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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 08 (PAGES: 28) | 22 TO 28 FEBRUARY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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IDMA - TATA nexarc Webinar :

Growth opportunities for Indian Businesses: Unlocking value to SMEs through BSE SME and start-up platform" to be held on 4th March 2022, 4 pm - 5.30 pm

(Details on Page No. 4)

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★ **Mandatory filing/issuance of Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) through the DGFT common digital platform from 01.04.2022** *(Page No. 17)*

★ **DGFT Helpdesk for Russia-Ukraine related International Trade Issues** *(Page No. 17)*

★ **Why MNC pharma companies are realigning their India operations** *(Page No. 21)*

★ **India-UAE trade pact set to boost pharma exports** *(Page No. 24)*

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IDMA BULLETIN

Vol. No. 53 Issue No. 08 22 to 28 February 2022

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TATA nexarc

Dear members,

Tata nexarc, in association with Indian Drug Manufacturers' Association (IDMA), is delighted to invite you to a webinar 'Growth opportunities for Indian businesses: Unlocking value to SMEs through BSE SME and start-up platform'.

Exclusive presentation by Mr. Anand Chari, DGM, SME Business Development at BSE on:

- SME and start-ups' IPO funding
- Unlocking value to SMEs through BSE SME and start-up platform

---

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4 March 2022, Friday 4 – 5:30 pm

Limited seats. Click here to register.

Regards,

Team Tata nexarc

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RNA BASED THERAPIES - A POSITIVE OUTCOME OF COVID-19

Dr. George Patani, *Associate Editor, Indian Drugs*

Dear Reader,

It was way back in December 2014 that Ella Watson-Stryker was named TIMES Person of the Year for 2014 and featured on the Cover of Time Magazine. Dr Watson-Stryker was recognised with the honour, which she shared with all the healthcare workers who, under trying circumstances,helped people in various west African countries fight the Ebola virus. While many experts predicted that the Ebola virus might cause a pandemic like situation across the world, the efforts of the healthcare workers ensured that Ebola virus was contained. However, the COVID-19 pandemic nearly five years later created a similar desperate situation not just in a small region of the world but all across the globe. This desperate situation however, has facilitated the rapid development and acceptance of a new class of therapeutics called RNA based therapies.

The 2006 Nobel Prize in Physiology and Medicine was awarded to Andrew Fire and Craig Mello for discovering RNA interference (RNAi). Alnylam Therapeutics won the first approval for a RNAi based drug in 2018. However, the COVID-19 pandemic has helped RNA based technology to evolve rapidly. Two companies Moderna Therapeutics and BioNTech gained approvals from the FDA in the US and exponentially increased their revenues to billions of dollars over the past two years by commercializing RNA based vaccines for COVID-19. Today an entire new class of drugs based on RNA technology, targeting various diseases is expected to come to the market at a much more rapid pace as a result of the acceptance of the RNA based vaccines. The earlier issues associated with the delivery of these RNA based therapeutics have been resolved and the successful delivery to the targeted site has been demonstrated with the use of Lipid carriers. India's first mRNA based vaccine by Gennova

Dr George Patani, *is a Pharmacist from the College of Pharmaceutical Sciences, Manipal. He completed his Masters in Medicinal Chemistry and Ph.D. in Drug Delivery from the Rutgers, The State University of New Jersey. He has approx. 22 years' experience at the INGA group of companies (namely Inga Laboratories P. Ltd and Inga Pharmaceuticals), developing and manufacturing phytochemical APIs and finished dose formulations. This experience has included an extensive record of project leadership in pharmaceutical formulation development and regulatory affairs. He has authored a number of scientific publications and book chapters with over a 1000+ citations from individual manuscripts.*

Dr Patani is currently the Vice-President (Western Region) of the Indian Drug Manufacturers' Association 2022-till date. He was previously the Hon. Gen Secretary 2020-2021, Hon. Treasurer of IDMA 2017-2019, Chairman of IDMA's publication committee since 2012 and Chairman of IDMA's Industry Institute Interaction Committee from 2014 to 2019. He has been a recipient of the Outstanding Alumnus Award 2016 and Distinguished Alumnus Award 2005 from Manipal University. He has served on various committees such as the Crude Drugs and Herbal Products Committee of the Indian Pharmacopoeial Commission and the Reach Monitoring Committee of the TIFAC CORE in genomics at Manipal Academy of Higher Education etc.

Biopharmaceuticals is currently undergoing Phase II and Phase III clinical trials. We look forward to the successful indigenous development of this new class of vaccine and eventually the development of a new class of drugs in India for the treatment of various diseases.This will put India on a faster trajectory of establishing itself not only as a formidable supplier of generic drugs but also as an innovation hub for drug discovery.

As we move into this mode of innovation and develop new therapies, it is important that we improve the quality and scientific rigor used in our research methodologies. This calendar year, we wish to thank all our Reviewers, Editorial Board Members and Editorial Advisory Board Members who have spent their valuable time reviewing the large number of manuscripts that we received. We are grateful to them for their dedication and commitment to improve the research ***temperament*** *of the manuscripts published in INDIAN DRUGS. An analysis of the manuscripts reviewed, indicates that only 25% of the manuscripts submitted are accepted for publication after an extensive peer review process by our editorial team.*

It is observed that when we provide feedback to the authors of the various manuscripts, some authors take the comments of our reviewers positively and revise the manuscript promptly and diligently, improving the quality of their manuscripts.On the other hand, many authors defend their manuscripts and find fault with the reviewers and insist on the acceptance of a poorly presented or designed research output.

In research conducted and published in the Journal Neuron (Bhanji, J. P. et al., Neuron. 2014 September 17; 83(6): 1369-1375), it was noted that on receiving a failing grade, while one student vows to do better, the other gives up. The student resolves to do better if failure was attributable to controllable factors i.e. he had studied differently, however a student gives up if failure was due to uncontrollable factors i.e.the professor was biased or the questions were unfair. Hence, our editorial team always suggest improvements that will help to improve the manuscript and facilitate acceptance. We look forward to increasing the acceptance rate of the manuscripts received, and hope the authors of the various manuscripts submitted to INDIAN DRUGS take control and address these suggestions positively resulting in greater acceptance ratios of all the manuscripts received.

Happy Reading and Wishing all a Happy New Year.

Courtesy: Indian Drugs, Editorial, 58 (12), December 2021

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Report on IDMA - SAP Webinar on "Generating global opportunities for a future-ready India today"

IDMA - SAP webinar on "Generating global opportunities for a future-ready India" was held on Friday, 4th February, 2022 from 3:00 PM - 4:00 PM. Webinar was successful with the active participation of members and excellent & elaborate addresses by the speakers.

Mr. Daara B. Patel, Secretary-General, IDMA welcomed all the participants and speakers. He informed this is the second in the series of SAP's initiative of Global Bharat Program. For those of you who had attended last year. We had the first webinar last year on 26th August 2021 wherein we learnt how a company can join the program and expand its reach to the global markets. *(Excerpts from Mr. Daara B Patel's welcome address is published in the following pages)*

Dr. Viranchi Shah, National President, IDMA in his opening remarks informed technology is a big enabler of business success. Adopting right technologies – both pharmaceutical technologies and Digital & Computational technologies - will be of critical for a successful companies of future. SAP is doing good work to help us get digital. There are other platforms also. Those of us who can use technology to grow have a very high probability to succeed. *(Excerpts from Dr Viranchi Shah's address is published in the following pages)*

Ms. Nikita Das, Sr Director, Brand, Midmarket & Business Marketing, SAP India discussed about Building a Global Bharat with SAP – Enabling Indian MSME compete globally.

Mr. Pavan Somayajula, Executive Vice President & CIO, Lorhan IT made a presentation on SAP Capabilities and its agenda. He informed Lohran is an SAP Partner and discussed what they do as a system integrator to support SAP.

The webinar had a panel discussion and an excellent Questions & Answers session.

Panel discussion moderated by Mr. Daara B. Patel, Secretary-General, IDMA and Panel members were;

- Mr. Rajesh Kuppuswamy, Life Sciences & Healthcare Industry, Advisor SAP
- Mr. Pavan Somayajula, Executive Vice President & CIO, Lorhan IT
- Mr. Dinesh Chindarkar, Founder Media Medic Communications
- Mr. Jay Patel, Joint Managing Director, Astral SteriTech Pvt. Ltd.

Following Questions were discussed at the webinar and they were been answered very well.

- Consumer acceptance of smart devices to receive care is changing the face of the way business is done in this industry. What according to you would be the primary trends in this evolving business model?
- As we are speaking more about digital collaboration here, we are talking about data, privacy and security. As a digital transformation enabler, how crucial is customer centricity?
- As we see the disruptions has brought in many challenges, it has also created some opportunities for Healthcare industries, What according to you can we recommended to ensure there are no loose ends & opportunities are addressed?
- There is a paradigm shift in how business was done in this industry few years back to now. What are your mantras of staying competitive?
- Is technology going to be the bridge between the changing times?
- What according to you will be the prospects of growth in this sector in the next 3-5 years?
- Would you say that new reforms & policies are imperative in strengthening the industries in MSME Segment within healthcare / pharma?
- Do you see technology as an enabler and if yes what advise you want to share with your counterparts in the industry?

Mr. S R Vaidya, Chairman, MSME Committee, IDMA proposed the vote of thanks. *(Excerpts from Mr. S R Vaidya's vote of thanks is published in the following pages)*

(For more details on the webinar and Questions & Answer sessions, members are requested to visit link https://youtu.be/InkrrRrbjS4)

Glimpses of webinar

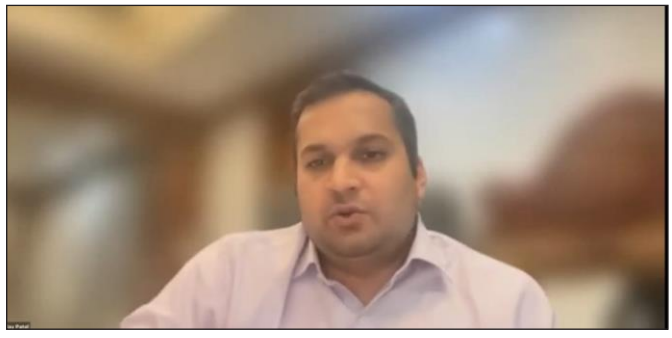
Dr. Viranchi Shah, National President, IDMA

Mr. Rajesh Kuppuswamy, Life Sciences & Healthcare Industry, Advisor SAP

Mr. Daara B Patel, Secretary-General, IDMA

Mr. Dinesh Chindarkar, Founder Media Medic Communications

Ms. Nikita Das, Sr Director, Brand, Midmarket & Business Marketing, SAP India



Mr. Jay Patel, Joint Managing Director, Astral SteriTech Pvt. Ltd.

Mr. Pavan Somayajula, Executive Vice President & CIO, Lorhan IT

Mr. S R Vaidya, Chairman, MSME Committee, IDMA

Welcome Address by Mr. Daara B Patel, Secretary-General, IDMA

Good Afternoon Ladies and Gentleman!

Greetings from Indian Drug Manufacturers' Association (IDMA), SAP and SAP's Partner Lorhan IT Services Pvt. Ltd.

It gives me great pleasure to welcome all of you, a warm welcome on behalf of our National President, Dr. Viranchi Shah and SAP, welcome to this very intriguing & need-of-the-hour webinar titled **"Generating Global opportunities for a future-ready India".**

This is the second in the series of SAP's initiative of Global Bharat Program. For those of you who had attended last year. We had the first webinar last year on 26th August 2021 wherein we learnt how a company can join the program and expand its reach to the global markets.

Global Bharat Program has been the next big wave of Digital Transformation in MSME a very important Segment of the Pharma Industry. This program has been designed to enable Indian MSMEs to become globally competitive by equipping them with digital technologies.

It's gives me great pleasure to kick off the first webinar of SAP Global Bharat 2022 in association with SAP Partner "LORHAN IT SERVICES" - An innovation-driven technology partner with more than a decade in IT services and offering services such as implementation, upgradation, custom extensions and annual maintenance services etc for India's MSME.

Indian Drug Manufacturers' Association (IDMA) has successfully completed 60 glorious years of its existence, providing support to its members for supplying quality affordable medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located in Tamil Nadu, Kerala & Puducherry, Gujarat, West Bengal, Haryana, Himachal Pradesh & Uttarakhand, Madhya Pradesh, Telangana & Karnataka.

The global crisis has forced a lot of businesses to reassess their strategies and include **'out of the box'** reforms and solution to not just sustain but grow their business.

India's MSME segment is one of our economy's most potent growth engines. Now with the clarion call to **Make in India** and build an **Atmanirbhar Bharat**, self-dependent India today, the national expectations are pinned on this sector more than ever. So it is time for Leaders like you to embrace technology for sustainable growth and greater resilience. IDMA & SAP invites you to join us in this webinar and discover how your business can access the right technology platforms and solutions to explore new global market opportunities and enable a digital-first company.

As you all are aware that there are many modules to support business requirements and I am sure that by using SAP programs we can process business in a seamless manner. We can integrate other ERP systems to SAP which enables better platform with tracking and traceability for different business processes. The different modules available in SAP are procurement management, warehouse management, production planning, plant maintenance, Quality management, etc. These modules are interconnected with each other. Hence, we can get end to end processing data of the business. Trending and evaluation of data is available immediately / 24x7 as data is available in electronic form. All the transactions and activities are traceable through audit trails. Hence all the processes are completed keeping the necessary compliance in mind.

In order to be globally competitive, MSMEs need to think of reinventing their business models. Therefore, Digitalization and Technology adoption should be the first step for MSMEs to be globally competitive. Global Bharat Program has proved to be an important milestone in this journey.

IDMA itself has a very important active MSME committee, which is headed by Mr. S.R Vaidya and under our new President Dr. 'Viranchi Shah IDMA has formed a New Committee titled **"DIGITAL INITIATIVES COMMITTE"** with Mr. Kamlesh C Patel of West Coast Pharmaceutical Works as our Chairman and Mr. Jay Patel of Astral Steri Tech Pvt. Ltd. as the Vice Chairman.

I request all Interested IDMA members have been invited to join this Digital Initiatives Committee.

We have excellent speakers from SAP and Lorhan IT Services Pvt. Ltd. who would be discussing the critical aspects of how technology is helping the MSME organizations to be future ready & be competitive in global market space. We have an esteemed panel from SAP, Lorhan & our own Experts from IDMA.

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we would all be more eager to join the program and know more about the Global Bharat initiative.

Till Then, Stay Safe, Stay Well and Stay Connected.

Thank you & Welcome

I am glad our National President, Dr. Viranchi Shah despite his busy schedule is present here and I request him to address the august gathering and welcome you all formally.

Dr. Viranchi Shah is Ph D

Entrepreneur & Pharmacist

Dr. Viranchi Shah was the first member to be elected to the position of Senior Vice President.

He took over as National President for the year 2022 – 2023 in Jan 2022.

A PhD (Business Admin), MBA, B.Pharm (Hons.) (Gold Medalist), He is also the Chairman of the Pharma & Healthcare Taskforce, Gujarat Chamber of Commerce & Industry (GCCI).

Member, Dept. of Pharmaceuticals Committee on Reducing Compliance Burden in Pharma, Ministry of Chemical & Fertilizers, Govt. of India.

He has been a trustee of B. V. Patel Pharma Education and R & D Centre.

A well-known Entrepreneur & Pharmacist. He is the Promoter and Director of Saga Laboratories Ltd.

He has been a Key note speaker at more than 100 National events and has won several National awards.

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Opening Remarks by Dr. Viranchi Shah, National President, IDMA

Dear Daaraji. Thank you for the introduction and a warm welcome.

Today, I came across a news that said that NASA has launched a NASA Deep Space Food Challenge that encourages experts to propose sustainable food solutions and ideas that could be used by NASA to solve food challenge for astronauts taking deep space expeditions, and that NASA will award a Million dollars to the best idea.

Today, IDMA, SAP India and the Growth forum are doing exactly the opposite; not only are we giving our Million Dollar ideas to IDMA members, but we are giving them for free, and bringing the solution right to their doorstep through the virtual mode.

Today, as we discuss the ideas for creating global opportunities for a future ready India, I am sure there will be great take-homes for the IDMA participants and some of the inputs will offer food for thought in framing their future growth strategies.

The Indian pharma is a great growth engine of the Indian economy, providing both the economic and strategic advantages to India. Exports suggest that most indicators and trends predict India scaling from current 45 Bn USD industry to 130 Bn USD by 2030. But that is not going to happen automatically. We shall need to make a START. The right START will get us the momentum to grow. I take a few minutes to highlight what START means.

S- Supply Chain, T – Technology, A – Automation, R- Research, T- Talent

I believe these 5 elements will play a major role in creating global champions from India.

Today, we have significant dependence on imports for Intermediates, APIs, Complex excipients etc. PLI has greatly helped us to prompt investments in these areas in order to bring these elements of our supply chain closer. Indigenization of these will help us truly realize our dream of making India a Self-Reliant Pharmacy of the world.

Technology is a big enabler of business success. Adopting right technologies – both pharmaceutical technologies and Digital & Computational technologies - will be of critical for a successful companies of future. SAP is doing good work to help us get digital. There are other platforms also. Those of us who can use technology to grow have a very high probability to succeed.

The cost and availability of skilled human resource is an important consideration for pharma industry. Automation in many areas will not only offset this, but will provide quicker means to do mundane and repetitive works, and will help utilize our human resources in more skilled and evolved tasks.

The current Indian product portfolio is concentrated around off-patented medicines. We need to evolve ourselves in the R&D aspects. Research need not only be NCEs, but also incremental innovations and NDDS can also be initially explored. This would help us climb up the value chain in future.

Talent is the most important resource for the industry. Cross pollination of pharmacy with data sciences, pharmacy with marketing, pharmacy with medicine, pharmacy with computational sciences- many such combos need to be developed. If we aspire to be global pharmacy, we must need to create great academic institutes- at least 2 out of top 10 global pharmacy institutes must be from India.

There is a great future in Pharmaceutical industry, should we all take the right steps forward.

Today we have a team of experts indulging and sharing their experiences with you. I wish you a happy listening and may some of these ideas help you grow.

Thank you once again for having me here. Best luck!

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Vote of Thanks by Mr S R Vaidya, Chairman, MSME Committee, IDMA

Good Evening Ladies & Gentlemen.

I am honoured and pleased to give the vote of thanks to this elite gathering. On behalf of our National President, Dr. Viranchi Shah and Secretary – General, Mr. Daara Patel, I thank SAP and SAP's Partner Lorhan IT Services Pvt. Ltd. along with their respective team members for organizing such a wonderful webinar and also for boosting the MSMEs with an Excellent Program – Global Bharat Program.

I am sure the IDMA Members specially the MSMEs Members would reap benefits from this program.

We had a fantastic panel discussion followed by an equally excellent questions & answers session. Thanks to all concerned for the same.

I thank Mr Jay Patel and Mr Dinesh Chindarkar for their time and support.

Special thanks to Dr Viranchi Shah our National President and Mr. Daara B Patel for giving our members such interesting and innovative webinars.

Request you all to take care, be safe and healthy.

Thank you.

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Building a "Global Bharat" with SAP: Enabling Indian MSME Compete Globally

Presentation by Ms. Nikita Das, Sr Director, Brand, Midmarket & Business Marketing, SAP India

Building a 'Global Bharat' with SAP

Enabling Indian MSME Compete Globally

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Why Global Bharat

Market	6.3 Crore MSMEs | Registered MSMEs : 57 Lakh 54L Micro Enterprises | 2.9L: Lakh **Small** Enterprises | 32.9 are **Medium** Enterprises
Drivers	Current Contribution- GDP: 29% | Exports : 49% | Employment 11 Crore Jobs | Add 5 Cr jobs Expected Contribution to Increase to 50% of the GDP | Contribution to Exports at 75% MSME friendly policies by the Government | Campaigns like Atmanirbhar Bharat, Make in India
Challenges	Unequipped to adapt to new business models, digital trends in consumer & enterprise behavior Still Faced with Core Issues: Talent, Financing, Market, Quality & Digitization
Focus Areas	Partner MSME's to Make India Globally Competitive • Support a Robust Supply Chain & Enable Market Access • Create avenues for recognition and guidance • Allow easier networking and knowledge sharing • Move from survival to resilience and finally growth with digital transformation

2

5

PILLARS OF GLOBAL BHARAT- 2022

Empower (with education)	Enable (with customers and technology)	Establish (by cementing leadership)
Mentorship – MENTORS OF GLOBAL BHARAT	Market Access – SAP Ariba	Business Transformation – RISE WITH SAP
Digital Literacy – code unnati	Digitization of Business – BHARAT ERP	Awards & Recognition – DARE2DREAM AWARDS 2021
Global Bharat Masterclass Series		

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Shipping Bill (Post export conversion in relation to instrument based scheme) Regulations, 2022 notified - reg.

Notification No. G.S.R.146(E), 11/2022-Customs (N.T.) dated 22/02/2022

In exercise of the powers conferred by section 157 read with section 149 of the Customs Act, 1962 (52 of 1962), the Board, hereby makes the following regulations, namely:-

1. Short title and commencement:

(1) These regulations may be called the **Shipping Bill (Post export conversion in relation to instrument based scheme) Regulations, 2022.**

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

(3) These regulations shall apply to shipping bills or bills of export filed on or after the date of publication of these regulations in the Official Gazette.

2. Definitions:

(1) In these regulations, unless the context otherwise requires, -

(a) "Act" means the Customs Act, 1962 (52 of 1962);

(b) "Conversion" means amendment of the declaration made in the shipping bill or bill of export to any other one or more instrument based scheme, after the export goods have been exported.

(c) "Instrument based scheme" means a scheme involving utilization of instrument referred to in explanation 1 to sub-section (1) of section 28AAA of the Act.

(d) "Jurisdictional Chief Commissioner of Customs" means the Principal Chief Commissioner or Chief Commissioner of Customs who has jurisdiction over the Customs station from where the export has taken place.

(e) "Jurisdictional Commissioner of Customs" means the Principal Commissioner or Commissioner of Customs who has jurisdiction over the Customs station from where the export has taken place.

(2) Words and expressions used in these regulations and not defined but defined in the Act, shall have the meanings as assigned to them in the Act.

3. Manner and time limit for applying for post export conversion of Shipping Bill in certain cases.-

(1) The application for conversion shall be filed in writing within a period of one year from the date of order for clearance of goods under sub-section (1) of section 51 or section 69 of the Act, as the case may be:

Provided that the jurisdictional Commissioner of Customs, having regard to the circumstance under which the exporter was prevented from applying within the said period of one year, may consider and decide, for reasons to be recorded in writing, to extend the aforesaid period of one year by a further period of six months:

Provided further that the jurisdictional Chief Commissioner of Customs, having regard to the circumstances under which the exporter was prevented from applying within the said period of one year and six months, may consider and decide, for reasons to be recorded in writing, to extend the said period of one year and six months by a further period of six months.

(2) For the purpose of computing the period of one year under sub-regulation (1), the period, during which stay was granted by an order of a court or tribunal, shall be excluded.

(3) The jurisdictional Commissioner of Customs, may, in his discretion, authorize the conversion of shipping bill, subject to the following, namely : –

(a) on the basis of documentary evidence, which was in existence at the time the goods were exported;

(b) subject to conditions and restrictions provided in regulation 4;

(c) on payment of a fee in accordance with Levy of fees (Customs Documents) Regulations, 1970.

(4) Subject to the provision of sub-regulation (1), the jurisdictional Commissioner of Customs shall, where it is possible so to do, decide every application for conversion within a period of thirty days from the date on which it is filed.

4. Conditions and restrictions for conversion of Shipping Bill. -

(1) The conversion of shipping bill and bill of export shall be subject to the following conditions and restrictions, namely :-

(a) fulfilment of all conditions of the instrument based scheme to which conversion is being sought;

(b) the exporter has not availed benefit of the instrument based scheme from which conversion is being sought;

(c) no condition, specified in any regulation or notification, relating to presentation of shipping bill or bill of export in the Customs Automated System, has not been complied with;

(d) no contravention has been noticed or investigation initiated against the exporter under the Act or any other law, for the time being in force, in respect of such exports;

(e) the shipping bill or bill of export of which the conversion is sought is one that had been filed in relation to instrument based scheme.

F.No.450/108/2017-Cus. IV

Manish Kumar Choudhary, Under Secretary, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi.

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Notification No. 13/2020 – Central Tax, dated 21st March 2020 amended - reg.

GST Central Tax Notification No. G.S.R.159(E), 01/2022, dated 24th February 2022

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

In the said notification, in the first paragraph, with effect from the 1st day of April, 2022, for the words "fifty crore rupees", the words "twenty crore rupees" shall be substituted.

F.No.CBIC-20021/1/2022-GST

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

Note : The Principal notification No.13/2020-Central Tax, dated the 21st March, 2020 was published in the Gazette of India, Extraordinary, vide number G.S.R.196(E), dated 21st March, 2020 and was last amended vide notification No.23/2021-Central Tax, dated the 1st June, 2021, published vide number G.S.R.367(E), dated the 1st June, 2021.

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Mandatory filing/issuance of Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) through the DGFT common digital platform from 01.04.2022

Trade Notice No. 35/2021-2022, dated 24th February 2022

To,
All Exporters/Members of Trade
All Registering Authorities (Export Promotion Councils/ Commodity Boards)

1. Reference is invited to Trade Notice No. 27 dated 30.11.2021. In this regard, it is informed that the electronic platform to facilitate electronic issuance/ renewal/amendment of Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) has been implemented. The objective of the platform is to provide an electronic, contact-less single window for RCMC/RC related processes.

2. In this reference, it is informed that from 1st April 2022, it will be mandatory for the exporters to file Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) applications (for issue/ renewal/amendment) through the common digital portal of eRCMC Platform.

The prevailing procedure of submitting applications directly to the designated Registering Authorities will continue only till 31.03.2022. All Registering Authorities as notified under Appendix-2T are requested to ensure that they are on-boarded on eRCMC portal before 31st March 2022.

3. Registering Authorities, who have already on-boarded are advised to adopt e-RCMC platform as single point for handling RCMC related processes. The Registering Authorities are also advised to conduct outreaches & issue suitable advisories to the members/exporters to use the e-RCMC platform before the stated timelines.

4. For guidance on application submission process, the Help Manual & FAQs may be accessed on Learn Section of DGFT website (URL: https://dgft.2.ov.in --> Learn --> Application Help & FAQs).

This issue with the approval of the competent authority.

File No. 01/02/68/AM-21/EG&TF

Deepak Jhalani, Deputy Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign, Trade, New Delhi.

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DGFT Helpdesk for Russia-Ukraine related International Trade Issues - reg.

DGFT Trade Notice No.36/2021-2022, dated 25th February 2022

To,
All Exporters/Importers/Members of Trade,
All Regional Authorities of DGFT/FT(CIS) Division,
All Export Promotion Councils/Commodity Boards.

1. In view of the current international situation, Department of Commerce and DGFT have undertaken to monitor the status and related difficulties being faced by stakeholders on Russia/Ukraine trade related issues. Department of Commerce/DGFT has operationalised a **Helpdesk to support and seek suitable resolutions to issues related to India's International Trade in this regard with immediate effect.**

2. **Export-Import community may submit details of their issues on the DGFT website,** on which support is required, using the following steps--

i. Navigate to the DGFT Website (https://dgft.gov.in) -- > Services -- > DGFT Helpdesk Service

ii. 'Create New Request' and select the Category as 'Russia-Ukraine'

Alternatively, you may send your issues directly over email to: dgftedi@nic.in with the subject header: 'Russia-Ukraine Trade Helpdesk', or call the Toll-Free No at 1800-111-550

3. The status may be tracked using the Status tracker under the DGFT Helpdesk Services. Email and SMS would be generated for immediate intimation as and when the status of these tickets are updated. Trade Community is requested to make use of the given Helpdesk facility suitably.

4. Further, a **weekly meeting** with concerned exporters/importers/other trade stakeholders will also be held by DGFT & FT(CIS) division of Department of Commerce **every Monday at 03:00 pm IST via Video Conference.** Concerned stakeholders may consider joining the said virtual meeting to flag specific issues. The web-link for the proposed Video Conference is as follows-

https://directorategeneralofforeigntrade.my.webex.com/directorategeneralofforeigntrade.my/j.php?MTID=m8aa668976ac27713b881875b9be0d085

Meeting Password: 1234

This issues with the approval of the competent authority.

File No. 01/02/08/AM22/EG&TF[E-27797]

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

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Amendment in Export Policy of Remdesivir Injection and API, Amphotericin-B Injections, Enoxaparin (Formulation and API) and Intra-Venous Immunoglobulin (IVIG) (Formulation and API) — reg.

Notification No. 56/2015-2020, New Delhi, Dated: 24th February, 2022

S.O. (E) In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes following amendment in **Notification No. 08/2015-20 dated 14.06.2021, Notification No. 07/2015-20 dated 01.06.2021 and Notification No. 50/2015-20 dated 10.01.2022** related to export of Remdesivir Injection and API, Amphotericin-B Injections, Enoxaparin (Formulation and API) and Intra-Venous Immunoglobulin (IVIG) (Formulation and API):

2. Effect of this Notification:

The export policy of Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients (API), Amphotericin — B injections, Enoxaparin (Formulation and API) and Intra-Venous Immunoglobulin (IVIG) (Formulation and API) falling under HS code as mentioned above or falling under any other IIS code has been made 'Free' with immediate effect.

S.No	ITC HS Codes	Description	Existing Policy	Revised Policy
207AA	Ex 293499 Ex 300490	Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients (API)	Restricted	Free

207AB	Ex 30049029 Ex 30049099	Amphotericin — B Injections	Restricted	Free
207 AE	Ex 2942 Ex 3001 Ex 3002	Enoxaparin (Formulation and API)	Restricted	Free
207 AF	Ex 3002	Intra-Venous Immunoglobulin (IVIG) (Formulation and API)	Restricted	Free

(Issued from F. No. 01/91/180/24/AM22/EC /E-27724)

(Santosh Kumar Sarangi)
Director General of Foreign Trade
Ex-Officio Additional Secretary, GoI
Email- dgft@nic.in

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Drugs Rules, 1945 amended (3rd Amendment of 2022) - reg.

Drugs & Cosmetics Notification G.S.R.158(E), dated 24th February 2022

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.840(E), dated the 29th November, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 29th November, 2021;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:-

1. (1) These rules may be called the **Drugs (3rd Amendment) Rules, 2022.**

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

2. In the Drugs Rules, 1945, in rule127, in sub-rule (1), under the heading (3) relating to "Coal Tar Colours", after the entry "Carmoisine" and before the entry "BLUE Indigo Carmine", the following entry shall be inserted, namely:-

Common Name of the Colour	Colour Index Number	Chemical Name
1	2	3
"Allura Red	16035	Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-Naphthalenesulfonic acid"

F.No. X.11014/22/2021-DR

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

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R.30(E), dated the 20.01.2022.

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Why MNC pharma companies are realigning their India operations

Earlier this month, Swiss drug major Novartis India sold its three established brands to Dr Reddy's Laboratories and terminated the employment of 400 staffers. In October, US drugmaker Eily Lily sold the marketing rights of its anti-diabetes drugs to Cipla and laid off 120 employees in India. Around the same time, Danish pharma company Lundbeck decided to exit India as part of its global strategy. In 2019, US drug major Pfizer closed two facilities manufacturing injectables in the country in response to falling demand.

At a time when the local market is assuming the centre stage of the growth strategy for Indian pharma companies, are restructuring their businesses in India - by selling brands, closing non-core units, or laying off employees. The stocks of listed MNC pharma companies have hardly been attractive for investors compared to those of their Indian counterparts. "Pharma MNCs do not consider India a favourable market - their product portfolios are inadequate, their penetration is limited to metros and tier-1 cities, and they get beaten by their Indian peers," said Salil Kallianpur, a pharma consultant and former executive vice president at GSK Pharma. "While input cost is rising, there are price caps to contend with in case of certain essential drugs. This creates pressure on P&L - leading to decisions like reducing staff. Besides, there is a lot of work yet to be done on the policy of marketing and distribution of drugs in India. Consequently, the MNCs are exploring newer models of doing business in India - right from outsourcing, contracting, marketing collaborations and out licensing of molecules," he added.

Numbers at a Glance

Performance of Listed MNC Pharma Companies in India

Companies	5-year CAGR (%)		No. of employees^	5 yr Stock Returns (%)
	Net Sales	Net Profit		
Abbott India	10.4	26	3585	264
Glaxosmithkline Pharma	2.4	1.5	4283	16
Novartis India	-12.7	-22.3	539	3.6
Sanofi India	5.2	12	2912	75
Pfizer	3.3	10.3	2358	150
Astrazeneca Pharma	10.6	46.8	1283	191

^ From last reported Annual Report

Compiled by ETIG Database

As per AWACS data, the Indian-MNC breakup in the local pharma market has been 80:20 for the past several years

According to Ajit Dangi, CEO of Danssen Consulting, pharma MNCs are basically restructuring their business in India to make it more responsive to the changing market environment. "IPR environment has improved, and it is no longer easy to copy patented molecules in India. No compulsory licence has been granted since 2014," he said.

"Regulatory approval for NCEs (new chemical entities) which are already approved in developed countries such as by the USFDA, UK MHRA or EU EMA can now be fast tracked in India. Over 328 irrational fixed dose combinations - most of them approved by the state FDAs - have been banned after a protracted legal battle. This has created space for original research molecules of MNCs to be promoted scientifically," he added.

During the pandemic, the MNC pharma companies were found to be involved in strategic collaborations with Indian companies. For instance, American drug company Gilead licensed its remdesivir molecules to seven pharma companies. The transfer of Covid vaccine technology by AstraZeneca to Serum Institute and J&J to Biological E, and Merck's voluntary licence to five Indian pharma companies for Covid antiviral pill molnupiravir for global supply are cases in point.

"MNCs are also known to focus on limited therapy areas and build bigger legacy brands," said Sheetal Sapale, president marketing at pharma market research firm AWACS. "In Covid times, players like GSK, Abbott, Janssen and Pfizer who had strong brands in pain, gastro and nutritional's category could make it big due to strong top-of-the-mind recall coupled with a surge in demand."

"There is hardly any pharma MNC that would want to exit the Indian market at this point of time given the improvement in drug affordability and accessibility and the secular growth story of the Indian pharma market," said Krishnanath Munde, associate director, India Ratings & Research.

However, stock market investors may not find any near-term positive trigger for the handful of pharma MNC stocks that are locally listed with limited free float. Besides, as seen in the case of Novartis India, the listed entity often houses a small proportion of the business compared to the unlisted arms in India.

Source: Kiran Kabtta Somvanshi, ET Bureau, 23.02.2022

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New Covid variants complicate the question of vaccine mandates

Officials mulling new pandemic policies need to know how quickly vaccine protection wanes. But scientists don't have a clear answer.

Post-infection immunity might be a strange topic for political strife, but it touches on Covid vaccine mandates and whether those who've had the virus should be exempt. And so when publications such as The Hill run headlines such as "CDC Finally Recognizing Natural Immunity – Legislators should Follow," it carries the implication the CDC has been ignoring some long-held scientific evidence. But the science is more complicated and unsettled than that.

The relevant science question isn't whether natural immunity exists but whether it's as protective and lasts as long as vaccine-induced immunity. Studies have given conflicting answers. The situation is now changing again, as the BA.2 variant is starting to take over. It's still considered omicron, but it looks to be wildly different from the version of omicron that's been dominant, called BA.1.

Scientists confirmed that an infection with SARS-CoV-2 creates some degree of immunity in May 2020, based in part on a study published in Science, which was led by Dan Barouch, director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center. "We did the study in May 2020, not so much to test natural immunity, but really as part of our vaccine program," he told me this week

Vaccines work by fooling the body into acting as if it's been infected, and so vaccines work best against diseases where post-infection immunity is strong and lasting, he said, such as measles, mumps and rubella. It hasn't worked for HIV, a virus that attacks the immune system and can't be cleared except in some rare cases with medical intervention.

With Covid, antibodies wane over time. That can decrease immunity, as can new variants. With the original variant, it looked like vaccines gave better protection than getting infected. But during the delta surge, some studies showed that had reversed. New data released by CDC show that a previous infection gave people better protection against delta than either one or two shots of a vaccine. But getting vaccinated in addition to getting infected gave people the strongest protection — so it wasn't overkill to recommend vaccination to people who'd been infected. Boosters also restored most of the effectiveness of the vaccines.

"There was an early perception that vaccination is hands down better than natural infection — and a lot of people still feel that will be the case," Barouch said. "But I think it's more nuanced now, and a lot of people think natural immunity gives you a substantial level of protection." But how much protection, compared to vaccination? "That's not clear." Barouch agrees with many other researchers I've talked to — that a confirmed Covid infection could probably substitute for a single shot.

Before the Covid-19 vaccines were developed, scientists told me that with other viral infections, vaccines are sometimes more protective than past infection and sometimes less so. One reason vaccines sometimes work better is that viruses often disable a person's immune response as part of their own survival strategy. That's happening with SARS-CoV-2 according to some studies, said Shiv Pillai, a professor of immunology at Harvard Medical School.

The disadvantage for Covid-19 vaccines is that they are designed to only produce antibodies that attack just one part of the virus — the spike protein. As the spike protein keeps mutating, the vaccines lose some efficacy. Getting infected might provide people with broader, multi-variant protection.

It seems absurd for anyone to try to get infected as a way to gain protection against getting infected, but it's possible some people might try to get infected if they are avidly anti-vaccine, and infection could satisfy a vaccine mandate or passport system. Vaccines are vastly safer than getting the virus, but not everyone is well informed or thinking clearly.

Omicron's heavy mutations changed the game. The vaccines still offer good protection against severe

disease, but neither vaccination nor infection with an earlier variant offers much protection against a mild omicron infection. This post by Eric Topol, a professor of medicine at Scripps Research, ties together a lot of studies, but he also points out that most of the studies comparing vaccine-induced immunity to past infection involve the original variant or delta. Now the pandemic is nearly all omicron — a strikingly different variant that's much better at escaping both kinds of immunity — and there's much less known.

The new BA.2 version of omicron is forcing scientists to recalculate — yet again. Barouch has been leading some of the first experiments testing how well BA.2 slips by defenses from past infection or vaccines. "It's slightly worse, but not a ton worse," he told me. It looks like omicron infection protects to an extent against BA.2, so the experts think it's unlikely to lead to the kind of massive infection wave caused by the original omicron. But there are scores of other unexpected things that could happen — good or bad — with this ever-changing pandemic.

Policy decisions about vaccine mandates can be informed by science but can't be determined by science. Those decisions depend on the ethics and legality of mandating vaccines, and whether staying unvaccinated harms society by increasing transmission or depleting precious hospital resources.

Policy aside, severely immune-compromised people are already being advised to get a second booster. Right now, there's no recommendation for an additional booster for the general public — doctors have told me it's rare to see fully boosted people be hospitalized for Covid. But that might change in the coming months, if there's a new wave, or evidence that immunity is fading. A past infection might play into that decision. (For those wondering whether they've been infected, it's possible to get a test that would pick up antibodies not generated by the vaccine, but those aren't widely available.)

Such decisions hinge on which new variants emerge in the future, ongoing research into the duration of immunity, and whether scientists eventually develop a more variant-proof coronavirus vaccine. The last two years may have gone by slowly, but we're still dealing with a new disease, and there's a lot yet to learn.

Source: Financial Express, 21.02.2022

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Exclude cheap drugs from price control: IPA

Indian Pharmaceutical Alliance (IPA), the lobby group that represents large domestic pharmaceutical companies, said it wants the government to extend the 10% annual hike to scheduled formulations under price control and not to cap prices of medicines below ₹5.

He cited examples of Covid antivirals remdesivir and molnupirivir, whose prices have dropped sharply. (Image used for representational purpose)

"We expect pricing policy should come anytime," Sudarshan Jain, secretary general of IPA, said in an interview to ET.

"We are not against price controls; what we are saying is that the government should exclude low-priced scheduled products from price control or allow at least 10% annual hike as it is done for non-scheduled formulations," Jain said.

"Less than ₹5 per tablet, why should they control the pricing," Jain added. Jain said that the prices of medicines in India are the lowest, and the intense competition will take care of prices.

He cited examples of Covid antivirals remdesivir and molnupirivir, whose prices have dropped sharply.

Jain said manufacturers of scheduled medicines are incurring losses, due to rising volatility of raw material prices and lack of flexibility to raise prices.

"The government doesn't allow them to exit the loss-making products. The manufacturers are either pushed to cut back on supplies or sell these products to other companies," Jain said.

"The thrust of the policy should be on ensuring quality and adequate supplies of these essential medicines," Jain added. At present, around 374 medicines are part of the National List of Essential Medicines which are subject to price controls.

Source: Viswanath Pilla, ET Bureau, 22.02.2022

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India-UAE trade pact set to boost pharma exports

UAE is a gateway as well as a re-export market, says Pharmexcil Indian drug-makers can look for significant gains in pharma exports to the United Arab Emirates, thanks to the new trade pact inked by India with the latter. Pharmaceuticals is one of the products that has been included in the vortex of Comprehensive Economic Partnership Agreement.

"There are many advantages that can hasten the product approvals and boost up demand for Indian pharmaceuticals in UAE," R Uday Bhaskar, Director General, Pharmaceutical Export Promotion Council (Pharmexcil), told *BusinessLine*. As of now, the process of approval for any dossier filed by Indian pharma companies in UAE may take up to 24 months.

"However, now those companies who have facilities approved by eight drug regulators including those of USFDA, EMA, UK-MHRA, TGA-Australia and Health Canada can get approval only in 90 days. This significantly hastens product approval period and thus augurs well for exports,'' Bhaskar said. UAE is also a gateway to exports to GCC and Africa regions and being a re-export country, it can expand the reach of Indian drugs further. GCC market has been estimated at $15 billion out of which $4.6 billion is for generics which is an advantage for India. The presence of large number of USFDA (741)and 743 European GMP approved facilities in India will also be a positive factor for India. "The cost advantage our exporters offer coupled with a strong tradition of product quality and credibility help us to adually increase presence/consumption of Indian generics in UAE and GCC,'' the Pharmexcil DG said.

Generic sector

India participates mostly in the generic sector of UAE. Though UAE pharma market size is of $3.5 billion, its generic market inclusive of vaccines is Just $ 718 million in 2021. Generic market is projected to grow at a CAGR of 7 per cent in the next five years. It may reach $1,000 million by 2026. "It is to be noted that UAE is developing as a mini logistical centre which can help Indian pharma exporters,'' the official said. India's pharma exports to UAE during the last five years ending FY-21 grew at a CAGR of 24 per cent which is much faster than UAE's local market. However, India's pharmaceutical exports to UAE are also re-exported to other countries and the data pertaining to the actual consumption in UAE of India's exports are not available. It is to be noted that the export growth recorded in FY2020-21 was 58.4 per cent ($322 million) is inorganic growth owing to the pandemic and the CAGR observed during 2015-16 to 2019-20 was 16.7 per cent. "As their local formulation industry is also fast developing India's exports may have a chance of increasing API's much faster than now (only 5 per cent CAGR during the last five years). Formulation exports, which have grown by a CAGR of 48 per cent during the last five years may register a smaller figure,'' Bhaskar said. One of the directors of a Hyderabad-based listed pharma company said diversification of geographies should be a top priority for pharma exporters and the trade pact with UAE would act as a catalyst.

A lab technician wearing a full-face mask and a protective suit holds tablets of investigational coronavirus disease (COVID-19) treatment drug "Favipiravir" at Eva Pharma Facility in Cairo, Egypt June 25, 2020. Picture taken June 25, 2020. REUTERS/Amr Abdallah Dalsh | Photo Credit: AMR ABDALLAH DALSH

Source : G. Naga Sridhar, The Hindu Business Line, 22.02.2022

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