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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **Anti Microbial Resistance Crisis** *(Page No. 15)*

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★ **Industry seeks deferment of implementation of Track & Trace system for export** *(Page No. 30)*

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Supported by: Indian Pharmacopoeia Commission, United States Pharmacopeia, Indian Drug Manufacturers' Association, National Chamber of Pharmaceutical Manufacturers of Sri Lanka.

Media Partner - Sahara News Network, Prestigious Partner - World Book of Records - London.

Speakers:

(1) ***Dr Mrunal Jaywant,*** *Senior Director, R&D at US Pharmacopoeia, Hyderabad,*

(2) ***Mr Atul Nasa,*** *Deputy Drugs Controller – Delhi.*

(3) ***Dr Diwakar Sukul,*** *Chairman - World Book of Records, London – UK.*

Guest of Honour/Speaker:
Mr Daara B Patel**,** Secretary General, IDMA.

For Registration and further information/clarification, please contact us at email: **office@socialtalks.in**

OBITUARY

Mr T R Gopalkrishnan
(21.01.1958 - 28.02.2021)

Mr T R Gopalakrishnan (Gopal, we used to call him) left for his heavenly abode on 28th February 2021, at the age of 63. He was a bachelor and his life was totally dedicated to IDMA from 1993. When Mr. Melvin of IDMA announced the sad news in our IDMA group on the morning of March 1st, we were all taken aback.

On hearing the sad news, Mr Mahesh Doshi, National President said that it was indeed very sad and shocking. We will surely miss him. May his soul rest in Peace. Dr Viranchi Shah, the Senior Vice President, expressing his shock, said that Gopal was a wonderful human being besides being a great asset to IDMA.

As mentioned by Dr George Patani, Hon General Secretary, IDMA, we have lost a great resource of information on the Pharmaceutical Industry and a strong member of our Publications team. Mr Daara Patel, Secretary General, IDMA said that Gopal as he was fondly called was a very good colleague and support for almost 15 years. He was extremely knowledgeable & hard working and there was hardly anything about the Pharma industry that he was not aware of. Not only the members of IDMA counted on his guidance but also the Secretariat Staff. He was also known for his sense of humor and wit. Gopal's absence has created a void in the IDMA Secretariat. May God grant his departed soul eternal peace.

Many senior members condoling his demise said that Gopal had devoted his entire life to IDMA and that his demise was a great and irreparable loss. Mr Bharat Desai commented that Gopal was a strong pillar at the IDMA Secretariat and that he was a kind and good human being. Our Past President, Mr Manish Doshi said "Gopal was a huge contributor to IDMA's efforts and representations. A true and silent worker, who will be missed badly. Mr Ashok Madan, Executive Director, IDMA-Delhi Office expressing his shock, said that demise of Gopal was a great loss to the Pharma fraternity. Mr S R Vaidya said that the shocking demise of Gopal is a personal loss and that he was a great soul in the Temple of IDMA.

Recalling that morning of 1st March, Dr. Gopakumar G Nair, Past President, said that this was sad and shocking news. He had started working together with Gopal when Mr Ivan Alva was the Secretary General in the nineties. To put it mildly (not to hurt anyone else) Gopal was the backbone of IDMA and IDMA Publications. He was an Encyclopedia of the Pharmaceutical Industry. He was a man of simple means, habits, always soft spoken and spiritual in life. He remained a bachelor and devoted his entire life to IDMA except for a couple of months break in between. He further added, "Tears are flowing not only from my eyes but from my heart too. Having lost him, I now realize that my love, affection and affinity to IDMA was also due to the presence of Gopal in IDMA. Praying for SAYOOJYA for GOPAL's Departed Soul and heartfelt Condolences to the IDMA SECRETARIAT and all IDMA LOVERS and WELL WISHERS."

Dr Amit Rangnekar stated that IDMA has lost a real pillar of strength in Gopal's sad demise. He further stated that Gopal was most affable, knowledgeable and a helpful person. In Mr Kamlesh Patel's words "Gopal was the hard disk of IDMA before computers came". Mr S M Mudda, lamented that Gopal was an encyclopedia of knowledge related to IDMA's representations on various topics and would readily recall even a decade old issue with ease. He was a humble human being ever ready to help. According to Mrs Samita Iyer, Gopal's demise is a huge loss to us. "His presence and contribution is inimitable".

Mr Veeramani, Past President stated "It is shocking and sad that dear Gopal has passed away. He is one person who knew all the developments of IDMA's past and stand on various matters. Like an Encyclopedia he would churn out all the details in quick time. His passing away is indeed a great loss to IDMA. A simple and unassuming person he was kind to all. Words fail to describe him. May his soul Rest in Peace at the Golden abode of God".

Mr T R Gopalakrishnan joined IDMA in 1993 as Asst. Secretary General. Later under Mr Daara Patel, who took over at the turn of the Millennium, Gopal became the Deputy Secretary General. Over and above administrative matters and drafting Government representations, Gopal played a major role in IDMA Publications, the IDMA Bulletin, the Research Publication, Indian Drugs and the IDMA Annual Publication. It is an unsurmountable LOSS TO ALL OF US AS HE WAS THE PIVOT IN THE INSTITUTION OF IDMA. THE ADMIN WILL HAVE TO BEAR THE BRUNT WITHOUT HIM. EVERY PAST PRESIDENT INCLUDING THE PRESENT ONE AND THE ENTIRE STAFF WILL FEEL THE PINCH INCLUDING OUR GREAT DAARAJI. MAY HIS SOUL REST IN PEACE. MAY HIS FAMILY BE STRONG ENOUGH TO ACCEPT THIS GREAT LOSS OF A GREAT SOUL.

We will miss "Gopal" for all time to come. May his soul Rest in Peace.

On behalf of our National President, Mr Mahesh Doshi, we thank Dr Gopakumar G Nair for this wonderful Obituary which truly expresses our feelings towards Mr T R Gopalkrishnan.

Caring for Life - The Cipla Story - since 1935

Dr Gopakumar G Nair

Once in a life time opportunity for me to review "Caring for Life - The Cipla Story since 1935". At the outset, I must thank Dr Yusuf Hamied and his Cipla office (Rosy in particular) for promptly forwarding a copy of the book fully anticipating the imminent threat of a review from me. I was prompt in expressing my thanks and views as follows:

It gives me immense pleasure to acknowledge receipt of the book "Caring for Life – The Cipla Story since 1935".

While it is indeed amazing to go through the life story of Cipla starting 1935, it is all the more astonishing to go even beyond, into the life story of Dr K A Hamied even beyond 1900's. The documentation provided in the book is mind-blowing and exciting. I read through the book once the parcel was opened with keen interest, enthusiasm and excitement.

Deeply appreciate the efforts of all concerned, including Tulsi Vatsal. Dr Yusuf Hamied deserves special congratulations for this excellent compilation.

Praying for Good Health and Long life to Dr Yusuf Hamied and wishing CIPLA and the families of all associated with the Hamied family and Cipla, the very best in years to come.

Mr Daara Patel, Secretary-General of IDMA was the first to communicate by me that I intend to review this valuable book. Dr George Patani supported me. Very soon, Dr Nagraj Rao, our co-editor of Indian Drugs suggested that the book is a valuable collection for any Pharma library and should be reviewed. Here I am, most happily joining the reminiscences of Dr K A Hamied (whom I had met a few times in person), Dr Yusuf Hamied of CIPLA, "Fire in the blood", Cipla palliative care, Cipla Foundation, "HIV-AIDS and Triomune", and of course the CSIR-NCL-Dr Rama Rao collaborations.

The book is valuable and must read for all science students as well as pharmacists across the board. The early struggles, pains and passions of Dr K A Hamied, the transformation from Jamia Millia to Germany and back to India to lay the foundation of CIPLA, the unique blend of cultures with roots in Afghanistan, Iran, Poland, Russia, Germany and the transitions and transformations from mathematics, physics to chemistry and pharmacy with sprinkling of tonics (Okasa), typewriters and sewing machines, eventually settling for Luba as life partner in 1928 and for registering CIPLA in 1935 as a final frontier in his various business initiatives. While delving with the evolution of CIPLA, major events of the seasons and relevant times, such as India's freedom struggle, economic scenario during the world wards, life and works of eminent Indian nationalist leaders like Mahatma Gandhi, Tagore, Zakir Hussain, a host of Nobel Laurates in chemistry, Literature and Indian initiatives on scientific development through research through CSIR, NCL and other Research Organizations.

Dr Yusuf Hamied's joining, through Cambridge in late 1950's, with Nobel Laurate Sir Alexander Todd and his return to India after Ph.D. in1960, his early trysts with Indian bureaucracy in clearing his joining Cipla (being a relative of Director – 1950 to 1970's or even upto 1990 was era of controls and regulations – excessive), the reframing of the vision and mission of CIPLA through research collaborations and strategic innovation initiatives are all vividly described in the book. From Diosgenin (steroids) to contraceptives (Carl Djerassi fame), the respiratory revolution by CIPLA leading to Indian and even global leadership in inhalers and inhalation therapy, the salbutamol saga, the dry powder inhaler devices, major break-through innovations in inhalation therapy and COPD and thereafter the second-generation transition in strategic management through Mr Punshi as Consultant, Mr Amar Lulla and other stalwarts joining the team. Once Dr Yusuf and Cipla made a brilliant research team with Dr A V Rama Rao and NCL, there was no looking back. The Research fever that gripped CIPLA has continued and still continues with many breakthrough products (of their times) such as Vinca Rosea derivatives and later leading to the leadership in AIDS/HIV treatment projects.

The developments on Uruguay Round, WTO-TRIPs and Indian Patent Act amendments are also elaborately dealt with in the book with historical narrative, including

on the Ayyangar Committee Report and consequent amendment of the Patents Act, 1970, abolishing product patents for Pharma, Chemical and fertilizers in which the contribution of IDMA is deservedly acknowledged in the book.

The Chapters on HIV/AIDS make interesting reading. The first affordable once-a-day pill TRIOMUNE from CIPLA went on to revolutionize the treatment through ARVs. With the NCL-Rama Rao-CIPLA team actively re-engaging in AZT and other ARVs, CIPLA and Dr Yusuf Hamied found new global partners across the world in making affordable access in HIV-AIDS treatment. Social initiatives such as Palliative Care and CIPLA Foundation are also dealt with in the book. Of course, there is a mention of the famous "fight for public good" in the Imatinib Mesylate was won by CIPLA in Supreme Court after seven years of multiple litigations (popularly known as "Gleevec" case).

A large range of modern processes, therapies and devices are covered in the concluding part. In short, the book is a must-read and must-possess for all pharmaceutical and disease management institutions and professionals.

To conclude, I wish Dr Yusuf Hamied a long and active healthy life, vibrant as always and CIPLA, a pioneer Indian Nationalist Pharma conglomerate (now a global leader) all the success under the next generation leadership of Ms Samina Hamied and her professional colleagues.

*(*Reviewed by **Dr Gopakumar G Nair**, CEO - Gopakumar Nair Associates, Founder – Gnanlex Hermeneutics Pvt Ltd, Designated Partner – Gnanlex Associates LLP., CEO - Patent Gurukul, President - Bharat Education Society, Kurla and Editor - IDMA Publications, Past President and now Chairman - IPR Committee, IDMA).*

(Note: A copy of the said Book is available in the IDMA Library so as to enable our Members to read).

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GOVERNMENT NOTIFICATIONS

Amendment to the Acetone (Quality Control) Order, 2020 - reg.

Chemicals & Fertilizers Notification No.S.O.1097(E), dated 8th March 2021 - reg.

(Published in the Gazette of India on 10th March, 2021)

1. In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Acetone (Quality Control) Order, 2020 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

2. In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the **14th September, 2021**."

F.No.13012/24/2019-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

***Note:** The Principal order for Acetone was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide number S.O.1896(E) dated the 16th June, 2020 and subsequently amended vide Notification Number S.O.3087(E) dated 09th September, 2020.*

● ● ●

CBIC notifies implementation of e-Invoicing for the taxpayers having aggregate turnover exceeding Rs.50 Cr from 01st April 2021 - reg.

Notification No.05/2021-Central Tax, dated 8th March, 2021

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

In the said notification, in the first paragraph, with effect from the 1st day of April, 2021, for the words "one hundred crore rupees", the words **"fifty crore rupees"** shall be substituted.

F.No.CBEC-20/13/01/2019-GST

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

Note: *The Principal Notification No.13/2020–Central Tax, dated the 21st March, 2020 was published in the Gazette of India, Extraordinary, vide number G.S.R.196(E), dated 21st March, 2020 and was last amended vide Notification No.88/2020-Central Tax, dated the 10th November, 2020, published vide number G.S.R.704(E), dated the 10th November, 2020.*

● ● ●

CBIC Clarification on refund related issues – reg.

GST Circular No.147/03/2021-GST, dated 12th March, 2021

To,
The Principal Chief Commissioners/Chief Commissioners/ Principal Commissioners/ Commissioners of Central Tax (All),
The Principal Director Generals/Director Generals (All).

1. Clarification on refund related issues:

Various representations have been received seeking clarification on some of the issues relating to GST refunds. The issues have been examined and to ensure uniformity in the implementation of the provisions of law across the field formations, the Board, in exercise of its powers conferred by section 168 (1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the issues detailed hereunder:

2. Clarification in respect of refund claim by recipient of Deemed Export Supply:

2.1 Representations have been received in respect of difficulties being faced by the recipients of the deemed export supplies in claiming refund of tax paid in respect of such supplies since the system is not allowing them to file refund claim under the aforesaid category unless the claimed amount is debited in the electronic credit ledger.

2.2 Para 41 of Circular No.125/44/2019–GST dated 18/11/2019 has placed a condition that the recipient of deemed export supplies for obtaining the refund of tax paid on such supplies shall submit an undertaking that he has not availed ITC on invoices for which refund has been claimed. Thus, in terms of the above circular, the recipient of deemed export supplies cannot avail ITC on such supplies but when they proceed to file refund on the portal, the system requires them to debit the amount so claimed from their electronic credit ledger.

2.3 The 3rd proviso to Rule 89(1) of CGST Rules, 2017 allows for refund of tax paid in case of a **deemed export supply** to **the recipient or the supplier**

of deemed export supplies. The said proviso is reproduced as under:

"Provided also that in respect of supplies regarded as deemed exports, the application may be filed by,-

(a) *the recipient of deemed export supplies; or*

(b) *the supplier of deemed export supplies in cases where the recipient does not avail of input tax credit on such supplies and furnishes an undertaking to the effect that the supplier may claim the refund"*

From the above, it can be seen that there is no restriction on recipient of deemed export supplies in availing ITC of the tax paid on such supplies when the recipient files for refund claim. The said restriction has been placed by the Circular No.125/44/2019-GST dated 18.11.2019.

2.4 In this regard, it is submitted that in order to ensure that there is no dual benefit to the claimant, the portal allows refund of only Input Tax Credit (ITC) to the recipients which is required to be debited by the claimant while filing application for refund claim. Therefore, whenever the recipient of deemed export supplies files an application for refund, the portal requires debit of the equivalent amount from the electronic credit ledger of the claimant.

2.5 As stated above, there is no restriction under 3rd proviso to Rule 89(1) of CGST Rules, 2017 on recipient of deemed export supply, claiming refund of tax paid on such deemed export supply, on availment of ITC on the tax paid on such supply. Therefore, the para 41 of Circular No.125/44/2019-GST dated 18.11.2019 is modified to remove the restriction of non-availment of ITC by the recipient of deemed export supplies on the invoices, for which refund has been claimed by such recipient. The amended para 41 of Circular no.125/44/2.019-GST dated 18.11.2019 would read as under:

"41. Certain supplies of goods have been notified as deemed exports vide notification No.48/2017- Central Tax dated 18.10.2017 under section 147 of the CGST Act. Further, the third proviso to rule 89(1) of the CGST Rules allows either the recipient or the supplier to apply for refund of tax paid on such deemed export supplies. In case such refund is sought by the supplier of deemed export supplies, the documentary evidences as specified in notification No.49/2017-Central Tax dated 18.10.2017 are also required to be furnished which includes an undertaking that the recipient of deemed export supplies shall not claim the refund in respect of such supplies and shall not avail any input tax credit on such supplies. Similarly, in case the refund is filed by the recipient of deemed export supplies, an undertaking shall have to be furnished by him stating that refund has been claimed only for those invoices which have been detailed in statement 5B for the tax period for which refund is being claimed and ***the amount does not exceed the amount of input tax credit availed in the valid return filed for the said tax period***. The recipient shall also be required to declare that the supplier has not claimed refund with respect to the said supplies. The procedure regarding procurement of supplies of goods from DTA by Export Oriented Unit (EOU)/Electronic Hardware Technology Park (EHTP) Unit/Software Technology Park (STP) Unit/ Bio-Technology Parks (BTP) Unit under deemed export as laid down in Circular No.14/14/2017-GST dated 06.11.2017 needs to be complied with."

3. Extension of relaxation for filing refund claim in cases where zero-rated supplies has been wrongly declared in Table 3.1(a):

3.1 Para 26 of Circular No.125/44/2019-GST dated 18th November 2019 gave a clarification in relation to cases where taxpayers had inadvertently entered the details of export of services or zero-rated supplies to a Special Economic Zone Unit/Developer in table 3.1(a) instead of table 3.1(b) of **FORM GSTR-3B** of the relevant period and were unable to claim refund of the integrated tax paid on the same through **FORM GST RFD-01A**. This was because of a validation check placed on the common portal which prevented the value of refund of integrated tax/cess in **FORM GST RFD-01A** from being more than the amount of integrated tax/cess declared in table 3.1(b) of **FORM GSTR-3B**. The said Circular clarified that for the tax periods from **01.07.2017 to 30.06.2019**, such registered persons shall be allowed to file the refund application in **FORM GST RFD-01A** on the common portal subject to the condition that the amount of refund of integrated tax/cess claimed shall not be more than the aggregate amount of integrated tax/ cess mentioned in the tables **3.1(a), 3.1(b) and 3.1(c)** of **FORM GSTR-3B** filed for the corresponding tax period.

3.2 Since the clarification issued vide the above Circular was valid only from 01.07.2017 to 30.06.2019,

taxpayers who committed these errors in subsequent periods were not able to file the refund applications in **FORM GST RFD-01A/ FORM GST RFD-01**.

3.3 The issue has been examined and it has been decided to extend the relaxation provided for filing refund claims where the taxpayer inadvertently entered the details of export of services or zero-rated supplies to a Special Economic Zone Unit/Developer in table 3.1(a) instead of table 3.1(b) of FORM GSTR-3B **till 31.03.2021**. Accordingly, para 26 of Circular No.125/44/2019-GST dated 18.11.2019 stands modified as under:

"26. In this regard, it is clarified that for the tax periods commencing from ***01.07.2017 to 31.03.2021***, such registered persons shall be allowed to file the refund application in FORM GST RFD- 01 on the common portal subject to the condition that the amount of refund of integrated tax/cess claimed shall not be more than the aggregate amount of integrated tax/ cess mentioned in the Table under columns 3.1(a), 3.1(b) and 3.1(c) of **FORM GSTR-3B** filed for the corresponding tax period."

4. The manner of calculation of Adjusted Total Turnover under sub-rule (4) of Rule 89 of CGST Rules, 2017.

4.1 Doubts have been raised as to whether the restriction on turnover of zero-rated supply of goods to 1.5 times the value of like goods domestically supplied by the same or, similarly placed, supplier, as declared by the supplier, imposed by amendment in definition of the "Turnover of zero-rated supply of goods" vide Notification No. 16/2020-Central Tax dated 23.03.2020, would also apply for computation of "Adjusted Total Turnover" in the formula given under Rule 89 (4) of CGST Rules, 2017 for calculation of admissible refund amount.

4.2 Sub-rule (4) of Rule 89 prescribes the formula for computing the refund of unutilised ITC payable on account of zero-rated supplies made without payment of tax. The formula prescribed under Rule 89 (4) is reproduced below, as under:

"Refund Amount = (Turnover of zero-rated supply of goods + Turnover of zero-rated supply of services) x Net ITC ÷Adjusted Total Turnover"

4.3 Adjusted Total Turnover has been defined in clause (E) of sub-rule (4) of Rule 89 as under:

"Adjusted Total Turnover" means the sum total of the value of-

(a) ***the turnover in a State or a Union territory, as defined under clause (112) of section 2****, excluding the turnover of services; and*

(b) *the turnover of zero-rated supply of services determined in terms of clause (D) above and non-zero-rated supply of services,*

excluding:

(i) *the value of exempt supplies other than zero-rated supplies; and*

(ii) *the turnover of supplies in respect of which refund is claimed under sub-rule (4A) or sub-rule (4B) or both, if any,* during the relevant period.'

4.4 "Turnover in state or turnover in Union territory" as referred to in the definition of "Adjusted Total Turnover" in Rule 89 (4) has been defined under sub-section (112) of Section 2 of CGST Act 2017, as:

*"Turnover in State or turnover in Union territory" means the aggregate **value of all taxable supplies** (excluding the value of inward supplies on which tax is payable by a person on reverse charge basis) and exempt supplies made within a State or Union territory by a taxable person, **exports of goods** or services or both and inter State supplies of goods or services or both made from the State or Union territory by the said taxable person but excludes central tax, State tax, Union territory tax, integrated tax and cess".*

4.5 From the examination of the above provisions, it is noticed that "Adjusted Total Turnover" includes "Turnover in a State or Union Territory", as defined in Section 2(112) of CGST Act. As per Section 2(112), "Turnover in a State or Union Territory" includes turnover/value of export/ zero-rated supplies of goods. The definition of "Turnover of zero-rated supply of goods" has been amended vide Notification No.16/2020- Central Tax dated 23.03.2020, as detailed above. In view of the above, it can be stated that the same value of zero-rated/export supply of goods, as calculated as per amended definition of "Turnover of zero-rated supply of goods", need to be taken into consideration while calculating "turnover in a state or a union territory", and accordingly, in "adjusted total turnover" for the purpose of sub-rule (4) of Rule 89. Thus, the restriction of 150% of the

value of like goods domestically supplied, as applied in "turnover of zero-rated supply of goods", would also apply to the value of "Adjusted Total Turnover" in Rule 89 (4) of the CGST Rules, 2017.

4.6 Accordingly, it is clarified that for the purpose of Rule 89(4), the value of export/zero-rated supply of goods to be included while calculating "adjusted total turnover" will be same as being determined as per the amended definition of "Turnover of zero-rated supply of goods" in the said sub-rule. The same can explained by the following illustration where actual value per unit of goods exported is more than 1.5 times the value of same/similar goods in domestic market, as declared by the supplier:

Illustration: Suppose a supplier is manufacturing only one type of goods and is supplying the same goods in both domestic market and overseas. During the relevant period of refund, the details of his inward supply and outward supply details are shown in the table below:

Net admissible ITC = Rs. 270

All values in Rs.

Outward Supply	Value per unit	No of units supplied	Turn-over	Turnover as per amended definition
Local (Quantity 5)	200	5	1000	1000
Export (Quantity 5)	350	5	1750	1500 (1.5*5*200)
Total			2750	2500

The formula for calculation of refund as per Rule 89(4) is :

Refund Amount = (Turnover of zero-rated supply of goods + Turnover of zero-rated supply of services) x Net ITC ÷Adjusted Total Turnover

Turnover of Zero-rated supply of goods (as per amended definition) = Rs. 1500

Adjusted Total Turnover= Rs. 1000 + Rs. 1500 = Rs. 2500 [and not Rs. 1000 + Rs. 1750] Net ITC = Rs. 270

$$\text{Refund Amount} = \frac{\text{Rs. } 1500*270}{2500} = \text{Rs. } 162$$

Thus, the admissible refund amount in the instant case is Rs. 162.

5. It is requested that suitable trade notices may be issued to publicize the contents of this Circular.

6. Difficulty, if any, in implementation of this Circular may please be brought to the notice of the Board.

F.No.CBEC-20/23/03/2020-GST

Sanjay Mangal,
Commissioner (GST),
Central Board of Indirect Taxes and Customs,
GST Policy Wing,
Department of Revenue,
Ministry of Finance,
New Delhi.

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COMPANIES LAW AMENDMENTS

Provisions of section 23(i) of the Companies (Amendment) Act, 2017 (1 of 2018) enforced - reg.

Corporate Affairs Notification Ref.File No.1/1/2018-CL.I, dated 5th March, 2021

In exercise of the powers conferred by sub-section (2) of section 1 of the Companies (Amendment) Act, 2017 (1 of 2018), the Central Government hereby appoints the day of **5th March, 2021** as the date on which the provisions of clause (i) of section 23 of the said Act shall come into force.

K V R, Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

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Companies (Management and Administration) Rules, 2014 amended (1st Amendment of 2021) - reg.

Corporate Affairs Notification Ref.F.No.01/34/2013 CL-V-(Pt-II), dated 5th March, 2021

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

1. Short title and commencement:

(1) These rules may be called the **Companies (Management and Administration) Amendment Rules, 2021.**

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

2. In the Companies (Management and Administration) Rules, 2014, (herein after referred as the said rules), in rule 11, for sub-rule (1), the following sub-rule shall be substituted, namely:-

"(1) Every company shall file its annual return in Form No.MGT-7 except One Person Company (OPC) and Small Company. One Person Company and Small Company shall file annual return from the financial year 2020-2021 onwards in Form No.MGT-7A";

(a). in the said rules, for rule 12, the following rule shall be substituted, namely,-

"12. Filing of Annual Return with Registrar; A copy of the annual return shall be filed with the Registrar with such fees as may be specified for this purpose".

(b). in the said rules, in rule 20, after proviso in sub-rule (2), the following explanations shall be numbered namely,-

"**Explanation-I:** For the purpose of this sub-rule, "Nidhi" means a company which has been incorporated as a Nidhi with the object of cultivating the habit of thrift and savings amongst its members, receiving deposits from and lending to, its members only, for their mutual benefit, and which complies with such rules as are made by the Central Government for regulation of such class of companies.

Explanation-II: For the purposes of this rule, the expression:

(i) 'agency' means the National Securities Depository Limited, the Central Depository Services (India) Limited or any other entity approved by the Ministry of Corporate Affairs subject to condition that the National Securities Depository Limited, the Central Depository Services (India) Limited or such other entity has obtained a certificate from the Standardisation Testing and Quality Certification Directorate, Department of Information Technology, Ministry of Communications and Information Technology, Government of India including with regard to compliance with parameters under Explanation (vi);

(ii) 'cut-off date' means a date not earlier than seven days before the date of general meeting for determining the eligibility to vote by electronic means or in the general meeting;

(iii) 'cyber security' means protecting information, equipment, devices, computer, computer resource, communication device and information stored therein from unauthorised access, use, disclosures, disruption, modification or destruction;

(iv) 'electronic voting system' means a secured system based process of display of electronic ballots, recording of votes of the members and the number of votes polled in favour or against, in such a manner that the entire voting exercised by way of electronic means gets registered and counted in an electronic registry in a centralised server with adequate cyber security;

(v) 'remote e-voting' means the facility of casting votes by a member using an electronic voting system from a place other than venue of general meeting'

(vi) 'secured system' means computer hardware, software, and procedure that:

(a) are reasonably secure from unauthorised access and misuse;

(b) provide a reasonable level of reliability and correct operation;

(c) are reasonably suited to performing the intended functions; and

(d) adhere to generally accepted security procedures;

(vii) 'voting by electronic means' includes "remote e-voting" and voting at the general meeting through an electronic voting system which may be the same as used for remote e-voting.".

(c). in the said rules, for Form No.MGT-7, the following forms No.MGT-7 and MGT-7A shall be substituted, namely*:-

F.No.01/34/2013 CL-V (Pt-II)

K V R Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Part II, Section 3, Sub-section (i) vide number G.S.R.260(E) dated 31st March, 2014 and subsequently amended vide the following notifications:-*

Serial Number	Notification Number	Notification Date
1.	G.S.R. 415(E)	23.06.2014
2.	G.S.R. 537(E)	24.07.2014
3.	G.S.R. 669(E)	28.08.2015
4.	G.S.R. 737(E)	24.09.2015
5.	G.S.R. 862(E)	16.11.2015
6.	G.S.R. 908(E)	23.09.2016
7.	G.S.R. 175(E)	16.02.2018
8.	G.S.R. 560(E)	13.06.2018
9.	G.S.R. 538 (E)	28.08.2020

Annexures/Relevant Forms attached to the said Notification are not reproduced here as the same runs into more than 25 Pages. Members-interested are requested to kindly visit MCA website:* ***www.mca.gov.in* *to download the same OR contact IDMA Secretariat at email:* ***mail_idma@idmaindia.com*** *so as to enable us to email soft copy of the said Notification.*

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INDIAN PHARMACOPOEIA

Omission of Monographs of 'Lorcaserin Hydrochloride Hemihydrate' and 'Lorcaserin Tablets' from the Indian Pharmacopoeia – reg.

ATTENTION MEMBERS

IPC has issued notice (as reproduced below) to omit Monographs of 'Lorcaserin Hydrochloride Hemihydrate' and 'Lorcaserin Tablets' from the Indian Pharmacopoeia. This is for kind notice and compliance by our members:

"IPC Notice Ref.F.No.T.11013/02/2018-AR&D, dated 10th March 2021

To

DCGI, CDSCO Zonal Offices, All SDCs, Members of the Scientific Body of IPC, Members of Sub-committee of the Scientific Body of IPC, Directors of Drugs Testing Laboratories, Government Analysts, IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations.

1. Based on the safety Clinical Trial and possible risk of cancer associated with Lorcaserin, manufacturer has voluntarily withdrawn the said product from the US market.

2. Subsequently, to safe guard the public health, manufacturer has also voluntarily withdrawn the distributed product from the Indian Market.

3. In view of above, monographs of 'Lorcaserin Hydrochloride Hemihydrate' and 'Lorcaserin Tablets' are omitted from the Indian Pharmacopoeia (IP) 2018.

4. All concerned are requested to bring it to the notice of all authorities under their control.

*Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad***".**

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Anti Microbial Resistance Crisis

MoH&FW Press Release dated 9th March 2021

Government of India has given due cognizance to the problem of Antimicrobial Resistance (AMR). Ministry of Health and Family Welfare (MoHFW) has initiated various activities for containment of AMR as under:

I. National Action Plan for containment of Antimicrobial Resistance (NAP-AMR) was launched on 19 April, 2017, involving stakeholders from various Ministries/ Sectors.

II. National Programme on Containment of AMR was initiated during the 12 Five Year Plan. National Centre for Disease Control (NCDC) coordinates this programme. Under the programme National AMR surveillance network of state medical colleges, labs (NARS-Net) have been established in order to generate quality data on AMR for seven priority bacterial pathogens of public health importance using WHONET software.

III. National Guidelines on Infection, Prevention and Control in Healthcare facilities were released in January, 2020. These Guidelines have been shared with various stakeholders across the country to be used in training modules for country-wide trainings in a systematic manner.

IV. Under the programme, NCDC conducts AMR surveillance through a network of 30 state medical college laboratories in 25 states. The network is expanded across the country in a phased manner.

V. Indian Council of Medical Research (ICMR) coordinates another AMR surveillance network of 20 laboratories located in tertiary care centres (both public and private) in the country.

VI. Antimicrobial stewardship (AMSP) activities**:** In order to promote rational use of antibiotics among the healthcare providers, a series of sensitization and training workshops have been organized in different healthcare facilities in the country for the benefit of the practicing clinicians. Standard treatment guidelines developed by NCDC for rational use of antibiotics have been made available to clinicians across the country.

VII. To create awareness among the public about AMR, various IEC activities like quiz competition in schools, participation in Perfect Health Mela, poster & quiz competition for healthcare workers at NCDC and the sites included in the NARS-Net during World Antibiotic awareness each year have been conducted to raise awareness about AMR. IEC material (audio/video/Print OD Media) to raise awareness about AMR and to prevent misuse of antibiotics has been made available on the website of NCDC for use by the States-UT Governments and other stakeholders.

As per Ministry of Environment Forest and Climate Change, draft Notification on emission and discharge standards for Bulk Drug and Formulation (Pharmaceutical) Industries was notified on 23.01.2020. According to the Ministry, thirty five suggestions were received from the Associations, NGOs, individual experts and industry. Stakeholders consultation were made. Necessary information and research is not available for prescribing the appropriate norms for limiting the concentration of antibiotics, monitoring and compliance verification and testing protocols for effluents discharged from Pharma industry. The Minister of State (Health and Family Welfare), Shri Ashwini Kumar Choubey stated this in a written reply in the Rajya Sabha today.

Source: PIB, MoH&FW Press Release, 09.03.2021

CBIC further amends Notification No.6/2016-Customs (ADD) dated 8th March, 2016 to extend the levy of Anti-Dumping duty on Phenol originating in or exported from European Union and Singapore, up to and inclusive of 7th June, 2021 - reg.

Notification No.11/2021-Customs (ADD), dated 3rd March, 2021

1. Whereas, the designated authority vide initiation notification No.7/41/2020-DGTR, dated the 31st December, 2020, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 31st December, 2020, has initiated review in terms of sub-section (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act) read with rule 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995 (hereinafter referred to as the said rules), in the matter of continuation of anti-dumping duty on imports of 'Phenol', originating in or exported from European Union and Singapore, imposed vide notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.6/2016-Customs (ADD), dated the 8th March, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.284(E), dated the 8th March, 2016, and has requested for extension of the said anti-dumping duty in terms of sub-section (5) of section 9A of the Customs Tariff Act.

2. Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the said rules, the Central Government hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Finance (Department of Revenue) No.6/2016-Customs (ADD), dated the 8th March, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.284(E), dated the 8th March, 2016, namely:-

In the said notification:

(a) in the TABLE, against Sr.No.12, for the entry in column (4), the entry "Any country other than those attracting anti-dumping duty" shall be substituted;

(b) in the TABLE, against Sr.No.15, for the entry in column (4), the entry "Any country other than those attracting anti-dumping duty" shall be substituted;

(c) after paragraph 2 and before the Explanation, the following paragraph shall be inserted, namely:-

"3. Notwithstanding anything contained in paragraph 2, the anti-dumping duty imposed on the subject goods specified against serial numbers 8, 9, 10, 11, 12, 13, 14 and 15 of the Table above shall remain in force up to and inclusive of the 7th June, 2021, unless revoked, superseded or amended earlier.".

F.No.354/202/2015-TRU(Pt-I)

Rajeev Ranjan,
Under Secretary,
Department of Revenue,
Ministry of Finance,
New Delhi.

Note: *The Principal Notification No.6/2016-Customs (ADD), dated the 8th March, 2016 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.284(E), dated the 8th March, 2016 and was last amended vide notification No.33/2016-Customs (ADD), dated the 14th July, 2016, published vide number G.S.R.697(E), dated the 14th July, 2016.*

Government imposes provisional anti-dumping duty on imports of Ciprofloxacin Hydrochloride originating in or exported from China PR for a period of five years - reg.

Notification No.13/2021-Customs (ADD), dated 11th March, 2021

1. Whereas, in the matter of **'Ciprofloxacin Hydrochloride'** (hereinafter referred to as the subject goods), falling under tariff item 2941 90 30 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act), originating in, or exported from the **People's Republic of China** (hereinafter referred to as the subject country) and imported into India, the designated authority in its preliminary findings *vide* notification No.6/36/2019-DGTR, dated the 15th June, 2020, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 15th June, 2020, had recommended imposition of provisional anti-dumping duty on the imports of subject goods, originating in, or exported from the subject country.

And, whereas, on the basis of the aforesaid findings of the designated authority, the Central Government had imposed provisional anti-dumping duty on the subject goods with effect from 2nd September, 2020 *vide* notification of the Government of India in the Ministry of Finance (Department of Revenue), No.28/2020-Customs (ADD), dated the 2nd September, 2020, published in the Gazette of India Extraordinary, Part II, Section 3, Sub-section (i) *vide* number G.S.R.544(E), dated the 2nd September, 2020.

And, whereas, the designated authority in its final findings *vide* notification No.6/36/2019-DGTR, dated the 7th January, 2021, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 7th January, 2021, while confirming the preliminary findings, dated the 15th June, 2020, has come to the conclusion that,-

(i) the product under consideration has been exported to India from the subject country below its normal value;

(ii) the Domestic Industry has suffered material injury;

(iii) material injury has been caused by the dumped imports of subject goods from the subject country.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 20 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, the Central Government, after considering the aforesaid final findings of the designated authority, hereby imposes on the subject goods, the description of which is specified in column (3) of the Table below, falling under the tariff item of the First Schedule to the Customs Tariff Act as specified in the corresponding entry in column (2), originating in the countries as specified in the corresponding entry in column (4), exported from the countries as specified in the corresponding entry in column (5), produced by the producers as specified in the corresponding entry in column (6), and imported into India, an anti-dumping duty at the rate equal to the amount as specified in the corresponding entry in column (7), in the currency as specified in the corresponding entry in column (8) and as per unit of measurement as specified in the corresponding entry in column (9) of the said Table, namely:-

TABLE

Serial number	Tariff Item	Description of Goods	Country of Origin	Country of of Export	Producer	Duty Amount	Cur-rency	Unit
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1	29419030	Ciprofloxacin Hydrochloride	China PR	Any country including China PR	Shangyu Jingxin Pharmaceutical Co., Ltd.	2.38	US$	Kg
2	29419030	Ciprofloxacin Hydrochloride	China PR	Any country including China PR	Zhejiang Langhua Pharmaceutical Co., Ltd.	0.91	US$	Kg

3	29419030	Ciprofloxacin Hydrochloride	China PR	Any country including China PR	Zhejiang Guobang Pharmaceutical Co., Ltd.	1.87	US$	Kg
4	29419030	Ciprofloxacin Hydrochloride	China PR	Any country including China PR	Any producer other than serial number 1, 2, and 3	3.27	US$	Kg
5	29419030	Ciprofloxacin Hydrochloride	Any country other than China PR	China PR	Any	3.27	US$	Kg

2. The anti-dumping duty imposed under this notification shall be levied for a period of five years (unless revoked, superseded or amended earlier) from the date of imposition of the provisional anti-dumping duty, that is, the 2nd September, 2020, and shall be payable in Indian currency:

Provided that the said anti-dumping duty shall not be levied for the period commencing from the date of the lapse of the provisional anti-dumping duty, that is, the 2nd March, 2021 upto the preceding day of the publication of this notification in the Official Gazette.

Explanation: For the purposes of this notification, rate of exchange applicable for the purpose of calculation of such anti-dumping duty shall be the rate which is specified in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), issued from time to time, in exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and the relevant date for the determination of the rate of exchange shall be the date of presentation of the bill of entry under section 46 of the said Customs Act.

F.No.354/95/2020-TRU

Rajeev Ranjan, Under Secretary, Department of Revenue, Ministry of Finance, New Delhi

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CBIC MATTERS

CBIC notifies New Exchange Rates w.e.f. 05th March 2021 - reg.

Notification No.26/2021-Customs (N.T.), dated 04th March, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.18/2021-Customs (N.T.), dated 18th February, 2021 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 5th March, 2021**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	58.15	55.75
2.	Bahraini Dinar	200.00	187.65
3.	Canadian Dollar	58.75	56.65
4.	Chinese Yuan	11.45	11.10
5.	Danish Kroner	12.05	11.60

6.	EURO	89.65	86.45
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	249.25	233.70
9.	New Zealand Dollar	54.35	51.95
10.	Norwegian Kroner	8.75	8.40
11.	Pound Sterling	103.60	100.10
12.	Qatari Riyal	20.70	19.45
13.	Saudi Arabian Riyal	20.10	18.85
14.	Singapore Dollar	55.75	53.85
15.	South African Rand	5.00	4.70
16.	Swedish Kroner	8.80	8.50
17.	Swiss Franc	81.05	77.90
18.	Turkish Lira	10.10	9.50
19.	UAE Dirham	20.55	19.25
20.	US Dollar	73.90	72.20

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	69.55	67.00
2.	Korean Won	6.70	6.30

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

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

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Revival of Closed MSMEs

Lok Sabha Starred Question No:44

Shri Rahul Ramesh Shewale:

Shri Omprakash Bhupalsinh Alias:

Pawan Rajenimbalkar:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): the details and number of Micro, Small and Medium Enterprises (MSMEs) closed in the country since the period of nationwide lockdown due to COVID-19 Pandemic, State/UT-wise;

(b): the contribution of such MSMEs in enhancing the unemployment rate in the country;

(c): the financial package announced by the Government for revival of such closed MSMEs along with number of MSMEs revived from such package so far, State/UT-wise; and

(d): the other steps taken/being taken by the Government for revival of MSME sector and to enhance its participation in growth of the country?

Answered on 4th February 2021

A. (a) to (d): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PART (a) to (d) OF THE LOK SABHA STARRED QUESTION No.44:

(a) & (b): The figures of the real GDP in India during the first quarter of 2020-21 indicate that economic activity contracted due to the strict lockdown measures imposed by the Government. This contraction has also had impact on the MSME Sector. However, as MSMEs are there in both formal and informal sector, data regarding temporary or permanent closure of the units are not maintained by the Government of India in Ministry of Micro, Small and Medium Enterprises (MSME).

(c) & (d): Post COVID-19, Government has taken a number of initiatives under *Aatma Nirbhar Bharat Abhiyan* to support the MSME sector in the country especially in COVID-19 pandemic. Some of which are:

i): Rs.3 Lakh crore Collateral Free Automatic Loans for business, including MSMEs.

ii): Rs.20,000 crore Subordinate Debt for Stressed MSMEs.

iii): Rs.50,000 crore equity infusion through MSME Fund of Funds.

iv): New Revised criteria for classification of MSMEs.

v): New Registration of MSMEs through 'Udyam Registration' for Ease of Doing Business.

vi): No global tenders for procurement up to Rs.200 crores.

The State/UT-wise numbers of MSMEs that benefited under the Rs.3 Lakh Crore Collateral Free Automatic Loans for business, including MSMEs and Subordinate Debt for MSMEs are annexed*. An online portal "Champions" has been launched on 01.06.2020 by Hon'ble Prime Minister. This covers many aspect of e-governance including grievance redressal and handholding of MSMEs. RBI has also announced several measures to reduce Financial Stress of MSMEs.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

*(*Not reproduced here)*

Relief Subsidies to MSME Entrepreneurs

Lok Sabha Unstarred Question No: 519

Shri Sanjay (Kaka) Ramchandra Patil:

Q. Will the Minister of **MICRO,SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether the Government proposes to give relief subsidies or fund to MSME entrepreneurs due to COVID pandemic situation;

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

(c): whether the Government proposes to relax the taxation & bank loan schedule for MSMEs due to Covid-19 pandemic situation and if so, the details thereof?

Answered on 4th February 2021

A. (a) & (b): Government has implemented a judicious mix of fiscal and monetary policies along with regulatory and structural reforms to mitigate the negative impact of COVID-19 on the MSME entrepreneurs. Government has already announced a series of measures in this direction, which inter-alia includes Rs.3 lakh crore collateral-free lending program with 100 percent credit guarantee for businesses including MSMEs, Rs.20,000 crore subordinate debt for stressed MSMEs with partial guarantee, Rs.45,000 partial credit guarantee scheme 2.0 for non-banking financial companies (NBFCs), housing finance companies (HFCs) to do fresh lending to MSMEs, Rs.50,000 crore equity infusion for MSMEs through Fund of Funds, credit facility for street vendors (P M S V A Nidhi).

(c): On the taxation front, Government has taken some regulatory and compliance measures such as postponing tax-filing and other compliance deadlines, reduction in penalty interest rate for overdue GST filings. Government has introduced IBC related relaxations for MSMEs, amongst others. Moreover, with a view to facilitate meaningful restructuring of stressed MSME accounts, RBI has permitted a one-time restructuring of loans to MSMEs. The restructuring of the MSME borrower account under the revised guidelines is to be implemented by March 31, 2021 and such borrower accounts which may have slipped in to NPA category between March 2, 2020 and date of implementation may be upgraded as 'Standard asset' as on the date of implementation of the restructuring plan.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Impact of GST on MSMEs

Lok Sabha Unstarred Question No:540

Shri Vijay Kumar:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether the Goods and Service Tax (GST) has had an adverse impact over MSMEs thereby affecting this sector a lot;

(b): if so, the details thereof;

(c): whether the Government has devised any robust policy to protect and free the micro, small and medium entrepreneurs from adverse impact of GST as well as to encourage them; and

(d): if so, the details thereof ?

Answered on 4th February 2021

A. (a) & (b): No such information have been received by this Ministry.

(c) & (d): The Government has taken numerous measures with a view to encourage micro, small and medium entrepreneurs. These include the following:

- No GST registration is required for inter-state and intra-state supply of services upto Rs.20 lakhs in a year (Rs.10 lakhs for the States of Manipur, Mizoram, Nagaland and Tripura).
- No registration is required for intra-State supply of goods upto Rs. 40 lakh in a year (Rs. 20 lakh in the states of Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Puducherry, Sikkim, Telangana, Tripura and Uttarakhand) w.e.f. 01.04.2019.
- Composition Scheme has been formulated for small businessmen being supplier of goods and supplier of restaurant services.
- Composition Scheme has also been formulated for supplier of services from FY 2019-2020.
- Filing of Annual Return in FORM GSTR-9 or FORM GSTRR-9A for FY 2017-18, 2018-19 and 2019-20 has been made optional for taxpayers having aggregate annual turnover less than 2 crore rupees.
- QRMP (Quarterly Return, Monthly Payment) Scheme: QRMP scheme has been launched with effect from 01.01.2021 under which registered persons having aggregate turnover up to five (5) crore rupees would be allowed to furnish return on quarterly basis along with monthly payment of tax. This would considerably reduce compliance under GST for such taxpayers. Flexibility has also been provided for taxpayers to easily opt-in and opt-out of the scheme throughout the year.
- Extension of compliance deadlines and waiver of late fees to cope with COVID-19 pandemic:

The due date for compliance which fell during the period from 20.03.2020 to 30.08.2020 was extended till 31.08.2020. Conditional waiver of late fees has been granted for delayed filing of FORM GSTR-3B for the period from July, 2017 to July, 2020. Late fee has also been waived for delayed filing of monthly FORM GSTR-1 (from March, 2020 till June, 2020) and quarterly FORM GSTR-1 (from January, 2020 to June, 2020).

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Technology Upgradation in MSME Sector

Lok Sabha Unstarred Question No: 542

Shri Raghu Ramakrishna Raju Kanumuru:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): whether the Government has any proposal of taking up Technology Up gradation in the Micro, Small and Medium Enterprises (MSME) Sector in the country;

(b): if so, the details thereof, and

(c): the details of the initiatives taken to allow the MSMEs to access the global markets, improved research and development and investments proposed to indigenous MSMEs?

Answered on 4th February 2021

A. (a) & (b): Yes, Sir. Ministry of Micro, Small and Medium Enterprises (MSME) is implementing various schemes and programmes to provide access to technology upgradation. These schemes include Credit Linked Capital Subsidy Scheme and Technology Upgradation Scheme (CLCS-TUS), Micro and Small Enterprise – Cluster Development Programme (MSE-CDP), MSME Technology Centres (MSME-TCs), Technology Centre Systems Programme (TCSP).

(c): Ministry of MSME is implementing International Cooperation scheme to facilitate the MSMEs business delegations to visit/participate in international exhibitions/trade fairs etc., of other countries for exploring new areas of technology infusion/ up-gradation, facilitating of joint ventures, improving market for MSMEs products, foreign collaborations amongst others.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Assistance to MSMEs:

Lok Sabha Unstarred Question No:571

Shrimati Mahua Moitra:

Q. Will the Minister of **MICRO,SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): the status and efficacy of the steps already taken such as loan waivers, moratoriums, etc. to assist MSMEs to recover from COVID-19 pandemic;

(b): whether the Government is taking steps to assist MSMEs in recovering from the pandemic and if so, the details thereof;

(c): the steps being taken the Government to make MSMEs go digitally (have website, email, communication apps) as many services and needs have suddenly gone online; and

(d): the steps/incentive being given for technology transformation for MSME sector?

Answered on 4th February 2021

A. (a) & (b): Post Covid-19, Government has taken a number of initiatives to support the Micro, Small and Medium Enterprises (MSME) Sector in the country and to help them recover. These steps inter-alia include Rs.20,000 crore Subordinate Debt for MSMEs under Credit Guarantee Scheme for Subordinate Debt (CGSSD), Rs.3 lakh crores collateral free automatic loans for business, including MSMEs under Emergency Credit Line Guarantee Scheme (ECLGS), Rs.50,000 crore equity infusion in MSMEs through Fund of Funds, revised criteria for classification of MSMEs, new registration of MSMEs through ''Udyam Registration'', doing away with global tenders for procurement up to Rs.200 crores etc. In addition to this, RBI has also announced several measures to Reduce Financial Stress of MSMEs. As on date 34 Banks have registered under CGSSD. As on 25.01.2021, guarantees to the tune of around Rs 2,01,364 crore has been issued under ECLGS.

(c): Government has launched an online Portal "CHAMPIONS" which covers many aspects of e-governance including grievance redressal and handholding of MSMEs. Registration of MSMEs has also been made completely online under 'Udyam Registration'. Ministry of MSME has also launched 'MSME SAMBANDH' portal for monitoring implementation of public procurement policy for the MSEs and 'MSME SAMADHAN' portal for enabling MSMEs to directly register their cases relating to delayed payments.

(d): Ministry of MSME is implementing various schemes and programmes to provide access to technology upgradation. These schemes include Credit Linked Capital Subsidy Scheme and Technology Upgradation Scheme (CLCS-TUS), Micro and Small Enterprise – Cluster Development Programme (MSE-CDP), MSME Technology Centres (MSME-TCs)

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

Ease of Doing Business for MSMEs

Lok Sabha Unstarred Question No: 661

Dr Krishna Pal Singh Yadav:

Shri Ram Kripal Yadav:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state;

(a): the steps taken/being taken by the Government for making a favourable environment to boost Micro, Small and Medium Enterprises (MSMEs) sector under 'Ease of Doing Business';

(b): the extent to which success has been achieved during the last two years till date ;

(c): whether the Government has enacted any model act to regulate the functioning of MSMEs in the country and if so, the details thereof; and

(d): if not, the steps taken/being taken by the Government in this regard?

Answered on 4th February 2021

A. (a) & (b): The Government of India has taken several initiatives to promote Ease of Doing Business; some of them are given below:

(i): Udyam Registration (UR) Portal to provide fully online, paperless and transparent MSME registration process. No documents or proof are required to be uploaded for registering an MSME. Only Aadhaar Number/PAN is enough for registration. PAN and GST linked details on investment and turnover of enterprises are taken automatically from Government data bases.

(ii): Digital Payments to pass on the benefits of the schemes of Ministry of MSME through digital payment gateway.

(iii): MSME SAMBANDH Portal - to help in monitoring the implementation of Public Procurement Policy for micro and small enterprises.

(iv): MSME SAMADHAAN Portal for empowering micro and small entrepreneurs across the country to register their cases relating to delayed payments.

(v): MSME SAMPARK Portal-A digital platform, wherein jobseekers (pass out trainees/students of MSME Technology Centers) and recruiters get connected.

(vi): Champions Portal for speedy redressal of grievances (online).

(vii):Returns under 8 Labour laws and 10 Union regulations to be filed once in a year.

(viii):Returns to be accepted through self-certification and only 10 percent MSME units to be inspected.

(ix): For minor violations under the Companies Act, entrepreneurs no longer have to approach court but can correct them through simple procedures.

(c) & (d): The Micro, Small and Medium Enterprise Development (MSMED) Act, 2006 has been already enacted. This Act is promotional and developmental in nature and applicable to all the States and Union Territories of India.

Minister of Micro, Small and Medium Enterprises (Shri Nitin Gadkari)

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Vaccine development software shows promise in influenza effort, could help defeat Coronavirus

A novel computer algorithm that could create a broadly reactive influenza vaccine for swine flu also offers a path toward a pan-influenza vaccine and possibly a pan-Coronavirus vaccine as well, according to a new paper published in Nature Communications.

"This work takes us a step closer to a pan-swine flu virus vaccine," said Bette Korber, a computational biologist at Los Alamos National Laboratory and a co-author on the paper. "The hope is to eventually be prepared with an effective and rapid response if another swine flu epidemic begins to spread in humans, but this swine flu vaccine could also be useful in a veterinary setting." The immune responses to the vaccine showed very promising breadth against diverse viral variants. "The same basic principles may be applicable to developing a Pan-Coronavirus vaccine to enable a rapid vaccine response to future Coronavirus cross-species jumps," said Korber.

The algorithm, Epigraph, has already been used to predict therapeutic HIV vaccine candidates, and it has also shown promising potential as a pan-filovirus vaccine against highly diverse Ebola and Marburg viruses, protecting against disease when tested in an animal model.

Vaccination with the Epigraph-designed product led to the development of a strong cross-reactive antibody response in mice, the study showed. In swine, it induced strong cross-reactive antibody and T-cell responses. The research was conducted in close collaboration with researchers from the Nebraska Center for Virology at the University of Nebraska, St. Jude Children's Research Hospital, and Los Alamos National Laboratory.

"We developed the Epigraph strategy for this kind of problem, and it can, in theory, be applied to many diverse pathogens," said Korber, who created it in partnership with her husband, James Theiler, a Los Alamos Fellow. "The tool creates a cocktail of vaccine antigens designed to maximize efficacy across a highly diverse population."

Since 2010, more than 460 swine-flu variant infections have been reported in humans in the United States. Pigs are susceptible to swine, avian, and human influenza viruses, making them the perfect "mixing vessel" for novel reassorted influenza viruses, the authors note. These novel reassorted viruses have significant pandemic potential if zoonosis (transfer from pigs to humans) occurs, as seen with 2009 H1N1 swine flu pandemic.

Source: Doe/Los Alamos National Laboratory, ScienceDaily, 02.03.2021 (Excerpts)

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Researchers discover SARS-CoV-2 inhibitors

A research team of pharmacists at the University of Bonn has discovered two families of active substances that can block the replication of the SARS-CoV-2 Coronavirus. The drug candidates are able to switch off the key enzyme of the virus, the so-called main protease. The study is based on laboratory experiments. Extensive Clinical Trials are still required for their further development as therapeutic drugs. The results have now been published in the journal *Angewandte Chemie.*

In order for the SARS-CoV-2 Coronavirus to replicate, it relies on the main protease as a key enzyme. The virus first has its genome translated from RNA into a large protein strand. The viral main protease then cuts this protein chain into smaller pieces, from which the new virus particles are formed. "The main protease is an extremely promising starting point for Coronavirus drug research," says Prof Dr Christa E Müller of the Pharmaceutical Institute at the University of Bonn. "If this enzyme is blocked, viral replication in the body's cells is stopped." The researcher is a member of the Transdisciplinary Research Area "Life and Health" at the University of Bonn.

The pharmaceutical chemists designed a large number of potential inhibitors based on the structure of the main protease and the mechanism by which the important virus-replicating enzyme works. "A suitable inhibitor must bind sufficiently tightly to the main protease to be able to block its active site," says Prof (Dr) Michael Gutschow, who heads an independent research group on such inhibitors at the Pharmaceutical Institute of the University of Bonn.

Fluorescent test system:

Then the experimental phase began. The researchers developed a new test system for high-throughput screening. They offered the main protease a substrate to which a reporter molecule was coupled. When the protease catalytically cleaved this coupling, the fluorescence of the product was measurable. However, if a simultaneously administered inhibitor successfully blocked the activity of the protease, there was no fluorescence.

"For most of the test compounds, we observed no enzyme inhibition. But on rare occasions in our comprehensive tests, fluorescence was suppressed: These were the hits we had hoped for in our search for inhibitors of the viral protease," reports Gütschow.

Like chewing gum at the catalytic center:

The researchers' high-throughput screening showed two classes of drugs that appeared to be particularly promising. Customized compounds of both classes were then newly synthesized. They stick to the main protease like chewing gum and block the crucial catalytic center, which prevents the main protease from preparing the virus replication. "Some of the compounds even have another effect," Muller reports. "They also inhibit a human enzyme that helps the virus enter body cells."

The participants contributed very different expertise to the study. "Only through great collaboration have we been able to design, synthesize and biochemically characterize suitable drug candidates," says Gütschow. "The best compounds represent promising lead structures for drug development," according to Muller. However, extensive Clinical Trials have yet to prove whether these candidates also inhibit SARS Coronavirus-2 replication in humans, Gutschow adds.

Source: University of Bonn, EurekAlert, 03.03.2021 (Excerpts)

Bombay HC gives time to Centre till April 28 to decide on granting Compulsory License to two patented anti-TB drugs

Bombay High Court on Wednesday, 10.03.2021 asked the Centre to decide by April 28 on a representation made last November for 'Compulsory Licenses' to import two patented life-saving anti-TB drugs Bedaquiline and Delamanid.

The Compulsory License would to ensure swifter and affordable access to the fairly new drugs that treat multi-drug resistant tuberculosis (MDR-TB) and extensively drug resistant (XDR) cases, said a Public Interest Litigation (PIL).

"Non-accessibility constitutes a violation of right to life," said Senior Counsel Anand Grover with advocate Rahul Kamerkar appearing for an NGO, Jan Swasthya Abhiyan and Thane resident Meera Yadav survivor of XDR-TB who filed the PIL. In 2019 according to India TB Report, Maharashtra had 2.27 lakh TB persons notified in Public and private sector, being one of the five states that contributed most to total notification, said the PIL before bench of Chief Justice Dipankar Datta and Justice Girish Kulkarni.

There is a rise in cases of MDR-TB and Mumbai particularly has high numbers, said the PIL. The PIL said these two drugs are found to be effective and "been recommended by World Health Organisation" and are immediately required as part of the treatment protocol of Government programme NTEP to treat those with multi drug resistant TB.

The PIL says drug resistant TB was already declared a national emergency in 2019 and if granted Compulsory License, generic companies can make drugs affordable and help India's goal to eradicate TB by 2025. Additional Solicitor General Anil Singh for the Centre will now inform the HC on the next date what decision the Centre takes. Bedaquiline is patended by Janssen Pharmaceuticals and Delamanid by Otsuka Pharmaceutical. The PIL said, "unfortunately the Centre is relying on donations by these two companies" and the numbers are far less compared to the need and otherwise they are priced very high for the masses. Drug Bedaquiline cost over Rs.26000 for a six month course while Delamanid, Rs.91000, ought to be made commercial license free or made Compulsorily non-commercial to save lives, it added. The PIL says drug resistant TB was already declared a national emergency in 2019 and if granted compulsory license, generic companies can make drugs affordable and help India's goal to eradicate TB by 2025. Yadav said in 2013 she was diagnosed with tuberculosis and had to undergo treatment. She added due to "stigma associated with TB" she was "forced out her own house and separated from her child." Ultimately after being told she may not live long, she regained her health back after a combination treatment with two new DR-TB drugs, Bedaquiline and Delamanid.

Source: Swati Deshpande, The Times of India, 11.03.2021

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Health schemes, lower drug prices led to annual saving of ₹50,000 crore for needy families: P M Modi

Prime Minister Narendra Modi dedicated to the nation the 7,500th Janaushadhi Kendra at NEIGRIHMS in Shillong

Prime Minister Narendra Modi on March 7 said the poor and needy have been able to save ₹50,000 crore annually due to various health-related measures taken up by his Government like providing affordable medicines, healthcare and reducing the prices of medical devices.

Mr Modi, who dedicated to the nation the 7,500th Janaushadhi Kendra at North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS) in Shillong, also said the move to provide affordable medicines through the Janaushadhi scheme is spreading across the length and breadth of the country.

In a virtual address at the *'Janaushadhi Week'* celebrated across the nation from March 1 to March 7 to

create awareness about the 'Janaushadhi' scheme, the Prime Minister said it is helping countrymen living in tribal areas in the North East and the mountainous areas.

"Today when the 7,500th centre has been inaugurated, it has been held in Shillong. It is clear from this how much public health centres are expanding in the North East," Mr Modi said.

The Prime Minister, who also interacted with people from different parts of the country, further said, "It is clear from my discussion with people who run the Janaushadhi centres at every corner of the country and some of its beneficiaries, that this scheme is becoming a very big companion of poor and middle-class families. This scheme is becoming the medium of both service and employment".

Underlining the various steps taken up by his Government to make healthcare affordable to the poor and needy, he said prices of essential drugs as well as medical devices such as stents and knee implants have been reduced manifold.

"It has led to the saving of ₹12,500 crore per year for the needy people. The Ayushman Bharat scheme is helping 50 crore people get ₹5 lakh worth of treatment. Over 1.5 crore people have already taken this benefit. It is estimated that it has led to savings of around ₹30,000 crore for people.

"It means that if we collate the savings being affected by Janaushadhi, Ayushman Bharat and decline in prices of drugs and stents [medical devices] if we only take Government schemes in the health sector, then poor and middle-income groups are saving around ₹50,000 crore per year," the Prime Minister said. Stating that for a long time health was considered to be the only subject of disease and treatment, he asserted that his Government considers that the subject of health is not just limited to disease and treatment, but it encompasses the entire economic and social fabric of the country. The effort of the Government has been to ensure that no one should be deprived of the benefits of medical science and treatment should be cheap, accessible for the public, he said, adding *"with this thinking policies and programmes are being made today"* by the Government.

To promote the Janaushadhi scheme, Modi said the incentive has been increased to ₹5 lakh from ₹2.5 lakh, while an additional incentive of ₹2 lakh incentive for women, SC/ST, and for North East people have been provided to help create the infrastructure. Highlighting India's achievement in the field of pharmaceuticals, he said the country is the world's pharmacy.

"Today, free Corona vaccine is being administered in Government hospitals. The cheapest in the world i.e. only ₹250 vaccine is being given in private hospitals. The country is proud of its scientists today that we have the Made-in-India vaccine for ourselves and also to help the world," Mr Modi said.

To enhance medical education, he said before 2014, where there were about 55,000 MBBS seats in the country. In 6 years, it has been increased by more than 30,000. Similarly, in the PG seats — which used to be at 30,000 — more than 24,000 new seats have been added.

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana aims to provide quality medicines at an affordable price.

Sales in the Financial Year 2020-21 (up to March 4, 2021) have led to a total saving of around ₹3,600 crore for citizens, as these medicines are cheaper by 50-90 percent than market rates.

To create more awareness about 'Janaushadhi', an entire week — from March 1 to March 7 — is being celebrated as "Janaushadhi Week" across the nation, with the theme of "Jan Aushadhi — Seva Bhi, Rozgar Bhi".

Source: PTI, The Hindu, 08.03.2021

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Sub-committee on FDCs considered as irrational by Prof Kokate Committee to hear stakeholders from April 19

The sub-committee, constituted for examining the Fixed Dose Combinations (FDCs) considered as irrational by Prof Kokate Committee, has invited concerned stakeholders for hearing from April 19, 2021.

Sub-committee of DTAB had been constituted under the Chairpersonship of Dr Nilima Kshirsagar, Emeritus Scientist, former Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR) to examine FDCs considered irrational by the Kokate Committee.

Accordingly, the subcommittee has invited the concerned stakeholders for a hearing from April 19, 2021. As regards to hearing for the particular FDC the schedule of hearing will be published from time to time on CDSCO

website **www.cdsco.nic.in.** Accordingly companies may regularly visit CDSCO website and avail the opportunity of hearing on the given date.

Union Health Ministry had on September 16, 2014 constituted a committee under the Chairmanship of Prof C K Kokate, former Vice-Chancellor, KLE University, Belgaum, Karnataka for examining the safety and efficacy of unapproved FDCs which were licensed by the SLAs without due approval of DCGI.

After holding a series of meetings the Kokate Committee had submitted its second assessment report to the Union Health Ministry on May 27, 2016 categorizing FDCs into "irrational (category 'a')", "requiring further deliberation (category 'b')", "rational (category 'c')" and "FDCs requiring generation of data (category 'd')".

The Drugs Controller General of India (DCGI) had earlier directed the drug manufacturers to submit data with reference to 66 Fixed Dose Combinations by May 30, 2020 in view of the Supreme Court (SC) directive on 294 irrational FDCs. DCGI had earlier directed manufacturers to submit data of 66 FDCs which required further generation of data based on the Kokate Committee report latest by September 30, 2019.

DCGI has further informed in the notice served to the manufacturers that in case of failure to submit the data by May 30, 2020, the decision will be made on the basis of information available before the DCGI office in light of the judgement of the Supreme Court in cases related to 294 FDCs.

DCGI in a notice stated, "This is in continuation to the DCGI letters and notices dated December 12, 2018, April 12, 2019 and August 27, 2019." The deadline on the same was further extended in view of representations received in the matter for extension of time for submission.

Central Drugs Standard Control Organisation (CDSCO) had extended the deadline for submission of the FDC data till August 16, 2019 from the earlier deadline of June 30, 2019 based on representations from manufacturers to give sufficient time.

The Union Health Ministry had earlier directed the manufacturers to submit specific information on irrational FDCs in the prescribed format along with supporting documents by June 30, 2019.

Besides other things, it was also asked to submit a one-page summary with the highest level of evidence, supporting the claim of postulated advantage or rationale of the FDCs.

The evidence should be enclosed in the form of a maximum of five relevant full text articles in peer-reviewed journals or relevant information from textbooks. Pharmacokinetic or pharmacodynamics rationality with half-life details of individual ingredients, dosage schedule of individual drugs and dosage schedule of FDC has to be provided, as per the Health Ministry directive.

A copy of the DCGI letter has also been sent to all State Drugs Controllers, CDSCO Zonal and Sub-Zonal offices and Indian Drug or Pharmaceuticals Association Forum.

Source: Shardul Nautiyal, Pharmabiz, 08.03.2021

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Union Government's new Science, Technology & Innovation Policy to accelerate traditional knowledge systems

Union Government's new Science, Technology and Innovation Policy (STIP) proposed by the Department of Science and Technology has the potential to accelerate Traditional Knowledge Systems (TKS). It aims to catalyse socio-economic development and enable global competitiveness.

STIP proposes establishment of a National STI Observatory as a central repository for all data related to and generated from the STI ecosystem.

The reality is that the extent of original medical research remains sub-optimal despite competence and facilities. One of the factors could be ignorance and a general lack of rational appreciation of India's TKS, which could be a good source of new ideas, and innovation. The existing silos do not allow sufficient cross-disciplinary dialogue between the mainstream biomedical community and those in the TKS to promote active and unbiased research, said Prof Bhushan Patwardhan, National Research Professor, Ayush, Savitribai Phule Pune University.

Strategy of Open Science Framework will be important to provide access to scientific data. Making all data generated from publicly-funded research available to the public is a welcome step. The idea of 'one nation, one subscription' would give legally appropriate access to global research articles. The policy intends to strengthen

innovative ecosystem and entrepreneurship, he added.

According to Subhash Chandra Lakhotia, Distinguished Professor (Lifelong) & SERB Distinguished Fellow, Department of Zoology, Banaras Hindu University, for a future-ready India, there is a need for active participation to transform the national STI landscape. It should fortify India's indigenous capacity while focusing on being globally connected.

There is a need for greater emphasis on promoting active research in TKS, so that the intertwined facts and myths are separated. This would develop indigenous technologies and encourage grass root innovation. The STIP also envisions to integrate TKS and grassroots innovation into education, research and innovation by collaborating with scientists. Obviously, there is a need to rationally verify and strengthen the validated traditional knowledge base, he added.

Both Prof Patwardhan and Prof Chandra, in the latest '*Current Science'* journal in an article titled TKS and new science policy thrust, said that the capacity to look at various disciplines is important for health research in India, where Ayurveda, Yoga, Unani, Siddha, Sowa Rigpa and several local health traditions exist. The proposed National Research Foundation will hopefully be aligned to promote transdisciplinary research on TKS. There is often a criticism that Ayush professionals are not involved in high quality research and the overall original research contribution in global context remains still small.

Indian scientific and medical community so far have not seriously looked at TKS. Those engaged in research involving TKS are not sufficiently trained in modern science methodology and often lack funding, resources and infrastructure for research. Barring a few, mainstream Indian scientists have not sufficiently appreciated and explored knowledge from Ayush systems, they noted.

Scientific research on Ayush should be a primary responsibility of the scientific community. It should not be perceived as the sole responsibility of vaidyas, hakims and siddhas. Universities and national institutions need to engage in unbiased research on TKS.

A competitive process, akin to that followed for the modern medicine graduates, be followed for Ayush scholars to provide them opportunities to join the cadre of scientists in national laboratories and universities. Presence of ayurvedic scholars in a molecular biology laboratory would benefit both disciplines and facilitate progress of good science. Many innovations may emerge if systematic research on TKS can be undertaken by mainstream researchers and physicians, they said.

Source: Nandita Vijay, Pharmabiz, 08.03.2021

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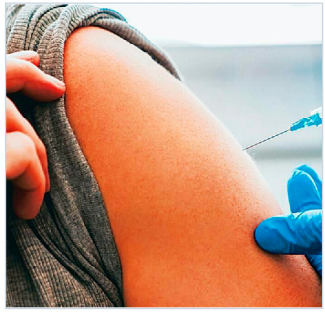
Tests on children: Expert panel asks Bharat Biotech to submit Covaxin efficacy data

Bharat Biotech's Covaxin received restricted use approval in an emergency situation on January 3 for use in those aged above 18. So far, the vaccine has been administered to healthcare and frontline workers "in Clinical Trial mode".



So far, the DCGI has approved Covaxin as well as Covishield (the Indian version of the vaccine developed by the University of Oxford and AstraZeneca) for restricted use in vaccinations against Covid-19.

An Expert body under India's top drug regulator has asked Bharat Biotech to submit data of Covaxin's efficacy to consider the company's request to test the Covid-19 vaccine on children, The Indian Express has learnt.

It has also directed Dr Reddy's Laboratories, which sought emergency approval for Russian-made Sputnik V, to submit final data on the vaccine's safety and ability to prompt an immune response from Indian Clinical Trials.

Bharat Biotech's Covaxin received restricted use approval in an emergency situation on January 3 for use in those aged above 18. So far, the vaccine has been administered to healthcare and frontline workers "in clinical trial mode" as part of the government's mass vaccination campaign against the virus.

The company had approached the Central Drugs Standard Control Organisation (CDSCO) for approval to conduct late-stage Clinical Trials of Covaxin in children aged 5-18, according to a source close to the development.

The Subject Expert Committee (SEC) that was looking into the request on Wednesday, 24.02.2021 told the Hyderabad vaccine-maker to submit data on Covaxin's

efficacy — a marker of how well the vaccine prevents symptomatic cases of Covid-19 — in adults.

"They have to first bring the interim efficacy data in adults. They are yet to submit it," the source told The Indian Express on condition of anonymity. "Without knowing about the efficacy in adults, the committee felt it was not advisable to (administer the vaccine in trials on) children yet."

Earlier this week, Bharat Biotech Chairman and Managing Director Dr Krishna Ella said the company was expecting interim data on the efficacy of Covaxin in two weeks.

The SEC also told Dr Reddy's to submit "the complete safety and immunogenicity data" of Sputnik V "as per the protocol approved" in order to be considered for a restricted emergency use approval, said the source. The Hyderabad company on February 19 announced that it had approached the Drug Controller General of India (DCGI), who heads CDSCO, for an emergency approval of the vaccine, which it has been testing on around 1,500 participants in mid-to late-stage trials in India.

The company had submitted interim data on the vaccine's immunogenicity (its ability to provoke an immune response) as well as Russian data on its efficacy in support of its application, according to the source.

Queries to Dr Reddy's and Bharat Biotech about when they may be able to submit the data sought by the SEC remained unanswered by press time on Wednesday, 24.02.2021.

So far, the DCGI has approved Covaxin as well as Covishield (the Indian version of the vaccine developed by the University of Oxford and AstraZeneca) for restricted use in vaccinations against Covid-19.

Source: Prabha Raghavan, The Indian Express, 25.02.2021

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Industry seeks deferment of implementation of track & trace system for export

Small and Medium Pharmaceutical Manufacturers have sought deferment of implementation of track and trace system for export of pharmaceuticals along with maintaining the parent-child relationship in packaging levels and their movement in supply chain, citing infrastructure and financial constraints faced by the industry in the wake of Covid-19 as well as lack of major importing countries' requirement for such system.

As per the Notification issued by the Directorate General of Foreign Trade (DGFT) on September 22, 2020, the implementation of the track and trace system for export of pharmaceuticals with respect to maintaining the parent-child relationship in packaging levels and its uploading on central portal will commence from April 1, 2021 for both SSI and non-SSI manufactured drugs.

As the date for implementation of track and trace system is approaching fast, Small and Medium Pharma Manufacturers Association (SMPMA), a pan India association of Indian MSME pharmaceutical companies has on March 8, 2020 written to DGFT urging it to defer the implementation of the drug authentication system for exported consignments.

The SMPMA stated that during the outbreak of Covid-19 pandemic followed by continuous nationwide lockdown there has been significant erosion of capital base and adverse financial health, exodus of laborers and workforce led to halt the production in the Pharma manufacturing units. Hence especially Pharma manufacturing units of the Small and Medium Sector are not in a position of to create requisite infrastructure involving huge financial investments to implement the trace and track system, being the genuinely severe constraints.

It is pertinent to mention that major importing countries for the Pharma products do not insist for such barcoding system for track trace system. As such the implementation of the above system may be deferred for present especially for the Pharma manufacturing units of the Small and Medium sector, unless the importing country requires, stated SMPMA in the letter.

The SMPMA in its earlier representation dated August 23, 2018 had also appealed to Secretary, Department of Commerce Anup Wadhawan to defer the implementation of track and trace system till 2023.

Said Nipun Jain, Chairman, SMPMA, "To the best of our knowledge, no country in the world has mandated such system specifically for exports, as in the general understanding the products to be exported are required to meet the labeling as per the importing country's norms and not that of the exporting country. We strongly believe that we should wait till an internationally acceptable harmonious system develops, so that our products that are meant for exports can be acceptable to the importing countries as such."

Earlier the Commerce Ministry, through the Centre for Development of Advanced Computing (C-DAC), was supposed to launch the Integrated Validation of Exports of Drugs from India and its Authentication (iVEDA) portal for drug authentication and tracking and tracing of the drug supply from April 1, 2020 which got extended till October 1, 2020 due to the Covid-19 pandemic and lockdown announced by the Government to contain its spread.

It was later extended by the DGFT by six months following industry's appeal. The manufacturers and exporters are required to barcode their products using GS1 standards along with the batch number, expiry date to facilitate authentication of exported drugs. They are also required to upload data on barcode on secondary and tertiary packaging of exported drugs on the iVEDA portal which is set to replace Drugs Authentication and Verification Application (DAVA) portal. Maintaining parent-child relationship between secondary and tertiary packaging is an optional.

The DAVA portal had hit technical glitches hampering manufacturers and exporters from uploading data on barcode on secondary and tertiary packs of drugs meant for export and maintenance of parent-child relationship between them.

Source: Laxmi Yadav, Pharmabiz, 10.03.2021

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Government approves 33 API applications with over Rs 5k cr committed investment under PLI scheme

The Government has approved a total of 33 applications with a committed investment of Rs.5,082.65 crore under the Production Linked Incentive scheme for Active Pharmaceutical Ingredients, an official release said on Thursday, 11.03.2021. Setting up of these plants will make the country self-reliant to a large extent in respect of these bulk drugs, it noted.

The Department of Pharmaceuticals has launched a PLI scheme for the promotion of domestic manufacturing by setting up Greenfield plants in four different target segments with a total outlay of Rs.6,940 crore for the period 2020-21 to 2029-30.

In total, 215 applications have been received for the 36 products spread across the 4 target segments, the Ministry of Chemicals and Fertilizers said in the release. Nineteen applications with a committed investment of Rs.4,623.01 crore have already been approved under Target Segment I, II and III, it added.

Besides, 174 applications were received for 23 eligible products under Target Segment IV. Out of 174 applications, 79 applications received for 11 eligible products were considered as per the decided evaluation and selection criteria by the Empowered Committee in its meeting held on February 27, 2021, the release said.

The applications of 14 companies that have committed minimum/more than the minimum proposed annual production capacities and fulfil the prescribed criteria have been approved, it added.

The setting up of these plants will lead to a total committed investment of Rs.459.47 crore and employment generation of about 3,715 by the companies, the release noted. The commercial production of these plants is projected to commence from April 1, 2023, onward.

It has been further decided to take up the remaining 95 applications under the Target Segment-IV till March 31, 2021, for scrutiny and approval, as per the release. The Government on February 25 also approved a Production-Linked Incentive (PLI) scheme for the pharmaceutical sector, entailing an outlay of Rs.15,000 crore.

Source: PTI, ETnownews, 12.03.2021

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IP rights are not bottlenecks to vaccine production: Pharma companies

The bottlenecks are the capacity, the scarcity of raw materials, scarcity of ingredients, and it is about the know-how, state companies

Manufacturing capacity and ingredients shortages are the main bottlenecks to expanding the COVID-19 vaccine

production, several global drug groups said, not patents that some critics are demanding to be removed.

"IP (Intellectual Property) Rights is not the issue," said Thomas Cueni, who heads the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). "The bottlenecks are the capacity, the scarcity of raw materials, scarcity of ingredients, and it is about the know-how."

Cueni spoke after a virtual meeting, organised partly by the World Health Organization-backed COVAX vaccine sharing programme. It included manufacturers, suppliers and international organizations seeking to boost vaccine supplies.

IP protections are being fiercely debated during the pandemic. Activists including from *Doctors Without Borders* are pushing for temporary patent waivers on certain COVID-19 technologies, while accusing rich countries of blocking vaccine production in poorer nations.

Today, World Trade Organization member states open talks on a joint proposal by India and South Africa to waive such IP rules. Cueni's group, and many developed nations, oppose such steps.

Others in the two-day supply chain meeting also contended that freeing up IP for vaccines was a far different proposition than Compulsory Licenses issued decades ago for simpler, small-molecule drugs including treatments for HIV/AIDS. Complex vaccines have hundreds of ingredients, from lipids to encase messenger RNA to modified viral vectors to deliver DNA. Giving away IP will not solve these challenges, said Rajinder Suri, Chief Executive of the Developing Countries Vaccine Manufacturers Network. "There are so many issues which one has to really understand before getting into the tech transfer," Suri said.

With the push on for 10 billion-plus COVID-19 vaccine doses in 2021, manufacturers and suppliers – and Governments tempted to block exports – must coordinate and cooperate to avoid stumbling over each other, said Richard Hatchett, who leads the Coalition for Epidemic Preparedness Innovations (CEPI).

The meeting's focus, Hatchett said, "was sorting out that problem and trying to create awareness among the different stakeholders about how we can successfully navigate these bottlenecks, rather than a conversation which was principally around intellectual property."

Source: Express Pharma News Service/Reuters, 10.03.2021

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DCC emphasizes need to regulate sale and distribution of medical devices

The Drugs Consultative Committee (DCC) has underlined the need to regulate sale and distribution of medical devices mandating registration of retail and distributor premises. This, according to the Committee, will bring in transparency of the sales outlets and provide credibility to the product safety.

However, the sale and distribution of regulated medical devices, coming under the definition of 3(b)(iv) of 'drug', will continue. There have been several representations by the associations and stakeholders to exempt the sale license for all imported medical devices provided a registration of premises where these equipment and instruments are stocked for sale and distribution.

At its 59th meeting held early this month, DCC noted there are inherent differences between the sale and distribution of drugs and medical devices. In order to be on par with the global practices, it recommended to regulate the sale of medical devices in a different manner than the drugs by creating a system of registration of the premises and person involved in the business. This would enable traceability, security and integrity of supply chain of medical devices. For this purpose, the Committee noted that CDSCO with CDAC needs to develop a portal to register the medical device traders/hospitals/firms who are involved in its sale, stock and use. The registration number generated online will help the licensing authority to have data to track and trace the movement of such medical devices.

Further, the DCC has constituted a sub-committee to examine and further frame the system. The sub-committee will be led by Dr S Eswara Reddy, JDC (I), CDSCO (HQ) as the Chairman. There will be four members: Dr H G Koshia, Commissioner, FDCA, Gujarat, D R Gahane, Joint Commissioner, FDA, Maharashtra, Amaresh Tumbagi, Drugs Controller, Karnataka and N K Ahooja, Drugs Controller, Haryana. Dr Ravi Kant Sharma, DDC (I), CDSCO (HQ) is the Convener of this sub-committee. For the registration, the application for both online and offline submissions need to be notarized to validate the submission.

The storage area and the qualification details of the competent personnel appointed to oversee the sale and distribution need to be submitted. The registration certificate needs to be displayed in a prominent place in the premises. The registration holder should ensure providing proper storage, adequate space, lighting and required temperature control for the medical devices such that it does not get damaged. He should personally supervise and ensure the competent technical staff consisting of at least one person who is a whole time employee has qualified an Intermediate Examination from a university recognized by State or Central Government and have one year experience in handling/stock/purchase/sale of medical devices. All records of the products, purchases and the personnel details need to be maintained, such that it is made available during regulatory inspections. The audit and inspection reports are mandated for the inspectorate teams to record the observations and non-conformity. Medical device regulation which is recent and taken up in phases, is currently sold directly to the hospitals and diagnostic centres. Very few medical devices or *in vitro* diagnostics, which are directly used by consumers, are sold to the consumers and usually prescription is not involved for such purchases, said DCC.

Source: Nandita Vijay, Pharmabiz, 11.03.2021

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INTERNATIONAL NEWS

Ministry of Industry and Advanced Technology convenes UAE's Pharma Industry to explore future Healthcare Resilience

The Ministry of Industry and Advanced Technology (MoIAT) on 07.03.2021 convened a number of the country's pharmaceutical and medical industry companies in the fourth session of its *'Future of Industry Dialogue'* series to discuss ways in which the Ministry can drive the strong growth of the sector in a post-COVID-19 economy.

Led by Dr Sultan Al Jaber, Minister of Industry and Advanced Technology, the virtual meeting drew the participation of Abdulrahman Al Owais, Minister of Health and Prevention, and a number of industry officials.

Dr Al Jaber commended the collective efforts of the public and private sectors in responding to the pandemic, from manufacturing Personal Protective Equipment (PPE) to the distribution and testing of vaccines.

Looking ahead, Dr Al Jaber said, "Ensuring the future growth and resilience of the UAE's healthcare sector in a post-pandemic world will depend on planning ahead, reinforcing critical supply chains and establishing a wider network of global partners."

He added, "There is one crucial enabler that we must weave into the DNA of our healthcare industry: the adoption of advanced technologies. We can and must enhance local production of pharmaceuticals and medical equipment by leveraging Artificial Intelligence (AI) and Industry 4.0 solutions. Not only will this diversify our economy and increase our local efficiencies, but it will improve our preparedness to scale production when it's most needed, and this is vital to the industry's future resilience."

The Minister underlined the role that MoIAT will play in working with all relevant stakeholders to develop the industrial ecosystem and accelerate the sector's growth in the UAE. He reaffirmed the Ministry's commitment to supporting the industrial sector to enhance in-country value, and boost its competitiveness locally, regionally and globally through creating a relevant and strong regulatory environment.

Other meeting participants included: Jurgen Lauterbach, CFO of Julphar; Basem Al-Barahmeh, General Manager of Global Pharma; Emad Nazih Baloosh, General Manager of Medpharma; Dr Shamsheer Vayalil, Chairman of LIFEPharma; Madhukar Tanna, CEO of Pharmax; Dr Salwa Sami, General Manager of Medysinal; Dr Zuhdi Sawalhi, CEO of Medisal; Helda Alosta, General Manager of Monrol; Dr Firas Razouk, General Manager of Fine Healthcare; Mohammed Hamad Al Badi, CEO of Tawam Medical Instruments Factory; Vivekananda Shenoy, General Manager of Micro Synergy Pharmaceuticals; Ashish Koshy, CEO of G42 Healthcare; and Farhan Malik, General Manager of Pure Health.

The high-level *'Future of Industry Dialogue'* initiative, a series of ongoing high-level virtual meetings, was launched in February 2021 by MoIAT to establish a new collaborative framework to build long-term synergies between Government and industry in the UAE. Reflecting the UAE's commitment to developing the national industrial ecosystem, the initiative focuses on identifying and mitigating sector-specific challenges and implementing

innovative regulatory, logistical and financing frameworks to drive sustainable industrial development to pave the way for the country to achieve its aspirations in a post-COVID-19 world.

Source: Emirates New Agency, 08.03.2021 (Excerpts)

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Ukraine keen on Covaxin

A three-member, high-power delegation from Ukraine led by its Health Minister held discussions with Bharat Biotech to secure supply of its Covid-19 vaccine, Covaxin. The Ukraine team visited Bharat Biotech's manufacturing facility on Wednesday, 24.03.2021 and had discussion with the leadership of the Hyderabad-based company.

"We discussed potential timelines for the supply of Covaxin to Ukraine on a priority and the prospects of a partnership for our BBV 154 intranasal vaccine," Krishna Ella, Chairman & Managing Director, Bharat Biotech International Ltd said in a release. Maksym Stepanov, Minister of Health, Ukraine said: "We will soon firm up the Covaxin delivery plan, and further strengthen our Partnership on intranasal vaccine supplies after initial results from its phase 1 trials."

Source: The Hindu Business Line, 25.02.2021

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Granules India gets US FDA nod for its Potassium Chloride ER Capsules USP

Granules India Limited has announced that the US Food & Drug Administration has approved its Abbreviated New Drug Application (ANDA) for Potassium Chloride Extended-Release Capsules USP, 8 mEq (600 mg) and 10 mEq (750 mg). It is bioequivalent to the reference listed drug product (RLD), Micro-K Extended-Release Capsules, 8 mEq and 10 mEq, of Nesher Pharmaceuticals (USA) LLC. The product would be manufactured at the company's Hyderabad facility and is expected to be launched shortly.

"We are pleased to announce approval of Potassium Chloride Capsule product within the first review cycle of 10 months from the filing date. This is fourth ANDA approval in our Potassium Chloride product basket," said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc.

Potassium Chloride is indicated for the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxications, and in patients with hypokalemic familial periodic paralysis. It is also indicated for the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop e.g., digitalised patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and certain diarrheal states.

Granules now has a total of 37 ANDA approvals from US FDA (36 Final approvals and 1 tentative approvals). Potassium Chloride ER Capsule products had US sales of approximately $43 million for the most recent twelve months ending in December 2020, according to IQVIA Health.

Source: The Hindu Business Line, 25.02.2021

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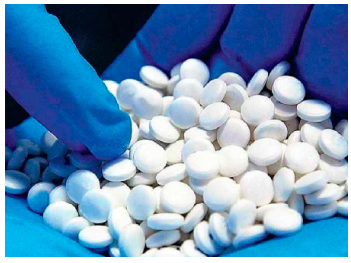
Need to maintain Indian Pharma's export competitiveness with RoDTEP

Dr Amir Ullah Khan, *Economist and Professor at the MCRHRDI of the Government of Telangana*

The recent proposal to replace Merchandise Export Incentive Scheme (MEIS) with the Remission of Duties or Taxes on Export (RoDTEP), since the former was non-WTO compliant, is believed to have been welcomed by most industry players



(Representative image)

As India moves towards self-reliance, the Government has been working to make Indian products more competitive in export markets and boost pharmaceutical exports. More so, the Pharma sector rose to the occasion and harnessed the opportunity during the pandemic to export life-saving drugs to needy patients across world and cemented its position as the pharmacy of the world. The recent proposal to replace Merchandise Export Incentive Scheme (MEIS) with the Remission of Duties or Taxes on Export (RoDTEP), since the former was non-WTO compliant, is believed to have been welcomed by most industry players.

Since its launch under the Foreign Trade Policy, MEIS has helped exporters be competitive across industries. However, the recently announced RoDTEP which has been extended to all export goods will reimburse the central, state, and local duties and taxes that were so far not being rebated or refunded. It must be noted that the Indian pharmaceutical companies were one of the principal beneficiaries under MEIS, as they exported close to $20 billion worth of products.

As per the scheme, pharmaceutical products received a three percent incentive on Free–on–Board (FOB) value for exports to Category A countries (US, Canada, Europe) and Category B countries (Emerging markets such as Russia, CIS, etc). However, currently with the transition of the schemes, the industry is burdened by embedded tax costs and duties. Disruption in transportation and logistics due to COVID-19 has also contributed to the overall financial impact adversely impacting the cost competitiveness in global exports.

To support recovery from previous losses and reinstate the industry in the competitive landscape as the 'Pharmacy to the world', the successful implementation of RoDTEP will be crucial. While India has abundant opportunities to secure a global competitive advantage, the challenge of ascertaining ceiling rate will be of high importance. Ceiling rates should be fixed considering several embedded tax costs and duties that pharmaceutical companies incur such as transportation cost, electricity costs, Research and Development, employee costs including staff welfare and transportation.

Although the scheme is ensuring for most players, RoDTEP benefits may not be offered to exporters availing benefits from other schemes like Advance Authorization (AA License), Export Oriented Unit (EOU), RoSCTL, Jobbing, EPCG, etc., according to recent Government Notification. Given that MEIS is being replaced by RoDTEP, it is essential that an equilibrium is maintained for all exporters in the value chain.

Specially, to avoid an imbalance that could affect the competitive advantage that the pharmaceutical industry currently enjoys. Efficiency in implementation will be paramount so that RoDTEP benefits are extended to all exporters uniformly, without any restrictions.

Determining an appropriate ceiling rate will not only provide Pharma industry with a competitive edge but also accelerate Pharma exports. Moreover, recently laid out budget and Economic Survey are key to India's export market. The various initiatives undertaken by the Government to promote exports, including Production Linked Incentive (PLI) Scheme, the Remission of Duties and Taxes on Exported Products (RoDTEP), emphasis on the improvement of trade logistics infrastructure, and use

of digital initiatives will certainly aim to aid 'ease of doing exports'.

(DISCLAIMER: The views expressed are solely of the author and ETHealthworld.com does not necessarily subscribe to it. ETHealthworld.com shall not be responsible for any damage caused to any person/organisation directly or indirectly.)

Source: ET-Health World/The Economic Times, 10.03.2021 (Excerpts)

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Pharmaceutical Contract Development and Manufacturing Market worth $146.1 billion by 2025 - Exclusive Report by Markets and Markets™

According to the new market research report "Pharmaceutical Contract Development and Manufacturing Market (Pharmaceutical, Biologics, Active Pharma ingredients, tablet, Parenteral, Oral Liquid, Semi-Solids), End User (Big Pharma, Small Pharma, Generic Pharma,CRO)-Global Forecast to 2025", published by MarketsandMarkets™, the global Pharmaceutical Contract Manufacturing Market is projected to reach USD 146.1 billion by 2025 from USD 100.7 billion in 2020, at a CAGR of 7.7% between 2020 and 2025.

The Pharmaceutical Contract Development Market Growth is driven mainly by factors such as rising demand for generics, increasing investments in pharmaceutical R&D, and investments in advanced manufacturing technologies by CDMOs. The increasing demand for biological therapies, growing focus on specialty medicines, growth in the nuclear medicines sector, and advancements in cell and gene therapies are also expected to offer market growth opportunities in the coming years.

On the basis of service, the Pharmaceutical Contract Development Market is broadly segmented into pharmaceutical manufacturing, biologics manufacturing, and drug development services. In 2019, the pharmaceutical manufacturing services segment accounted for the largest share of the market. The large share of this segment can be attributed to the limited finances of Pharma manufacturers, capacity constraints, need for reductions in the time-to-market, complex manufacturing requirements, large investments required for establishing manufacturing facilities, and the growing pipeline, all of which have prompted the shift toward Pharmaceutical Contract Manufacturing.

Based on end users, the Pharmaceutical Contract Manufacturing Market is segmented into big pharmaceutical companies, Small & Medium-sized pharmaceutical companies, generic pharmaceutical companies, and other end users. In 2019, big pharmaceutical companies accounted for the largest share of the Pharmaceutical Contract Development and Manufacturing Market, and this trend is expected to continue during the forecast period. The large share of this end-user segment can be attributed to factors such as the high demand for end-to-end services in big pharmaceutical companies, rising pricing pressure and pipeline challenges in their operations (resulting in a shift toward contract development and manufacturing), and the growing need to streamline execution costs as a result of the patent expiry of blockbuster drugs.

The Asia Pacific region is estimated to grow at the highest CAGR in the pharmaceutical contract manufacturing market during the forecast period, this is mainly due to factors such as increasing investments and expansions by big Pharma companies in countries such as China, India, and South Korea.

Some of the prominent players in the pharmaceutical contract development and manufacturing market include Thermo Fisher Scientific Inc. (US), Catalent, Inc (US), Lonza Group Ltd (Switzerland), Recipharm AB (Sweden), AbbVie Inc (US), Aenova Group (Germany), Almac Group (UK), Siegfried Holding AG (Switzerland), and Ingelheim International GmbH (Germany).

Source: PR Newswire, 10.03.2021 (Excerpts)

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