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# IDMA BULLETIN

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## Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS

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# IDMA BULLETIN

**Vol. No. 52** **Issue No. 26** **08 to 14 July 2021**

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# "It Is Now or Never; for Enhanced Research Collaboration, Nay, Partnerships Between Industry and Institutes/Academia"

***Dr Gopakumar G Nair,*** *Editor, Indian Drugs*

*Dear Reader,*

*Pens have gone dry and words have run out, highlighting the need for Industry-Academia collaboration. However, it is indeed deeply dismaying that very little progress has been made in "building the bridges" we have been advocating and promoting over the last few decades, when the necessity and urgency of innovative research leading to IP/Patent protection and technology licensing is recognised as a priority. Except for couple of pockets of excellence, there have been very few "box office" hits to write about. One example to quote is the Venture Centre at the NCL (National Chemical Laboratory, Pune) headed by Dr. V. Premnath. A few exceptional achievements in a relatively short time by this innovation/start up incubation centre are worth taking note of.*

*The Venture Centre, Pune is a technology business incubator specialising in promoting technology start-ups offering products and services exploiting scientific expertise in the area of materials, chemicals, biological sciences & engineering. A few exceptional achievements of this innovation/start up incubation Venture Centre are worth mentioning here.*

- *Served more than 500 entrepreneurs since its inception in 2007.*
- *Support more than 70 resident start-ups at any given time*
- *Several of the start-ups are developing First-in-India technologies*
- *10+ spin-out companies*
- *key focus areas include material science, bio, energy as well as social innovation*

*Dr. Gopakumar G. Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.*

*Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.*

*Another credit-worthy initiative is RIIDL at Somaiya, Vidyavihar, Mumbai. They have nurtured and developed so many breakthrough start-ups, "Pharmeasy" being the most successful among them. IIT, Bombay also claims innovation-based start-ups and inventors of repute.*

*It is time to breakthrough with the movement at National level. Universities and even autonomous colleges and institutes must have dedicated specific IP cells and innovative research departments which tie up with one or more industries and commercial ventures. Just having IP cells and activities for qualifying for funds is the 'bar' set up by many. You need to go beyond and inculcate and create culture and passion for innovation. If not one research unit with one or more industry, the Research professionals from such publicly funded (or even outstanding private universities and institutes) must be allowed or even compelled to join hands with corporate in their respective fields on a long-term basis. We have at least one model example to emulate. In the eighties and nineties (1990 to 1995) or even thereafter, Dr. A.V. Rama Rao from NCL, Pune tied up with CIPLA (with Dr. Yusuf Hamied in particular) to roll out a large number of innovative molecules, both patent-based as well as synthetic, which were all commercialized by CIPLA successfully. In turn, Dr. Rama Rao, who later moved from NCL to IICT, Hyderabad, benefited immensely with the corporate vision and strategies which he imbibed from the CIPLA alliance. This led him to set up AVRA Laboratories, which became a hub of innovation, licensing, technology transfer and of course self-commercialisation. AVRA is a model for aspiring research scientists to pursue and replicate.*

*Why the above model is not being replicated? Why more of such collaborative partnerships "Avatars" are not being born again? Has the brilliant times of CDRI (Central Drug Research Institute, Lucknow) when Dr. Nityanand and his successors created marvellous innovations become history? What is ailing the Indian public funded research organizations? Have they lost focus? Are they only looking for "funding-crumps" from DST/DBT or UGC, DSIR, CSIR, AICTE, DRDO and the like by creating and fulfilling the criteria on paper? Is there too much politics in Indian pharma and biotech research? Should not the government release the "research industry" from controls and bureaucracy? Should not the industry take initiative in utilizing the facilities available in public research laboratories, including the human research resources?*

*I will be failing in my thought-provoking editorial and critical evaluation of the current relatively dismal scenario, if I do not quote some more examples of emerging lights at the end of the otherwise dark tunnel. The JSS Group of colleges especially at Ooty have been quietly but passionately undertaking high quality research projects. Sree Chitra Tirunal Institute for Medical Sciences and Technology and Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram are also remarkably contributing to innovative research. SRM, Amity, Punjab University, Andhra University and many more have immense potential to take India forward in coming decades, if not years to make INDIA, the "Pharma-Bio Research Capital" of at least Asian countries. If I have not quoted the Chinese, Japanese and Korean success stories, it is only because, I feel India can make it big, purely by repeating the earlier Indian success models and not by copying overseas stories.*

*Courtesy: Indian Drugs, Editorial, Vol. 58 (04) April 2021*

● ● ●

# IDMA Congratulates Shri Mansukh Laxmanbhai Mandaviya the New Hon'ble Minister of Health & Family Welfare and Chemicals and Fertilizers of India

| Year | Life Journey |
|---|---|
| 1st June, 1972 | Born in a village Hanol in Palitana Taluka, District Bhavnagar of Gujarat. Belongs to a farmer's family.<br>Shri Mandaviya holds a Masters Degree in Political Science from Bhavnagar University and also pursuing PhD. |
| 1992 | At the age of 20 years, he became the member of Akhil Bharatiya Vidhyarthi Parishad. Through his organization skills, he soon became State Executive Member of Akhil Bharatiya Vidhyarthi Parishad. |
| 1996 | **First Step in Politics**<br>1996 was the year when Shri Mansukh Mandaviya joined politics by becoming a member of Bharatiya Janata Yuva Morcha (BJYM). He played key role in various activities in the State of Gujarat. |
| 1998 | He became President of Palitana Taluka BJP organization. |
| 2002 – 2007 | Major turn of events in his political career. He got elected to the Gujarat Assembly. **One of the youngest MLAs in Gujarat Legislative Assembly.** |
| 2004 | As a Member of Legislative Assembly he undertook a 123 KM long Padyatra, titled "Kanya Kelavani Jyot Padyatra" for the Social Cause 'Beti Bachao-Beti Padhao' for 45 educational backward villages of his constituency. Due to this initiative school enrollment ratio of Palitana for girls reached 1007 and drop-out ratio could be lower than State average for girls. |
| 2006 | In 2006, he again organized 127 KM **padyatra** connecting 52 villages of his constituency with the title "Beti Bachao-Beti Padhao, Vyasan Hatao" |
| 2010 | **Shri Mansukh Mandaviya became Chairman, Gujarat Agro Industries Corporation Ltd.** As a Chairman he took innovative measures like E-Radiation treatment plant at Bavla, which is First Government Facility; Poha (Flattened Rice) plant at Navsari; Modern banana Pack house at *Achaliya (Bharuch) and Bio-Fertilizers Plant at Gondal.* |
| 2012 – 2018 | **Entry into National Politics**<br>Shri Mandaviya got elected to Rajya Sabha as a member. He was quite active in the debates of the Parliament. He has been a part of various important Standing and Consultative Committees, namely 'Petroleum and Natural Gas', Chemical & Fertilizers and Industries', 'Environment, Forest & Climate Change', 'Textiles', 'Select Committee for Real Estate Bill-2015'<br>Shri Mandaviya has been part of various delegations, twice with the President and once with the Vice-President to sign MOUs and develop bilateral relations with other nations. |

| | |
|---|---|
| 2013 | **State Secretary, Gujarat BJP**<br>Got nominated as State Secretary in BJP Organization |
| 2014 | **In charge, BJP Membership Drive, Gujarat State**<br>Lead BJP's Hightech Membership Drive in Gujarat State and achieved highest members in all states of India. On completion of the membership drive, BJP became world's largest political party. |
| 2015 | **State General Secretary, Gujarat BJP**<br>Considering his organizational skills, he was appointed as General Secretary in BJP. He is youngest State General Secretary of BJP Organization.<br>**Represented India at United Nations - 19th October, 2015**<br>For his intellectual analysis and thoughtful leadership Shri Mandaviya was selected to represent India at United Nations in 2015 where he delivered his speech on **'2030 Agenda for Sustainable Development'.** |
| 5th July, 2016 | **Took oath as Minister of State in the Council of Ministers, Government of India**<br>During his term as Minister of State he was allocated Ministries of Road Transport and Highways, Shipping, Chemicals and Fertilizers Ministries as Minister of State.<br>As a Minister with his decisive and bold leadership, he has helped increasing the per day road construction speed, decreasing the cost of Urea and other fertilizers. He introduced a scheme called "Jan Aushadhi" through which anyone can avail generic medicines at cheap prices establishing establishing more than 7800 Jan Aushadhi stores to provide more than 1402 medicines and more than 200 Surgical items and medical devices at affordable rates and reducing the cost of 'heart stent' and 'knee implants'. Above this, he has not left any stone unturned to help the common man, farmers and businesses. |
| 2018 | **Re-elected as Member of Parliament, Rajya Sabha**<br>On Completion of First successful term as a Member of Rajya Sabha, he was re-elected for Upper House for the period 2018-2024 |
| January, 2019 | Shri Mandaviya undertook Padyatra for the third time in his political career. This 150 km long Padyatra was organized in Bhavnagar District, Gujarat coinciding with the celebrations of 150th birth anniversary of Pujya Bapuji. Through the virtual platform Hon'ble Prime Minister joined the culmination ceremony. Hon'ble Prime appreciated this initiative and urged Members of Parliament to organize such padyatras. |
| 28th May, 2019 | Shri Mandaviya was awarded **"Men for Menstruation" by UNICEF** on Menstrual Hygiene Day for his initiative of "Suvidha Sanitary Napkin" under PMBJP Scheme. |
| 30th May, 2019<br>Till Now | **Took oath as Minister of State (Independent Charge) in the Council of Ministers, Government of India**<br>He was Minister of State (Independent Charge) in the Ministry of Ports, Shipping and Waterways. Also, he holds the portfolio of Ministry of Chemicals & Fertilizers Ministry as Minister of State. |
| Jan,2020 | **He represented India in World Economic Forum, Davos, Switzerland** |

Shri Mandaviya has been a part of various delegations, twice with the President and once with vice president to sign MOUs and develop bilateral relations with other Nations. In the Asian Continent he has visited China, Israel, Oman, Nepal, Dubai and Uzbekistan. He also visited European countries like England, Germany & Hungary, South American countries like Brazil & Argentina. He has visited lot many countries in Africa like Kenya, Uganda, Tanzania, Rwanda, Algeria, Equatorial Guinea, Swaziland and Zambia. In an Oceania Region, Shri Mandaviya visited New Zealand, Tonga, Fiji and Australia.

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# Module for online processing of applications for issuance of Written Confirmation Certificate (WCC) - reg.

**7-5/2015/Misc/034 (e-Governance), dated 07th July 2021**

*To,*
*1. Bulk Drug Manufacturers Association India (BDMAI),*
*2. All Stakeholders through CDSCO Website.*

CDSCO in pursuance to implementation of the e-Governance mechanism has launched various online services through the "SUGAM" portal on 14.11.2015. In continuation to same, CDAC in collaboration with CDSCO has developed a module for online processing of applications for issuance of Written Confirmation Certificate as per requirement of EU for import of active substances into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2) (b) of Directive 2001/83/EC.

The module is finalized and has been made functional, which can be accessed through https://cdscoonline.gov.in. All concerned stakeholders are requested to avail this facility and any comments/suggestions to help improve the module shall be welcomed and addressed properly.

Thereafter, the WC application processing will be online and physical application for issuance of WCC may not be accepted **after 23.07.2021** in this regard.

*Dr V G Somani,*
*Drugs Controller General (India),*
*Central Drugs Standard Control Organisation,*
*International Cell Division,*
*Directorate General of Health Service,*
*New Delhi.*

● ● ●

PRESS RELEASE

# IGBA LAUNCHES A WHITEPAPER: A VISION FOR THE GLOBAL GENERIC AND BIOSIMILAR MEDICINES INDUSTRY

Today the International Generic and Biosimilar Medicines Association (IGBA) is launching a whitepaper: A Vision for the Global Generic and Biosimilar Medicines Industry, which covers the strong contribution of this pharmaceutical sector to global health outcomes and economies, the opportunities, challenges and disruptions for the industry, its 2030 vision as well as actions needed to achieve this vision.

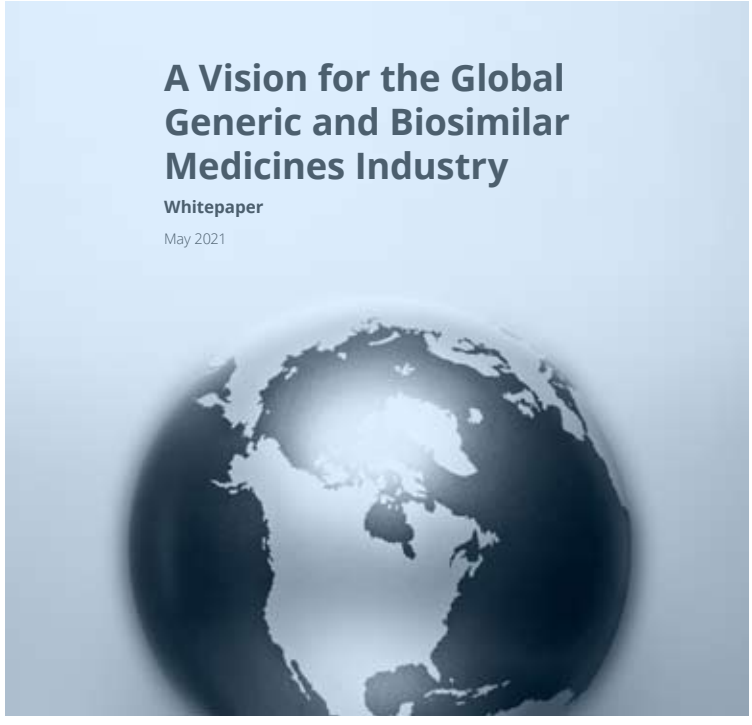
"The generic and biosimilar medicines industry has played and continues to play a crucial role in the ongoing Covid-19 public health crisis and in the overall healthcare ecosystems" commented Sudarshan Jain, IGBA Chair. "The IGBA 2030 vision reflects our efforts to ensure that this industry can continue to contribute deeply to enhancing reach and access to high quality and cost-effective therapies globally. They are needed more than ever", Sudarshan Jain added.

The whitepaper is the result of extensive input from fourteen generic and biosimilar medicines companies and IGBA member associations, and supports the global recovery efforts to rethink, build and secure a future which addresses the inequalities in healthcare, while supporting sustainability.

"To help industry achieve its 2030 vision, we need efficient, supportive and consistent regulatory frameworks, equitable patent and litigation systems fostering innovation while enabling access, open international borders and secure trade flows as well as encouragement for investment in new technology and innovation", concluded Suzette Kox, IGBA Secretary General.

*Source: Press Release, Geneva, 7th July 2021*

IGBA
INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION



# Foreword

Dear Reader,

Since 2020, the global community has been facing multifaceted challenges triggered by the Covid-19 pandemic. Individuals, families, communities, organizations, institutions, and governments have been put under pressure. The pandemic has highlighted the centrality of health and its role in allowing individuals, as well as communities, to thrive. The global recovery efforts should now become the unique opportunity to rethink, build and secure a future which addresses the inequalities in healthcare, while supporting sustainability. At the same time, all stakeholders need to continue contributing to the advancement of the United Nations 17 Sustainable Development Goals (SDGs). Goal 3 seeks to ensure health and well-being for all, at every stage of life. It addresses all major health priorities, including communicable, non-communicable and environmental diseases, universal health coverage, and access for all to safe, effective, quality, and affordable medicines and vaccines.

One of the key roles of the generic and biosimilar medicines industry is specifically to promote the widest possible access to affordable medicines with high quality, safety, and efficacy for patients globally by introducing competition into the markets. Despite the many hurdles, the generic medicines companies have clearly lived up to the challenges posed by the pandemic as it is an industry that is quick to adapt and agile in manufacturing scale-up. During the outbreak of COVID-19, this industry was providing most of the medicines needed in Intensive Care Units to ventilate critically ill COVID patients. It is also providing most of the quality medicines dispensed around the world, especially for increasingly prevalent chronic diseases and is therefore a strong contributor to health outcomes globally.

Furthermore, the generic and biosimilar medicines industry is a key source for healthcare savings. It has become a cornerstone of healthcare systems around the world and makes profound economic contributions across regions.

The generic and biosimilar medicines industry will continue to play this important role in the healthcare ecosystem provided it continues to invest, adapt and innovate, and the market and regulatory policies provide appropriate frameworks and support to sustain and grow its contributions to healthcare systems and economies globally.

IGBA has therefore taken the opportunity to reach out to Business Leaders of global generic and biosimilar medicines companies to reach a common vision as well as identify the key enablers to achieve this. This Whitepaper is based on their extensive input.

I would therefore like to warmly thank all interviewees for their enthusiastic, informative, and insightful contributions. We were delighted to receive input from Alvotech, Apotex, Aurobindo Pharma, Celltrion, Cimed, Dr Reddy's Laboratories, Hikma, Insud Pharma, Intas Pharmaceuticals, Polpharma, Sandoz, Sawai Pharmaceutical, Sun Pharma and Teva. Special thanks also to the IGBA Leadership initiating this exercise and to the IGBA Member Associations for their input and support during the entire process.

This Whitepaper is mainly meant to be a reference for industry, which never ceases to evolve, but also for all stakeholders, who are an important part of the increasingly complex healthcare ecosystems.

This report is also an invitation to dialogue - we therefore hope you find it an interesting read and welcome your comments.

Yours,

**Suzette Kox**
IGBA Secretary General

info@igbamedicines.org

June 2021

# Contents

# Chapter 1: Generic and Biosimilar medicines industry – contributions and evolving context

Over the last few decades, the Generics and Biosimilars industry has evolved to become a cornerstone of healthcare systems across the world. On the back of world-class capabilities across the value chain, the industry now contributes deeply to enhancing reach and access to high quality and cost-effective therapies globally. This has enabled the industry to drive strong impact on health outcomes, while also making deep economic contributions across regions. The contributions of the industry was even more prominent during the COVID-19 pandemic, when it played a vital role in scaling up supply and access to medicines.

## A strong contributor to global health outcomes

Since its inception, the global Generic and – more recently – Biosimilar medicines industry has brought about significant contributions in enhancing access and improving global health outcomes. Today, Generics represent 60-80% of all medicine volume sales in key markets globally, with penetrations in many countries at even higher levels (e.g. 90%+ in the US, 80%+ in Australia, 90+% in India and ~85% in Jordan).[1] This scale combined with industry's ability to maintain cost-effective prices has enabled the industry to significantly expand reach and access of several therapies globally. For example, generic HIV therapies have helped increase treatment coverage 3-fold since 2010 in Eastern and Southern Africa and reduce the number of deaths by 44%[2]. Similarly, within a year of launch of generic antivirals for hepatitis C, the number of people who initiated treatment rose by 50%[3]. Over a decade (2006-2016), therapy volume in 7 therapy areas has doubled in Europe, while lowering spend on these treatments significantly at the same time (Exhibit 1). Generic partners within the Medicines Patent Pool have distributed ~50 million patient-years of HIV and hepatitis C products across the world from 2012 and to 2020[4].

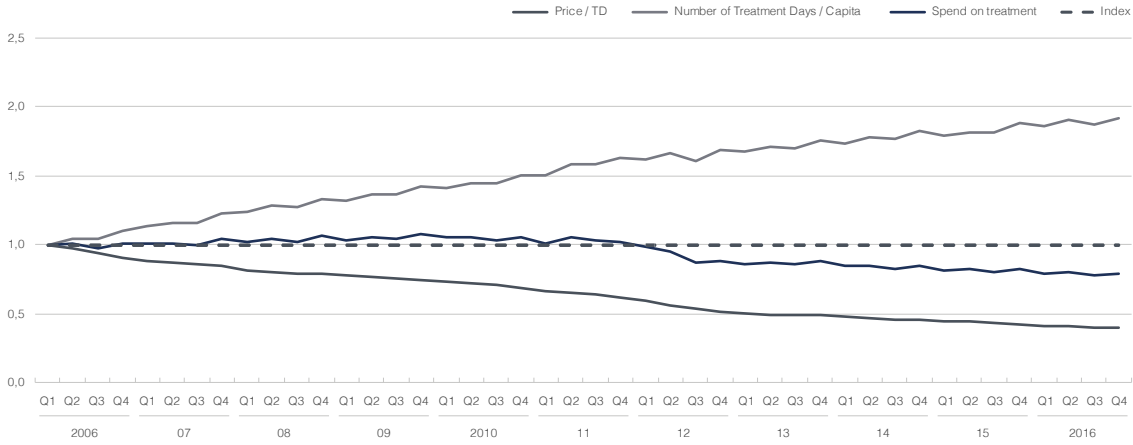
Increased accessibility to affordable medicines has been one of the key enablers for lowering the disease burden in many countries. For example, India's per person disease burden measured as Disability Adjusted Life Years (DALYs) dropped by 36 percent between 1990 and 2016 after adjusting for changes in the population age structure. Similarly, in Africa the burden of disease measured in DALYs dropped by 30% in the same period[5]. Between 2000 and 2019, globally there was a 39% reduction in new HIV infections and 51% reduction in HIV-related deaths, with 15.3 million lives saved due to antiretroviral treatment[6].

1 IGBA, The positive impact that generics and biosimilar medicines have on patients and health systems. 2020. https://www.igbamedicines.org/doc/20191025_Data.pdf
2 Avert, HIV and AIDS in East and Southern Africa Regional Overview, 2020. https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/overview
3 WHO, Progress on the access to Hepatitis C Treatment, March 2018. https://www.who.int/hepatitis/publications/hep-c-access-report-2018/en/
4 Medicines Patent Pool, Leading Generic Drug Makers Unite to Pledge Capacity for Developing and Delivering Affordable COVID-19 Interventions as Pandemic Intensifies", 2020. https://medicinespatentpool.org/news-publications-post/covid-19-generic-pledge-press-release/
5 Our World in Data, Burden of Disease, 2016. https://ourworldindata.org/burden-of-disease
6 WHO, HIV/AIDS Fact Sheet, 2020. https://www.who.int/news-room/fact-sheets/detail/hiv-aids

Exhibit 1

## Access expansion and healthcare expenditure optimization in Europe

Europe : Evolution of therapy volume, price of treatment and overall treatment cost in 7 therapy areas[1]




1 Rx retail market from Q1 2006-Q4 2016, Normalized to population growth. Netherlands data indexed from Q2 2011.
Selected therapy areas: Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics
Rx, retail, oral molecules only, combinations excluded, 26 European countries.

Source: Medicines for Europe, based on data from IMS MIDAS, MAT Dec 2016 and WorldBank

The COVID-19 pandemic has put yet another spotlight on the industry's contributions to safe-guarding access and affordable treatments around the world. For instance, 18 generic drug manufacturers became signatories of an open pledge to accelerate global access to effective COVID-19 treatments via a pool for voluntary product licences[7]. Multiple generic manufacturers have formed licensing agreements to produce medicines such as Remdesivir and Molnupiravir to enhance access, including in low- and middle-income countries.[8, 9]

Over a longer term, the Generic and Biosimilar medicines industry is an important source of competition and thus driver for innovation to the healthcare systems. The price erosion triggered by generic medicines entry fosters originators to focus on development of newly innovative therapies that address unmet medical needs. Those in turn will become available for broader access upon completion of their protection period, creating a virtuous cycle of innovation and improvement in health outcomes.

## A key source for healthcare savings and economic development

Generics and Biosimilars not only improve access to medicines but also create substantial cost savings for patients and health systems globally. As an example, competition by the industry has helped in bringing down the treatment costs of several life-threatening diseases such as Chronic Myeloid Leukemia and Hepatitis C substantially.[10, 11]

7 Medicines Patent Pool, "Leading Generic Drug Makers Unite to Pledge Capacity for Developing and Delivering Affordable COVID-19 Interventions as Pandemic Intensifies", 2020.
https://medicinespatentpool.org/news-publications-post/covid-19-generic-pledge-press-release/
8 Pharmaceutical Technology. "Merck signs deals with five Indian firms to boost supply of oral Covid-19 drug". April 2021.
https://www.pharmaceutical-technology.com/news/merck-licensing-indian-firms-drug/
9 Gilead, "Voluntary licensing agreements for remdesivir". 2021.
https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir
10 Trooskin et al., Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy, 2015.
https://pubmed.ncbi.nlm.nih.gov/26270682/
11 Conti et al. Changing the cost of care for chronic myeloid leukemia: the availability of generic imatinib in the USA and the EU, 2015.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4598066/

Patients and the healthcare system in the US saved approx. USD 313 billion in 2019 through use of generics and an additional USD 2.2 billion in 2019 through use of biosimilars medicines[12]. Over the last decade, savings add up to USD 2.2 trillion and USD 4.5 billion through use of generic and biosimilar medicines respectively.

The beneficial impact of Biosimilars competition on health economic savings has most extensively been witnessed in Europe to date. Here, Biosimilars represent a market of EUR 8.4 billion and represent 8% of biologics market volume.[13] The total clinical experience with EU-approved biosimilar medicines now exceeds 2 billion patient treatment days in Europe, having doubled every ~1.5 years for the past 10 years.[14] Granulocyte-Colony Stimulating Factors (G-CFS), the medicine class with the longest use of Biosimilars, have grown substantially since the introduction of Biosimilar competition. Visible list price reductions of Biosimilars have reduced budgets for medicines by approximately 5% since 2014 overall, and up to 67% for established classes such as Erythropoetin. The effective savings offered to healthcare systems can be suspected to be higher in several countries if accounting for confidential net discounts.[15]

At the same time, the Generic and Biosimilar medicines industry is a direct and major force for economic growth and employment in several countries. Estimates suggest that the industry directly and indirectly provides employment to over 2.7 million people, in high-skill areas like R&D and manufacturing.[16] The industry also helps generates significant contribution for the economy, especially in some of the developing markets (e.g. over USD 11 billion of trade surplus every year in India).[17]

## A growing industry with strong fundamentals, but facing several discontinuities

The contributions above have enabled the Generics industry to grow to a scale of approximate USD 390 billion, making it nearly a third of the USD ~1,200 billion worldwide pharmaceutical market.[18, 19] The continuous growth of the industry has been made possible by the significant step-up in capabilities across the value chain, including development capabilities across technology platforms, high quality and compliance standards in manufacturing, and agile supply chain.

It is noticeable, however, that the industry's growth trajectory has slowed and it seems the industry is now at a crossroads. Sustained and substantial price erosion – often triggered by consolidated buying power and shifts in regulatory policies is putting strong pressure on margins and sustainability of the industry in many markets. Competition in the industry also continues to rise, with boundaries between various categories of unprotected products and the companies active in the field becoming more and more dispersed. Global supply chains are coming under threat driven by disruptions due to the pandemic and protective policies being adopted in several geographies.

12 Association for Accessible Medicines, 2020 Generic Drug & Biosimilars Access & Savings in the US Report.
https://accessiblemeds.org/2020-Access-Savings-Report
13 IQVIA, The Impact of Biosimilar Competition in Europe, 2020.
https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe
14 Medicines for Europe, 2020
https://www.medicinesforeurope.com/wp-content/uploads/2020/12/BIOS5.pdf
15 IQVIA, The Impact of Biosimilar Competition in Europe, 2020.
https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe
16 IFPMA, The Pharmaceutical Industry and Global Health, 2017.
https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf
17 Export Import Data Bank, Department of Commerce, PHARMEXCIL, IDMA report on "Journey towards Pharma 2020 & beyond".
https://ficci.in/spdocument/20594/FICCI-Life%20sciences-Knowledge-Paper.pdf
18 Precedence Research, Generic Drugs Market, 2021.
https://www.precedenceresearch.com/generic-drugs-market
19 Statista, Revenue of the worldwide pharmaceutical market 2001 to 2020, 2021.
https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/

At the same time, sustained pipeline of innovation opportunities, uptick in adoption of biosimilars and digitally supported expansion of access/ offerings suggest ample opportunities for the industry to continue to grow and drive global health and economic outcomes.

Given the opposing forces, concerted action from the industry and supporting stakeholders will be critical to help the industry to maintain its contributions to the healthcare system and economies globally. Subsequent chapters of this report lay out in more depth these opportunities and challenges, a vision for the industry in light of these and the actions and support that the industry will need to achieve its vision.

# Chapter 2: Road ahead – opportunities, challenges and disruptions for the industry

As we assess the outlook for the industry, there are several underlying tailwinds and emerging opportunities which have the potential to help the industry sustain its momentum and grow further. However, tapping these opportunities may not be easy and will require the industry to confront several challenges and discontinuities which have the potential to disrupt the growth and sustainability of the industry.

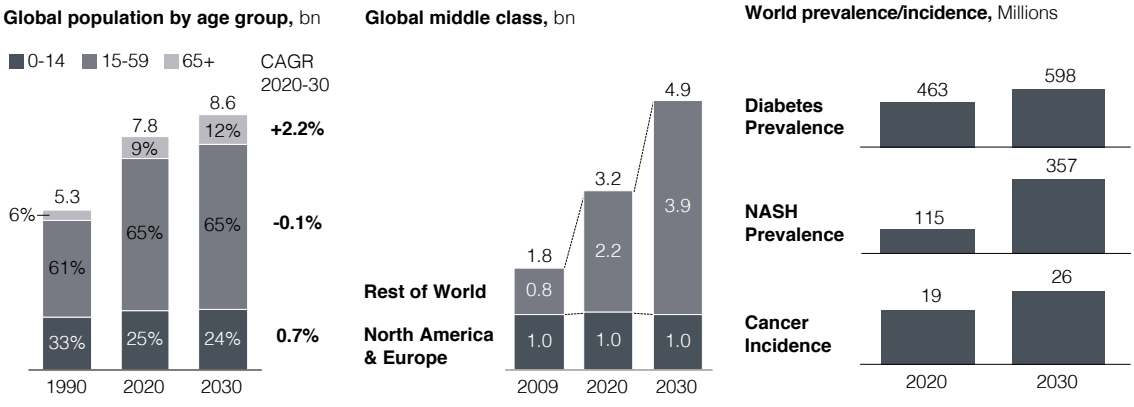
## Key opportunities which can enable the industry

### (1) Underlying socio-economic fundamentals

At the broadest level, demand for healthcare will see sustained growth on back of sustained growth in population across the world[20], while a shift in population mix across both age (with population in 60+ age group expected to see 4x faster growth than the 15-59 age group) and income profile (with middle income class expected to grow to 55-60% of global population) will drive both need and availability of funds healthcare. Prevalence of chronic diseases continues to see upward trajectory, further driving demand for high quality medicines to help patients globally (Exhibit 2).

Exhibit 2

**Socio-economic fundamentals of demand for generic and biosimilars medicines**




1.Based on daily consumption per capita ranging from $10 to $100 (in purchasing power parity terms)

Source: OECD, WHO Core Health Indicators, ICP Global Results, EIU, Diabetes Research and Clinical Practice, Sung et al. (2021) CA Cancer J Clin., Thun et al. (2010) Carcinogenesis, Global Liver Institute

At the same time, cost containment pressures in healthcare systems will sustain and may likely to get accentuated. This pressure will also continue to drive the need for cost effective Generic and Biosimilar medicines across all indications.

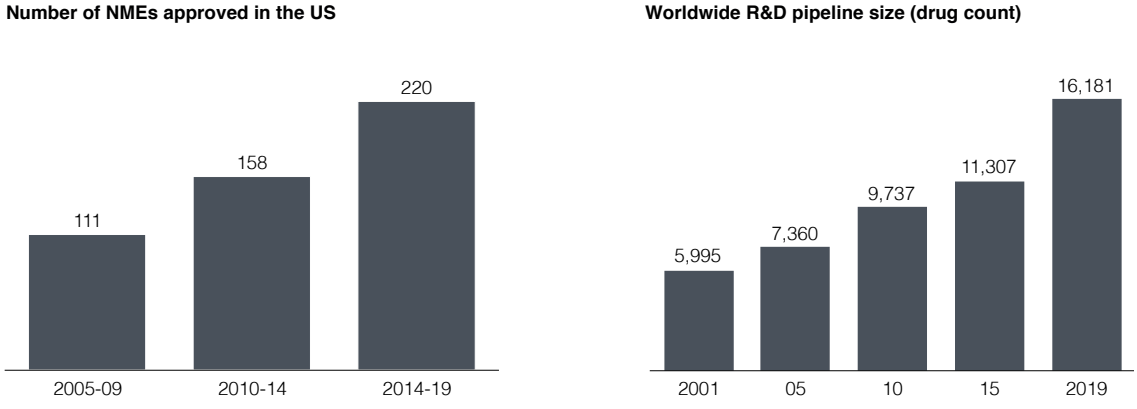
20 United Nations, World Population Prospects 2019, 2019. https://population.un.org/wpp/

### (2) Continued trajectory in the innovation pipeline

Innovation pipeline and subsequent Loss of Exclusivity (LOEs) are a key driver for growth of the industry. While the innovation pipeline saw a brief period of stagnation around 2010, it has rebounded since then with the number of New Molecular Entities (NMEs) launched being greater than before in markets like the U.S. and the number of pipeline assets (across phase 1-3) almost doubling over the past decade (Exhibit 3). The NME launches are expected to translate into a cumulative LOE opportunity at similar magnitude over the next 5 years than seen in the past several years. While the LoE pipeline will see a sharp increase in new modalities (both biologics and beyond), small molecules continue to account for an estimated ~60% of the LoE pipeline and have similar relevance in the clinical pipeline for the originator industry. This will provide a sustained opportunity for the classic small-molecule generic medicines launches after LOE , as well as incrementally innovative strategies on these assets.

Exhibit 3

**Rise in number of NME approvals and pipeline assets**




Source: US FDA CDER database, PharmaProjects Pharma R&D Annual Review 2019

### (3) Biosimilars opportunity finally coming to fruition

After witnessing considerable challenges in its early years, the promise of the biosimilar medicines is finally starting to materialize with the industry scaling up significantly over the last 5 years. With streamlining of regulatory guidelines and increasingly positive clinical experience and hence perceptions by various healthcare stakeholders, adoption curves have accelerated, and market penetration has reached high levels, particularly in Europe. In key markets such as Germany, for instance, penetration of Adalimumab, Bevacizumab and Rituximab biosimilars have reached 72%, 80% and 85% share in DDDs, respectively[21]

Going forward, the market is expected to see continued double-digit growth with potential for the industry to scale-up significantly. Sustained opening up of the market in the U.S. on the back of favorable regulatory and increasing stakeholder acceptance will be key drivers for this growth. In emerging markets where affordability has been a challenge, emergence of affordable Biosimilars

21 ProBiosimilars, Biosimilars Under the Microscope. March 2021.
https://probiosimilars.de/publikationen/marktdaten/marktdaten-maerz-2021/

will further help enhance growth of the market. The market is also likely to see a pronounced build-up of the Biosimilars product map with a strong LoE pipeline over the next decade, particularly in spaces like oncology and autoimmune diseases. As a result, cumulative savings from biosimilars are expected to reach $285 billion globally over the next 5 years, with annual savings exceeding $100 billion in 2025 alone.[22]

At the same time, the Biosimilars market is also witnessing a steep rise in competitive intensity with only early entrants in a product having the potential to recover the significant investments made in product development. Thought through portfolio strategies (e.g. focus on niche opportunities which are much more prevalent in the upcoming pipeline) with deep capabilities in development, manufacturing and commercialization will be critical to succeed in this space. .

### (4) Digital as a key enabler to help industry deepen reach and further strengthen operations

The potential for digital and analytics application in the industry has been promoted to the forefront over last few years on back of the rapid advancements in technology as well as shifts in market landscape and stakeholder behavior due to the pandemic. Digital evolutions can drive significant benefits for the industry across the entire value chain.

On the front end, digital already played a significant role in maintaining the connect between the industry, health care professionals and pharmacists in face of restricted physical interactions. This trend is likely to stay with traditional, face-to-face detailing based commercial approaches increasingly being complemented by digital engagement models. This will not only provide an opportunity for the industry to further deepen connect and hence enhance adoption of generic medicines, but will also offer an economically viable option to rapidly scale-up reach into territories which otherwise remain uncovered due to constraints of the representative-based economic model.

Similarly, on the backend, digital and analytics has the potential to enhance capacity considerably by improving efficiency, quality outcomes and creating an environment of zero-deviations. Drug development and product transfers can be sped up significantly in the future through the use of simulations and in-silico batch modeling.

### (5) Continuous innovation to sustain value creation opportunities

On back of strong capabilities across development and manufacturing, generic companies can continue to explore the opportunity to broaden their activities in the innovation space. Continuous innovation opportunities around existing molecules, under the label of Value-added Medicines, has been the first horizon of focus across several players. For example, generic companies have consistently accounted for ~1/3$^{rd}$ of 505(b)(2) applications in the US over 2015-2020[23].

22 IQVIA Institute. Global Medicine Spending and Usage Trends - Outlook to 2025.
23 FDA, NDA and BLA Calendar Year Approvals, 2021.
https://www.fda.gov/drugs/nda-and-bla-approvals/nda-and-bla-calendar-year-approvals

However, with increasing stringency in the payor landscape, the bar for what is considered "value-added" is rising continuously and this has made successes in the segment few and far between. Looking forward, successfully competing in the segment will require focus on real differentiation in product offerings with boundaries between 505(b)2 and NME opportunities becoming more and more irrelevant. Players may also need to look for some synergies in areas of focus with their core Generics and Biosimilars business, identify segments which require calibrated, but deep investments in go-to-market infrastructure to compete with large incumbent originators, build new capabilities across the value chain and explore strategic partnerships to win in the space.

### (6) Blurring of boundaries with adjacent opportunities

Beyond the traditional definitions of Generics and Biosimilars offerings, the industry is increasingly finding relevance of its core capabilities across a number of adjacent opportunities. While each of these areas require specific capability augmentation for success, several of these present interesting opportunities to enhance access for patients. Few notable example of these opportunities include:

- **Consumer health –** Prior to disruptions by COVID-19, the consumer health industry witnessed meaningful growth. Driven by physician access in several branded markets, established brands with strong patient recall, deep formulation capabilities to address patient unmet needs and established distribution channels, players are now looking to engage simultaneously in both prescription and consumer health segments in focus markets. These franchises will be driven through Rx-OTC cross-promotions in branded markets (e.g. CEE) and can include some adjacent spaces in the broader health/ wellness space (e.g. medically proven food supplements)

- **Digital therapeutics –** Across markets and segments, there is a collective quest by regulators, companies and other stakeholders to build integrated healthcare solutions that go beyond medication only (Exhibit 4). Patients increasingly demand value added services, and payors are moving to outcomes-based reimbursement models that require close oversight and substantial data collection. Digital therapeutics – typically including companion diagnostics or stand-alone digital solutions - begin to form a part of the treatment landscape and are increasingly receiving regulatory approvals. Some Generics companies may be well placed to tap into this opportunity given their deep understanding of focus therapies and access to physicians , patients in markets with branded products. However, question marks remain with regards to generating sufficient clinical evidence for these solutions as well as defining appropriate business models to support them.

- **Contract development and manufacturing –** The global CDMO space is expected to further grow fostered by continuous outsourcing along the value chain and need for increase biologic manufacturing capacities and capabilities. Many Generic and Biosimilar companies already engage in this space and are looking to leverage the tailwinds in the segment to enhance their presence on the back of their high-quality, cost-effective manufacturing and development capabilities. Success in the segment will require focus on selected niche plays or consolidation strategies in specific therapeutic areas and will go a long way in enabling improved economic access for patients. Long term opportunities may also emerge in some of the new modalities such as cell and gene therapy, driven by the fact that manufacturing capabilities are limited for all companies in these areas.

Exhibit 4

## Digital therapeutics solution spectrum

| | Digital companion to drug | | Stand-alone digital solutions | |
|---|---|---|---|---|
| | **Drug-specific** | **Drug-agnostic** | **Behavior modifying** | **Physiology modifying** |
| **Description** | Drug-specific digital therapeutics | Digital therapeutics that can be used with multiple drugs; not tied to specific drug | Pure digital interventions leading to changes in patient behavior | Pure digital interventions impacting the underlying physiological response of the patient |
| **How they can improve outcome** | • Adherence tracking<br>• Disease monitoring<br>• Dose optimization | • Adherence tracking<br>• Disease monitoring<br>• Predictive algorithms | • Modify behavior through coaching/communication | • Modify physiological response (e.g., hormone release, pain sensitivity) |
| **Business Model** | • Primarily B2B | • B2B2C<br>• Some B2C | • B2C<br>• Some B2B2C | • B2C<br>• Some B2B2C |

Source: Press articles, market interviews.

## Key headwinds and disruptions for the industry

### (1) Sustained price pressures from regulators and customers

Price erosion is a natural given in the Generics industry, and a driver of its substantial health economic contributions. Since 2015, customer consolidation in the US had increased price pressures in the market, affecting both standard Generics as well as more complex products such as topical and inhaled formulations. While the pricing pressure on marketed products seems to be moderating since 2019, it continues to remain at a relatively high level (Exhibit 5).

Similarly, reimbursement restrictions, claw back regulations and related measures in various countries in Europe and Rest of world challenge the pricing level in these markets as well. As an example, Japan is moving from price revisions every other year to annual revisions, with off-year revision introduced in April 2021 for products with dispenser margin above 5% affecting 8,200 generic products.[24]

Concurrent to stronger and faster adoption, Biosimilars launches have also witnessed accelerated price erosion curves across markets. In recent anti-TNF launches, erosion of the price reaches ~25% average at the time of entry of the first Biosimilar. In products with significant number of competitors (5 or more) and market modalities making strong use of tenders, erosion can reach up to 70% relatively quickly.[25]

The sustained pricing pressure will require stringent containment of operating costs beyond what is bare minimum required by the industry to deliver high-quality products, particularly in light of input cost raises. If not managed carefully, this could create unfavorable economics and lead to significant negative impact on availability and access of critical products.

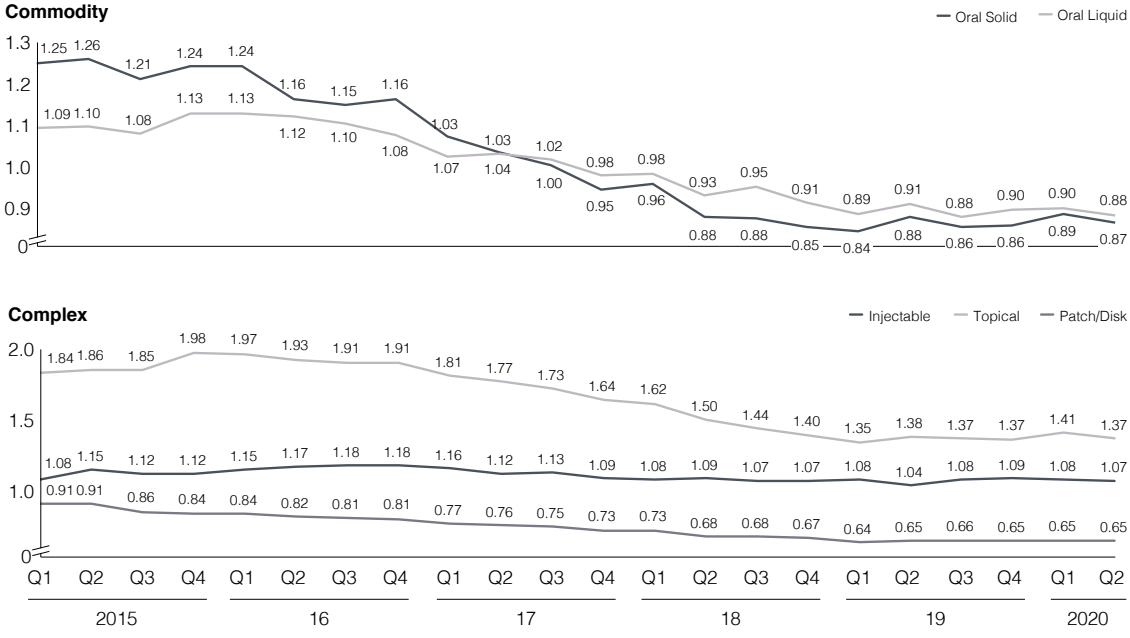
24 Pharma Japan, "MHLW Announces New Drug Prices for 1st Off-Year Revision in April", March 5 2021. https://pj.jiho.jp/article/243953

25 JI Diaz, 2020 'The Second Wave Of Biosimilars: New Scenarios, New Rules', https://www.biosimilardevelopment.com/doc/the-second-wave-of-biosimilars-new-scenarios-new-rules-0001

Exhibit 5

## US Generics price trends 2015-2020

Average price (net[1]) Index for generics drugs within a given quarter (Jan 1 2014 = $1)




1 Net prices based on NADAC survey results - National average drug acquisition cost survey of retail pharmacies

Source: Analysis based on findings from NADAC survey (National average drug acquisition cost survey of retail pharmacies)

### (2) Regulatory hurdles slowing down access to Generics and Biosimilars

Regulatory processes for standard Generics are by now widely established in regulated markets and mechanisms like GDUFA (Generic Drug User Fee Act) in the U.S. were introduced to speed up the delivery of safe and effective drugs to the public and improve upon the predictability of the review process. There are however still some barriers particularly with regards to complex Generics even in established markets. For instance, the evidence generation required in product areas like respiratory and some long-acting injectables are still substantial, driving up investments and impacting broader availability of generic products in these segments. Requirements for using market-specific reference samples across key geographies further enhances cost and risk profile of bringing these products to market. Sometimes this goes along with IP challenges and litigations, whereby originators are granted prolonged protection periods beyond the initial term foreseen for the innovation provided, ultimately delaying Generics access.

Similarly, while approval pathways for Biosimilars have been clarified considerably, clinical trial cost requirements remain substantial. This results in a high degree of risk of developers and manufacturers, even though advancements in regulatory science and in characterization capabilities are expected to minimize the need for such requirements[26].

Some of the emerging markets also continue to face challenges in having the right enabling regulatory framework (e.g. complexity in approval process, lack of well-defined approval timelines, lack of clarity on clinical study design, need for capacity augmentations, etc.) to ensure accelerated development

26 IGBA. IGBA Applauds UK MHRA Biosimilar Guidance Revision: Science-driven Evolution for Sustainable Access to Biologics. Press Release. May 2021.

of products. While these affect Generics and Biosimilars developments, their impact is even more pronounced as players attempt to build out a more innovative pipeline. Further streamlining of regulatory guidelines will be critical to enable speedy access to markets, while ensuring adequate quality and efficacy. This includes among others, regulatory convergence, harmonization and reliance, mutual recognition of compliance inspections, and regulation of IP rights in trade agreements.[27]

### (3) Vulnerability of global manufacturing and supply networks

The COVID-19 pandemic has revealed the sensitivity and vulnerability of global supply networks to disruption. The limited number of supply sources particularly for APIs / KSMs has emerged as a risk for the industry's supply chain, and the pandemic has put additional spotlight on this topic given short supply of COVID-related products which were prioritized for local requirement. In response, many governments have strengthened their efforts to build local manufacturing competency and on-/near-shore supply for a variety of medicines.

While these moves have the potential to accelerate localized production in a number of markets, such policies combined with already existing push for local manufacturing across several markets face the risk of spilling over into protectionist trends, which can have significant impact on overall product access and economic viability. Fragmenting production footprint of products across multiple locations may not only lead to loss of economies of scale thereby driving increased cost for patients but also lead to substantial challenges in maintaining strong quality and compliance standards across locations. These however continue to be high up on the regulatory agenda, and have been subject to escalating requirements over the years. As in the past this has not only led to an increased cost base for the industry, but also supply disruptions as a result of adverse inspection outcomes.

Environmental standards continue to become more stringent, with growing pressure from investors, customers, regulators and employees. This has significant implications for pharmaceutical companies at large. For example, reducing GHG emissions will require a re-look at the supply chain. Similarly, reducing the waste footprint will require re-design of products and production flows.

Balanced approach on these issues, both in terms of recognizing criticality of global supply chain while fulfilling local market needs (for example, through diversification), as well as on quality and environmental standards requirements will be critical to help the industry manage its competitiveness and ensure supply security across markets.

### (4) New modalities and technologies in the innovation pipeline increasing risk-profile of investments

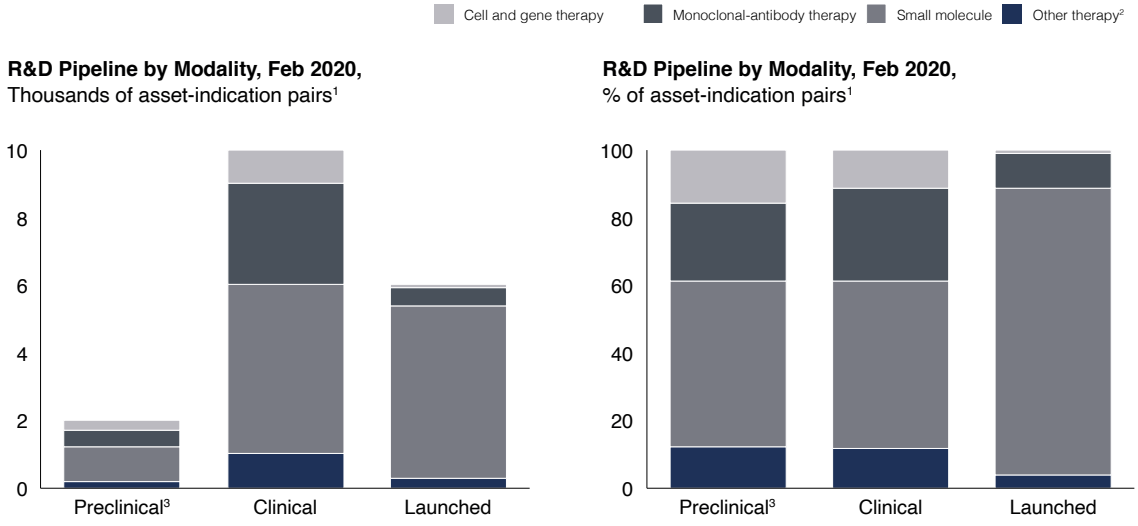
While opening growth apertures, the emergence of the pipeline dealing with non-conventional therapies poses a significant disruption for the industry. Shift away from oral solid products to more complex small molecule opportunities (such as long-acting injectables, inhalers) and Biosimilars already represented a significant scale-up in capabilities and investments for the industry, given the complex nature of these developments and more stringent clinical trials requirements. This had already increased risk-profile considerably for players participating in these opportunities.

27 IGBA. Trade principles: Generic and biosimilar medicines. June 2019.
https://www.igbamedicines.org/doc/IGBATradePrinciples.pdf

Looking further ahead, the pipeline is now seeing emergence of new modalities such as Cell and Gene therapy (Exhibit 6). There are already ~1,000 Phase I-III projects in cell and tissue therapies in the pipeline, with their number growing at increased pace over the last 5 years, and at higher rates compared to traditional opportunities). While this represents a new set of opportunity for the industry, it will require a completely new set of capabilities and substantial investments for success. In addition, patient populations for these product classes may be smaller, making it difficult to craft a scalable business proposal, and the regulatory pathways for follow-ons in this space remain to be laid out.

Exhibit 6

**R&D pipeline by modality**




1. Asset-indication pair: 1 trail per asset indication (e.g., trail of KYMRIAH for refractory B-cell acute lymphocytic leukemia)
2. Includes vaccines, proteins, and peptides
3. Underestimation of preclinical pipeline, as most manufacturers don't disclose preclinical assets

Source: Pharmaprojects, Informa, pharmaintelligence.informa.com

## (5) Emerging market continuing to pose challenges for building presence

While emerging markets represent a traditional growth opportunity and a key playing ground for improved access to medicines, they also present severe competitive and structural market challenges for Generics and Biosimilars companies. While on one hand intense local competition continues to be a challenge for players to build presence in these markets, factors such as volatile economic fundamentals, increasing price controls, push towards local manufacturing in several markets as well as non-harmonized regulatory requirements are also impacting ability of players to effectively focus on these markets. Additionally, currency effects in some of the countries may countereffect underlying growth for international players, making it less attractive to engage in these markets and support their development. Moves around partnerships or acquisitions in the past have also seen mixed successes limited overall growth performance for players in these markets.

In these conditions, opportunity as well as responsibility to develop emerging markets can shift even more to local players familiar with their respective markets' dynamics. International players will need to focus on careful selection of target markets (e.g. markets which have regulatory requirements convergence to other markets such as US, EU) and adopt a focused portfolio approach to avoid costly expansion endeavors without immediate payoff.

### (6) Gradual shift in commercial models and channel dynamics

Concurrent to the pricing challenge in many markets is a gradual shift in commercial models. Branded product niches persist, and receptiveness of classic commercial levers in promotion and sales excellence are not to be neglected. However, there is a trend towards rise in tendering and substitution requirements, with INN-prescribing and pharmacy substitution increasingly encouraged also in markets formerly known as purely physician-driven. While these regulations are likely to help drive Generic penetration further and thus will be beneficial to economic access, it is important to maintain competitive balances intact and not scrutinize price levels to unsustainable levels. The introduction and subsequent removal of tender processes in select markets and regions in Europe may be attributed to the resulting undersupply after these processes.

At the same time, channel landscape is also seeing significant disruption. While channel consolidation from integrated wholesale/ retail companies is gradually increasing in Europe (including several CEE markets), entry of non-traditional players looking to disrupt the channel and broader healthcare ecosystem will further shift competitive dynamics in this part of the value chain. These disruptions have already had significant impact in markets like China, which has seen emergence of several ecosystems. Developed as well as emerging markets are now seeing increasingly aggressive moves such as scale up into end-to-end ecosystem plays by incumbents, as well as entry of digital-first players and large conglomerate along the value chain.

Generic companies will need to develop effective trade management skills and portfolio strategies that enable attractive value bundles for new customers and partners, while at the same time thinking about innovations in commercial models to de-risk against some of these emerging competitive moves.

# Chapter 3: 2030 Vision for the Generic and Biosimilar medicines industry

The industry continues to be in a strong position on the back of its deep capabilities, contributions to healthcare systems globally and the set of tailwinds that it can continue to focus on. At the same time, the challenges/ headwinds described earlier have the potential to disrupt the outlook and sustainability for the industry. In light of this context, the Generics and Biosimilars industry would need to work towards an integrated 2030 vision, which enables it to broaden the access and reach it provides to patients and globally, while also strengthening the role it plays in the broader healthcare system (Exhibit 7).

Exhibit 7

## 2030 Vision for the Generic and Biosimilar medicines industry

***"An industry embedded in an end-to-end healthcare ecosystem, benefitting patients and institutions globally by providing access to cost-effective and high-quality modern medicines and healthcare solutions, while enabling sustainable economic contributions for all stakeholders"***

1. Expand patient access to high-quality and affordable medicines across traditional and emerging modalities
2. Step up to become a confident, well-respected strategic partner to institutions globally
3. Broaden role to help form end-to-end healthcare ecosystems along the entire continuum of care
4. Enable sustained economic contributions for economies, healthcare systems and all stakeholders

Such vision would be built around 4 pillars:

### 1. Expand patient access to high-quality and affordable medicines across traditional and emerging modalities

In line with its historic contributions, the industry should continue to expand the access that it provides to high-quality affordable medicines for patients on four dimensions. First, this access should expand to a broader set of products, including complex Generics and Biosimilars, where the industry will drive the same level of penetration and savings for patients and healthcare systems as it did for small molecules. Second, the industry should continue to innovate its commercial models (including leveraging partnerships and digital) and deepen its capabilities to enhance access to a new set of patients globally. Third, the industry should continue to introduce competition at the end of patent periods for medicines and push the originator industry to come up with next horizon of innovation for patients. Finally, the industry will also lay the ground for building its capability and providing economic access for newly emerging modalities (e.g. CGT) over the next decade.

### 2. Step up to become a confident, well-respected strategic partner to institutions globally in ensuring access

Similar to its actions during the COVID-19 pandemic, the industry should step up its role to increasingly collaborate with various institutions – providers, payers, governments, associations – even more intensively as a confident strategic partner focused on serving patients globally. Building on its critical role for population health, the industry should move forward from acting as an "on the spot" supplier of medicines to working increasingly together with institutions in ensuring equitable development of the entire Generic and Biosimilars value chain and ensure availability of critical medicines. Putting patient centricity at the forefront, the industry should partner with institutions in a way which secures innovation-oriented development, high-quality and cost-effective manufacturing and commercialization of products.

### 3. Broaden role to help form end-to-end healthcare ecosystems along the entire continuum of patient care

While traditionally the industry's focus has been on provision of affordable medicines, it is apparent that patients and healthcare institutions increasingly look for end-to-end solutions which lead to delivery of overall health outcomes, including prevention of illnesses and effective management of diseases. Rather than acting as a supplier to this trend, industry should play a central role in developing these solutions by leveraging its deep understanding of patients and science across therapies. While some of this will come in the form of individual product solutions (e.g. digital therapeutics) which the industry should develop within its focus areas, it may also need to leverage partnerships to seamlessly integrate/ build broader ecosystems. In doing so, Generics and Biosimilar companies should address the full continuum of care, and effectively team up with diagnostics providers, healthcare providers and technology companies to bring about patient-centric solutions.

### 4. Enable sustained economic contributions for economies, healthcare systems and all stakeholders

While delivering on the above, the industry should also engage in safeguarding the viability of its operations, which is critical to ensure continued medicine access and contributions to healthcare systems. The industry should aspire for continued technological advances to unlock efficiencies across the entire value chain and engage with its stakeholders, suppliers and customers to maintain an environment that supports equitable pricing and fair competitive dynamics across global markets. Beyond just ensuring sustainability of the industry, this will also help in maintaining the industry's contributions towards savings for healthcare systems globally (either directly through optimized healthcare expenditures, or indirectly through improved public health) and ensure job creation across markets.

# Chapter 4: Actions needed to achieve 2030 vision

Given the opportunities and challenges that the industry currently faces, a concerted effort across stakeholders – industry, regulators and government – will be required to help the industry achieve the outlined 2030 vision. Players across the industry should focus on strengthening core capabilities across the value chain and adopting new operating models to serve new and emerging opportunity areas. At the same time support from government and regulators will be critical in creating regulatory and policy enablers that enables the industry to bring products to the market with the right speed and cost structure.

## Imperatives for the industry to focus on

The industry should focus on 7 imperatives to help achieve the vision 2030.

### (1) Secure impeccable quality and agility in supply chain while strengthening cost position even further

The past few years have seen an increase in quality requirements and regulatory stringency. While the industry has strived hard to raise the quality and compliance standards with visible improvement in performance, it will be imperative to continue to strengthen quality and compliance even further to keep pace with evolving regulatory requirements and strive for an impeccable compliance track record.

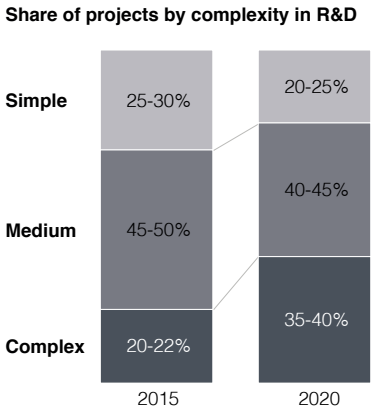
COVID-19 has also highlighted the vulnerabilities in the supply chain. Landed costs may no longer be the only metric of relevance as focus shifts to the cost implications of location risk. There is a need to re-evaluate supply chain strategy, risk tolerance and overall network footprint. Resilience may need to be built in through increased dual / multi-sourcing and geographic diversification. The demands on risk mitigation will need greater transparency across the value chain. Suppliers, drug manufacturers and distributors should collaborate to create better stock visibility and improve forecasting.

Strengthening of quality standards and increasing agility in supply chain may put upward pressure on industry cost curves. Therefore, it may be important for industry players to continue to innovate on their practices to enhance cost position even further. Industry may also explore targeted partnerships to source best cost capabilities/ expertise to further improve cost positions. This may pave the way for the emergence of specialists with deep capabilities across cost, quality and agility, and lead to a more partnership-led approach across manufacturing networks.

### (2) Balance portfolio choices across technology/ complexity with high focus on driving R&D efficiency and capability

Exhibit 8

**Generic pipeline composition by R&D complexity**




Source: Schematic illustration from market expert consultations

Over the last few years, with the shifting landscape in the global markets, we have seen a significant shift in the R&D pipeline of the industry towards more complex opportunities. Industry participants report 35-40% of their pipeline to be focused on complex projects in 2020, versus ~20% in 2015 (Exhibit 8). While this has allowed the industry to focus on areas with relatively less competition, it has also led to a rise in the risk profile of the pipeline.

Going forward, there will be a need to balance R&D efforts across standard and complex Generics and Biosimilars opportunities to ensure an optimized pipeline risk-profile, while also enabling the build-out of capabilities for newer modalities. Players should rely on smart portfolio choices to identify value creation opportunities even in competitive segments (e.g. products with limited API sources in solid oral formulations), while picking targeted bets in complex technologies for focus.

Players may need to build out a "two-pronged" operating model in R&D. One stream will leverage traditional but highly efficient process to deliver standard products at low cost and fast timelines and keep abreast of the efficiency improvements seen across the industry. The other stream could focus on strong science-based reviews and cross-functional, expert led de-risking to ensure successful development and early to market delivery of complex products. This stream will require a sharp focus on upgrading technical capabilities, onboarding of new skill sets to deliver the chosen complex pipeline (e.g. for managing large-scale patient outcome studies), and potential investments in complex manufacturing (within own or through partnered network). Players should choose their activities wisely and increasingly leverage the know-how from specialist development companies with deep focus and expertise in certain technology areas.

### (3) Reimagine commercial models to be ready for disruption

Increasingly today, physicians and other stakeholders are expecting personalized engagement. This demand, combined with changing market dynamics across geographies (e.g. increasing channel consolidation) and need for increased resource efficiency is likely to drive significant shifts in commercial operating models.

Digital adoption will see a sharp uptick to enable more targeted physician engagement, while also helping companies scale-up reach and access to a deeper set of geographies. A hybrid "phygital" model may become the norm for engagement. There may be fewer physical touch points between reps and physicians, with greater emphasis on customized content that is based on physician preferences and product lifecycle (rather than broad-based outreach with standardized information focus). Players may need to start investing in digital talent and production capabilities to support rapid content creation and experimentation, as well as a data and analytics infrastructure that can ensure the best support to HCPs and patients along the entire treatment journey. Physicians and

patients may benefit from more coordinated customer interfaces that bring together stakeholders across the company's organization and ensure targeted linkage with all partners in the commercial operations.

At the same time, players will also need to experiment with new commercial models that bring pharmaceutical companies closer to the patient and allow them to serve a broader set of unmet needs, as part of patient centric ecosystems. In addition, given the growing consolidation in the channel, players will also need to explore new models to deepen their engagement/ transparency with the channel.

### (4) Embed digital and analytics as core capability along entire value chain

While much has been undertaken by industry players to date to leverage the power of digital and analytics, companies will need to further double down on this area as a core capability to embed along the entire value chain.

In R&D, we already witnessing opportunities along all development stages including, for instance, dynamic planning and scheduling of lab operations, in-silico modelling of lab and scale-up batches, real time batch monitoring to speed up scale-up and exhibit as well as predictive modeling to optimize clinical trials design and execution (e.g. RWE led site selection for accelerating recruitment). Increasing application of such digital and analytics applications across areas will gradually make Generic and Biosimilars R&D more efficient and effective, benefitting patients through shortened development cycles and lower costs.

Companies will also need to leverage the full potential of data and analytics in the manufacturing and supply operations. Advanced analytics and artificial intelligence can come together to improve demand and supply planning, resulting in improved forecast accuracy, lesser inventory, and more capacity. In manufacturing this will not only help drive improvement in efficiency levels in the plant (e.g. OEE) and reduce conversion cost even further but will also help players strengthen their compliance levels even further. This will help create further capacity and lower cost position for increasing access for critical medicines across markets. Capturing this opportunity will require deployment of a set of digital use cases (e.g. AR/ VR enabled changeovers) as well as analytical models (e.g. to better understand process-critical parameters simulations to reduce OOS, deviations and improve yields).

Lastly, there is vast potential of digital and analytics also in the commercial area through digital marketing content, targeted customer support and deeper patient and physician relationship building via a more focused engagement which was already highlighted in the previous imperative.

While the benefits of the digital evolution are vast and largely undisputed, it will be critical for industry players to overcome the operational challenges with its progression. Embedding digital and analytics at scale requires companies to invest heavily in their data infrastructure, technological base as well as their employees' digital capabilities. Gradual reskilling of the workforce in line with the technological advances (e.g. through partnership with universities) and attracting a new type of talent (e.g. data scientists) will be paramount to keep up with the pace of change the industry is facing.

### (5) Scale step-outs beyond the core with purposeful reallocation of resources

To maintain the industry's healthy growth progression, as well as benefitting healthcare systems globally, companies will need to strike a careful balance between focusing on the core Generics and Biosimilars activities, as well as scaling its presence to select adjacent segments. Each of these adjacent step-outs will have a selected set of players focusing on them and will require its own set of imperatives for success, but if done well can significantly enhance industries ability to cater to a broader set of unmet needs for patient and can help shape the end-to-end healthcare ecosystems to improve patient outcome in line with the industry's vision. Some example of potential focus areas in this context can include

- **Branded/ Specialty pharma:** This move up the value chain will represent the next step in evolution of the industry but will require sharp prioritization of focus area (e.g. disease areas with limited physician coverage requirement), deep insights to cater to real unmet needs for patients (e.g. real safety or efficacy improvement rather than just delivery improvement) and significant build-out of capability across the value chain (e.g. across clinical, medical affairs, market access and physician detailing).

- **Consumer healthcare:** Focus here can enable industry to cater to leverage its deep scientific understanding to serve patient needs on broader wellness and prevention of ailments, rather than just treatment. However, success in the segment will require players to focus on leveraging their deep understanding and presence in home markets, bring out differentiated and personalized offerings (e.g. in self-medication and food supplement spaces) and invest smartly in brand-building

- **Digital therapeutics and solutions:** The industry can enable smart patient support in the form of companion diagnostics, empower physicians and healthcare professionals through better interplay between medication and medical devices for treatment and diagnostics, as well as craft fully digital health solutions in line patient's overall healthcare needs. Success in the segment will require deep understanding of unmet needs for patients, ecosystem of partnerships to bring together the right set of partnership and augmentation of capabilities (e.g. digital platform build-out and outreach)

Stepping out beyond the core will require a dynamic and more scientific approach to resource re-allocation. Players should look to allocating a certain portion of their capital toward step-outs and take a stage-gated approach to investments. It will be imperative, as new capabilities are built, to avoid the sunk-cost fallacy and prudently manage investments.

### (6) Drive systematic M&A and partnerships to support aspirations

There has been a steady rise in M&A and partnerships in the pharmaceuticals industry in recent years. There was some set back in 2020 due to COVID-19 pandemic implications, however by the second half of 2020 M&A deal volumes increased by 25% relative to the first half of the year.[28]

28 PWC, Global M&A Industry Trends in Health Industries, 2021.
https://www.pwc.com/gx/en/services/deals/trends/health-industries.html

Over the past years, several originators have carved out their Generics businesses, and continue to do so with a range of off-patent established products. Programmatic M&A can help industry players to scale their core activities with the additional scale and efficiency benefitting the industry as a whole. M&A can also enable players to rapidly access new capabilities and accelerate build-out of step-out opportunities highlighted earlier.

Beyond M&A, with the increasing complexity of Generics and Biosimilars development, manufacturing and commercialization, no single player will likely be able to serve all its customer needs in a fully organic evolution manner. The industry will increasingly rely on partnerships among its players to best leverage know-how and expertise of players across both traditional areas (e.g. Generics manufacturing) as well as emerging capabilities (e.g. Biosimilars). This will also get more pronounced as industry pushes to form end-to-end healthcare solutions and serve patients along their entire health journey.

Given the increasing risk-profile of pipeline and increasing focus on step-outs, industry players will also look at more diversified sources of funding and new models of partnerships to access capital. Private equity has become an important partner in funding expansion and may continue to do so with private equity dry powder at significant heights. Similarly, players will need to explore innovative setups (e.g. carve-outs) to manage the increasing risk-profile in high-investment areas (e.g. Biosimilars, specialty/ innovation, ecosystem plays).

### (7) Embed agility and new capabilities, while welcoming post-pandemic working models

Throughout the pandemic, the healthcare industry has rallied to not only ensure supply of key medicines across borders, but also the health and safety of its workforce. Organizations have become even more empathetic and pragmatic than at pre-crisis levels, focused on improving the quality and ease of work for employees. Industry players will put continued emphasis on this fact, welcoming flexible working models and ensuring a sustainable balance of company contributions and personal growth and job enrichment for its associates.

The later will be crucial as new capabilities will be needed across the value chain. In particular, the workforce will shift from manual skills to more technical skills. Rising adoption of automation, and digital and analytics tools, will place greater emphasis on talent that can program, operate, and interpret data from new technologies. Similarly, evolution of pipeline step-out into new domains will require augmentation of new skills in the organization. These shifts will need significant up-skilling and capability-building efforts and companies will need to develop a culture that fosters learning and effective onboarding of new talent even more so than in the past.

Finally, the pandemic has also led to step-up in industries capabilities to deal with disruptions. Given the likely shifts and rapid changes that the industry will continue to face, players will need to draw from these learnings and embed an agile approach of working in the organization to continue to respond effectively to disruptions.

## Enablers for the industry to achieve vision 2030

Support from key stakeholders (i.e. regulators, government and associations) will be required across 4 key areas to help the industry achieve its 2030 vision.

### (1) Enabling, efficient and consistent regulatory, compliance frameworks

A regulation and policy framework which enables speedy and cost-effective access to market, fair pricing and protection of patient safety is a key prerequisite for enhanced access and sustainable industry growth. 3 areas that regulators can focus on to enable this include

- **Simplification of guidelines in line with advancements in science** to allow for speedy and cost-efficient access of Biosimilars as well as complex Generics (e.g. inhalers). For example, increasingly advanced analytical technology will be applicable to demonstrate robust evidence of biosimilarity. Consistent recognition of this fact across markets would significantly simplify development processes for Biosimilar companies and free up substantial resources from clinical trials for new product development. Similarly, requirement of large scale patient-end point studies for complex Generics such as inhalers and long-acting injectables needs to be revisited.

- **Convergence of approval pathway across markets** will enable more cost-effective development by removing the need for market-specific development in few areas. While some positive movement has been made in this context, few areas (e.g. use of different reference standards and PK guidelines for complex Generic products) still need focus to enable industry to bring more products to market and enhance access for such high-value products.

- **Easing of regulatory approvals to aid move up towards innovation space** especially in some of the developing markets like India. This will involve simplifying guidelines to remove duplicate approvals across bodies, enhance consistency and quality of reviews/ guidance for these innovative offerings, increase capacity/ capability of regulatory bodies and enhance transparency/ collaboration with the industry

Like regulatory, industry will need support from regulators and government in establishing internationally consistent quality and compliance standards, and will look for opportunities for joint enforcement where possible. At the same time, regular dissemination of information on industry quality records and the industries' continuous improvement activities would help foster confidence in Generic and Biosimilar medicines quality for physicians, patients and the broader public.

### (2) Equitable patent and litigation systems, fostering innovation while enabling access

Generics and Biosimilars companies can only live up to their vision of expanding patient access to high-quality and affordable medicines if they are granted the chance to market their products as soon as appropriate protection periods for originator products have expired. Such periods shall be crafted in the spirit of fostering innovation, which implies they need to end timely enough so as to inspire Generics and Biosimilars companies to create their cost effective solutions as well as to urge originators to pursue the next level of development innovation. Repeated prolongation of protection for incrementally innovative lifecycle management activities may put this principle into danger and should be avoided.

Internationally consistent approaches to grant originator protection are desirable, so as to avoid overly complex management requirements and development coordination for Generics and Biosimilars companies. Similarly, consistent litigation systems with aligned approaches to enforce or challenge such protection rights will benefit the industry's confidence to invest into the next generation of cost effective medicines.

### (3) Open international borders and secure trade flows

While the global pandemic has revealed the vulnerability of global supply chains, a radical and uncoordinated shift to fully localized manufacturing would have detrimental effects on the Generics and Biosimilars industry by driving cost increases and ultimately endangering global access to medicines. No region is currently self-sustaining, and the industry will perform at its best if it can leverage the specific cost, capacity and capability advantages offered by players across various regions. Companies will want to ground their manufacturing and supply set-ups in confidence on the secure trade flows for products and the key ingredients for their manufacture. Thus, unilateral calls for "localization" should be avoided. Rather, international policy should proceed in a coordinated manner to safeguard critical supply of medicines for all countries in need, and enable global cooperation of companies jointly striving to support this cause.

### (4) Support for encouraging investments in new technology and innovation

In order to create the next generation of cost-effective medicines and move up the value chain to offer more innovative offerings, companies will need to make significant investments and take on considerable risk in R&D. Risk profile of these investments will be further elevated by the uncertainty in market access and adoption. Targeted support for the industry in managing this risk profile can lead to significant increase in level of investment and output from the industry. This is best spurred by continued policy that fosters adoption of complex Generics, Biosimilars and future modalities, not only through regulatory frameworks but also through stakeholder information, engagement and proper incentives. Targeted funding support for investment in R&D can help accentuate innovation focus, either in the product itself or in its underlying manufacturing and development processes. Generics and Biosimilars companies require a healthy reward for innovation in the form of equitable and sustainable price levels, independent of the specific price formation mechanisms which may vary across markets. This reward will trigger continued technological advances and enable the industry to help shape the healthcare ecosystem of the future.

## Conclusion

The Generic and Biosimilar medicines industry is an indispensable part of the global healthcare system, contributing to affordable access to medicines and significant health economic savings globally. As this report has laid out, the industry has ample opportunities to expand its critical role further in the next decade and beyond but will need to thoughtfully address the challenges and disruptions laid out above as well.

The 2030 vision postulated here is an attempt to lay down a common north-star for the industry participants as well as all its stakeholders as they collectively look towards shaping the next horizon of the industry by addressing these opportunities and challenges.

Achieving this vision will require concerted actions from the industry participants across the 7 dimensions. Support from all stakeholders on the enabling 4 imperatives will be critical to support the industry in this journey.

By addressing the imperatives suggested, the industry and its stakeholders will further advance the contributions of Generic and Biosimilar medicines in the future, benefitting patients and healthcare systems globally.

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NATIONAL NEWS

### Centre approves Rs 23,123 cr emergency response package to fight Covid-19

***The Centre on Thursday approved Rs 23,000 crore emergency response package for combating Covid-19 pandemic.***

*The package approved by Cabinet is to be implemented by Centre and states from July this year to Mar 2022.*

The central government on Thursday approved a Rs 23,000 crore relief package for combating Covid-19 and dealing with issues which occurred during the second wave.

Addressing the media after the first Cabinet meeting following the reshuffle, newly appointed health minister Mansukh Mandaviya said the Centre would provide Rs 15,000 crore and states Rs 8,000 crore and the plan would be implemented jointly by them across all the 736 districts of the country to improve medical infrastructure at primary and district health centres.

"Rs 23,000 crore package will be given to deal with the problems that occurred in the second wave of Covid-19. It will be used jointly by the central and state governments to boost emergency health infrastructure," Mandaviya said.

Underlining the need for a collective fight against Covid-19, Mandaviya stated the package will be implemented over the next nine months till March 2022.

"We have to collectively fight against Covid. The package approved by Cabinet is to be implemented by the Centre and states from July this year to Mar 2022. We have to get it done quickly. State governments will have to do it quickly and our duty is to help the state in every possible way," he added.

Mandaviya said this is the second phase of the 'Emergency Response and Health System Preparedness Package' as the Central government had given Rs 15,000 crore earlier for setting up Covid-dedicated hospitals and health centres across the country.

Amid fears of an impending third wave, the minister informed that around 2.4 lakh normal medical beds and 20,000 ICU beds would be created, of which 20 per cent would be specially earmarked for children.

Mandaviya said that 1050 Liquid Medical Oxygen (LMO) storage tanks with Medical Gas Pipeline System (MGPS), with an aim of supporting at least one such unit per district, would be installed under the plan.

"The plan aims to accelerate health system preparedness for immediate responsiveness for early prevention, detection and management of Covid with the focus on infrastructure development including for Paediatric Care and with measurable outcomes," he added.

The Centre would also provide support for expanding the National Architecture of e-Sanjeevani tele-consultation platform to provide upto 5 lakhs of tele-consultations per day from the present 50,000 tele-consultations per day. "This includes support to the states/UTs to enable tele-consultations with Covid patients at the Covid Care Centres (CCCs) by strengthening Hubs for eSanjeevani Tele-consultation in all the districts of the country," Mandaviya said.

*Source: India Today, 08.07.2021*

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## Moderna COVID-19 vaccine: India offers legal indemnity, but with riders

***The proposal, which has been further sent to Moderna, will be taken up by its board of directors and once granted approval, will enable immediate import by India of around seven million doses of the company's vaccine.***

India has forwarded a proposal to the US, according legal indemnity to Moderna for shipping its COVID-19 vaccine, albeit with specific conditions.

The proposal, which has been further sent to the Massachusetts-based drugmaker, will be taken up by its board of directors and once granted approval, will enable immediate import by India of around seven million doses of the company's vaccine.

"The Indian government has agreed to the indemnity clause in the best way we could. There were certain country-specific changes we wanted and we have gone ahead with such a proposal," a senior government official told the Economic Times.

The development comes briefly after Mansukh Mandaviya took charge as health minister. Last week, India's drug controller had granted approval to the import of Moderna's mRNA COVID-19 vaccine through Cipla. However, the US biotech major demanded legal indemnity in the country before making its vaccine available.

The government said on Friday that it is working actively with Moderna to see how its vaccine can be imported and made available in the country.

"Moderna vaccine is under emergency use authorisation. The government is working actively with the manufacturers to see how to make this vaccine available in the country, importing it into the country, those efforts are on the process that has to be gone through is being actively pursued," said VK Paul, member, Niti Aayog, on Friday.

Moderna's COVID-19 vaccine was granted emergency use authorisation last month. Government officials said if the company gives its consent to the proposal, it may set a precedent for the other US drugmakers Pfizer and Johnson & Johnson to bring their coronavirus vaccines to India.

*Source : BusinessToday.In, 10.07.2021*

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## Abbott expects self-use Covid test to facilitate return to work, school

***It will be priced at ₹325 for a single pack***

Abbott's Covid-19 antigen self-use test will facilitate the process of return to work and school, say top executives with the American healthcare company.

The product has been rolled out across India's retail chemist network, on the same day a similar move was initiated in Singapore. The diagnostics and pharma affiliates of Abbott have collaborated to get the product to about 5,000 chemists and five lakh pharmacies in India, across urban, semi-urban and rural areas, said

Ambati Venu, Vice President, Pharmaceuticals, Abbott India.

The product is being imported from Korea, he said, adding that he did not see constraints on the supply side. Available in multiple packs of one, 10 and 20 tests, it is priced at 325 for a single pack.

It till be a game-changer, given an imminent third wave, he told *BusinessLine*, adding that it will be available in a tiered-model for home use, assisted testing at primary health centres, labs and clinics.

**Self-test**

The Panbio antigen self-test for detection of the SARS-CoV-2 virus in adults and children with or without symptoms involves using a nasal swab (not the deep nasopharyngeal swab) as indicated on the pack. The kit contains all the materials required, including nasal swabs, test devices and reagent ampules. No additional instrumentation is required to conduct the test, said the company.

With results in just 15 minutes, the test allows people who test positive to self-isolate and not infect others. It is used along with Abbott's NAVICA mobile app that offers a self-registration and automatic reading of results and easy reporting as per ICMR guidelines, the company explained.

Sanjeev Johar, President (Asia-Pacific) with Abbott's Rapid Diagnostics, said India was the second country in the region, after Singapore, to have the product. It was launched a month ago in Singapore, where supplies were more restricted and handled by the Health Ministry.

But from Monday, it will be in convenience stores and supermarkets, he said. Addressing the issue of high false positives with antigen tests, he said the Panbio professional test demonstrated 95.7 per cent sensitivity and 97.6 per cent specificity when benchmarked against RT-PCR tests, indicating high reliability. It has a European regulatory CE mark for asymptomatic use and supervised nasal swab collection and was on the WHO Emergency Use Listing, said the company.

*Source : PT Jyothi Datta , Business Line, 13.07.2021*

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## Submitted all documents for Covaxin EUL to WHO: Ella

Hyderabad: Bharat Biotech has submitted all the documents required for emergency use listing (EUL) of indigenously developed Covid-19 vaccine Covaxin to the World Health Organisation (WHO), its chairman and managing director Dr Krishna Ella said on Monday.

He said this marks the beginning of the review process for the vaccine. "All documents required for EUL of Covaxin have been submitted to WHO as of July 9. The review process has now commenced with the expectation that we will receive EUL from WHO at the earliest," said a statement by Dr Ella tweeted by Bharat Biotech's official Twitter handle.

WHO had accepted the company's expression of interest (EOI) for Covaxin in mid-June following which the company made public, earlier this month, its final Phase-3 trials data which shows that the vaccine has an efficacy of 77.8%.

Over the weekend, during a webinar, WHO chief scientist Sowmya Swaminathan had indicated that Bharat Biotech has submitted the complete data and the global health body is expected to take a decision on Covaxin's EUL over the next four to six weeks.

A WHO nod would be a major booster shot for Covaxin as it would grant it global acceptance and ease concerns of international travellers about travel restrictions on those who have taken vaccines that are not yet approved by WHO.

*Source : Swati Bharadwaj , TNN , 13.07.2021*

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## PLUSS to provide transport, storage solution to Dr Reddy's for Sputnik V vaccine

**PLUSS Celsure box controls and maintains the temperature at -18° to ensure vaccine's efficacy**

Pluss Advanced Technologies (PLUSS) has announced that it will supply its Celsure Covid Suraksha box to Dr Reddy's Laboratories for temperature-controlled transport and storage of the Sputnik V vaccine in India.

The company's PLUSS Celsure box with 'phase change material' technology controls and maintains the temperature at minus 18 degree centigrade (-18°C), required to ensure the efficacy of Sputnik V vaccine.

The partnership entails turnkey engagement with Dr Reddy's for Celsure packaging. PLUSS provides pre-conditioned Celsure box at Dr. Reddy's warehouse to be used for Sputnik V packing. A separate specialized conditioning centre has been set up locally in Hyderabad with a fleet of 'rapid PCM recharging stations' and mechanisms built for "track and trace."

The Celsure COVID SURAKSHA box can maintain inside-temperature passively, without electricity.

Dr. Reddy's pilot soft launch of the Sputnik V vaccine in Hyderabad on May 14 has been scaled up to over 27 cities across India ahead of the commercial launch.

Samit Jain, CEO, PLUSS in a statement said, "It is a privilege to be a part of Dr. Reddy's effort to provide the Sputnik V vaccine. In order to meet the demand, we have added to our manufacturing capacity and will continue work towards ensuring that the vaccine reaches safely to its destination."

**Customisation**

The Celsure box can be customized to maintain inside temperatures in over 40 different ranges, from -77°C to +89°C, for time ranging for a few hours to a few days.

This allows maintenance of the integrity of pharmaceutical products, including vaccines, during transit, dispensing the need of electricity or fuel powered cold rooms, refrigerated trailer trucks or refrigerators at vaccination sites. It has developed over 35 temperature maintenance products using phase change materials, for a variety of applications.

*Source : Business Line, 13.07.2021*

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## Pharma biggies likely prime bidders for Kokapet land

Hyderabad: Ahead of the much-publicised Kokapet land auction on July 15, market sources indicate that majority of big-ticket bidders are likely to be pharmaceutical and hospital giants — most of them headquartered in Hyderabad. While multiple real estate majors from Bengaluru, Chennai and Mumbai too are expected to be in the fray, they maintain that the pharma sector will emerge as key player. "That's that most cash-rich industry at the moment," said a senior property consultant from the city. "The rumblings within real estate sector suggest these firms are planning to buy the land and enter into joint ventures with developers, both for commercial and residential projects. It is learnt that the government too is encouraging them to participate in the bidding, and has been holding one-on-one meetings with some pharma heads."

According to the plan, Thursday's e-auction will see 65 acres of unutilised land — at Neopolis and Golden Mile in Kokapet and Khanamet — go under the hammer. Government officials say that 80 to 90 individuals/groups are likely to participate in it. They also admit to a keen interest among pharma companies, to acquire land. "At least four leading names from the pharma industry had participated in the pre-bid meeting that was held in June. So, it seems likely that they will invest in Kokapet," said a senior government official privy to the developments. The bidding price, he indicated, could range between Rs 30 crore and Rs 35 crore per acre. "With the pharma sector's participation, we can even expect it to hit Rs 40 crore per acre, for some plots. In fact, the government is hoping to make at least Rs 2,000 crore from this auction," said another senior realtor, in discussion with some prospective bidders. He reiterated: "Though we might see many mainstream developers joining in, it might not be viable for them to buy land at this price. They would, much rather, partner with pharma owners to develop the area." In 2006, the Hyderabad Metropolitan Development Authority auctioned 166 acres under Golden Mile for Rs 14.5 crore per acre.

*Source : Sudipta Sengupta , TNN, 13.07.2021*

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## Tamil Nadu to launch pneumococcal vaccine immunisation today


Every child will take three doses of PCV

CHENNAI: The state government will on Tuesday launch the Pneumococcal Conjugate Vaccine (PCV) under universal immunisation programme. It is expected to help reduce deaths due to pneumonia and meningitis among children below five. Roughly 9.23 lakh children are expected to benefit from the programme in the coming year. Health minister Ma Subramanian will inaugurate the programme at a staterun health centre in Poonamallee,

said director of public health Dr TS Selvavinayagam. Every child will take three doses of PCV — in the 6th week, 14th week and 9th month —for protection from pneumonia, one of the major causes for death in children below five. PCV will be provided free to children along with other vaccines under the UIP. Currently, a six-week old child receives oral polio vaccine (OPV), rotavirus vaccine (oral drops), inactivated polio vaccine (IPV) and penta vaccine (intramuscular injection). Now PCV will join the list, said a senior health department official. Pneumonia is mostly caused by Haemophilus influenzae and Streptococcus pneumoniae. The incidence of pneumonia due to H influenzae was earlier around 85%. Now, it has reduced to 15% because of the penta vaccine administered by the government under the UIP PCV will help reduce pneumonia due to Streptococcus pneumoniae and eventually reducing the infant mortality rate, the official added. Paediatrician S Balasubramanian, part of earlier PCV trials, said the programme helped countries like the US in reducing pneumonia deaths not only in children but even among adults. It has been two decades since PCV arrived in India. First came PCV 7 and then PCV 13. "In the public domain, it is expensive at 1,500- 3,200. So it is a welcome thing that the government is administering it under the UIP," said Dr Balasubramanian from Kanchi Kamakoti Childs Trust Hospital.

Tamil Nadu rolled out PCV programme in 2019 but only for babies with low birth weight. Later, it was extended to children who suffered from lung diseases and those who underwent cardiac surgeries.

*Source : Times of India, 13.07.2021*

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## Alembic Pharmaceuticals gets USFDA final approval for Erlotinib Tablets

***Erlotinib Tablets are indicated for the treatment of patients with metastatic non-small cell lung cancer and locally advanced, unresectable or metastatic pancreatic cancer***

Alembic Pharmaceuticals announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Erlotinib Tablets, 25 mg, 100 mg, and 150 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tarceva Tablets, 25 mg, 100 mg, and 150 mg, of OSI Pharmaceuticals.

Erlotinib Tablets are indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Erlotinib Tablet in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Erlotinib Tablets, 25 mg, 100 mg, and 150 mg, have an estimated market size of $37 million for twelve months ending March 2021 according to IQVIA. Alembic has a cumulative total of 148 ANDA approvals (130 final approvals and 18 tentative approvals) from USFDA.

*Source : Express Pharma News Bureau, 09.07.2021*

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## Centre identifies items for customs exemptions review, invites industry views

***Importers, exporters, domestic industry and trade associations are invited to give views on the subject for consideration by the government by August 10 on the 'MyGov.in' portal***

*Giving a list of 97 notifications, the Government said certain Customs exemptions have been identified for purpose of further review*

The government has identified a host of customs exemptions for review and has invited suggestions from trade and industry bodies on the same.

Importers, exporters, domestic industry and trade associations are invited to give views on the subject for consideration by the government by August 10 on the 'MyGov.in' portal.

Some key products covered under the list include fabrics, games/sports requisites, magnetron for microwave manufacturing, specified parts for PCB, set-up box, routers, broadband modem, contraceptives and artificial kidney.

The list also includes magnetic tapes, photographic, filming, sound recording/ radio equipment, parts/ raw material for manufacture of goods supplied for off-shore oil exploration, specified machinery/ parts covered in textile industry.

Finance Minister Nirmala Sitharaman in her 2020-21 Budget speech had announced that a further review of existing customs exemption notifications would be undertaken through extensive consultations.

Giving a list of 97 notifications, the Government said certain Customs exemptions have been identified for purpose of further review.

"Suggestions are invited in respect of their review which may include the need for review of the notification, amendment in wording of the notification for bringing clarity, consolidation, other relevant factors such as extent of use, etc," it added.

The Central Board of Indirect Taxes and Customs (CBIC) last year too had conducted this crowdsourcing exercise to identify the customs duty exceptions which need to be reviewed. Following that, the government has now drawn up a list of notifications and invited stakeholder views for a comprehensive review.

Exemptions from customs duty have been given in public interest from time to time and a review of the Customs laws and procedures would help to align them with the needs of changing times and ease of doing business.

Abhishek Jain, Tax Partner, EY, said the government seems to be looking at exemptions prevalent for divergent sectors as is evident from the list of targeted Customs exemption entries released by the government.

"As such, the various industries should see if their goods are being covered in the said exemption entries, and provide their recommendation to the government in a timely fashion, so as to ensure certain scope for further liasioning in case the government has any further queries. "The suggestions are most likely are to vary from sector to sector considering parameters such as how much that sector is ready to manufacture the currently imported product in India, the possible threat to the domestic players in case of further customs duty reduction," Jain added.

*Source : PTI,11.07.2021*

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## Covid-19 pandemic: Pfizer seeks US regulator's nod for booster shot

***FDA and EU regulator say no need for extra dosage at this time***

Pfizer and partner BioNTech plan to ask US and European regulators within weeks to authorise a booster dose of its Covid-19 vaccine, based on evidence of greater risk of infection six months after inoculation and the spread of the highly contagious Delta variant.

The US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) said, however, in a joint statement that Americans who have been fully vaccinated do not need a booster shot at this time.

The European Medicines Agency (EMA), too, said it was early to determine whether more than the two shots that are currently required would be called for, saying it was confident for now that the established regimen was sufficient.

The World Health Organization (WHO) has said it is not clear whether booster vaccines shots be useful to maintain protection against the virus. "We don't know whether booster vaccines will be needed to maintain protection against Covid-19 until additional data is collected, but the question is under consideration by researchers," the global agency said in a reply to a Reuters query.

On the other hand, Pfizer's chief scientific officer, Mikael Dolsten, said the recently reported dip in the vaccine's effectiveness in Israel was mostly due to infections in people who had been vaccinated in the beginning of this year. Israel's health ministry said vaccine effectiveness in preventing both infection and symptomatic disease fell to 64 per cent in June.

"The Pfizer vaccine is highly active against the Delta variant," Dolsten said. But after six months, he said, "there likely is the risk of reinfection as antibodies, as predicted, wane." The data would be submitted to the FDA within the next month.

*Source : Business Standard, 9.07.2021*

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## WHO's Soumya Swaminathan calls for vaccine technology pools, IP waiver

***A vaccine manufacturing task force has been launched by WHO that announced the first MRna vaccine hub in South Africa. This is expected be a good pilot to figure how new technology can be taken to other countries.***


*The target at present is to vaccinate at least 10% of the vulnerable in every country by September.*

Soumya Swaminathan, a scientist at the World Health Organisation (WHO), has urged countries to explore options for increasing vaccine production, including voluntary licences, technology pools, use of TRIPS flexibilities and waiver of intellectual property provisions. Countries would need to invest in local vaccine manufacturing capacities and it is a good time as there was lot of political momentum, she said.

A vaccine manufacturing task force has been launched by WHO that announced the first MRna vaccine hub in South Africa. This is expected be a good pilot to figure how new technology can be taken to other countries.

The COVAX target was to delivery two billion doses by end of 2021 to ensure equitable distribution of vaccine and have a 20% coverage and Serum Institute of India's Covishield vaccine was to be the main supplier. COVAX has so far delivered 100 million doses. None of the manufacturers had prioritised COVAX and as a result supplies have been delayed. The target at present is to vaccinate at least 10% of the vulnerable in every country by September.

Large volumes of vaccines are expected to go out in the last quarter of this year and help achieve the two billion dose target. WHO's goal is 40% coverage in every country by end of this year and 70% of the population by the middle of next year, Swaminathan said. A short term quick win in supplies was possible with dose sharing by those who have excess doses and have achieved 30-40% coverage, she suggested.

Nearly 77% of all doses have been administered in top 10 countries and 41% in the top one. Low income countries have received just 0.3% of doses, Swaminathan said on Friday at a Down to Earth webinar on vaccines – the global race between the virus, its variants and the vaccines.

There were 105 Covid-19 vaccine candidates in clinical evaluation and out of these 27 were in Phase 3/4 while 184 candidates were in preclinical evaluation. Six vaccines have received WHO Emergency Use listing. Bharat Biotech has started uploading data on to the WHO portal and that will be the next vaccine viewed by the expert committee, she said. A decision about listing was expected in four to six weeks.

COVAX had dealt with indemnity issues and fear among vaccine companies about law suits by creating a system where each country did not have set up a compensation mechanism and a fund. COVAX paid premium for insurance coverage so any person in the 192 countries suffered an adverse event or death due to the vaccine, they would be eligible for compensation without having to go individually and fight legal cases.

Swaminathan was worried about rise in cases and subsequent increase in deaths. In the last 24 hours there have been 4.84 lakh new cases and 9,391 deaths across the world. Brazil, India, Indonesia, US and UK accounted for the highest new cases. Europe had reported a 32.2% rise in new cases in the last seven days. There was a 21.2% rise in cases in Eastern Mediterranean and 18.2% rise in Africa. She attributed this rise to the rise case to the Delta variant which was very transmissible with one person infecting seven to eight people compared as opposed to the original Wuhan strain where one person would infect two to three people. The social mixing seen in many countries, relaxation of public health measure and inadequate vaccine coverage was also causing rise in case.

*Source : Financial Express, 10.07.2021*

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Communication Feature



**Mahendra Patel**
*Managing Director*, Lincoln Pharmaceuticals Ltd

# Lincoln Pharmaceuticals Ltd on a strong growth momentum for FY22

**Strong Foundation for the next big leap**

- Debt Free company; 5 Year PAT CAGR of 20% plus
- Exports increased to 65% of in FY21 from 11% in FY13
- Setting up a Cephalosporin Plant with estimated capex of ₹40-45 crore.
- Promoter Group raise holding to 37.26% in Mar 21 from 32.36% in Mar 20 – rise of 4.9%.
- Rating Agency ICRA Upgraded Rating and Outlook of the company

Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies, is expected to continue its strong growth momentum in FY22. Strategic growth initiatives, geographical and product expansion, strong performance in the domestic and international markets, EU approval along with operational efficiency and debt-free status are likely to contribute to healthy growth and maximise value for all stakeholders in the near to medium term. Established in 1979, the company develops and manufactures affordable and innovative medicines for healthier lives. The company has developed 600+ formulations in 15 therapeutic areas and has a strong product and brand portfolio.

This includes anti-infective, respiratory system, gynaecology, cardio and CNS, anti-bacterial, anti-diabetic and anti-malaria products, among others. The company has filed 25+ patent applications and has been awarded with seven patents. It has a strong presence in the domestic market nationally with a dedicated field force of over 600 personnel who cater to more than 30,000 doctors and chemists across the country. Lincoln Pharmaceuticals has a wide national distribution network through 21+ super stockists and over 50,000 retailers in 26 states across India.

## Expansion Plans

Expanding the product basket, the company plans to introduce 6-7 new products in the domestic markets and expects 20-25 new dossiers' approval for the export market. The company is also investing around ₹40-45 crore in setting up a Cephalosporin plant. "For the next phase of growth, the company is building a strong portfolio in lifestyle and chronic segments, especially dermatology, gastro and pain management to complement its strong presence in the acute segment," said Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Ltd.

## Export Business

The export business of the company has shown remarkable growth in the last few years and has increased to 65 per cent of total sales in FY21 from 11 per cent of total sales in FY13. The company currently exports to 60+ countries including East and West Africa, Central and Latin America and Southeast Asia.

For FY21, exports grew 18.4 per cent to ₹270 crore. During FY20 the company received EU GMP from FDA, Germany. It has started product registration in the EU and plans to enter the dermatology, gastro and pain management segments in the first phase and gradually expand the product portfolio. With the EU certification, the company will expand its business network to 90+ countries.

## Strong Financials

The liquidity position of the company is on a strong foundation, supported by healthy cash accruals, no term debt and healthy return ratios. For FY21 the company reported healthy ROCE at 22.1 per cent, RONW at 17.5 per cent with net profit margin of 14.6 per cent. The book value of the company was ₹188 per share while the net worth was ₹376 crore as on March 2021. During FY21 the promoter group of the company increased its holding to 37.26 per cent – rise of 4.9 per cent from 32.36 per cent as on March 2020. The promoter group bought 9.8 lakh shares from the secondary market during the year.

## Business Outlook

Over the last five years the company has delivered a robust 20 per cent CAGR in profits and higher single-digit growth in sales. Backed by improvement in the company's financial risk profile, steady growth in scale and margins and healthy profitability, rating agency ICRA has upgraded the company's long term and short term ratings. "We expect the same growth momentum to continue in the coming years. Our strategic growth initiatives, product and geographical expansion and operational efficiency are likely to maximise value for all stakeholders in the near to medium term. For FY21-22 the company is looking at sales growth of 15-20 per cent while maintaining healthy EBITA and net profit margins," Patel said.

**Financial Performance in Last Decade**

| Year | Revenue | EBITDA | PAT | Share Price |
|---|---|---|---|---|
| FY21 | 424 | 92 | 62 | 316* |
| FY11 | 189 | 13 | 6 | 35 |
| 10-Year CAGR (%) | 8.4 | 21.6 | 26.3 | 24.6 |

* Share price as on June 25, 2021.

*Source : Dalal Street Investment Journal, July 05-18, 2021*

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