice-Chairman-IPEC India, the discussion revolved around the need for mandatory IP compliance, GMP adherence and supply chain issues.

Vishakha Metkar, Sr Manager, regulatory, Colorcon Asia and Chairman Regulatory Committee IPEC-India, said that not much headway has been made in the harmonisation of IP monographs with other pharmacopoeias. "IPEC India is working on reviewing of the IP monographs for excipients to bring it in line with the global standards."

Nilesh Gandhi, Consultant and ex-Assistant Commissioner, Maharashtra FDA provided an overview on the regulatory framework for excipients. "Indian regulators are much more receptive to new ideas and initiatives which is a positive sign," he said.

Since supply chain is a critical component for all industries including excipients, Kesava Menon, Senior Manager, Materials, Colorcon said the pandemic's impact on the sector was severe. All the aspects of supply chain: ocean, air and road freight were hit during the global and national lockdown. The transport operators were unwilling to move without a substantial volume as it was not economically viable. Now, the situation is more or less stabilised.

In his introductory remarks Kaushik Desai, Secretary General, IPEC-India said that one of the objectives of IPEC India is to support development of third party certification and extend advice on source of quality of excipients.

Pressing for better visibility of the Indian excipient sector, the panel also noted that Government support for

application labs for research is much-needed. The whole focus currently in the country is to become self-reliant in APIs and Key Starting Materials (KSMs) by the Government with not much attention given to excipients. India currently imports 10 lakh metric tons of excipients as against 1.20 lakh tons of exports, which can be reversed only with Government support.

Source: Nandita Vijay, Pharmabiz, 04.08.2020

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Freebies to Doctors: Income Tax Deduction to Pharma Companies can't be denied invoking CBDT Circulars, says ITAT

The Mumbai bench of the Income Tax Appellate Tribunal (ITAT) has held that the income tax department cannot deny Income Tax Deduction to Pharma companies on expenses incurred on providing freebies to doctors on the basis of a CBDT circular and the Indian Medical Council regulations. The IMA regulations prohibit the practice of acceptance of any gifts, freebies by doctors from the pharmaceutical companies.

"The CBDT has no power to extend the scope of the IMC regulation to pharmaceutical companies without any enabling provision either under the Income Tax Act or the IMA regulations," the bench observed. The ITAT said CBDT circulars cannot impose a burden on an assessee, let alone create a new burden, by enlarging the scope of a regulation issued under another legislation.

The ITAT was hearing a plea by a Mumbai-based Medley Pharmaceuticals Ltd in September 2012, declaring a total income of Rs.29.29 crore. An income tax official assessed the company's income at Rs.49.23 crore in March 2015, after disallowing expenses of Rs.5.37 crore in freebies to doctors as a deduction. The scope and ambit of statutory provisions in the Indian Medical Council Act, 1956, related to professional conduct are restricted to medical practitioners registered with the State Medical Council, and those whose names are entered in the Indian Medical Register, the bench said.

The Tribunal recalled its own order in a different case wherein it was observed that "even if the assessee had incurred expenditure on distribution of "freebies" to doctors and medical practitioners, the same though may not be in conformity with the Indian Medical Council (Professional Conduct, Etiquette and Ethics) regulations, 2002, but then, as the same only regulates the code of conduct of the medical practitioners/doctors, therefore, in the absence of any prohibition on the pharmaceutical companies in incurring of such sales promotion expenses it cannot be held to have incurred an expenditure for a purpose which is an offense or is prohibited by law."

The scheme of the Indian Medical Council Act, 1956, deals only with the conduct of individual registered medical practitioners, the ITAT said in the order. "Even otherwise, the enlargement of the scope of MCI regulation to the pharmaceutical companies by the CBDT is dehors (outside the scope of) any enabling provision either under the Income Tax Act or under the Indian Medical Council regulations," it said. The ITAT said that though the CBDT can tone down the rigors of law in an order to ensure fair enforcement of the provisions by issuing circulars for clarifying statutory provisions, "it is divested of its powers to create a new impairment adverse to an assessee, or to a class of assesses, without any sanction or authority of law."

Source: www.taxscan.in, 02.08.2020

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COVID-19 drugs & vaccines give fresh impetus to kick-start Cinical Trials for CROs: Dr Arun Bhatt

With the outbreak of the COVID-19 pandemic in India and elsewhere in the world, efforts to bring out a slew of drugs and vaccines have gained momentum which in turn has given the much needed fresh impetus to kick-start Clinical Trials for the Clinical Research Organisations (CROs), said Dr Arun Bhatt, Consultant, Clinical Research & Drug Development.

When the COVID-19 started spreading in the country, there have been impediments in patient recruitment and retention to complete the studies. CROs were concerned about the suspension of current trials and the delay in achieving key milestones which have also resulted in loss of revenues.

Now, COVID-19 drug or vaccine trials are a short term boost for the CROs which can quickly organize human studies, he added. There is also a paradigm shift in Clinical Trials. The field is moving from physical to digital approach which requires investments, training, and adaptation, Dr Bhatt told.

The impact of the pandemic on Clinical Trials is Volatile, Uncertain, Complex and Ambiguous (VUCA). The risk of

second wave, continuing growth of the Coronavirus disease in developing countries, high risk of complications and mortality, persistence of COVID-19 symptoms, absence of effective treatment and ambiguity of universal availability of vaccine are some factors which make the socio-economic-medical pattern VUCA, said Dr Bhatt.

The reality is that the focus has shifted from clinical research to patient care across hospitals as the Coronavirus infected patients throng across facilities. In the current scenario, Clinical Trial participants are unwilling to visit hospitals. There is reluctance at the investigator sites where safety of staff is a prime concern and the need to screen participants prior to enrollment are a concern. Even the Ethics Committees are looking at protection of participants as the fear protocol deviations and adverse events, said Dr Bhatt.

Quoting a Clinical Accelerator report, that indicated between February and May this year, at least 1,118 trials which were sponsored by the industry were stopped due to COVID-19, Dr Bhat said not able to conduct these studies is detrimental to the access of new drugs. The indications for which drugs are under trial in India and globally are same as before as it covered cancer, cardiovascular, neurology, diabetes and infections.

However, there is a need to prioritize trials based on patients' needs, safety, and disease severity. There is also a need to look at potential patients and site burdens besides availability and allocation of programme resources, said Dr Bhatt at a recent webinar organised by Karnataka Registered Pharmacists Association (KRPA).

Although India is on par with global regulations for Clinical Trials, it still needs to put in place a new drug registration process. There is need for animal toxicity and testing. Its R&D ecosystem needs the required infrastructure for capacity building, he said.

In pandemic situation, based on Ebola experience, there is a global consensus to expedite vaccine development. However, all regulatory authorities require demonstration of safety and efficacy in large number of participants, before they give approval for marketing.

Even repurposed drug studies on humans is the easiest option for generating Clinical Trial evidence rapidly as the risk: benefit, and safety profile are well-established and thoroughly reviewed by regulatory authorities, said Dr Bhatt.

Source: Nandita Vijay, Pharmabiz, 01.08.2020

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Changes in healthcare system in post-COVID period may bring multiple opportunities for Clinical Pharmacists: DCG(I)

A structural change in healthcare interventions is likely to be imminent in the post-COVID period, consequently Clinical Pharmacists will largely be required to play significant roles in the medication management therapy system in the years to come, according to Dr V G Somani, Drugs Controller General of India (DCGI).

Dr Somani observed this while delivering the inaugural address of the 4th Annual Conference of the Indian Association of Colleges of Pharmacy (IACP) digitally on July 31. He finds that the life of human beings and the face of human society are likely to mutate into different patterns in the post-COVID pandemic period. This change may invite newer approaches to treat diseases, simultaneously preventive care will also have a dominant role. In treatments, medicines from biological origins and newer forms of medical devices will play vital roles in the total healthcare system.

Assessing various factors, the DCGI said that with a paradigm shift in healthcare interventions, the role of pharmacists will also change into a new way of profession and practice, mostly into a medication management therapy expert from the position of a drug dispenser. But such a situation will require vast knowledge and information in relevant areas to cater to the needs of both the physician and the patient. In this context, the Clinical Pharmacists can play important roles.

Hailing the Doctoral Pharmacy programme (Pharm D) introduced by the PCI, Dr Somani said this programme has generated a set of clinically trained pharmacists in the country, who will be made useful for the healthcare management sector in the post-COVID period. Pointing out the myriad opportunities to be emerged in the near future, he expressed the hope that Pharm D graduates will get a lot of opportunities in clinical research areas as team leaders and India is emerging as a hub of clinical research for a second time.

The national drug regulator further said from the side of the CDSCO and of the Government, efforts are being made to create job opportunities for the Pharm D holders. Congratulating IACP office-bearers for their supportive efforts towards advancing pharmacy education in the country, Dr Somani opined that this year's IACP conference was the full-fledged Pharma Conference hitherto organized online in India. In the beginning of the virtual conference, the Guest of Honour, Dr B Suresh, President of the PCI, made a comprehensive talk on progressing pharmacy education in India.

Prof Jayakar, Secretary of the IACP welcomed the online gathering and presented a report of the association's activities. Professor K Chinnaswamy delivered the Presidential Address and Jayapal Reddy proposed the vote of thanks. More than 1,000 registered delegates and 2,000 people with pharmacy backgrounds attended the first online convention of the pharma sector.

Source: Peethaambaran Kunnathoor, Pharmabiz, 03.08.2020

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Maharashtra Government to bring face masks under price control amidst reports of indiscriminate pricing by retail supply chain and e-commerce platforms

The Maharashtra Government is planning to bring face masks under price control amidst reports of indiscriminate pricing of masks in the retail supply chains as well as through e-commerce platforms.

The Maharashtra Government's move in this regard comes in the backdrop of the fact that the state Food and Drug Administration (FDA) had detected several cases of overpricing of N-95 masks by the manufacturers in the recent months. In its crackdown on cases of overpricing of N-95 masks, the state FDA detected over 20 new cases of mask overcharging by the manufacturers.

According to official sources, the compelling reason to bring masks under price control is that manufacturers are yet to register themselves on the online Sugam medical device portal, as per Union Health Ministry's directive. The state Government will soon come out with the decision to cap prices of face masks also in view of the increase in its demand as people at homes and healthcare settings are supposed to wear masks as per WHO, Union Health Ministry and Center for Disease Control (CDC) Guidelines.

Drugs Controller General of India (DCGI) had earlier asked manufacturers to voluntarily get registered on the CDSCO medical device online portal – cdscomdonline.gov.in to monitor quality of masks in the country.

The Ministry of Consumer Affairs vide its Notification dated March 13, 2020 with a view to regulate the production, quality, distribution, logistics of masks (2 ply and 3 ply surgical masks and N-95 masks) declared them as essential commodities and subsequently fixed the retail prices to a maximum of Rs.10 for 3 ply mask and Rs.8 for 2 ply mask. Government had notified an order under the Essential Commodities (EC) Act to declare these items as essential commodities up to June 30, 2020, by amending the schedule of the EC Act 1955," the Consumer Affairs Ministry had said in a statement.

The decision would empower the Government and States/UTs to regulate production, quality and distribution of masks for smooth sale and availability of these items. It will enhance the availability of masks to the general people at reasonable prices or Maximum Retail Price (MRP), the Ministry stated.

While the World Health Organization (WHO) has recommended the significance of wearing a face mask to prevent transmission of the virus from one another, Cofsils, a brand under Cipla Health Ltd, recently launched single-use disposable face mask at affordable price that provides three levels of protection against harmful viruses and bacteria. The product is Center for International Regulatory Assistance (CITRA) certified and costs Rs.16 per mask.

According to reports from Maharashtra FDA vigilance department, stocks of N-95 masks were being sold at exorbitant prices in several pockets of Mumbai like Andheri and Ghatkopar. NPPA had also recently issued a list of price reduction in N-95 masks by four major N-95 mask manufacturers, namely Venus Safety and Health Pvt Ltd, Magnum Health and Safety, Yash Care Life Sciences and Joseph Leslie & Company.

The national drug price regulator also shared the revised MRPs reported by these manufacturers of N-95 masks with the State Drug Controllers (SDCs). The list indicates that the makers of N-95 masks reduced the cost of their products up to 47 percent after NPPA issued an advisory on May 21, 2020 recommending manufacturers to voluntarily lower prices.

Raids on illegal sale of N-95 masks at several premises in Mumbai were conducted under the guidance of Rajendra B Shingne, Maharashtra FDA Minister, in consultation with A B Unhale, Commissioner, Maharashtra FDA, Sunil Bhardwaj, Maharashtra FDA Joint Commissioner (Vigilance). Maharashtra FDA has also appealed to the people to contact the toll free number 1800 222 365 for reporting black marketing of N-95 masks among other essential products.

Source: Shardul Nautiyal, Pharmabiz, 07.08.2020

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NPPA asks SDCs to ensure smooth production, supply of clofazimine across country for treatment of MDR TB

The National Pharmaceutical Pricing Authority (NPPA) has asked all State Drug Controllers (SDCs) to ensure smooth production and supply of clofazimine across the country used in the treatment of Multi Drug Resistant (MDR) TB. Drug clofazimine is a part of regimen for the treatment of MDR TB under the National TB Elimination Programme (NTEP). According to NPPA, there were references received from national advocacy group on shortage of clofazimine, which falls under the scheduled drug list.

"Matter regarding shortage or non-availability of the drug was also taken up by the NPPA with the Union Health Ministry. Now, It has been confirmed by Union Health Ministry that under NTEP, they have continuous supply of clofazimine and there are sufficient stocks in the pipeline for future consumption. Also, no shortage or non-availability of the drug has been reported by SDCs when asked in the matter," as per NPPA.

Taking abundant caution and to ensure smooth production or supply across the country of the drug, companies have also worked on to further streamline the production and supply of the drug in the retail supply chain. NPPA has directed SDCs that If still there are any instance of shortage or non-availability of the drug, the same may be brought to the notice of the authority on helpline number 1800111255 and email id - monitoring-nppa@gov.in

At the start of 2020, the Central Government renamed the Revised National TB Control Programme (RNTCP) as the National Tuberculosis Elimination Programme (NTEP). As envisaged, the Union Government would be achieving the sustainable development goal of ending TB by 2025, five years ahead of the global targets.

Clofazimine is a highly lipophilic antimicrobial riminophenazine dye generally used in combination with other agents, such as dapsone, for the treatment of leprosy. Although it carries in vitro activity against mycobacterium tuberculosis, it is generally considered an ineffective treatment in comparison to classic tuberculosis treatments such as rifampicin and isoniazid.

Source: Shardul Nautiyal, Pharmabiz, 06.08.2020

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Industry seeks exemption on 'only for mandatory export activities' for availing loan under PTUAS to boost SMEs

The Pharmaceutical industry in the country has sought exemption on provision of 'only for mandatory export activities' for availing loan under Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) in consideration of SMEs' plea for improving manufacturing standards and hence quality of products to serve the domestic market.

The Department of Pharmaceuticals (DoP) has revised PTUAS to take the much-awaited interest subvention scheme for small pharmaceutical manufacturers forward. In the revised PTUA Scheme, the number of Pharma MSMEs to be covered is targeted about 4,500 units. PTUAS, a subsidy plan on sanctioned loans, is aimed at helping drug manufacturing companies improve technology and infrastructure to migrate from Schedule M to WHO-GMP standards.

According to Indian Drug Manufacturers' Association (IDMA) National President Mahesh Doshi, "Our manufacturing plants produce high quality products for export and the domestic market meeting requirements of various pharmacopoeias. Hence, upgradation of facilities proposed in the upgradation scheme will benefit both the domestic and export production."

One of the major concerns raised by the industry is the mandate under 'Performance Conditions' linking compulsory export activities to avail loan stating that "beneficiary SMEs must achieve incremental export revenue in excess of the sanctioned loan amount within 36 months of the last withdrawal of the loan. This condition of 'export activity' needs to be delinked from availing of loan under PTUAS due to the limitation it imposes, the IDMA has recommended. It further recommended that with respect to export conditions we may mention that export registrations of company and products may

take 3 or 4 year time depending on the country. Hence it will be difficult to fix time limits. Further, many SMEs are interested in upgrading their manufacturing standards to WHO-GMP level which is compulsory for participating in many Government tenders for supplying to Government institutions.

Another condition is all beneficiary Pharma SMEs to whom benefit of interest subvention is to be extended, must obtain WHO-GMP certification within 2 years from the date of first disbursement of loan. IDMA has recommended that this period be revised to 36 months from the date of last loan disbursement, as the timeline for acquiring WHO-GMP approval is uncertain. WHO GMP involves the upgradation of machinery, buildings and software.

It has also recommended that the moratorium period is also required to be extended to at least 5 years for API and pharmaceutical manufacturing industries. Upgradation to WHO-GMP from Schedule M would entail upgradation of both the hardware and software. This will involve minimum additional expense of approximately Rs.10 crore. So it has been recommended that the loan amount needs to be revised from Rs.4 crore to Rs.10 crore. Mr Doshi further explained, "Our suggestion to increase the amount to be disbursed is based on the current cost of equipment and materials. Further, the suggestion to increase time to obtain GMP approval is based on the current timelines taken to obtain WHO-GMP certification and register products in the various countries. These are reasonable and realistic suggestions proposed for the success of program.

We also wish that a large number of Small and Medium units get the benefits of this scheme proposed by the Government. We wish Government will finalise a simple disbursement scheme for interested firms." Industry has welcomed DoP for initiating the PTUAS and releasing the 'Guidelines for Implementation' for the growth of Pharma manufacturing sector. Proposed duration of PTUAS is 2018-22 (13th Five year plan). Earlier scheme was proposed only for medium enterprises. IDMA had represented to include small enterprises also.

Source: Shardul Nautiyal, Pharmabiz, 06.08.2020

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INTERNATIONAL NEWS

Import bans hit Pakistan's Pharma industry

Geopolitics and a fraught relationship with its neighbors are hurting Pakistan's pharmaceutical industry and the ability of people to access Active Pharmaceutical Ingredients (APIs) and modern drugs.

"The recent issue that the Pharma industry is facing is with imports of APIs from India," Zahid Saeed, President of the Pakistan Pharmaceutical Manufacturers Association (PPMA), told. "Very few medicines were imported in finished form from India which included vaccines."

Pakistan may be forced to find other sources of raw materials, said Saeed, including boosting the small portion of materials imported from Europe or even boosting imports of APIs from China.

As much as 95% of the drugs made in Pakistan are generic pharmaceuticals made by more than 750 factories. Companies like Indus Pharma (Pvt) Ltd., Pharmevo (Pvt) Ltd and Sami Pharmaceuticals (Pvt) Ltd in Karachi, CCL Pharmaceuticals (Pvt) Ltd in Lahore; Ferozsons Laboratories Ltd – one of five companies to manufacture and distribute Remdesivir in Pakistan – and others have been forced to import almost two-thirds of their APIs from India.

But, as a result of the curbs in imports, supplies of many essential drugs have fallen and prices have increased between 30% to 40%. According to data from the PMAA, raw material prices have risen by as much as 300% throughout the pandemic while drug sales are down by half as fewer people visit doctors.

Pakistan's Pharmaceutical market is worth around $3.5 billion per year but has plenty of room for growth, with the average Pakistani spending around $6.50 per year on medicines, according to PMAA data.

The future of the industry is now facing headwinds from both domestic Government policies but also competition and the powerful manufacturing machines of neighboring India and China. Over the last seven decades, Pakistan's Pharmaceutical industry has become dependent on supplies of APIs from both suppliers.

"The national Pharma industry has shown progressive growth over the years. The industry has invested substantially to upgrade itself in the last few years and today the majority of the industry follows Good

Manufacturing Practices (GMP), in accordance with domestic as well as international guidance," Zaki Ahmed, a PPMA spokesman, told.

"Currently, the industry has the capacity to manufacture a variety of products ranging from simple pills to sophisticated biotech, oncology and value-added generic compounds. Although Pakistan's pharmaceutical and health care sectors are expanding and evolving rapidly, the geopolitical situation, specially the relationship with India, also affects the industry," the spokesman said. "That is why about half the population has no access to modern medicines."

The current challenges started in August 2019, when the Indian Government of Prime Minister Narendra Modi revoked the special status of the Indian-controlled but disputed territories of Jammu and Kashmir. Pakistan Prime Minister Imran Khan responded with bans on trade with India, although the ban on trade of life-saving drugs was reversed a month later after lobbying from Pakistan's pharmaceutical industry.

In May, the Government started investigating imports from India and put in place temporary embargoes on imports of drugs to fight polio, dengue and a number of chemicals as well as treatments for tuberculosis, polio and tetanus.

At the same time, the Drug Regulatory Authority of Pakistan published a list of drugs imported from India. That list includes 429 APIs, 59 drugs and 12 different kinds of vitamins.

"Pakistan has a high dependence on Indian raw material for manufacturing drugs," said PPMA Senior Vice Chairman Syed Farooq Bukhari. "If the Government does not revoke the ban on imports there would be a 50% loss in drug production. The situation would not only cause shortage of drugs and an increase in prices, but also weaken the country's capability to fight COVID-19."

The COVID-19 pandemic is adding to the challenges. As much as half of all the raw materials the industry needs have not been able to leave China due to COVID-19 restrictions, which is adding to the challenges created by the ban on Indian imports, said Qaiser Mehmood, another senior member of the PPMA.

Source: Khawar Khan, Bioworld, 07.08.2020

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Pfizer to make Gilead's COVID-19 treatment Remdesivir

Pfizer Inc said on Friday, 07.08.2020 it signed a multiyear agreement to make COVID-19 treatment Remdesivir for developer Gilead Sciences Inc, which is under pressure to increase tight supplies of the antiviral drug. Gilead is aiming to make enough of the drug by the end of the year to treat more than 2 million COVID-19 patients, and agreed to send nearly all of its Remdesivir supply to the United States through September.

But hospital staffers and politicians have complained about difficulties in gaining access to the drug, which is one of only two to have demonstrated an ability to help hospitalized COVID-19 patients in formal Clinical Trials. There are also fears of shortages outside the United States, and separately on Friday, 07.08.2020, Britain's Hikma Pharmaceuticals Plc said it has started manufacturing Remdesivir at its Portugal plant. Gilead said its manufacturing network for the drug had grown to more than 40 companies in North America, Europe and Asia to add capacity.

Earlier this week, a bipartisan group of US state attorneys general urged the federal Government to allow other companies to make Gilead's Remdesivir, to increase its availability and lower the price of the antiviral drug. Pfizer will provide contract manufacturing services through its McPherson, Kansas, plant, the drugmaker said. It was not immediately clear if Pfizer would supply only for the US market. The US Food and Drug Administration sent a warning letter to Pfizer in 2017 saying that the process for manufacturing sterile injectable drugs at the Kansas plant was "out of control" and put patients at risk.

The FDA said several products were contaminated with multiple foreign particulates but a subsequent FDA inspection found that the issues had been resolved. Pfizer, with Germany's BioNTech, is also rushing to develop a vaccine against the Coronavirus. Pfizer has helped other drugmakers manufacture their products before. It makes Epipen emergency allergy treatments through its Meridian Medical Technologies business and also operates a contract manufacturer called Center One.

(Reporting by Manas Mishra in Bengaluru; Editing by Anil D'Silva and Matthew Lewis)

Source: Thomas Reuters, wkzo.com, 08.08.2020

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Rival drugmakers launch joint trial of medicines for COVID-19

Rival drugmakers AbbVie Inc (ABBV.N), Amgen Inc (AMGN.O) and Takeda Pharmaceuticals Inc (4502.T) said they have begun treating patients in a trial to quickly show whether a drug from each company can be repurposed and used against COVID-19, the disease caused by the novel Coronavirus.

The COVID-19 pandemic is an "all hands on deck moment," David Reese, Amgen's Research and Development Chief told. "We wanted a trial to be able to quickly sift through multiple agents and prioritize." The study is a collaboration among pharmaceutical industry members of the recently formed COVID Research & Development Alliance, Quantum Leap Healthcare Collaborative, a partnership of medical researchers and investors, and the Food and Drug Administration.

The first segment will test whether Amgen's psoriasis drug Otezla, Takeda's anti-inflammatory Firazyr and AbbVie's cenicriviroc, which has been tried in patients with HIV, will help with the overactive, and potentially damaging, immune response that sometimes happens in patients with severe COVID-19.

The study's "adaptive platform" means several treatment candidates can be tested at the same time, with the most promising moving forward and the least promising dropping out, Quantum Leap co-founder Dr Laura Esserman told.

"We could have some results in as early as six weeks," she said, adding that additional drugs will soon be added to the roster. Company officials said Otezla may be able to suppress inflammation from an overactive immune response; Firazyr may help limit fluid in the lungs; and cenicriviroc, which blocks activity of certain immune system cells, could reduce the severity of acute respiratory distress caused by the virus.

The drugs are being dosed in combination with Gilead Sciences Inc's (GILD.O) antiviral drug Remdesivir and generic steroid dexamethasone, both of which have been shown in rigorous trials to help COVID-19 patients and are now considered to be standard care, Dr Esserman said. A comparison group of patients will be given Remdesivir and Dexamethasone alone.

Hospitals have tried other anti-inflammatory drugs in COVID-19 patients, including Regeneron's (REGN.O) Kevzara and Roche Holding's (ROG.S) Actemra, but trials of both arthritis drugs failed to show effectiveness. Roche is continuing to test Actemra in combination with Remdesivir.

The National Institute of Allergy and Infectious Diseases' ongoing adaptive COVID-19 trial is studying Remdesivir in combination with Olumiant, an arthritis drug sold by Eli Lilly & Co (LLY.N). Those results are expected next month.

Since the outbreak began seven months ago, so far killing more than 675,000 people worldwide, hundreds of Clinical Trials have been launched around the world to test whether existing drugs or experimental compounds could be effective treatments. "There are a huge number of trials that for all the best intentions have been stood up around the world, but many are smaller - what we would call underpowered - and will not provide definitive answers," Amgen's Reese said.

(Reporting By Deena Beasley; Editing by Aurora Ellis)

Source: The Thomson Reuters, 03.08.2020 (Excerpts)

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Ahead of registering world's first covid vaccine, Russia reveals how it will work

Russia plans to register the world's first Covid vaccine against COVID-19, reports said, citing Deputy Health Minister Oleg Gridnev. Now, the chief of the lab developing the vaccine has dropped some hints on how the covid vaccine will work. The vaccine has been developed jointly by the Gamaleya Research Institute and the Russian Defence Ministry.

Alexander Gintsburg, Director of the Gamaleya National Research Centre, said that vaccine used inanimate particles created on the basis of adenovirus, according to Sputnik News. He said there are no concerns that the vaccine could potentially cause harm to a person's health. "The particles and objects that can reproduce their own kind are the ones that are considered alive. The particles in question cannot multiply," he said.Some people naturally have a fever when immune system of the person being vaccinated receives a powerful boost but this "side-effect"

can easily be overcome by taking paracetamol, he added. Reports had said that Professor Alexander Gintsburg, Head of the Gamaleya institute and other researchers tried the vaccine on themselves.

Russian Health Minister Mikhail Murashko had earlier said that members of “risk groups," such as medical workers, may be offered the vaccine this month. Deputy Prime Minister Tatyana Golikova promised to start “industrial production" in September, and Murashko said mass vaccination may begin as early as October.

As Russia gets ready to register the coronavirus vaccine, top US infectious disease specialist Dr. Anthony Fauci however sounded a note of caution “I do hope that the Chinese and the Russians are actually testing a vaccine before they are administering the vaccine to anyone, because claims of having a vaccine ready to distribute before you do testing I think is problematic at best," he said. In April, President Vladimir Putin ordered state officials to shorten the time of clinical trials for a variety of drugs, including potential coronavirus vaccines. The World Health Organization said all vaccine candidates should go through full stages of testing before being rolled out. (With Agency Inputs)

Source: livemint, 09.08.2020

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Novartis to provide 'no profit' COVID-19 drugs to low-income countries

Novartis said it would provide medicines ranging from antibiotics and steroids to diarrhea pills to 79 countries on the World Bank's list of low-and lower-middle income nations

Novartis's Sandoz division will not make a profit on 15 generic drugs it is making available to developing countries to treat symptoms of COVID-19, the Swiss drugmaker said on Thursday. Novartis said it would provide medicines ranging from antibiotics and steroids to diarrhea pills to 79 countries on the World Bank's list of low- and lowermiddle income nations.

The Basel-based drugmaker plans to maintain the zero-profit programme until the pandemic ends or a vaccine or cure is found, Novartis Global Health Chief Operating Officer Lutz Hegemann said in an interview. While Novartis has not seen supply-chain shortages despite increasing demands for COVID-19 medicines, Hegemann said this new programme aimed to help to keep vulnerable healthcare systems in Africa, Asia, South America and European countries Ukraine and Moldova from becoming overloaded.

"We shouldn't underestimate the stress that COVID-19 puts particularly on fragile health systems," Hegemann told Reuters, adding Novartis hopes to work with health authorities, faith-based organisations and NGOs to eliminate big markups.

"We are not targeting classical commercial distribution channels, but very direct channels, to influence that to the extent we can," he said.

Novartis's brand-name drugs have had little application in treating the new coronavirus, but Sandoz generics are among medicines commonly used to treat symptoms of those hospitalised.

The list includes antibiotics amoxicillin, ceftriaxone, clarithromycin, vancomycin and levofloxacin, steroids dexamethasone, prednisone and prednisolone, gout treatment colchicine, heart failure drug dobutamine, antifungal fluconazole, blood thinner heparin, anti-diarrhea drug loperamide, reflux medicine pantoprazole and lung drug salbutamol.

Its malaria generic, hydroxychloroquine, is not included after some COVID-19 trials concluded it did not work and the United States cancelled emergency authorisation, though Novartis continues to provide it for trials and on government requests.

Hegemann did not give specifics on the drugs' eventual costs, compared to commercial prices. The drugs have been around for decades and are comparatively cheap to make.

(Reporting by John Miller. Editing by Jane Merriman)

Source: Reuters/ET-HealthWorld, 16.07.2020

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US will end reliance on China, other nations for pharmaceuticals, says Donald Trump

The US will end its reliance on China and other foreign nations for pharmaceuticals and medical supplies, President Donald Trump has said, asserting that Beijing would have to pay the price for the wound it has inflected

on America and the world by spreading the deadly coronavirus.

US President Donald Trump speaks at a Whirlpool Corporation washing machine factory in Clyde, Ohio, US on August 6, 2020. (Reuters File Photo)

President Trump and leaders of several countries have accused China of not being transparent in reporting the deadly disease, leading to huge human casualties and economic crisis across the world. China, however, has denied US' accusation of covering up the extent of its coronavirus outbreak and accused America of attempting to divert public attention by insinuating that the virus originated from a virology laboratory in Wuhan.

"What China did is a terrible thing. Whether it was incompetence or on purpose, it was a terrible thing that they did … not only to the United States, but to the world. A terrible thing," Trump told reporters at the White House on Thursday, 06.08.2020 before flying to Ohio to visit a Whirlpool manufacturing plant.

What China did to the rest of the world and the US is a disgrace, said the president, asserting that Beijing would have to pay the price for the wound it has inflected on America and the world by spreading the deadly coronavirus.

Hours later addressing workers at the manufacturing plant in Ohio, Trump alleged that the previous Obama-Biden administration was perfectly happy to let China win. "Over the course of the next four years, we will bring our pharmaceutical and medical supply chains home and we will end reliance on China and other foreign nations," Trump said as he laid out his vision to bring millions more jobs and thousands more factories back to American shores.

"Today, to define our path forward, I am making our incredible workers six more promises that I will keep over the next four years. First and foremost, we will defeat the China virus," he said, adding that the strategy shelters those at highest risk while allowing those at lower risk to get safely back to work and school.

Instead of a never-ending blanket lockdown, causing severe long-term public health consequences, "we have a targeted and data-driven approach", he said.

"Today, using the Defense Production Act, we are engaged in the most rapid industrial mobilisation since World War II. Over the last six months, we have witnessed one manufacturing miracle after another," he said.

Trump said he had signed a new executive order to ensure that when it comes to essential medicines, the US buys American. This executive order will require that the US government agencies purchase all the essential medicines it needs from American sources.

"My fifth promise to American workers is to bring back American jobs and factories using every tool at my disposal—including tariffs, countervailing duties, and new trade deals based on the principle of fairness and reciprocity," he said.

"As long as I am President of the United States, I will fight for you with every ounce of energy and strength that I have. I will be your voice. I will defend your jobs. I will stand up to foreign trade cheaters and violators," Trump said.

As seen in this pandemic, the United States must produce essential equipment, supplies, and pharmaceuticals for itself, he said.

"We cannot rely on China and other nations across the globe that could one day deny us products in a time of need. We can't do it. We can't do it. We have to be smart," he said.

"And speaking of pharmaceuticals, we instituted four moves, rebates, favourite nations, and other things buying from other nations where they have the product, the same exact pills, identical, made in the same factory for a fraction, just a small fraction of the cost.

We buy from other countries as opposed to buying through this ridiculous quagmire of political scam that we've been going through for many years," Trump said.

Source: Kanishka Sarkar, PTI, Hindustan Times, 07.08.2020

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Deep dive into big Pharma AI Productivity: One Study shaking the Pharmaceutical Industry

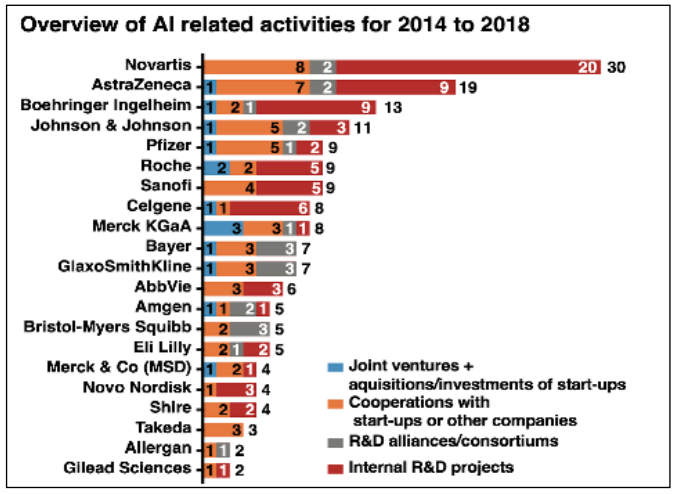
Alex Zhavoronkov

The pharmaceutical business is perhaps the only industry on the planet, where to get the product from idea to market the company needs to spend about a decade, several billion dollars, and there is about 90% chance of failure. It is very different from the IT business, where only the paranoid survive but a business where executives need to plan decades ahead and execute. So when the revolution in Artificial Intelligence fueled by credible advances in deep learning hit in 2013-2014, the pharmaceutical industry executives got interested but did not immediately jump on the bandwagon. Many pharmaceutical companies started investing heavily in internal data science R&D but without a coordinated strategy, it looked more like re-branding exercise with the many heads of data science, digital, and AI in one organization and often in one department. And while some of the pharmaceutical companies invested in AI startups no sizable acquisitions were made to date. Most discussions with AI startups started with "show me a clinical asset in Phase III where you identified a target and generated a molecule using AI?" or "how are you different from a myriad of other AI startups?" often coming from the newly-minted heads of data science strategy who, in theory, need to know the market.

However, some of the pharmaceutical companies managed to demonstrate very impressive results in the individual segments of drug discovery and development. For example, around 2018 AstraZeneca started publishing in generative chemistry and by 2019 published several impressive papers that were noticed by the community. Several other pharmaceutical companies demonstrated impressive internal modules and Eli Lilly built an impressive AI-powered robotics lab in cooperation with a startup.

However, it was not possible to get a comprehensive overview and comparison of the major pharmaceutical companies that claimed to be doing AI research and utilizing big data in preclinical and clinical development until now. On June 15th, one article titled **"The upside of being a digital Pharma player"** got accepted and quietly went online in a reputable peer-reviewed industry journal Drug Discovery Today. I got notified about the article by Google Scholar because it referenced several of our papers. I was about to discard the article as just another industry perspective but then I looked at the author list and saw a group of heavy-hitting academics, industry executives, and consultants: Alexander Schuhmacher from Reutlingen University, Alexander Gatto from Sony, Markus Hinder from Novartis, Michael Kuss from PricewaterhouseCoopers, and Oliver Gassmann from University of St Gallen. Upon a closer look it turned out to be not a perspective but a comprehensive research study with a head-to-head comparison of the pharmaceutical companies by their efforts in AI in Research and Development.

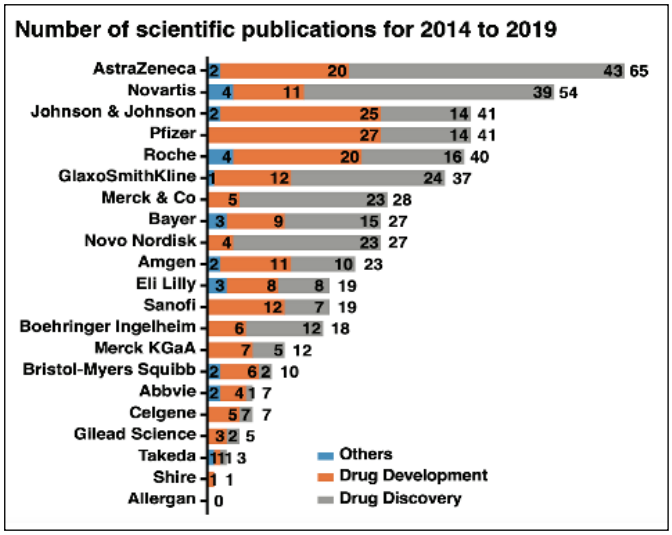
The study compared the pharmaceutical companies by the internal AI R&D projects, Partnerships with AI startups, investments in AI startups and R&D alliances and consortiums between 2014 and 2018. It also compared the pharmaceutical companies by the number of scientific publications from 2014 and 2019 segmented into discovery, development, and others showing the clear leadership of Novartis in internal efforts and AstraZeneca in publications.



Alexander Schuhmacher et al, modified by Alex Zhavoronkov.

Before this study came out, to the industry insiders performing regular literature reviews it did feel like AstraZeneca was publishing more than any other pharmaceutical company. Only in 2019 AstraZeneca scientists published about 1,300 scientific papers. It also felt that Bayer had a few nice papers. The highest number of publications across all segments was 65. For reference, a startup like Insilico Medicine published about 100 papers

and about 30 patents in the same period not counting AI conference papers. Several other startups also did quite well in that area and it would be great to see similar analysis.



Alexander Schuhmacher et al, modified by Alex Zhavoronkov.

I posted a screenshot of the study on Linked in and almost immediately the post was viewed about 20,000 times primarily by the colleagues from the pharmaceutical industry. Surprisingly, very few of the viewers "liked it". I suspect that many of them were quite disappointed to see that on the grand scheme of things the industry itself is still in its infancy. The study made it clear that there are many benefits of being a digital Pharma player but we are still early in the process.

The authors of the study certainly deserve to be referred to as industry experts in the pharmaceutical AI R&D as they did a gargantuan amount of work to compile the three relatively simple figures in the study and at the moment no other study like that exists.

To learn more about the study, I wrote to the authors and asked them a few questions about the study and about their vision of the future of the pharmaceutical industry:

1. **Looking under the hood of the top 21 big pharmaceutical companies and analyzing their activities in digital and AI is a gargantuan piece of work. Many analysts are trying to do the same thing with little success. How long did it take you and how did you manage to do it?**

   Gassmann: *Indeed, it was a big piece of work. Much is publicly available, such as patents and scientific publications. In general, most valuable are interviews with executives in the pharma sector. Building up the reputation took for most of us more than 20 years.*

   Gatto: *In addition, a key success factor was the interdisciplinary background of the authors – including Pharma strategy, R&D and AI competencies.*

2. **Did any of your findings surprise you?**

   Kuss: *The findings were not surprising as such. But the early mature status with respect to the use of AI in Pharma R&D seems to be a big challenge for the industry.*

   Schuhmacher: *The future availability of low prized AI-applications in combination with faster and cheaper hardware will boost the trend of digitalization of Pharma R&D. The immense need to increase R&D efficiency will do its part for the success of AI in Pharma.*

3. **Did you see any conclusive case studies where AI dramatically outperformed humans or any of the published work where AI replaced the need for experiments?**

   Gatto: *We could identify several cases where we saw that there is the potential that AI might replace the need for experiments or outperforms humans. All in front a recent publication in Nature Biotechnology on de novo small-molecule design highlighting the huge potential of AI in drug discovery.*

4. **I am certain that some of the Pharma CEOs, CFOs, and other executives saw your paper by now. Did you get any comments? What was their initial reaction?**

   Schuhmacher: *We did not get direct feedback yet, as the publication is brand new. In general, we noticed that Pharma R&D executives have shown their interest in our recent work on virtualizing Pharma R&D.*

   Gassmann: *In addition, we can observe a slow change in Pharma towards the digital side of health care. While 10 years ago many Pharma managers could not believe that data based companies can really capture a larger part of the health care value chain, today it is more widely accepted that software eats the world, data change the Pharma industry.*

5. **You even made a comparison of scientific publications between 2014 and 2019. My company published over 100 papers in that period, while the largest number for big Pharma was 65 and some had zero publications. To me, it seems dramatically low. Why do you think this is the case?**

   Schuhmacher: *It looks like that AI is still not part of the core strategies of some of the leading companies. And they still rely too much on the closed innovation paradigm: Publishing is not part of their revenue and R&D models. But this might change: Pharma companies need to be attractive to data scientists and other experts and need to show their excellence and competitiveness.*

6. **One of the major challenges in AI for drug discovery is intellectual property and many of the methods have blocking IP. In my opinion, one of the reasons why Deep Mind was acquired early by Google was its strong IP portfolio. Did you look at the AI-related patents filed by these big pharmaceutical companies?**

   Gatto: *Looking at the pure figures of AI-related patents reveals that there is a huge discrepancy between pharmaceutical companies and IT giants such as Google. But this pattern might change over time, when Pharma is changing its R&D model and the way of how to exploit AI-related IP.*

7. **What do you think is going to happen in the next 1-2 years in this field?**

   Gassmann: *1-2 years is a short time for the Pharma sector but AI will further come. Companies from the consumer electronics like Apple and data field like Google have already FDA registered wearables. Today those devices are still very unreliable but performance will increase fast. Chronical diseases such as Alzheimer, diabetes, or cancer will be the entry field for digital health interventions where longitudinal data create a lot of value. Pharma have to rethink the way they innovate and to start thinking in ecosystems.*

   Kuss: *In our view, reimagine R&D as a crowd sourced ecosystem is the key for future success of Pharma: pharmaceutical R&D will no longer be limited to predominantly internal value creation but will capitalize on a network of internal and external ideas, technologies (including AI), and resources.*

8. **Are you planning to update this report next year? And are you planning to add more pharmaceutical companies to the list?**

   Gassmann: *This research should be just the start. For the next years we are planning to build up a collaborative center on Pharma innovation research that will advance the insights on Pharma and biotech R&D management in context of AI and other emerging technologies.*

9. **Can you tell me about the future directions for your research?**

   Schuhmacher: *AI will have an immense impact on future R&D models and on the Pharma R&D ecosystem as such. This together with other strategic and technological transformations will drive our research agenda for the coming months.*

   Kuss: *Smart contracts based on distributed ledger technologies will play a key role in this change process.*

Source: Forbes.com, 15.07.2020

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Ending the pandemic will require big Pharma to put ethics before profits

Nicole Hassoun

As COVID-19 surges in the United States and worldwide, even the richest and best insured Americans understand, possibly for the first time, what it's like not to have the medicines they need to survive if they get sick. There is no Coronavirus vaccine, and the best-known treatment, Remdesivir, only reduces hospital recovery time by 30% and only for patients with certain forms of the disease.

Poorer people have always had trouble accessing essential medicines, however—even when good drugs exist to prevent and treat their conditions. In the US, where there is no legal right to health, insurance is usually necessary for medical treatment. Remdesivir costs about $3,200 for a typical treatment course of six vials, though critics argue its manufacturer, Gilead, could make a profit off much less. Internationally, high drug prices mean that critical medicines are often available only to the richest patients. Access to medicines, in other words, is usually an ethical problem—not a scientific one. And that's going to complicate the global Coronavirus fight. Experts worry that any COVID-19 vaccine is likely to have a high price tag and, as a result, be unequally distributed according to countries' purchasing power, not need. With a little imagination, this challenge can be overcome. My new book, *Global Health Impact: Extending Access to Essential Medicines*, documents how in past epidemics, from polio and Ebola to HIV, the international community managed to get lifesaving drugs to patients—no matter where they lived or how much they earned.

Past wins:

It took years for scientists to identify an effective treatment for HIV. But by 1997, most people diagnosed with HIV in Europe and the US. were living long and

productive lives thanks to antiretroviral drugs. Meanwhile, the disease was still killing 2.2 million people each year in sub-Saharan Africa because pharmaceutical companies claimed it was impossible to lower the US$10,000 to $15,000 annual cost per patient for antiretrovirals.In response, human rights activists galvanized a global AIDS campaign, educating African patients about antiretrovirals, giving them the tools they required to demand treatment, and even suing drug companies. Eventually, mass protests erupted in South Africa and elsewhere, shifting public opinion on access to medicines. By 2000, competition from generic drug manufacturers brought the price of antiretrovirals down to around $350 per patient per year, allowing millions more worldwide to take them.

Egyptian patients will get little to none of the Remdesivir produced by the Egyptian drug company Eva Pharma because the US has bought up the world's supply. [Photo: Fadel Dawood/picture alliance/Getty Images]

Around the same time, a similar story was playing out with tuberculosis, which had greatly diminished in the US and Europe but remained deadly in many other places. The rise of drug-resistant strains—especially in the former Soviet Union and parts of Africa and Asia—posed a particularly terrible challenge. Conventional wisdom held that people with drug-resistant TB couldn't be saved. The drugs were too expensive, treatment courses too long, and disease management too complicated. The organization Partners in Health disproved that excuse by successfully treating 50 tuberculosis patients in Peru, then one of the world's poorest countries. That project helped convince the World Health Organization to endorse multi-drug-resistant TB treatment. Global funding for TB treatment increased greatly, and generic medicines were produced. Today more than 70% of people diagnosed with drug-resistant TB receive treatment.

Ending COVID-19 ethically:

Both of those health campaigns demonstrate the virtue I call creative resolve, which is a fundamental commitment to overcoming apparent tragedy. Other examples include the adoption of "ring vaccinations" in the 1960s—a contact tracing-based immunization strategy pioneered after mass vaccinations failed to stop smallpox—and a 2010 campaign to give children in Afghanistan their polio vaccinations at the circus.

Ending the global Coronavirus pandemic will require a similar creative resolve. Recently, the US agreed to pay $1.2 billion for early access to a promising COVID-19 vaccine in the United Kingdom and secured first access to another by the French pharmaceutical company Sanofi, enraging citizens of those countries. Such arrangements also harm manufacturing countries such as Brazil, Egypt, and India, whose people have little access to the medicines their factories pump out. Unequal access to COVID-19 medicines isn't just a moral problem. In a global pandemic, an outbreak anywhere threatens people everywhere. There is some creative resolve on display in the COVID-19 fight, though. For example, the Medicines Patent Pool—a United Nations-backed organization that encourages companies to share their patents in order to speed up innovation—is pushing this method for advancing the Research and Development of COVID-19 drugs.

Other health experts are proposing new medicine distribution mechanisms that would send drugs and vaccines where they're most needed based on the net health benefits a population would receive. That plan and others require smart data use. The Global Health Impact Project, a research collaboration that I direct, measures the effectiveness and availability of lifesaving medicines. The idea is that if we know which drugs are actually addressing pressing health needs and where, policymakers and health organizations can craft more targeted treatment access plans. Such information could be also used creatively to reward drug companies for their global health impact. Governments could create an international prize, say, that awards funds to companies based on the lives saved by their COVID-19 drugs and other essential medicines. That could offset profit as the primary motivation for drug Research, Development, and sales. And if pharmaceutical companies don't voluntarily help people in poor countries, those Governments can do what they've done in past health crises: Let other companies produce generic versions of patented medicines, to protect the common good.

(Nicole Hassoun is a Professor of Philosophy at Binghamton University, State University of New York. This article is republished from The Conversation under a Creative Commons License).

Source: Fastcompany.com, 20.07.2020

GST, Customs & Income Tax implications on the Pharmaceutical Industry

August 19, 2020 (Wednesday) | 3:00 PM – 4:30 PM

We are pleased to inform you that Indian Drug Manufacturers' Association (IDMA), in association with Lakshmikumaran and Sridharan (L&S) is organising a Webinar on "GST, Customs & Income Tax implications on the Pharmaceutical industry".

The Webinar will focus on:

1) **Interplay of GST, Customs and Direct Tax implications on:**
   - R&D Activities: For domestic & cross border arrangements.
   - Contract manufacturing arrangement & contract development arrangement.
   - Co-marketing Arrangements & other distribution models like limited risk model, profit share arrangement.
   - Promotional Expenses.
   - Treatment of Samples, expired stocks.
2) **Classification issues under Customs & GST: Hand Sanitizers.**
3) **Export and Refund related issues.**
4) **Recent developments: COVID-19 related, amendments in law & procedures like faceless assessment, important case laws.**
5) **Question and Answer session.**

Speakers:

Mr V Lakshmikumaran - *Managing Partner, L&S*.
Mr Bipin Verma – *CEO & Executive Partner, L&S.*
Mr Jigar Shah – *Partner, L&S.*
Ms Lakshmi Menon – *Partner, L&S.*
Mr S Sriram – *Joint Partner, L&S.*
Mr Anurag Kapur – *Joint Partner, L&S.*

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Indian Drug Manufacturers' Association

Gujarat State Board, Ahmedabad

E-mail : idmagsb@gmail.com • Ph. : 079-26406680

Webinar on

"Operational Excellence in Pharmaceutical Manufacturing"

Block your Calender

Friday 21, August, 2020

04:30 PM - 6:00 PM

Moderator

Dr. SHRENIK K. SHAH

Sr. Vice President, IDMA-GSB

Director-Montage Lab

Opening Remarks

Mr. MILAN R. PATEL

Chairman, IDMA-GSB

Jt. MD, Troikaa Pharmaceuticals Ltd.

Eminent & Expert Panelists

Mr. N C NARAYANAN

Founder Chairman of

SSA Group of Companies

MR. VIJAY DHONDE

CEO, SSA Business Solutions-

Asia Pacific

Dr. Adil Billimoria

President

Quality & Compliance Alkem Labs

	Indian Drug Manufacturers' Association **Gujarat State Board** **Ahmedabad** **Email: idmagsb@gmail.com Ph: 079 – 26406680**	Indian Drug Manufacturers' Association (IDMA - GSB)

Webinar : "Operational Excellence in Pharmaceutical Manufacturing"

Day & Date: Friday 21, August, 2020	**Time: 04:30 PM to 06:00 PM**

Moderator : Dr.Shrenik Shah, Sr. Vice Chairman , IDMA GSB

Program Flow		
04: 30 PM to 04:40 PM	Opening Remarks & Welcome Address	Mr. Milan R. Patel Chairman IDMA GSB
04:40 PM to 05:00 PM	**Speech:** "The Big Picture: Current Challenges & Future Opportunities in Pharma Industries"	Mr. N. C. Narayanan Founder Chairman SSA Group of Companies
05:00 PM to 05:20 PM	**Speech:** • Operational Excellence Tools & Techniques: Pragmatic Way of Application • Case Study: OPEX for Yield Improvement, Capacity Enhancement	Mr. Vijay S. Dhonde CEO SSA Business Solutions - APAC
05:20 PM to 05:40 PM	**Speech:** Need for Pharmaceutical Operational Excellence: Experience Sharing of Achieving Breakthrough Results	Dr. Adil Billimoria President – (Q &C) Alkem Laboratories Ltd.
05:40 PM to 05:55 PM	Panel Discussion with Q&A Session	
05:55 PM to 06:00 PM	Vote of Thanks	Mr. Sumit J. Agrawal Hon. Secretary IDMA GSB

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