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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022, Hotel Sahara Star, Mumbai

(Details on Page: 4)

HIGHLIGHTS

A Publication of
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IDMA ACTIVITIES:

INDIAN PHARMACOPOEIA COMMISSION: PRESS RELEASE:

DGFT MATTERS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
1961 – 2021 (60 Glorious Years)

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IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022
Hotel Sahara Star, Mumbai

Dear Member,

Greetings from Indian Drug Manufacturers' Association (IDMA).

We, at IDMA, humbly request our Members to whole-heartedly participate in the IDMA 60th Year Celebrations by way of **Registrations, Advertisements & Sponsorships.** Your support is very much desirable and necessary in strengthening your Association as well as for the success of any initiatives taken up by your Association. We are sure that with your support the 60th Year Celebrations is going to be a massive and glorious success story in the history of your Association.

The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry.

The main objectives of the celebrations are:

- **Showcasing Pharmaceutical and Allied Industries across the Globe**
- **Disseminating knowledge on various subjects**
- **Highlighting the achievements of IDMA**

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. **IDMA Margi Memorial Best Patent Awards**
2. **IDMA ACG-SCITECH Research Paper Awards**
3. **IDMA Corporate Citizen Awards**
4. **IDMA - N. I. Gandhi Emerging Leader of the Year Award**

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been achieved in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government, Regulators and other Associations. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

We are sure you will be an integral part of the Grand Celebrations.

IDMA 60th ANNUAL PUBLICATION 2022

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc. and leave an enduring impression on everyone connected with the Industry.

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We would be extremely pleased if you would accept one of the below Sponsorship for this celebrations :-

PLATINUM SPONSOR	**:**	**Rs. 25 Lakh**	**GOLD SPONSOR**	**:**	**Rs. 10 Lakh**
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Sponsors will be provided special benefits & privileges as per the copy attached: For details please contact IDMA Secretariat.

REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
Delegate	Rs.6,000/- plus GST @ 18%
(For more than 4 registrations from one Company, the 5th registration will be complimentary)	

For further details, please contact:

Mr. Melvin	Ms. Geeta	Ms. Batul	Ms. Parivaz
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actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com	idma2@idmaindia.com

ROOM RATES :

We have negotiated special room rates for our members. **The special room rate would be Rs.6,000/- per night for a Single Occupancy and Rs.7,000/- per night for a Double Occupancy.** The room rate includes complimentary breakfast and internet facilities.

Kindly note that those members who desire to stay at Hotel Sahara Star, please forward their details to the IDMA Secretariat.

Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

With best regards,

Bharat Shah
Chairman, Organizing Committee, IDMA
60th Year Celebrations

Mahesh H Doshi
National President

Daara B Patel
Secretary - General

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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ATTENTION MEMBERS

Invitation to Participate in 'IDMA MARGI MEMORIAL BEST PATENT AWARDS 2019 - 2021'

Dear Member,

As you will be aware, the **IDMA Margi Memorial Best Patent Awards** recognise the **'Best Patents of the Year',** both national and international. We request you to kindly send us details of your **patent/s granted during the period 1st April 2019 & 31st March 2021.** An Expert Panel will examine and evaluate the applications received and recommend their selection for the Award.

Applications should be forwarded in a closed and sealed envelope marked **"IDMA Margi Memorial Best Patent Awards 2019-2021"** along with an **ENTRY FEE of Rs.15,000/- plus GST @ 18% (Total Rs.17,700/-)** per Member Company immediately to reach us **latest by 15th December 2021**. Hard copies of the patent are not required to be submitted along with the application.

For the convenience of the panelist, soft copies of the application along with relevant supporting patent documents may also be forwarded separately at **technical@idmaindia.com** / **actadm@idmaindia.com**. Only a soft copy of the Patent granted should be enclosed to enable the Panel to evaluate the Patent for the Award.

Applications for the Award will need to comply with certain criteria as enumerated in the **Guidelines (Do's and Don'ts)** for IDMA Margi Memorial Best Patent Awards 2019 - 2021 (copy attached). Kindly peruse the same before applying for the Award.

The winners will be notified by email after the Expert Panel finalizes selection of Award Winners. The Awards will be presented at the **IDMA 60th Annual Day Celebrations on Friday, 7th January & Saturday, 8th January 2022 at Hotel Sahara Star, Mumbai.**

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

The Expert Panel, constituted to scrutinise the Applications, has set the following **DOs and DON'Ts** for consideration for Awards as below:

DOs

1. Applications must include Patents granted only during the period 1st April 2019 to 31st March 2021 for evaluation.
2. A Member-Company can apply for more than one Patent. Multiple Patents can be listed in a single application.
3. The Applicationis to be submitted both as Soft Copy as well as Hard Copies with a Summary of the Patents. However, complete Patents may please be sent only in Soft copy.
4. All Family Patents belonging to same invention will be considered as one patent. Country-wise validations for EU or ARIPO patents will not be considered as independent patents. Divisional patents granted with similar inventions will be considered along with parent patent.
5. Different inventions having same title with common priority document will be identified and considered as One Patent.
6. Group companies (including Research Centres) applying independently may indicate if they wish to be considered together or separately. If patent is granted to other than the applicant, the documents justifying the inclusion of such patents (group status) need to be attached.
7. Applications for Awards for Patents granted to individuals will be considered with documentary support of rights transferred to the Applicant (Member company)
8. Applicants are requested to self-certify the authenticity of information submitted to minimise the review and verification work by IDMA.
9. The Application must be forwarded under a covering letter /or by email duly signed by an authorised signatory along with name, designation and contact details.
10. The covering letter should carry a declaration that "We have read 'The Guidelines and Criteria for Evaluation of Patents submitted for IDMA Margi Memorial Patent Awards 2019 - 2021and abide by the same".

DON'Ts

1. Please do not apply for Patents granted earlier than 1st April 2019 or after 31st March 2021. It will not be considered for this year's Awards.
2. Please do not apply for a pending patent. It will not be considered and will be disqualified.
3. Please do not apply for Patents which are already withdrawn, abandoned, not maintained or revoked will obviously not be considered.
4. An Application of a patent of the same family (of an invention which has already qualified for award in earlier years), even if granted in another country in the relevant year will not be considered.
5. If the data submitted is found to be not correct or factual, the applications will be disqualified.

Inaugural session for the Elets Digital Pharma Summit on 17-18 Nov 2021

Theme : Decoding Pharma Technologies Post Pandemic

*Our Secretary General, Mr. Daara B Patel along with Mr J. Jayaseelan, our Chairman for Tamil Nadu, Kerala & Puducherry State Board addressed the August gathering at the *Inaugural Session at Elets Digital Pharma Summit on 17th November 2021**

Good Morning Ladies and Gentlemen

Greetings from Indian Drug Manufacturers Association (IDMA).

It gives me great pleasure and honour to address the august gathering at **Elets Digital Pharma Summit** today wherein we focus on the theme **"Decoding Pharma Technologies Post Pandemic".**

Technology is impacting every aspect of our lives today. The need of the hour is that the Pharma Companies must become ready with the Next Level Pharma Technologies while aiming at engaging the consumer at every step. The agility to adapt to the changing sector requirements across the globe and deliver to meet the ever-increasing demands of the healthcare sector has made pharmaceutical companies respond effectively in pandemic induced times. Digital transformation in the pharmaceutical Industry is essential for improved patient care, cost-effectiveness, greater transparency, improved production and drug development.

We are going through a complete disruption in healthcare. Similarly a lot of acceleration has happened in the pharma industry as well. We are talking of augmented reality, virtual reality, artificial intelligence, predictive analysis and so on are the buzzwords within the industry.

The challenging times during this pandemic has called for technology – induced transformation. Pharmaceutical companies are trying very hard to keep up with the revolution brought through digital technology - Mobile communications, big data and cloud computing, advanced analytics, digital marketing and the internet of things (IOT) are among the innovations that are beginning to transform the healthcare industry.

Industry 4.0 is the digital transformation of manufacturing/production and related industries and value creation processes. The Fourth Industrial Revolution (4IR or Industry 4.0) is the ongoing automation of traditional manufacturing and industrial practices, using modern smart technology. Large-scale machine to-machine communica-

tion (M2M) and the internet of things (IoT) are integrated for increased automation, improved communication and self-monitoring, and production of smart machines that can analyze and diagnose issues without the need for human intervention.

Industry 5.0 refers to people working alongside robots and smart machines. ... As machines in the workplace get smarter and more connected, Industry 5.0 is aimed at merging those cognitive computing capabilities with human intelligence and resourcefulness in collaborative operations.

We can assure quality through digitalization. There should be proper integration between IT and technically qualified pharma professionals.

In fact most companies are comfortable with virtual quality audits.

The Indian Pharma Market is valued at approx.. USD 44 billion of which approx. 50% is Exports. The Indian pharmaceuticals market is the third largest in terms of volume and the 13th/14th largest in terms of value. It has established itself as a global manufacturing and a research hub. A large raw material base and the availability of skilled workforce gives the industry a definite competitive advantage. The domestic pharmaceutical industry includes a network of approx. 3,000 drug companies and approx. over 10,500 manufacturing units and 60K formulations.

Digital Technology is going to play a pivotal role in ensuring that the pharma industry continues to function to the best of its abilities providing both Health Care Practitioners (HCPs) and patients with the necessary vital support required.

According to me, the following digital technologies would be required by the pharma companies to remain relevant :

1. Virtualized HCP Marketing

   Pharma companies would have to shift away from traditional digital channels towards more engaging platforms such as virtual peer-to-peer sessions, medical hybrid webinars on treatment protocols. This would be an evolution in how business is being done.

2. Remote Patient Support

   As healthcare shifts more towards a self-service model, remote monitoring, instructional / advisory content and facilitation of online patient communities are all ways pharma can engage with patients and support HCPs in the process. Tools like data visualization and deeper content personalization will allow pharma companies to communicate insights or share results with patients more intuitively.

3. Data Driven Decision Making

   As the impact of Covid-19 on other conditions / illnesses becomes clearer, the healthcare system as a whole will become more reliant than ever on data and artificial intelligence (AI) to identify emerging patterns and respond accordingly. Firms would need to recruit data science talent to ensure they are equipped to deal with complex consumption patterns certain to emerge in the post covid-19 landscape.

4. Technology powered Trails

   Digital strategies considered for Clinical Trails assessments includes telemedicine, remote electronic medical record access and virtual monitoring.

   Companies who have already become more digitally skillful are examining what more can be done virtually across clinical trials, help improve processes and gain efficiencies in the units, resources and time management.

5. Cloud enabled and start-up inspired collaborations

   Pharma has woken up to the potential of the cloud especially in the field of drug development. Cloud facilitates closer collaboration between organizations by making it easier to share data. In turn, this can speed up the process of finding new treatments.

   In parallel, the covid-19 crisis has drawn a powerful response from dynamic tech start-ups. Digital health entrepreneurs have the ability to respond rapidly to changes in the market, with solutions ranging from Apps and chatbots.

Nowadays there are Webinars, Virtual Meetings, Training Programs, AGMs, Shareholder Meetings, Job Interviews, Panel Discussions, Television Interviews on virtual platform. Even the Doctor visits/calls are virtual. Infact Doctors prefer Virtual Calls.

Starting from research and development to manufacture and supply chain, marketing and sales, the very best technology expertise are needed across the value chain. The potent openings hence will exist combining pure science with data science and digital technology.

However, the reality is that the industry generally has been quite unwilling to embrace changes. Sometimes the new technology can be adopted slowly, or absolutely not. The COVID pandemic has changed this situation and acted as a facilitator for change.

Virtual meetings are here to stay:

- Webinars, training programs
- Quality Audits are also done virtually and they are very effective.

Despite the fact that things are slowly moving to Normal, virtual is still the norm. Companies have given up huge chunks of space & encourage employees to work from home or anywhere, thereby achieving HUGE savings.

Digitalisation will proliferate every kind of activity. India being a fragmented market, everyone can be digitally connected and we have to learn from each other.

Whilst ensuring Digitalisation, we need to remember one thing, do not do digital for the sake of it. Look at digital as a tool to achieve your goals but do not force it into the system.

Thank you

● ● ●

INDIAN PHARMACOPOEIA COMMISSION: PRESS RELEASE

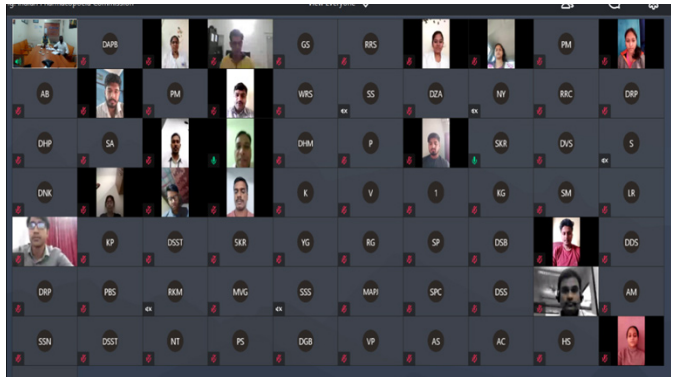
19th Skill Development Programme on Pharmacovigilance for Medical Products

The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) located at Indian Pharmacopoeia Commission Ghaziabad, organized the 19th Skill Development Programme on Pharmacovigilance for Medical Products from 08th to 12th November, 2021 through virtual mode. The training started with welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI and extended his warm greetings and best wishes to all the participants on behalf of IPC.

A total of 189 registered participants from Maharashtra, Tamil Nadu, Uttar Pradesh, West Bengal, Andhra Pradesh, Telangana, Gujarat, Karnataka, Kerala, Uttarakhand, Haryana, Punjab, Odisha, Bihar, Madhya Pradesh, Chhattisgarh, Meghalaya, Delhi, Puducherry and Andaman and Nicobar islands, participated in this training programme. The participants included Industry Professionals, Physicians, Academicians, Coordinators & Pharmacovigilance Associates of ADR monitoring Centres, Research Scholars, Students (Pharmacy and Medical) across the country. Dr. Shashi Bhushan, Dr. R.S Ray, Mr. Akash Deep Rawat, Mr. Girjesh Vishwakarma, Mr. Omkar Mishra from NCC PvPI supported during the workshop.

During the 5 days Skill Development Programme, 18 technical sessions were conducted on various topics of Pharmacovigilance including Basics of Pharmacovigilance to in-depth Signal detection method and Regulatory intervention/outcomes in an understandable language to the participants. All participants appreciated the Skill Development Programme.

Note: Please visit IPC website (www.ipc.gov.in) for regular updates.



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De-Activation of IECs not updated at DGFT - reg.

Trade Notice 25/2021-22, dated 19th November 2021

To,

1. *All IEC Holders/Members of Trade*
2. *DGFT Regional Authorities*
3. *Export Promotion Councils/Commodity Boards/ other Industry Associations.*

1. Reference is drawn to Notification No. 58/2015-2020 dated 12.02.2021, 11/2015-2020 dated 01.07.2021, 16/2015-2020 dated 09.08.2021 and Trade Notice 18/2021-2022 dated 20.09.2021 whereby it was mandated by DGFT to all IEC holders to ensure that details in their IEC is updated electronically every year during April-June period (for which no user charges will be borne by the IEC holder). Based on representations received from the IEC holders who had not updated their IECs, the period of updation was extended upto 31st July 2021 and subsequently to 31st August 2021.

2. In continuation to the aforementioned notification and as per para 2.05(e) of the Foreign Trade Policy (FTP), IECs which are not yet updated shall now be de-activated. This de-activation activity is being initiated in a phased manner.

3. **All IECs which have not been updated after 01.01.2014 shall be de-activated with effect from 06.12.2021.** The list of such IECs may be seen at the given link **https://www.dgft.gov.in/CP/?opt=LIEC** . The concerned IEC holders are provided a final opportunity to update their IEC in this interim period till 05.12.2021, failing which the given IECs shall be de-activated from 06.12.2021. Any IEC where an online updation application has been submitted but is pending with the DGFT RA for approval shall be excluded from the de-activation list.

4. **It may further be noted that any IEC so de-activated, would have the opportunity for automatic re-activation without any manual intervention** or any visits to the DGFT RA. For IEC re-activation after 06.12.2021, the said IEC holder may navigate to the DGFT website and update their IEC online. Upon successful updation the given IEC shall be activated again and transmitted accordingly to Customs system with the updated status.

This issues with the approval of the competent authority.

File No. 01/02/30/AM-22/EG&TF)

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

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Exporters in east go to west Indian ports

NEW DELHI: Until a few weeks ago Patton International, an engineering goods company, was moving more than half its containers from Kolkata to Mumbai for exports to the US due to a shortage of containers on the east coast.

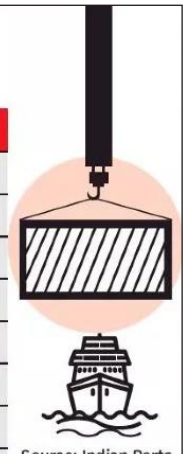
"It's a nightmare, no one would like to do it. Despite having a port in the city, you still have to do all this," said Sumit Goyal, who leads the operations, adding that the situation has improved a little over the last few weeks due to efforts taken by the Kolkata Port Trust.

While globally, exporters have been grappling with a shortage of containers and a massive spike in freight post-Covid reopening, this appears to be far worse on the eastern front as goods have to be transported by road to Mumbai, Visakhapatnam or Cochin to find shipping lines that are headed to the right destination. The strained supply chains across the world is seen to be one of the factors adding to inflationary pressures, particularly in the US.

IN TROUBLED WATERS

Container traffic (No. Of Containers)

April-Oct	2019	2020	2021
Kolkata	408	306	333
Haldia	102	80	103
Vishakhapatnam	299	290	301
Chennai	859	692	941
Ennore	76	69	273
Cochin	364	346	424
JNPT	2,975	2,348	3,179
All ports	5,940	4,941	6,421



Source: Indian Ports Association

The problem is visible in the numbers. Indian Ports Association's latest data shows that during April-October, container traffic at Kolkata remained 18% lower than 2019 level, when the national average for all ports was an increase of over 8%. Haldia Docks just about managed to overtake the prepandemic level (see graphic).

From Kolkata, goods are shipped either to Colombo or Singapore before they head to their final destination. And, the draught in Kolkata often plays a part. So, when the container crisis started, shipping lines were taking empty containers from the port to meet the requirements in other destinations, until the port authorities clamped down on it.

While the Centre is trying to tackle the problem, government officials as well as businesses concede that this issue is unlikely to be resolved for several more months. Exporters in the eastern part are hoping that the acute shortage is resolved as they have to shell out 10% more.

A tea exporter said transport cost per container adds up to around Rs 1 lakh and then there are other charges such as those paid for warehousing, loading and unloading, which add up to another Rs 30,000-40,000.

"The problem is less in west and north India. This is in addition to the higher freight," said Mahesh Keyal, a ferro alloy exporter, who was until recently paying nearly Rs 2,000 a tonne for shipping goods via Vishakhapatnam.

It now costs $1,400-1,500 to ship a container from Kolkata to Chittagong, over three times the pre-pandemic rates, said Keyal. Similarly, the tea exporter said, shipping a container to CIS countries can cost around $11,000, as against $5,500-6,000 about June.

What's worse is that few shipping lines are not taking consignments to these countries, resulting in Indian exporters losing out to competitors in Sri Lanka or Kenya. "Our cargo is packed and lying. We are incurring interest cost, our delivery and payment cycles have got elongated, resulting in higher working capital requirements," the exporter said.

Source: Sidhartha , TNN, 17.11.2021

New-gen issues in India's line of sight as it eyes trade deals

India has been trying to look West for quite some time, but none of the deals have fructified so far

As India goes into firming up trade deals with developed nations like Australia, the United Kingdom (UK) and the regional bloc, and the European Union (EU), it will have to be well prepared to negotiate on new-generation issues, such as data protection regulation, e-commerce, and environment.

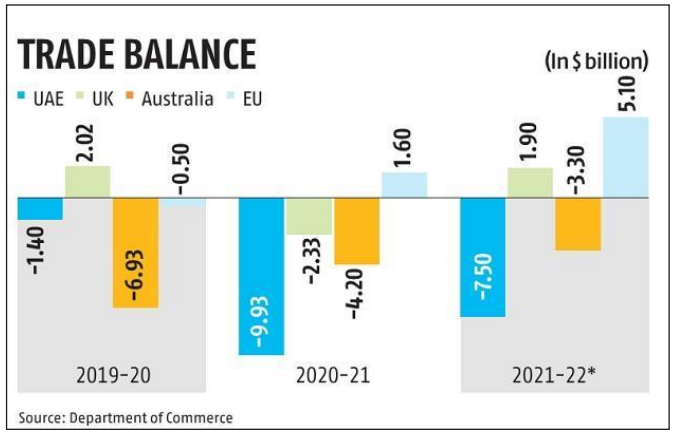
India is yet to negotiate pacts with its trading partners on these evolving issues since discussions between them have until now been largely focused on tariff and non-tariff barriers and the rules of origin.

"We can no longer look at trade just as trade. We have to look at it in totality of global and regional conditions. Today, international trade needs to be looked at inclusive of many issues, such as investment, clean energy, digitalisation, movement of people, intellectual property, and technology," said Amitendu Palit, senior research Fellow, Institute of South Asian Studies, National University of Singapore.

This is where India faces a challenge in negotiating free trade agreements (FTAs), said Palit.

"Today's FTAs, particularly those India is negotiating, will be more exhaustive and complex than the earlier ones," said Palit.

Elaborating, he said without any sustainable trade practices or clean energy practices, most trade agreements (with developed nations) may not be possible.



To buttress his point of view, he cited the example of the EU which has a 21st century template as far as FTAs are concerned. This template may include subjects like environment, labour, competition policy rules for state-owned public enterprises, among others, said Palit.

Similarly, Australia may demand data protection for investors in India. The UK may want India to open up its domestic legal market (with reciprocity).

"The concern is whether India is equipped to handle negotiations on these evolving issues, especially with stiff deadlines with respect to finalising these trade agreements," he further said.

Over the past decade or more, India had signed trade agreements with countries on its east —Singapore, Thailand, Japan, trade blocs, such as the Association of Southeast Asian Nations, among others. However, there has been a visible shift now.

India has been trying to look West for quite some time, but none of the deals have fructified so far. Now, India is girding up its loins to cement stronger strategic and economic ties with these nations.

"Today, India is looking at trade from a geostrategic, geoeconomic, and political perspective. As a result, it is looking to work out bilateral trade deals with its important strategic allies. Many of these allies are on India's west, some like Australia on its east," said Palit.

India has revamped its trade strategy and is in a rush to negotiate a spate of FTAs with its top trading partners — the UK, the EU, the United Arab Emirates (UAE), and Australia.

This assumes more importance now since India is not a part of any major regional trade bloc. A year ago, India walked away from the China-backed Asian trade bloc Regional Comprehensive Economic Partnership (RCEP)

after negotiating the deal for seven years, prioritising needs and demand of the domestic industry.

RCEP was signed by 15 nations in November last year to create the world's biggest free trade bloc.

Right now, the message India wants to send is clear — that it wants to engage with the rest of the world, or else it will shut itself out from the global markets.

Over the past six months, countries have set ambitious deadlines to fructify them, and in most cases, India is strategising to first ink a mini trade or an early-harvest deal, which will be a precursor to an FTA that will be signed in a year or so.

With the stiff target of finalising early-harvest deals with Australia, the UAE, and the UK next month, these mini pacts have to be drafted carefully.

India is also keen on inking a trade pact with Canada that got further delayed by the outbreak of the pandemic and elections in that country.

Last month, India and Israel also decided to renew negotiations on an FTA and a deadline of mid-2022 has been set.

Arpita Mukherjee, professor at Indian Council for Research on International Economic Relations, said the immediate priority should be to quickly focus on reducing tariffs on areas amicable to India and the country it is signing these deals with.

"With stiff targets ahead, nations should not complicate early-harvest agreements by bringing in issues pertaining to non-tariff barriers, such as adhering to standards, or government procurement norms in respective countries," said Mukherjee.

Source: Shreya Nandi, Business Standard, 16.11.2021

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Pfizer-BioNTech, Moderna jabs show better immunity

Research at Johns Hopkins Medicine has found immune cells existing even post six months

Immune system cells, or helper T cells, persist even after six months in people who received either the Pfizer-BioNTech or Moderna vaccines and help protect against the delta variant of SARS-CoV-2, according to a study by researchers at Johns Hopkins Medicine, US.

The study showed that helper T cells remained at levels only slightly reduced from what was observed at two weeks after vaccination, for over six months.

The study published in the Clinical Infectious Diseases journal showed that helper T cells remained at levels only slightly reduced from what was observed at two weeks after vaccination, for over six months; also, the levels were significantly higher than what was seen in people who were not vaccinated.

According to the US Centers for Disease Control and Prevention, the delta variant, the predominant strain of SARS-CoV-2 across the world at present, causes more infections and spreads faster than earlier variants of the virus.

"Previous research suggested that humoral immune response, where the immune system circulates virus-neutralizing antibodies, can drop off at six months after vaccination, while our study indicates that cellular immunity, where the immune system directly attacks infected cells, remains strong," said Joel Blankson, professor of medicine at the Johns Hopkins University School of Medicine, and a senior author of the study.

"The persistence of these vaccine-elicited T cells, along with the fact that they're active against the delta variant, has important implications for guiding covid-19 vaccine development and determining the need for covid-19 boosters in the future," he said.

Blankson and his colleagues obtained blood samples from 15 study participants (10 men and five women) across three timelines: prior to vaccination, between seven and 14 days after their second Pfizer-BioNTech or Moderna vaccine dose, and six months after vaccination. The median age of the participants was 41 and none had evidence of prior SARS-CoV-2 infection.

The CD4+ T lymphocytes, or helper T cells, assist another type of immune system cell, the B lymphocyte

(B cell), to respond to surface proteins (antigens) on viruses such as SARS-CoV-2. Activated by the CD4+ T cells, immature B cells become either plasma cells that produce antibodies to mark infected cells for disposal from the body, or memory cells that "remember" the antigen's biochemical structure for a faster response to future infections.

Therefore, a CD4+ T cell response can serve as a measure of how well the immune system responds to a vaccine and yields humoral immunity.

The researchers also looked at the ability of CD4+ T cells six months after vaccination to recognize spike proteins atop the SARS-CoV-2 delta variant. They discovered the number of T cells recognizing the delta variant spike protein was not significantly different from that of T cells attuned to the original virus strain's protein.

"The robust expansion of T cells in response to stimulation with spike proteins is certainly indicated, supporting the need for more study to show booster shots do successfully increase the frequency of SARS-CoV-2-specific T cells circulating in the blood," said Blankson. "The added bonus is finding that this response also is likely strong for the Delta variant."

In its latest weekly epidemiological update, the World Health Organization (WHO) said that the delta variant of SARS-CoV-2 virus has shown predominance globally with declining prevalence of other variants among sequences submitted to publicly available datasets or detections reported to WHO, the UN health agency said.

The delta variant, which was first detected in India, is now present in more than 104 countries.

India is expected to soon roll out Pfizer and Moderna vaccines for its nationwide vaccination drive. "The number of the fully vaccinated individuals has surpassed the partially vaccinated eligible population for the first time in the country.

India has in total administered more than 1.13 billion doses as per the 7 am provisional reports today (Wednesday) with the administration of 67,82,042 vaccine doses in the last 24 hours," said Mansukh Mandaviya, Union minister for health and family welfare. "The country will have vaccinated every Indian by the end of the month-long Har Ghar Dastak campaign," he said.

Source: Neetu Chandra Sharma, Mint, 18.11.2021

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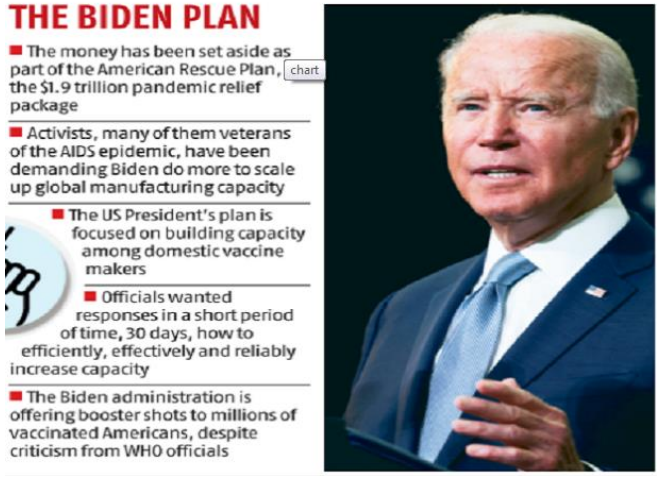
US lines up big money on Covid jabs, to produce a billion doses every year- Business Journal

The White House, under pressure from activists to increase the supply of coronavirus vaccines to poor nations, is prepared to invest billions of dollars to expand U.S. manufacturing capacity, with the goal of producing at least one billion doses a year beginning in the second half of 2022, two top advisers to President Biden said in an interview on Tuesday.

The investment is the first step in a new plan, to be announced on Wednesday, for the government to partner with industry to address immediate vaccine needs overseas and domestically and to prepare for future pandemics, said Dr. David Kessler, who oversees vaccine distribution for the administration, and Jeff Zients, Mr. Biden's coronavirus response coordinator.

"This is about assuring expanded capacity against Covid variants and also preparing for the next pandemic," Dr. Kessler said. "The goal, in the case of a future pandemic, a future virus, is to have vaccine capability within six to nine months of identification of that pandemic pathogen, and to have enough vaccines for all Americans."

The idea for the new public-private partnership is still in its early stages, and the price tag is uncertain. Dr. Kessler, who has been working on the proposal for months, estimated it at "several billion."



The money has been set aside as part of the American Rescue Plan, the $1.9 trillion pandemic relief package that Mr. Biden signed into law in March.

The Biomedical Advanced Research and Development Agency intends to issue a "request for information" to solicit ideas from companies that have experience manufacturing vaccines using mRNA technology. Mr. Zients said that officials wanted responses "in a very short period of time, 30 days, to understand how most efficiently, effectively and reliably we can increase manufacturing." That is what the plan is for now.

Activists, many of them veterans of the AIDS epidemic, have been demanding for months that Mr. Biden do more to scale up global vaccine manufacturing capacity. Some, furious with what they regard as the administration's slow progress, turned up at the home of Ron Klain, Mr. Biden's chief of staff, in September and deposited a fake mountain of bones on the sidewalk in protest.

At the same time, the administration is offering booster shots to millions of vaccinated Americans, despite criticism from World Health Organization officials and other experts who say the doses should go to low- and lower-middle-income countries first.

The Food and Drug Administration is aiming to authorize booster doses of Pfizer-BioNTech's Covid vaccine for all adults as early as Thursday, according to people familiar with the agency's plans.

Whether the new Biden plan will satisfy the administration's critics is unclear. Many activists have demanded that the administration build up manufacturing capacity overseas, particularly in Africa, but the Biden plan is focused on building capacity among domestic vaccine makers.

"This effort is specifically aimed at building U.S. domestic capacity," Dr. Kessler said. "But that capacity is important not only for the U.S. supply, but for global supply."

Source: Business Journal, 18.11.2021

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Expert panel seeks additional info on Merck's Covid-19 drug

Synopsis

Molnupiravir is the first oral antiviral approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of mild-to-moderate Covid-19 in adults and could potentially be the game changer in ending the pandemic.

The Indian drug regulator's expert panel on Thursday sought additional data from the companies seeking emergency use authorisation (EUA) for MSD's Covid-19 antiviral medication molnupiravir.

The Subject Expert Committee (SEC), which advises the drug regulator on applications seeking approval for vaccines, new drugs and clinical trials, reviewed the applications of Dr Reddy's along with other firms including Hetero Labs, Natco -0.77 % Pharma, Aurobindo Pharma -4.05 %, Optimus Pharma, Strides Pharma, MSN Pharma, and BDR Pharmaceuticals. The SEC will meet again as it sought additional data from the companies," sources told ET.

"We await official communication from the SEC on the outcome of the meeting," a spokesperson at Dr Reddy's told ET.

Molnupiravir is the first oral antiviral approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of mild-to-moderate Covid-19 in adults and could potentially be the game changer in ending the pandemic.

The drug is under review by the US Food and Drug Administration for the emergency use authorisation. The

advisory committee of USFDA will be meeting on November 30 to discuss the available data supporting the use of molnupiravir to treat mild-to-moderate Covid-19 infection in adults who have tested positive for Covid-19, and who are at high risk for progression to severe Covid-19, including hospitalization or death.

In the Phase-3 trial by Merck , molnupiravir significantly reduced the risk of hospitalisation or death by around 50% among newly infected people, and also prevented 100% of deaths.

As reported by ET on Thursday, the Drug Controller General of India office had requested the firms to send a detailed summary of proposals and powerpoint presentations to SEC.

"The companies made their presentations before the SEC today, however, it was decided that a final decision will be taken in the next meeting, likely to happen next week," the same person said.

Source: Teena Thacker, ET Bureau, 19.11.2021

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Natco Pharma launches cancer drugs

Natco Pharma has launched in India a fixed-dose combination of Trifluridine and Tipiracil, which is indicated for treatment of advanced colorectal and gastric cancers and 10mg strength of Everolimus tablets (generic for Afinitor) used in treatment of certain cancers in the US market.

Tipanat, the brand name under which the fixed-dose combination tablet has been launched, is a novel antineoplastic nucleoside. Approximately 1.25 lakh new cases of advanced colorectal and gastric cancers are reported every year in India. Tipanat will be available in a pack of 20 tablets in a bottle, the drug maker said in a release.

In another release, the company said marketing partner Breckenridge Pharmaceutical Inc has launched the 10mg strength of Everolimus tablets in the US market. The 10mg strength of Afinitor generated annual sales of $392 million during the 12 months ending July 2021, the company said citing industry sales data. Earlier this year, Breckenridge had launched Everolimus tablets in 2.5mg, 5mg and 7.5mg strengths in the US market, it said.

Source: The Hindu, 19.11.2021

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PM asks pharma industry to increase output of raw materials for medicines and vaccines

Popularise Indian traditional medicines globally'

Prime Minister Narendra Modi, on Thursday, asked the Indian pharmaceutical industry to focus on increasing domestic production of key raw materials for medicines and vaccines, with a clear intent to make India self-reliant in this crucial pharma space.

The Prime Minister, while addressing the Global Innovation Summit 2021 by Indian Pharmaceutical Alliance (IPA), asked the industry to also focus on development of traditional Indian medicines/ herbal medicines in the backdrop of their growing global demand.

Highlighting the two areas, the PM asked the industry to explore them carefully.

On the raw material requirements, Modi said: "While we have been fighting the pandemic, we found that this was one issue that needed much more attention. Today, when 1.3 billion people of India have taken it upon themselves to make India Atmanirbhar (self-reliant), we must think about ramping up domestic manufacturing of key ingredients for vaccines and medicines. This is one frontier that India has to conquer," he said in his virtual address.

Supply shortages

Notably, during the pandemic, the Indian pharmaceutical industry had to suffer due to supply shortages of key active pharmaceutical ingredients (APIs) from China due to pandemic-induced logistical disruptions. China commands dominance in supply of APIs to Indian formulations makers and supply disruptions cause sharp price rise.

On the vaccine production front, when India was passing through the worst second wave, the vaccine production at Serum Institute of India (SII) for Covishield faced uncertainties following the decision by its raw

material supplier US invoking the Defense Production Act curbing the export of crucial vaccine raw materials. The issue was resolved only after a top-level diplomatic involvement.

In a bid to secure raw material supplies for medicines and vaccines, the PM asked the entrepreneurs to invest for raw material production. "I am sure that investors and innovators are keen to work towards overcoming this challenge," he said.

The Union Minister for Health, Mansukh Mandaviya, also reiterated the point while inviting the global pharmaceutical investors to invest, innovate and produce in India.

"India has all the necessary infrastructure and ecosystem to become the healer of the world. This pandemic has given the world many lessons. The importance of drug security is one of that. "When any country invests in India, the drug security is an important factor they consider while putting up a manufacturing facility."

The Prime Minister also emphasised on popularising the Indian traditional medicines on the global front. "There is now significant and growing demand of these products in the international markets. This can be seen through the sharp rise in exports of these products as in 2021 India exported herbal medicines worth $1.5 billion. Also, the WHO is working to set up its global centers for traditional medicines in India," said Modi

Industry doyens, including Pankaj Patel, Chairman of Zydus Cadila, and Samir Mehta, Chairman of Torrent Pharmaceuticals, who is also the Chairman of IPA, addressed the gathering, giving a highlight about the prowess of India's pharmaceutical industry

"India constitutes 20 per cent share of the global supply chain of medicines by volume and supplies about 60 per cent of the vaccines required globally. The Indian pharma industry is a $45 billion in size and ranks third in production of volume and 13th in value. India has played a vital role in supply of high-quality medicines for several chronic diseases. India is polio-free because of strong collaboration between vaccine makers, healthcare providers, government and development organisations," said Patel.

IPA Chairman Samir Mehta stated that the theme of the summit is 'Discover in India: Accelerating the Innovation Journey of the Indian Lifesciences Industry' and apt in the current Covid backdrop. "The summit is the first-of-its-kind being organised in the country with key objectives such as discuss recommendations to improve innovation landscape in India, share learnings and emerging trends in the global innovation landscape and provide a platform for entrepreneurs and researchers to showcase their ideas/ innovation."

Source: The Hindu Business Line, 19.11.2021

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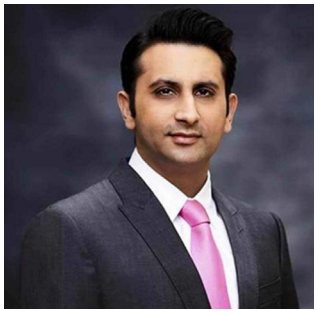
Covid-19: Vaccine hesitancy biggest threat to overcoming pandemic, says Serum Institute CEO Adar Poonawalla

More than 22.45 crore doses are still available with states and union territories and the Union government has provided 128.49 crore doses to the states and UTs till date.



The government is reaching out to districts where less than 50% of the eligible population has been vaccinated.

Serum Institute of India (SII) CEO Adar Poonawalla has said vaccine hesitancy is now the greatest threat in overcoming the Covid-19 pandemic. "The vaccine industry has worked tirelessly to provide enough stocks for the nation. Today, there are over 200 million doses available with states. I urge all adults to get vaccinated as soon as possible. Vaccine hesitancy is now the greatest threat in overcoming this pandemic," he said in a tweet.

India on Thursday crossed the 115-crore vaccination mark with 73.44 lakh Covid-19 vaccine doses administered in the last 24 hours. More than 22.45 crore doses are still available with states and union territories and the Union government has provided 128.49 crore doses to the states and UTs till date.

Saying that there was no shortage of vaccine doses in the country, Union health minister Mansukh Mandaviya urged people to come forward for the second dose.

Till late Wednesday evening, the country had administered over 75.57 crore first doses and over 38.11 crore of the second dose. The government is reaching out to districts where less than 50% of the eligible population has been vaccinated.

India reported 11,919 Covid-19 cases on Thursday with active caseload at 1.28 lakh cases with weekly positivity rate of 0.94%.

Source: FE Bureau, 19.11.2021

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AstraZeneca's Antibody Cocktail Helps Prevent COVID-19 for at Least 6 Months

(Reuters) -AstraZeneca on Thursday cemented its lead in bringing a preventative COVID-19 shot to market, saying its antibody cocktail offered 83% protection over six months, providing another possible weapon in the fight against the pandemic.

The therapy, called AZD7442 or Evusheld, had previously been shown to confer 77% protection against symptomatic illness after three months, in an earlier readout of the late-stage PROVENT trial https://www.reuters.com/business/healthcare-pharmaceuticals/astrazeneca-antibody-works-prevent-treat-covid-19-longer-term-studies-2021-11-18 in August.

The data give hope of additional protection for people who do not respond well to vaccines, such as cancer patients.

The Anglo-Swedish company also said a separate study in patients with mild-to-moderate COVID-19 showed a higher dose of AZD7442 cut the risk of symptoms worsening by 88% when given within three days of the first symptoms.

The antibody treatment, enhanced to remain intact in the body for months, is given in one go, as two sequential shots in the arm.

The latest results from the longer-term follow-ups potentially position AstraZeneca, like rival Pfizer as a future supplier of both COVID-19 vaccines and treatments, with AstraZeneca having said the therapy's "real advantage" was as a preventative shot.

The full results will be submitted for publication in a peer-reviewed medical journal.

Pfizer https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-files-us-authorization-covid-19-pill-2021-11-16 has presented promising efficacy data on its oral COVID-19 treatment candidate, which can be more easily distributed than injections, and is also a leading vaccine supplier with partner BioNTech.

"These new data add to the growing body of evidence supporting AZD7442's potential ... We are progressing regulatory filings around the world and look forward to providing an important new option against SARS-CoV-2 as quickly as possible," AstraZeneca Executive Vice President Mene Pangalos said in a statement, referring to the coronavirus that causes COVID-19.

The group last month sought approval for the medicine from U.S. https://www.reuters.com/world/us/astrazeneca-files-us-approval-drug-prevent-covid-19-2021-10-05 and European authorities https://www.reuters.com/business/healthcare-pharmaceuticals/eu-begins-real-time-review-astrazeneca-covid-19-antibody-cocktail-2021-10-14. Monoclonal antibodies from Regeneron, Lilly and GSK-Vir have been approved by U.S. regulators for treating unhospitalised COVID-19 patients.

Earlier this month, Regeneron https://www.reuters.com/business/healthcare-pharmaceuticals/regenerons-antibody-therapy-shows-long-term-protection-against-covid-19-2021-11-08 said a single dose of its antibody cocktail reduced the risk of contracting COVID-19 by 81.6% in a late-stage trial.

LONG-TERM

"This is an important addition to the therapeutic armamentarium for COVID" if the published study confirms the data released on Thursday, said Penny Ward, visiting professor in pharmaceutical medicine at King's College London.

While the injection may be seen as a potential alternative to vaccines, antibody drugs cost significantly more, which may limit their use to particularly high-risk groups.

Antibody cocktails typically cost above $1,000 per dose, while COVID-19 shots have on average sold for between $3 and $30 per dose.

Astra's Executive Vice President for vaccines and immune therapies, Iskra Reic, said on a call with media that unlike its vaccine, the drug would be priced commercially as it negotiates supply contracts with governments around the globe.

Chief executive Pascal Soriot said the treatment was more complicated to produce than a vaccine but that there would be enough production capacity around the world to meet demand.

Monoclonal antibody drugs deliver lab-made versions of the body's natural antibodies to fight off infection, while vaccines spur the body to make its own antibodies and build its own immunity.

AstraZeneca has said the shot is primarily meant to help immunocompromised and at-risk individuals but at some point a wider group could benefit, such as military personnel on tours of duty or cruise ship passengers.

It would be administered in addition to vaccines, the company has said. It added that about 2% of the global population was considered to inadequately respond to a COVID-19 vaccine.

For AstraZeneca's PROVENT trial, close to 5,200 participants without an infection were randomly split into two groups, with one volunteer receiving an ineffective placebo without knowing for every two receiving Evusheld.

Participants were at risk of suffering severe COVID-19 if infected or were immunocompromised, meaning they were in cancer care, or receiving drugs due to an autoimmune disease or an organ transplant. The trial volunteers were not vaccinated, even though high-risk groups have been prioritised in global vaccination campaigns. Anyone opting to get vaccinated during the trial was excluded from the analysis.

Trial volunteers will be followed up for 15 months to provide evidence of longer-lasting protection.

(Reporting by Pushkala Aripaka in Bengaluru and Ludwig Burger in Frankfurt Editing by Mark Potter, Josephine Mason and Barbara Lewis)

Source: Pushkala Aripaka and Ludwig Burger, Reuters, 18.11.2021

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Pfizer enters deal with UN-backed MPP to license COVID drug in 95 countries including India

Synopsis

Pfizer said it will waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

MPP has invited expression of interest (EoI) from potential sublicensees based anywhere in the world for sublicences to manufacture and sell the co-pack of PF-07321332; ritonavir in the licensed territory. The deadline for submitting EoI will be ending on December 6, 2021.

US drug giant Pfizer on Tuesday announced a deal with the Medicines Patent Pool (MPP) a UN-backed public health organization, to issue royalty free voluntary license to manufacture generic versions of oral antiviral Covid-19 medication Paxlovid in 95 middle and low income countries (LMIC) including India.

Pfizer said it will waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization. Under the terms of the head license agreement between Pfizer and MPP, qualified generic medicine manufacturers worldwide that are granted sub-licenses will be able to supply Paxlovid (PF-07321332 in combination with ritonavir) to 95 countries, covering up to approximately 53% of the world's population.

MPP has invited expression of interest (EoI) from potential sublicensees based anywhere in the world for sublicences to manufacture and sell the co-pack of PF-07321332; ritonavir in the licensed territory. The deadline for submitting EoI will be ending on December 6, 2021.

"The agreement will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population," Pfizer said in a release.

Pfizer earlier this month said the interim data from Phase 2/3 of its experimental antiviral pill Paxlovid which is a combination of PF-07321332 and anti-HIV drug ritonavir, has cut the chance of hospitalisation or death for adults at risk of severe disease by 89%.

MPP last month reached a similar deal with MSD for its Covid antiviral pill, molnupiravir, to be made and sold inexpensively in 105 poorer countries. Like molnupiravir Indian generic drug makers are once again expected to be in the forefront to seek voluntary licenses to produce Paxlovid as well..

"Pfizer remains committed to bringing forth scientific breakthroughs to help end this pandemic for all people. We believe oral antiviral treatments can play a vital role in reducing the severity of COVID-19 infections, decreasing the strain on our healthcare systems and saving lives," said Albert Bourla, Chairman and Chief Executive Officer of Pfizer.

"This license is so important because, if authorized or approved, this oral drug is particularly well-suited for low- and middle-income countries and could play a critical role in saving lives, contributing to global efforts to fight the current pandemic," said Charles Gore, Executive Director of MPP.

Source: Viswanath Pilla, ET Bureau, 16.11.2021

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India may ship goods as break bulk cargo to tide over the container shortage crisis

New Delhi: India is exploring shipping goods as 'break cargo' to tide over the container shortage crisis, said officials. Break bulk cargo is transported in bags or boxes and takes less space in ships, thereby allowing more cargo to be transported, aiding faster exports.

The commerce department has sought information from the industry on the type of packaging being used for their cargo and shipment weight to finalise the list of goods that can be exported as break bulk cargo. "The idea is to create a database of all commodities which can be exported via priority berthing as break bulk cargo in order to facilitate faster export of suitable commodities," said an official, who did not wish to be identified.

The solution is being considered at a time when ships' berthing time is more than a month in the US and Europe. Bulk and break bulk freights are generally 25-30% lower than containerised cargo depending on the trading area of the vessel.

"Not only is there a shortage of containers but also of ships," an industry representative said on condition of anonymity, adding that of late a lot of trade is happening via containers as it is considered safe. "However, the cost of bulk cargo is lower without compromising the safety of the cargo." A vessel with a capacity to carry 12,000 metric tonne load can carry only 8,000 metric tonnes if loaded with containerised cargo. However, it can transport up to 11,000 metric tonnes if the cargo is in break bulk form. "Once both buyers and sellers agree on this kind of an arrangement after assuring safety of the cargo, this will resolve the container issues to a large extent," said the industry representative.

Source: Business Versatile Content Creator, 19.11.2021

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National digital drugs databank will help address 'information asymmetry' in pharma space: CCI study

Synopsis

A national digital drugs databank will help in addressing "information asymmetry" as well as provide key inputs in mapping the regulatory needs of different states, according to a pharmaceutical sector study conducted by the Competition Commission of India.

A national digital drugs databank will help in addressing "information asymmetry" as well as provide key inputs in mapping the regulatory needs of different states, according to a pharmaceutical sector study conducted by the Competition Commission of India. The fair trade watchdog, which works on ways to foster competition and curb anti-competitive practices, in the market study found that brand competition overrides price competition in the domestic market where generic formulations are marketed with distinct brand names. Generic drugs play an important role in bringing down drug prices, thereby reducing healthcare costs and improving access. In India,

Another suggestion is to have an institutional quality-signalling mechanism through the printing of standard compliance marks on unbranded drugs, which meet the quality standards.

generics dominate pharmaceutical sales, and the generic manufacturing within each molecule/formulation market is characterised by the presence of multiple manufacturers. The Competition Commission of India (CCI) has pitched for a multi-pronged and harmonised regulatory response to the issue of drug quality, including setting up a national digital drugs database.

"A comprehensive, online, centralised drug databank consolidating real-time data on active pharmaceutical manufacturing companies in the country, therapeutic class wise/formulation-wise approved branded/unbranded products along with their manufacturing and marketing entities may be created, maintained, and made accessible to regulators, industry, physicians and consumers," it noted. Such a database, the watchdog said, will help address information asymmetry and provide important inputs in mapping the regulatory needs in different states.

Information gaps on grant of licences, inspections and prosecutions for non-compliance, among others, could be bridged through real-time data that could be published on a central online portal, it added.

Promotion/ facilitation of generic entry, prescription by generic drug name and substitution between generics by chemists, which are reckoned as vital pro-competitive instruments, can yield the desired outcome of exposing pharmaceutical expenditure to significant price competition, subject to certain conditions. "...only when all generic drugs in a therapeutic class in their unbranded and branded versions are considered interchangeable and equally efficacious by stakeholders," the study noted.

Another suggestion is to have an institutional quality-signalling mechanism through the printing of standard compliance marks on unbranded drugs, which meet the quality standards.

"This may provide the necessary confidence to the physician community to prescribe generic names. This can also boost consumer confidence in unbranded generic drugs," the study said.

Uniform and effective implementation of existing quality standards, better transparency, quality control across the supply chain as well as in public procurement are among the other suggestions.

About online pharmacies, the study said such entities should adopt self-regulatory measures in the areas of collection, use, sharing of data and privacy.

"However, for safeguarding patient privacy and protecting sensitive personal medical data, necessary regulations need to be enforced until the country legislates its data protection law," it added.

Source: Economic Times, 19.11.2021

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