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RNI REGN. NO. 18921/1970
REGNEGN NOO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 ISSUE NO. 41 (PAGES: 28) 01 TO 07 NOVEMBER 2021 ISSN 0970-6054 WEEKLY PUBLICATION

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
Indian Drug Manufacturers' Association
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 Issue No. 41 01 to 07 November 2021

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

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Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

IDMA 60TH YEAR CELEBRATIONS 2022

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

We are happy to inform you that our Association will be completing 60 glorious years in 2022. 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

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been met 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 and Regulators. 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

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We invite sponsors for our 60th Year Celebrations as below:

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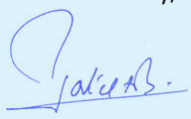
Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical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

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

Thanking you,

Yours faithfully,



Daara B Patel
Secretary–General

COMBINATORIAL DRUGS

Dr Nagaraj N Rao, *Associate Editor, Indian Drugs*

Dear Reader,

At the University of Sydney's Westmead Applied Research Center in Australia, Professor Clara Chow's team has discovered in a long-duration study that a combination of four drugs commonly used to treat blood pressure - at only a quarter of their usual doses - is much more effective in getting blood pressure under control compared to the standard treatment with one or two drugs. The new combination could remarkably bring the blood pressure under control in 80% of the participants within 12 weeks. The four drugs were given in the form of a pill. Apart from the lower concentrations of the drugs required, ease of administering and patient compliance of the new quadruple strategy are obvious additional advantages. This discovery, published recently in Lancet, might contribute to basic changes in the management of patients having high blood pressure. Professor Chow laments that control of hypertension is not ideal anywhere, and in some regions such as Africa fewer than one in ten have it under control. The prevalence of hypertension is expected to increase to 29%(!) of the global population in four years from now.

Heart failure with reduced ejection fraction (HFrEF) is treated in a multi-modal strategy with a combination of several drugs as the foundation for symptomatic and prognostic improvement in all patients. A recent study at the Baylor Heart and Vascular Institute in Dallas of current approaches suggests that patients with HFrEF should be treated early with a combination of (so-called "fantastic") four drugs, namely, an ARNI, beta-blocker, MRA, and SGLT2 inhibitor in order to benefit from substantial and sustained reductions of mortality, heart failure hospitalizations and symptoms.

Researchers at the Institute of Central Research in London led a study on the treatment of blood cancer myeloma using a combination strategy

Dr. Nagaraj Narayan Rao *obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the "Transactions of the MFAI" for a few years. He contributes a monthly 'Report from India' to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.*

Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

of the drugs lenalidomide, dexamethasone and cyclophosphamide, along with the newer drug carfilzomib, and observed a significant slowdown in its progression. The results of Phase III clinical study, conducted over a three-year period, have recently been published in the journal "PLOS" Medicine. The researchers found that the so-called quadruplet KRdc therapy did not notably increase side effects. Myeloma accounts for over 6000 deaths annually in India itself.

In the case of some liver cancer patients who would normally not be considered for surgery, a newly developed combination therapy might make curative surgery possible. The two drugs are the kinase-inhibitor drug cabozantinib and the immunotherapy drug nivolumab. Researchers at the John Hopkins Kimmel Cancer discovered the benefits of this drug combination. Similarly, scientists at the University of Paris-Saclay in France have discovered a novel combination of well-known drugs to prolong the life of patients afflicted with prostate cancer: it was found that the addition of abiraterone acetate plus prednisolone (AAP) to standard therapy lengthened survival compared to standard therapy alone. In the case of advanced unratifiable hepatic cellular carcinoma, a triple combination therapy for treating advanced HCC had a very significant therapeutic effect with a high conversion surgical rate. The study was carried out in Tianjin, China. The triple combination therapy comprised of angiogenesis inhibitors (oral apatinib 250 mg day-1, lenvatinib 8 mg day-1, or sorafenib 400 mg BID), anti-programmed cell death 1 antibodies (iv camrelizumab or sintilimab, 200 mg every 3 weeks), and hepatic arterial infusion chemotherapy (FOLFOX every 4-8 weeks). The combination therapy is also being investigated for the treatment of bladder cancer.

In the current scenario, where the seizure of narcotics is in the limelight in the Indian media, scientists in the USA have found that a combination of two existing medications might help in battling the debilitating methamphetamine use disorder. The combination of naltrexone, an injectable drug currently used to treat alcohol and opioid addictions, and the anti-depressant bupropion led to significant benefits and is considered to be first ever positive treatment for this addiction. Their results have been published in the New England Journal of Medicine.

The US FDA has recently approved an topical retinoid and anti-bacterial fix dose combination, which has been developed by Sol-Gel Technologies Ltd, for treating acne vulgaris in patients above 9 years of age. The tretinoin and benzoyl peroxide combination is sold as a cream under the brand name Twyneo. It uses micro encapsulation technology to separate the two active ingredients and ensure their stability. 3% Benzoyl peroxide and 0.1% tretinoin were encapsulated. About 9.4% of the global population suffers from acne vulgaris.

It is estimated that the prevalence of inflammatory bowel diseases (IBD) is to the extent of about 400 per lakh persons annually. As the current therapeutic approaches leave much to be desired and do not seem to be able to overcome the plateau in the rates of response and/remission, focus is now on trying rational combination therapies with complementary mechanisms of action. Current clinical trials of combination therapies in IBD include vitamin D, anti-tumour necrosis factor-a-products, microbiome alteration and combination of immunosuppressants.

Similar to the development of computational chemistry for drug design, efforts are being made to use artificial intelligence to get leads for combinatorial therapies. The challenges, however, are galore. Understanding the biological rationale for the combination as well as incorporation of novel predictive biomarkers are necessary. Innovative statistical approaches and data mining of the individual drugs are needed to give effective answers using such theoretical approaches. Network-based rational drug combination screenings as well as exploration of the relationship between drug-target modules and disease modules via network proximity in the whole set of molecular interactions in human cell will lead to effective solutions. As the number of drugs in a combination therapy increases, the complexity also increases severalfold.

Challenges exist with regard to valuing and paying for treatment combinations, for example, in oncology, since the individual drugs rarely come from the same company. Stakeholders include academia, industry, regulatory authorities and the medical fraternity. In November 2019, the Bellberry Group conducted a three-day international workshop to discuss this issue. To what extent the value of a combination treatment should be attributed to each of the individual components treatments is a tricky affair. Developing methods of attributing values is itself a subject of research.

Developing suitable and stable user-friendly formulations, once the doses in a combination therapy are fixed, is a challenging subject for pharmaceutical technologists. Developing analytical techniques is equally crucial. The interpretation of clinical data in combination therapies might require newer approaches. All said and done, combination therapies are here to stay and grow in numbers.

Happy reading!

Courtesy: Indian Drugs, Editorial, 58 (08), August, 2021

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CUSTOMS MATTERS

Duty on Petrol & Diesel under Notification No.18/2019-Customs, dated the 6th July, 2019 reduced

Notification No.52/2021-Customs dated 3rd November, 2021

1. In exercise of the powers conferred by section 111 of Finance Act, 2018 (13 of 2018), read with sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government, being satisfied that it is necessary in the public interest so to do, hereby makes the following further amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.18/2019-Customs, dated the 6th July, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R.475(E), dated the 6th July, 2019, namely:-

In the said notification, in the Table-

(i) against Sl.No.1, for the entry in column (4), the entry "Rs. 13 per litre" shall be substituted;

(ii) against Sl.No.2, for the entry in column (4), the entry "Rs. 8 per litre" shall be substituted.

2. This notification shall come into force **with effect from the 4th November, 2021.**

F.No.354/72/2021-TRU

Gaurav Singh,
Deputy Secretary,
Government of India,
Department of Revenue,
Ministry of Finance,
New Delhi

Note: *The principal notification No. 18/2019-Customs, dated the 6th July, 2019 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number 475(E), dated the 6th July, 2019 and last amended vide notification No.21/2020-Customs, dated the 5th May, 2020, vide number G.S.R.277(E), dated 5th May, 2020.*

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Amendment in import policy condition of Urea [Exim Code 31021000] in the ITC (HS) 2017, Schedule-I (Import Policy)

DGFT Notification No.40/2015-2020 dated 3rd November, 2021

1. In exercise of powers conferred by Section 3 and Section 5 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends the policy condition of Urea [EXIM code 31021000] of Chapter 31 of ITC (HS), 2017, Schedule-I (Import Policy), with immediate effect, as under:

2. Effect of the Notification:

In addition to Rashtriya Chemicals & Fertilizers Limited (RCF), Import of Urea is allowed through National Fertilizers Limited (NFL) and Indian Potash Limited (IPL) subject to Para 2.20 of Foreign Trade Policy, 2015-2020. The NFL and IPL are designated as STE for import of Urea on Government account. However, IPL is allowed to import Urea on Government account **till 31.03.2022 only.** Henceforth, the **MMTC and STC are de-notified as STE for import of Urea.**

Exim Code	Item Description	Policy	Existing Policy Condition	Revised Policy Condition
31021000	Urea, whether or not in aqueous solution	State Trading Enterprise	Import allowed through STC, MMTC and RCF subject to Para 2.20 of Foreign Trade Policy, 2015-2020. However, import of Technical Grade Urea (TGU) meant for non-agricultural purpose/industrial use/ NPK Manufacturing shall be Free.	Import allowed through RCF and NFL subject to Para 2.20 of Foreign Trade Policy, 2015-2020. In addition import of Urea is also allowed through IPL for a period upto 31.3.2022. However, import of Technical Grade Urea (TGU) meant for non-agricultural purpose/ industrial use/ NPK Manufacturing shall be "Free".

This issues with the approval of Minister of Commerce & Industry.

F.No.01/89/180/102/AM-02/PC-2(A)Part-II/E-1715

Amit Yadav, Director General of Foreign Trade & Ex-officio Addl. Secretary to GoI Ministry of Commerce & Industry, Department of Commerce Directorate General of Foreign Trade, New Delhi.

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Last Date for filing claim at the Online IT module for Scrip based Schemes - MEIS/SEIS/ROSL/ROSCTL - reg.

DGFT Trade Notice No.22/2021-22 dated 02/11/2021

To,
Exporters/Members of Trade All EPCs, SEPC, Industry Associations and Trade Bodies

1. In September 2021, Government had released about Rs 56,000 Crore for issue of duty credit scrips under the FTP Schemes. Filing of online applications and subsequent issue of duty credit scrips has also started.

2. In this regard, attention of the trade & industry is drawn to Notification no. 26 dated 16.09.2021, wherein 31st December 2021 has been stipulated as the revised last date for making online applications under MEIS/ SEIS/ RoSL/RoSCTL schemes. Exporters may kindly note that after 31.12.2021, the Online IT system will not be operational and no applications/claims under the mentioned schemes can thereafter be submitted.

It has also been notified that the facility for filing applications, with a late cut provision, would also not be available and all applications will get time barred after 31st December 2021.

3. Trade and Industry is requested to take note and ensure that applications/ claims are submitted Online within the stipulated timeline of 31.12.2021 for timely release/ issue of scrips by DGFT RAs.

4. Export Promotion Councils are also requested to give wide dissemination to this Trade Notice in the interest of exporting community. SEPC/FIEO and organizations with service exporters as their members may also approach their constituents with a request to file their SEIS claims at an early date and in any case not later than 31.12.2021.

This issues with the approval of Competent Authority.

F.No.01/61/180/179/AM18/PC-3

Dr Praveen Kumar, Deputy Director General of Foreign Trade, India, Ministry of Commerce and Industry, Department of Commerce Directorate General of Foreign Trade, New Delhi.

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Amendment in Appendix 2T (List of Export Promotion Councils/Commodity Boards/Export Development Authorities) of Foreign Trade Policy 2015-2020 - reg.

DGFT Public Notice No.33/2015-2020 dated 02/11/2021

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy 2015-2020, the Director General of Foreign Trade hereby makes the following amendments under Appendix 2T (List of Export Promotion Councils/ Commodity Boards/Export Development Authorities) of the Handbook of Procedures, 2015-2020 :-

S. No. in Appendix 2T	Name of Export Promotion Councils/ Commodity Boards	Existing Address in Appendix 2T	Revised Address in Appendix 2T
6.	Council for Leather Exports (CLE)	CMDA Tower-II, 3rd Floor Gandhi Irwin Bridge Road, Egmore Chennai-600 008 Tel: 044-28594367-71 Fax : 044-28594363-64 Website: www.leatherindia.org E-mail: cle@cleindia.com	No.1, Sivaganga Road, Nungambakkam, Chennai — 600034 Phone : 044 48684380 — 84 Email: cle@cleindia.com Website: www.leatherindia.org
12.	Gem Jewellery Export Promotion Council (GJEPC)	Head Office and Registered Office: Office No. AW 1010, Tower A, G Block, Bharat Diamond Bourse, Next to ICICI Bank, Bandra-Kurla Complex, Bandra - East, Mumbai Tel: 91 - 22 - 26544600 Fax: 91 - 22 - 26524764 Website: www.gjepc.org	Office No. AW 1010, Tower A, G Block, Bharat Diamond Bourse, Next to ICICI Bank, Bandra-Kurla Complex, Bandra - East, Mumbai Tel: 91 - 22 - 26544600 Fax: 91 - 22 - 26524764 Website: www.gjepc.org Email: ho@gjepcindia.com

		Email: ho@gjepcindia.com Exhibition Cell: exhibitions@gjepcindia. com Exhibition Cell G-6, Radhe Vallabh CHS (Modi Chambers) French Bridg Corner, Opp. Opera House Mumbai-400 004 Tel: 02223894957/20532896/ 23802788 Fax : 022-23804958 Website : www.iijs.org , www.gjepc.org.intl E-mail: iijs@gjepcindia.com; exhibition@gjepcindia.com	Exhibition Cell of GJEPC stands removed from Appendix 2T.

2. Effect of this Public Notice:

Under Appendix 2T of FTP, 2015-2020, the address of the Council for Leather Exports (CLE) has been updated and the Exhibition Cell of Gem Jewellery Export Promotion Council (GJEPC) has been de-notified, with immediate effect.

F.No.01/93/180/08/AM-19/PC-2(B)/E-11168

Amit Yadav, Director General of Foreign Trade & Ex-officio Addl. Secretary to the GoI Ministry of Commerce & Industry, Department of Commerce Directorate General of Foreign Trade, New Delhi.

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GOVERNMENT NOTIFICATION

Provision of clause (2) of Explanation of Section 22 of the Food Safety and Standards Act, 2006 enforced on 02nd day of November, 2021

Health & Family Welfare - Other Notification S.O.4601(E) dated 2nd November, 2021

(Published in the Gazette of India on 3rd November, 2021)

In exercise of the powers conferred by sub-section(3) of section 1 of the Food Safety and Standards Act, 2006 (34 of 2006), the Central Government hereby appoint the 02nd day of November, 2021, as the day on which the provision of clause (2) of Explanation of Section 22 of the said Act, shall come into force.

F.No.P.15014/9/2019-FR

Dr. Mandeep K. Bhandari, Joint Secretary, Ministry of Health and Family Welfare Department of Health and Family Welfare, New Delhi.

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Registration of Indian Drug companies with Bahrain-reg.

Dear Member,

We have received a communication from Mr. Sanjay Meena, Section Officer (Policy, IC and FDI) DoP, Ministry of Chemicals and Fertilizers in regards to Registration of Indian drug companies with Bahrain as per the DoP Letter dated 03-11-2021 (as reproduced below). IDMA members are requested to attend the proposed meeting which would be intimated in due course.

Interested members are requested to forward their names, designation, mobile no. and email id to IDMA Secretariat at idma2021@idmaindia.com

Thanks & regards,

Daara B Patel
Secretary – General

Registration of Indian drug companies with Bahrain - reg.

No. 35022/25/2021-Policy, dated the 3rd November, 2021

To
IPA, IDMA, Pharmexcil

1. I am directed to refer to DO Letter No. Bah/Com/201/07/2020 dated 10.10.2021 received from Ambassador of Bahrain wherein it is inter-alia conveyed that the National Health Regulation Authority (NHRA) of Bahrain is willing to relax/simplify the registration process and also willing to facilitate export of generic drugs to Bahrain by Indian Drug Manufacturers.
2. It is also stated that there is a good opportunity for Indian Pharmaceutical companies to explore possibilities of JV / investment in Bahrain, which is a gateway to USD 1.5 trillion GCC market in addition to their own domestic market.
3. In view of the foregoing, pharmaceutical associations are requested to sensitize their member companies to register their products with NHRA to maintain their market share and benefit from the upcoming opportunities. Further, the Ambassador has also informed that they are planning to conduct a webinar with the concerned agencies of Bahraini Government i.e. National Health Regulatory Authority (NHRA), Economic Development Board (EDB), pharmaceuticals importers and exporters from India and Bahrain to discuss overall challenges faced by Indian companies to register their products in Bahrain as well as explore possibilities of JV/investment by Indian Pharmaceutical/vaccine manufacturing companies in Bahrain.
4. In view of above, it is requested to sensitize your member companies in this regard their information, awareness and active participation in the proposed meeting with the Bahraini side, details of which shall be intimated in due course.
5. This issues with the approval of the Competent Authority.

Encl:- As above.

Yours faithfully,

Sanjay Meena,
Section Officer,
DoP,
Ministry of Chemicals and Fertilizers,
New Delhi.

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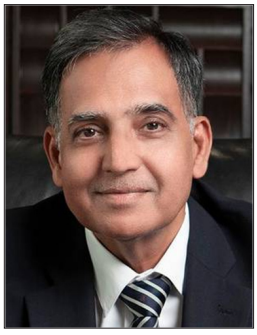
'Booster shots, pediatric jabs to keep vaccine demand high,' says Emcure MD

Phase II, III trials underway for COVID vaccine: Satish Mehta, Emcure MD



Emcure Pharmaceuticals Ltd is seeing new growth opportunities in biologics and vaccines which it intends to introduce in various emerging markets. Being the first Indian company to have developed an indigenous mRNA platform, it is in the process of developing an mRNA COVID-19 vaccine via its subsidiary Gennova Biopharmaceuticals Ltd., for which it has received funding from the Government of India. Three other vaccines on its mRNA platform are in development stages, targeted at Zoster, Zika and Rabies, said ***Satish Mehta****, MD and CEO.*

At what stage is your COVID vaccine?

In August, the Vaccine Subject Expert Committee (SEC) reviewed the interim Phase I data, and found that our vaccine candidate HGCO19 was safe, tolerable, and immunogenic in the participants of the study.

The Drug Controller General of India then approved Phase II and Phase III study protocols for the vaccine, which are currently underway in India.

We are committed to fulfilling the target of 60 million doses of our mRNA vaccine to the Government of India. As we near the final stages of trials for our vaccine, we look forward to positively contributing in the nation's fight against the pandemic.

Most Indians will be vaccinated by the time it is out. Are you not late in the game?

We are constantly watching the developments in India and all over the world. Our assessment as well as commentary by various experts indicate there will be a reasonable demand for booster shots of COVID-19 vaccines in India. There is also likely to be an additional demand from countries where large part of population has not yet been vaccinated. There is also expected to be a demand for the paediatric category in India. We will continue to work towards addressing these opportunities where mRNA platform has shown promising prospects (especially given our candidate being stable between 2-80 degree Celsius).

What is the new drug discovery pipeline at the company? How and when will they be monetised?

We are an R&D driven company and our focus has always been on science first. We have a strong track record in developing portfolios of differentiated products across several platforms, including chiral molecules, complex APIs, biologics and novel drug delivery systems. Our aim is to bring first to market specialty or differentiated generic drugs through the company's own R&D efforts which we continue to [make] to address the needs in the various geographies where we operate (i.e. India, Europe, Canada).

What are the core therapeutic areas of your work? What is the scale-up and investment plan?

In India, we are present in 19 different therapeutic areas that makes our offerings well-diversified. Seven of our brands namely Orofer, Exhep, Metpure, Asomex, Zostum and Bevon are among the top 300 selling brands in India. Our approach has been to develop a customised basket of diverse product offerings which we feel are suitable for the market allowing us to do well in various regions.

We are the largest pharmaceutical company in India in the gynaecology, blood-related and HIV antivirals therapeutic areas. We have also outgrown the Indian pharmaceutical industry in some other key areas like cardiovascular, oncology, vitamins, minerals and nutrients, anti-infectives and anti-diabetics.

We also have a good portfolio of biosimilars where three of our six brands namely Elaxim, Tenectase and Hamsyl, were each ranked first in our domestic market for FY21, in terms of sales in India for their respective

molecules. Complex injectables is another focus area for us as a technology platform. We also intend to expand our market share in newer target areas like neurology, diabetes, respiratory and gastrointestinal.

Are you planning any acquisitions?

We rely in part on inorganic growth to increase our revenue and expand our geographic presence. We have, in the past, evaluated and executed strategic acquisitions of companies, products and technologies or entered into partnerships to strengthen our product and technology infrastructure. We intend to continue to pursue strategic acquisitions across key markets and in-licensing of pharmaceutical products of other companies for our key and focus therapeutic areas

What is your five-year growth plan?

Our market share domestically has been growing steadily over the years. In the last few months, we have constantly outgrown the IPM and are now ranked among the top 12 companies in India by market share. We aspire to continue to climb the ranks in the domestic market through execution and new product launches.

For international markets, we will continue to drive growth through a combination of entering new markets, and gaining additional share in existing markets driven by new product registrations and pipeline, thanks to our R&D efforts.

How much debt do you carry? What is the debt-reduction plan?

As on March 31, our net debt stood at ₹1,589 crore. We intend to utilise a majority of the net proceeds from our forthcoming IPO towards repayment or prepayment of all or a portion of the principal amount on certain loans availed by us and the accrued interest.

Source: Lalatendu Mishra, The Hindu, 06.11.2021

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Little droplets make the ocean of drug discovery

How sound waves can speed up the quest for new medicines

Imagine a valiant king, skilled in combat and raring to go to battle, waiting droopily on the steps of his palace for his charioteer and horses, who are delayed at lunch!

In drug discovery, there are many such 'horses' that are meant to take the drug to the right cell in the body. They transport cells and chemicals to the target region. In a process already fraught with uncertainty and high chances of contamination, these 'horses' should ideally be on-demand — ready to move or retire instantaneously.

While trying to discover a drug, you are essentially getting thousands of different molecules to react with thousands of cells, to find out which molecule works best on which cell — to pick a winner.

The conventional way is to put the cells in thousands of "micro-wells" to react with different molecules. But that is laborious, expensive.

Prof Ashish Kumar Sen of the Department of Mechanical Engineering, IIT Madras, working in collaboration with the Lund University of Sweden, has come up with a novel method — generating droplets using sound waves. Each droplet (about a trillionth of a litre) is like a micro-well — so, at one go, you have thousands of droplets containing the cell and a molecule; you take the droplets past a detector, you will be able to see which molecule works best. While the 'droplet' method itself is not new, Prof Sen's innovation is in using sound waves to produce them.

Lab-to-market speed

Conventionally, a droplet is made of a minuscule volume of a liquid surrounded by another immiscible fluid, and is generally produced by adjusting the volume flow rates of the two parallel streams of fluids in contact with one another. The formation of droplets in such a process is due to an instability caused by the minimisation of interfacial energy, related to interfacial tension and hydrodynamic force.

The IIT Madras researchers have, for the first time, produced droplets through an alternative way: exposing the parallel streams of fluids to sound waves.

Sound-induced on-demand droplets can be produced within 10 milliseconds, as compared to 100 milliseconds in the conventional process. Do the few tens of milliseconds make such a difference? On a scale of 1,000 by 1,000 imponderables, it does.

And this, Prof Sen believes, could cut the time taken to discover new drugs. "The typical cycle for a new drug to hit the market is 10 years. This could be significantly reduced with technology like sound-induced droplets."

Chemical reactions take place inside droplets. Droplets carrying different types of cells and others carrying different types of chemicals can be merged in various combinations to facilitate reactions for high throughput screening in an automated fashion, he explains.

A range of applications

The use of sound to control droplet formation, rate and size is also well suited for applications that require on-demand and fast transition, such as microfluidics, emulsification, and encapsulation.

The team is now working towards using their sound-based droplet generation to encapsulate biological cells in droplets. This would enable single-cell analysis techniques, which, in turn, would help in designing improved diagnostic and therapeutic processes.

Not only drug discovery, droplets are useful in drug delivery, too. For example, they are used in timed-release tablets. When the time taken to create these droplets is cut by a tenth, and it is also 'on-demand', Prof Sen says the whole process could likely be speeded up for the manufacture of drop-encapsulated drugs. "There is a good chance (of that happening)... we haven't really noticed studies, in that sense. The technology is here as a proof of concept."

The icing on the cake is that labs don't need sophisticated equipment to produce sound to induce droplets. "We used a simple piezoelectric transducer; any average lab can procure it for a couple of thousand rupees."

Source: K Bharat Kumar , The Hindu Business Line, 07.11.2021

Centre places purchase order for one crore doses of Zydus Cadila's needle-free Covid vaccine

The Union Health Ministry is learnt to have given the go ahead to initiate the preparatory work for the introduction of the indigenously developed world's first DNA-based Covid jab, which in all probability will be given to adults initially under the country's vaccination drive, sources in the know of developments said.

NEW DELHI: Zydus Cadila's three-dose Covid vaccine ZyCoV-D is set to be included in the national anti-coronavirus inoculation programme this month with the Centre placing a purchase order with the Ahmedabad-based firm for one crore doses, official sources said on Sunday.

The Union Health Ministry is learnt to have given the go ahead to initiate the preparatory work for the introduction of the indigenously developed world's first DNA-based Covid jab, which in all probability will be given to adults initially under the country's vaccination drive, sources in the know of developments said.

ZyCoV-D is the first vaccine cleared by India's drug regulator for inoculation of those aged 12 years and above.

"The Centre has already placed a purchase order with Zydus Cadila for supply of one crore doses of ZyCoV-D, each costing around Rs 358 excluding taxes, at the earliest. This price includes the cost of a disposable painless jet applicator which has to be used for administering each dose," an official source said.

"The vaccine in all probability will be given to adults initially because of limited production capacity," the source said.

Zydus Cadila is in a position to provide one crore doses of ZyCoV-D per month, company officials are learnt to have conveyed to the ministry.

For administering to adults, frontline workers and vaccinators will be provided a brief training for using the needle-free pharma jet application in actual field settings. The three doses of ZyCoV-D are to be administered 28 days apart, with each dose comprising a shot in both arms. ZyCoV-D received emergency use authorisation from the drug regulator on August 20.

Meanwhile, a comprehensive programme for paediatric immunisation including developing a priority list of comorbidities is being worked out by the NTAGI (National Technical Advisory Group on Immunisation) for the launch of ZyCoV-D and Covaxin.

As for the emergency use approval for Bharat Biotech's Covaxin in the 2 to 18 years age group by the Drugs Controller General of India, it is under expert opinion and evaluation, official sources said.

The Subject Expert Committee (SEC) on COVID-19 of the Central Drug Authority on October 12 had recommended granting emergency use authorisation to Covaxin for children and adolescents in the 2 to 18 years age group with certain conditions.

At present, every citizen who is 18 years or above is eligible for the vaccination drive.

Source: ETHealthworld.com, 07.11.2021

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Directors can't be booked just because firm violated law: SC

NEW DELHI: The Supreme Court has asked investigating and prosecuting agencies not to proceed mechanically against directors of erring companies merely because of the post held and said such avoidable prosecution leads to humiliation and loss of reputation in the society.

Quashing prosecution and summons issued to a director of a company which allegedly failed to pay minimum wages to some workmen, a bench of Justices R S Reddy and Sanjiv Khanna said, "A person cannot be prosecuted and punished merely because of their status or position as a director, manager, secretary or any other officer, in a company unless the offence in question was committed with their consent or connivance or is attributable to any neglect on their part."

The important clarification will offer relief to persons holding these positions.

Section 22C of the Minimum Wages Act provided that "if the person committing any offence under this Act is a company, every person who at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly".

It said the exact role of the officer proceeded against must be delineated by the prosecution. The SC said vicarious liability would be attracted only when the offence was committed with the consent, connivance, or is attributable to the neglect on the part of a director, manager, secretary, or other officer of the company and not merely because the person holds a responsible post in the company.

Justices Reddy and Khanna said that arresting directors and officers of a company, without them having even any remote role in the perpetration of the alleged violation of law by the company, is fraught with serious consequences and must be avoided at all costs.

"Initiation of prosecution and summoning of an accused to stand trial has serious consequences. They extend from monetary loss to humiliation and disrepute in society, sacrifice of time and effort to prepare defence and anxiety of uncertain times. Criminal law should not be set into motion as a matter of course or without adequate and necessary investigation of facts on mere suspicion, or when the violation of law is doubtful," the bench said.

"It is the duty and responsibility of the public officer to proceed responsibly and ascertain the true and correct facts. Execution of law without appropriate acquaintance with legal provisions and comprehensive sense of their application may result in an innocent being prosecuted," it said.

Source: Dhananjay Mahapatra, TNN, 06.11.2021

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India reaches out to more countries to accept Covaxin

Simultaneously efforts are ongoing to impress upon countries to recognise Covaxin, said people aware of the matter. The list of co- ANI untries accepting Indians vaccinated with Covaxin is expected to rise following the WHO's decision, they said.

More than 20 countries have allowed vaccinated Indians entry – mostly with Covishield and some with both Covishield and Covaxin – without being quarantined and vice versa, according to the MEA data.

Buoyed by the World Health Organization's approval of Covaxin for emergency use, India has launched a diplomatic initiative to expand the list of countries that would mutually recognise vaccine certificates enabling smoother travel for Indians.

The Ministry of External Affairs (MEA) and India's diplomatic missions globally have been holding negotiations with their interlocutors to secure mutual recognition of vaccine certificates and the WHO's decision on Bharat Biotech's locally made Covaxin has boosted their efforts, ET has learnt.

Simultaneously efforts are ongoing to impress upon countries to recognise Covaxin, said people aware of the matter. The list of countries accepting Indians vaccinated

with Covaxin is expected to rise following the WHO's decision, they said.

Apart from Australia, the countries which have approved Covaxin include Mauritius, Oman, Philippines, Nepal, Mexico, Iran, Sri Lanka, Greece, Estonia and Zimbabwe.

Travellers who have taken both doses of Covaxin will be allowed to enter the US from November 8. The new US travel rules will also accept travellers fully vaccinated with Pfizer-BioNTech, Johnson & Johnson, Moderna, Oxford-AstraZeneca, Covishield, Sinopharm and Sinovac.

Seven countries – Hungary, Serbia, Estonia, Kyrgyzstan, Palestine, Mauritius and Mongolia – have decided to mutually recognise vaccine certificates, and the numbers are expected to rise based on the ongoing discussions in the various world capitals, said the people.

More than 20 countries have allowed vaccinated Indians entry – mostly with Covishield and some with both Covishield and Covaxin – without being quarantined and vice versa, according to the MEA data.

At the recently concluded G20 Summit in Rome, India had proposed mutual recognition of Covid-19 certificates. Subsequently, the G20 leaders decided to work towards reopening international travel by acknowledging mutual recognition of vaccine certificates. "Issue of vaccination certificates was discussed especially with EU representatives.

There was a conversation on mutual recognition of vaccines...a doable mechanism to facilitate easier international travel... Details will be worked out bilaterally," foreign secretary Harsh Shringla had told media persons after the PM's meetings with the EU leadership in Rome on the sidelines of the G20 meet on October 29.

"Fact of the matter is that the point the PM tried to make (on vaccine certification) has been received. Most countries are quite happy with the idea of facilitating smoother international travel...and feel that we need to collectively work on it," Shringla had said.

Source: Dipanjan Roy Chaudhury, ET Bureau, 06.11.2021

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Finance Ministry invites suggestions for changes in direct, indirect taxes from trade, industry bodies

The Finance Ministry has invited suggestions for changes in direct and indirect taxes in the Union Budget, from trade and industry bodies. Suggestions can be submitted on or before November 15, 2021.

The Union Budget for Fiscal Year 2022-23 is expected to be presented on February 1. **Direct taxes include Personal Income Tax, Corporate tax, Equalization levy and Securities Transaction Tax, while indirect taxes refer to Central Excise Duty and Custom Duty.**

"You may like to send your suggestions for changes in the duty stricture, rates and broadening of tax base on both direct and indirect taxes, giving economic justification for the same," a Revenue Department's letter addressed to Trade and Industries Association said.

Talking about direct taxes, the department said: **"As can be seen that the Government policy with reference to direct taxes in the medium term is to phase out tax incentives, deduction and exemptions, while simultaneously rationalizing the rates of tax."**

Accordingly, it said that it would also be desirable that while forwarding the suggestions/ recommendations, positive externalities arising out of the said recommendations and their quantifications are also indicated. **"You may also like to give suggestions for reducing compliances, for providing tax certainty and reducing litigation,"** the letter said.

The 2020-21 budget noted that the Income-tax Act provided more than one hundred exemptions and deductions of different nature. **"I have removed around 70 of them in the new simplified regime. We will review and rationalise the remaining exemptions and deductions in the coming years with a view to further simplifying the tax system and lowering the tax rate,"** Finance Minister Nirmala Sitharaman had said.

Similarly, for indirect taxes, **the 2020-21 budget withdrew 80 exemptions related to customs duty, while the 2021-22 budget proposed to review more than 400 old exemptions through extensive consultations from October 1, 2021.**

The department clarified that **GST related requests were not examined as part of the Annual**

Budget. Hence, **recommendations and suggestions should be related to Central Excise and Custom Duty. GST related issues have been discussed and decided by the GST Council since 2017.**

The department has asked trade and industry bodies to supplement and justify their suggestions and views by relevant statistical information about production, prices, revenue implication of the changes and any other supporting information.

The department made a specific mention about the inverted duty structure (higher duty on input and lower duty on output). It said the request for correction of an inverted duty structure for a commodity should necessarily be supported by value addition at each stage of manufacturing. **"It would not be feasible to examine suggestions that are either not clearly explained or which are not supported by adequate justification/statistics,"** the department said.

Source: The Hindu Business Line, 05.11.2021

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Explained: What it takes to run child trials for a Covid-19 vaccine

JAB AT HAND: From encouraging people to volunteer to screening kids and winning their confidence

If the staff senses hesitancy in the child, it does not enrol the kid for trials even if parents have consented

Anjana Tewari (name changed) is unhappy that she got late by a day for registering her two-and-a-half-year-old daughter for paediatric vaccine trials at the All India Institute of Medical Sciences (AIIMS) Patna. She says she did have apprehensions about possible adverse reactions during the trial, "but is there no risk in keeping my daughter unvaccinated? My husband and I are both fully vaccinated with Covaxin and we worried about our daughter not having the same level of protection."

AIIMS Patna was among a dozen sites nationwide that were earmarked for phase 2 and 3 paediatric trials of Covaxin. And among those who took a leap of faith was an associate professor at the hospital, who chose to register both her sons, aged seven and 14, for the trials. In December 2020, this doctor had also volunteered for phase 3 adult trials of Covaxin, the Covid-19 vaccine domestically manufactured by Bharat Biotech.

The first vaccine to get emergency use authorisation (EUA) for 12- to 18-year-olds in India is the needle-free Zycov-D from Zydus Cadila. This is a three-dose vaccine, to be given on day zero, day 28 and day 56. Bharat Biotech's Covaxin, already in use for adults, is awaiting EUA. And paediatric trials are on for the third vaccine, Covovax, which will be manufactured by the Serum Institute of India in partnership with US-based Novavax Inc.

Behind each of these vaccines are hundreds of parents who had the courage and conviction to come forth with their children for the trial of a vaccine, which was, until then, untried in that age group. India has a large paediatric population — estimated at anywhere between 42 and 44 per cent, hence the urgent need for a children's vaccine, and for volunteers.

At AIIMS Patna, trials were conducted in three batches, says Sanjeev Kumar, head of Cardio Thoracic Surgery and the nodal officer for Covid-19: first, for 12-18-year-olds, then 6-12 and lastly for 2-6. Older children were given the doses first because the chance of any adverse reaction in them is lesser. Adults have "more cardiac reserve than kids; they have better developed organs, so any adverse reaction can be dealt with better," Kumar explains.

Vax trial on boarding

In the 12-18 age group, AIIMS Patna screened 185 children but only 90 were ultimately administered both doses of Covaxin. The rejections were due to the exclusion criteria, which included fever or existing acute illness, severe malnourishment or previous exposure to Covid-19.

Kumar said nearly every second child of the 185 tested was found sero positive (had Covid-19 antibodies) and had to be turned back.

"We used print media and television for appeals to the public to come forward for trials, told them about benefits of vaccines and also pointed out that by allowing their children to participate in these trials, parents would be creating history," says Kumar. "We also assured parents that only 50 per cent of the participants would be getting the vaccine; the remaining 50 per cent would be given a placebo. And also pointed out that those children who get vaccinated during the trials would become safe from Covid-19 much before other children do."

The doctor from the hospital who registered her children for the trial was also actively involved in a month-long campaign to enrol kids, and she coordinated with Delhi Public School, Patna and Foundation School, Buxar. These two, and other local schools, were roped in for educating parents about the benefits of the vaccine and encouraging them to bring their children for trials. She says that in Buxar, she shared her own experience of participating in the adult trial and to convince parents, she emphasised that the vaccine shot produced "minimal side effects".

Teachers, senior students and principals of different schools in the state were spoken to, and she says that apart from a few, most children who eventually participated in the trials were from non-medical families.

The trial was on for two months for the 12-18-year-olds. Some kids developed fever and some had pain at the injection site. But none faced any severe allergic reaction and no participant needed hospitalisation, Kumar says. Then the hospital turned to the 6-12-year group. Here, nearly 60 kids participated in the trials; and for the 2-6 age bracket, 50 were administered the vaccine. In neither of these two age groups, too, were there any adverse events, says Kumar.

Well aware of how kids feel about needles, the hospitals tried to take some sting out of the exercise. For smaller kids, the vaccination site was made child friendly, and decorated with colourful posters, toys and balloons. Children were allowed to remain in their parents' lap when the injection was being administered. And parents were offered up to Rs 800 as conveyance reimbursement for bringing their kids for the vaccine trial.

A matter of trust

Pune's KEM Hospital is one of the 10 designated sites for paediatric trials for Covovax. Ashish Bavdekar, paediatric consultant with the hospital, says KEM did not encounter any hesitancy in parents, and initial recruitments for paediatric trials happened smoothly.

KEM Hospital has been conducting large vaccine trials for the last 20 years and has a full clinical trial unit. It was also the site for adult trials for Sputnik and Covishield vaccines, besides adult trials for Covovax. Bavdekar says parents are generally not hesitant because the vaccine maker is well known and trusted; there is enough data already available to assure them of nearly 95 per cent protection, and paediatric trials done in other countries have been safe. "Most adults are already vaccinated and hence not keen to take part in studies for new vaccines themselves, but they are keen to get their kids vaccinated," he says.

However, if the staff senses hesitancy in the child, it does not enrol the kid for trials even if parents have consented because multiple visits and jabs are needed for the trial and in the follow-up period. At PGIMER Chandigarh, too, paediatric trials for Covovax are starting. Madhu Gupta, the principal investigator, says the first batch will comprise kids between the ages of 7 and 12; and 2-7-year-olds will follow.

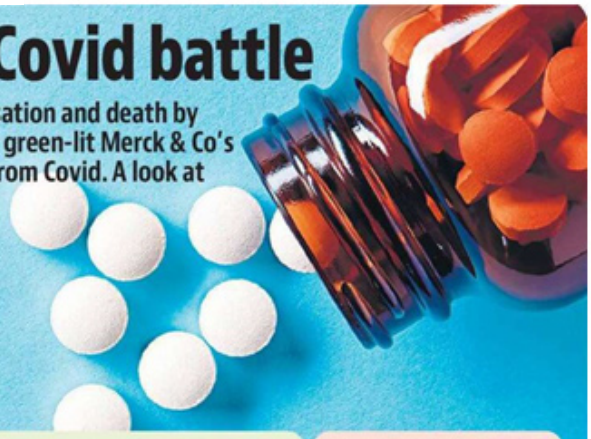
All the approved trial sites follow competitive recruitment. So each site competes for the number of children recruited in each age group from the approved sample size. PGIMER has made registration easily accessible by putting up a link on its website. The trials are sponsored by SII. The notice makes it clear that participation is "purely on a voluntary basis" and that children over 12 can self-register. Gupta says no incentives — not even toys — are on offer, and only the travel spend of parents will be reimbursed. Only word-of-mouth publicity is being done for the paediatric trials but the hospital may consider more publicity programmes if the need arises. The target is to recruit 150-200 children between 2-17 years and ultimately conduct trials on 100. "Generally people trust PGIMER, so that trust will help in encouraging parents to bring their kids for trials," Gupta says.

Vaccines and trust clearly go a long way.

Source: Sindhu Bhattacharya , Business Standard, 08.11.2021

Pills that look to transform Covid battle

Pfizer's experimental antiviral pill for Covid-19 cuts the rate of hospitalisation and death by nearly 90%, the company said on Friday, a day after the United Kingdom green-lit Merck & Co's antiviral drug which claims to halve the risk of hospitalisation or death from Covid. A look at how these two pills may transform the world's battle against Covid.



WHY A PILL-BASED TREATMENT IS CRUCIAL

Currently nearly all Covid-19 treatments being widely used require an IV or injection. Researchers worldwide have been racing to find a pill against Covid-19 that can be taken at home to ease symptoms, speed recovery and reduce the crushing burden on hospitals and doctors.

TO BUTTRESS VACCINATION: Expert stress that vaccination still remains the best way to protect against infection, but with billions in the world still unvaccinated, effective, easy-to-use treatments will be critical to curbing future waves of infections.

Pfizer PAXLOVID BY PFIZER

↓89% RISK OF HOSPITALISATION OR DEATH

Pfizer's drug, called Paxlovid, achieved an 89% reduction in risk of hospitalisation or death among adult patients with Covid who are at high risk of progressing to severe illness, the drugmaker said

THE FINDINGS

1,219 unvaccinated adults were part of the drug trial

IN THE TREATMENT GROUP

0.8% people were hospitalised | **0** deaths

IN THE CONTROL GROUP

7% people were hospitalised | **7** deaths

"We were hoping that we had something extraordinary, but it's rare that you see great drugs come through with almost 90% efficacy and 100% protection for death."
— Dr MIKAEL DOLSTEN, chief scientific officer, Pfizer

HOW IT WORKS: The drug binds to an enzyme called a protease to stop the virus from replicating itself. Some drugs for HIV work in a similar way.

APPROVAL SOUGHT: Pfizer said it will ask the US Food and Drug Administration (FDA) and international regulators to authorise its pill as soon as possible. Once Pfizer applies, the FDA could make a decision within weeks or months.

MERCK INVENTING FOR LIFE MOLNUPIRAVIR BY MERCK

↓50% RISK OF HOSPITALISATION OR DEATH

Merck's Covid-19 pill was on Thursday approved in Britain, which became the first country to approve a potentially game-changing treatment. It will be administered as soon as possible following a positive Covid-19 test and within five days of the onset of symptoms, the regulator said, citing clinical data.

THE FINDINGS

775 unvaccinated adults were part of the drug trial. In the of five days of treatment, the pill dramatically reduced the rate of hospitalisation

IN THE TREATMENT GROUP

7.3% people were hospitalised | **0** deaths

IN THE CONTROL GROUP

14.1% people were hospitalised | **8** deaths

HOW IT WORKS: Molnupiravir is designed to introduce errors into the genetic code of the coronavirus and is taken twice a day for five days

ROLL-OUT ALREADY BEING PLANNED: Professor Stephen Powis, national medical director for the National Health Service (NHS) in England, said the drug would be administered to patients at higher risk of complications. A wider rollout will follow if it is shown to be clinically and cost effective

CURRENT OPTIONS FOR TREATMENT

There are currently two other major Covid-19 treatment options that are widely used across the world. These are

- GILEAD'S INFUSED ANTIVIRAL **REMDESIVIR**

- GENERIC STEROID **DEXAMETHASONE**

However, these are generally only given after a patient has been hospitalised and are administered by IV or injection at hospitals or clinics

Source: Hindustan Times, 06.11.2021

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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 07.11.2021

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**