



INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

A Vision for the Global Generic and Biosimilar Medicines Industry

Whitepaper

May 2021



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,

A handwritten signature in black ink, appearing to read 'Suzette Kox', with a stylized flourish at the end.

Suzette Kox
IGBA Secretary General

info@igbamedicines.org

June 2021

Contents

Chapter 1:	
Generic and Biosimilar medicines industry – contributions and evolving context	7
A strong contributor to global health outcomes.....	7
A key source for healthcare savings and economic development	8
A growing industry with strong fundamentals, but facing several discontinuities	9
<hr/>	
Chapter 2:	
Road ahead – opportunities, challenges and disruptions for the industry	11
Key opportunities which can enable the industry	11
Key headwinds and disruptions for the industry	15
<hr/>	
Chapter 3:	
2030 Vision for the Generic and Biosimilar medicines industry.....	20
<hr/>	
Chapter 4:	
Actions needed to achieve 2030 vision	22
Imperatives for the industry to focus on.....	22
Enablers for the industry to achieve vision 2030	27
<hr/>	
Conclusion.....	29

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 2020⁴.

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 period⁵. 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 treatment⁶.

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>

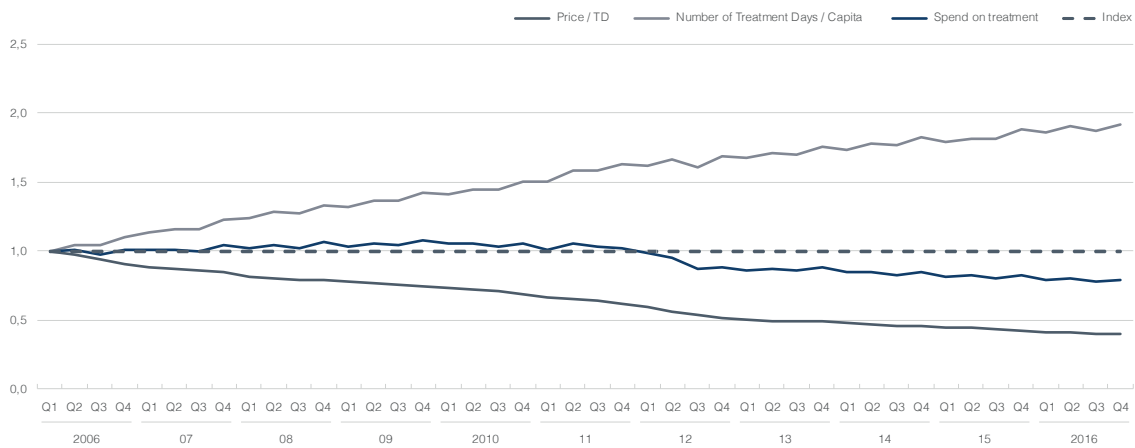
6 WHO, HIV/AIDS Fact Sheet, 2020.

<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 areas¹



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 safeguarding 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 licences⁷. 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 medicines¹². 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 generate 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.

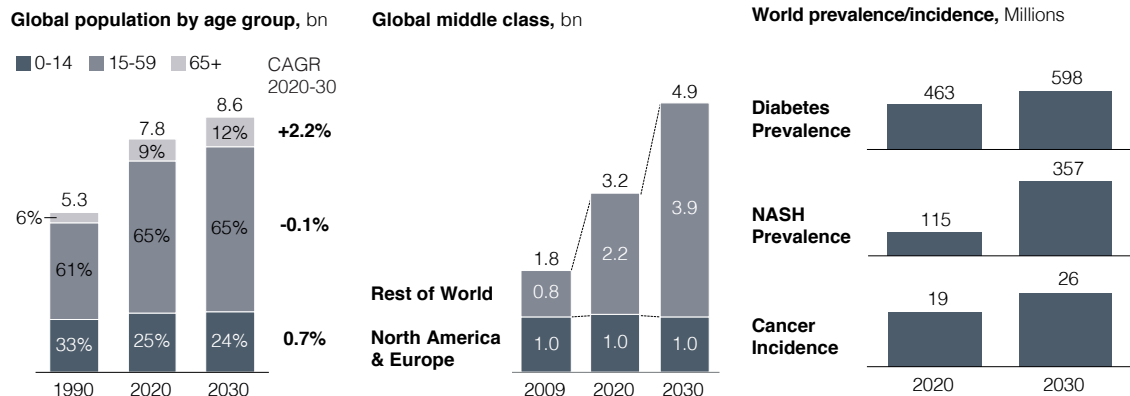
Key opportunities which can enable the industry

(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 world²⁰, 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/>

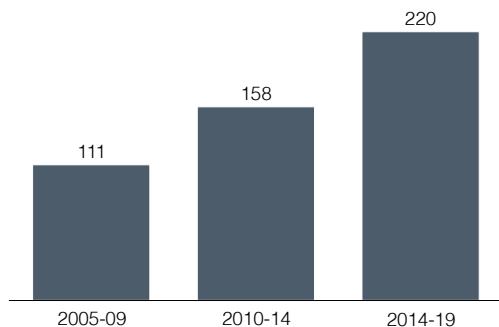
(2) Continued trajectory in the innovation pipeline

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.

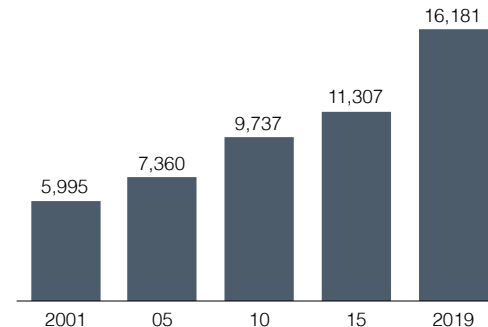
Exhibit 3

Rise in number of NME approvals and pipeline assets

Number of NMEs approved in the US



Worldwide R&D pipeline size (drug count)



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, respectively²¹

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 ~1/3rd of 505(b)(2) applications in the US over 2015-2020²³.

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	<ul style="list-style-type: none"> Adherence tracking Disease monitoring Dose optimization 	<ul style="list-style-type: none"> Adherence tracking Disease monitoring Predictive algorithms 	<ul style="list-style-type: none"> Modify behavior through coaching/communication 	<ul style="list-style-type: none"> Modify physiological response (e.g., hormone release, pain sensitivity)
Business Model	<ul style="list-style-type: none"> Primarily B2B 	<ul style="list-style-type: none"> B2B2C Some B2C 	<ul style="list-style-type: none"> B2C Some B2B2C 	<ul style="list-style-type: none"> B2C 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

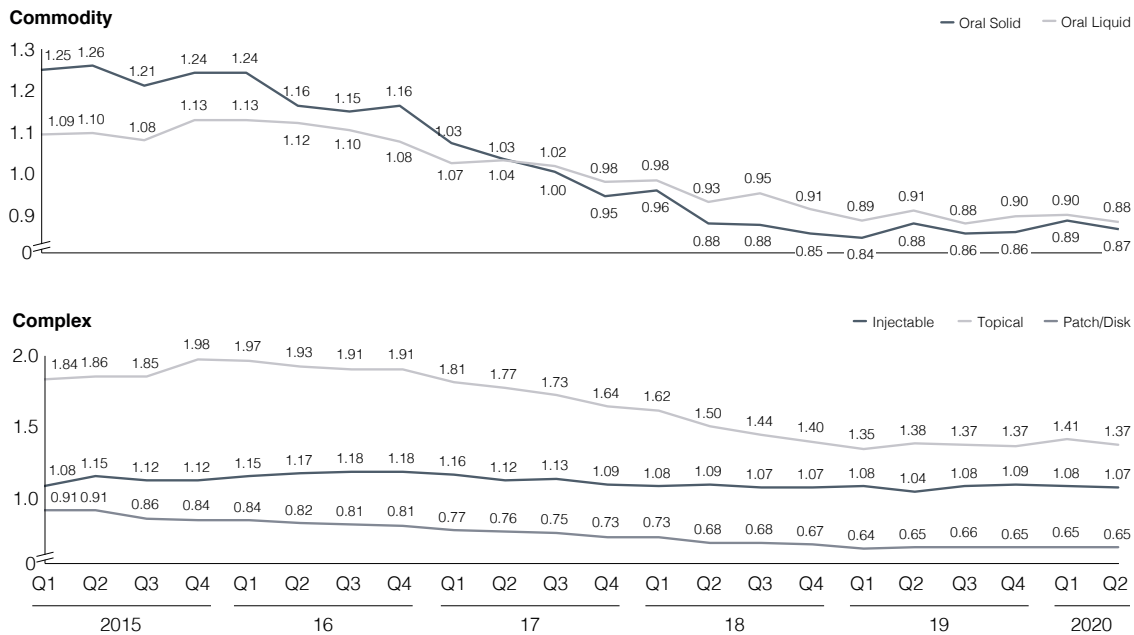
The sustained pricing pressure will require stringent containment of operating costs beyond what is bare minimum required by the industry to deliver high-quality products, particularly in light of input cost raises. If not managed carefully, this could create unfavorable economics and lead to significant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

US Generics price trends 2015-2020

Average price (net¹) 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 requirements²⁶.

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

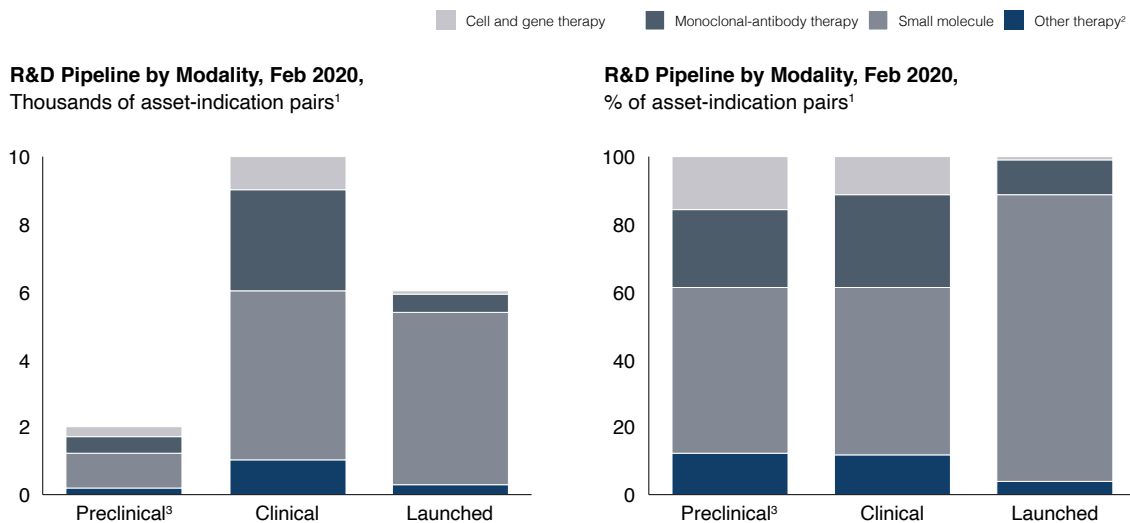
While opening growth apertures, the emergence of the pipeline dealing with non-conventional therapies poses a significant disruption for the industry. Shift away from oral solid products to more complex small molecule opportunities (such as long-acting injectables, inhalers) and Biosimilars already represented 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.

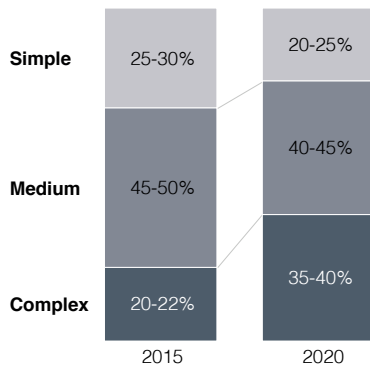
Strengthening of quality standards and increasing agility in supply chain may put upward pressure on industry cost curves. Therefore, it may be important for industry players to continue to innovate on their practices to enhance cost position even further. Industry may also explore targeted partnerships 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

Share of projects by complexity in R&D



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.