

# Assessing pharma companies' response to COVID-19 and the threat of future pandemics

## SPECIAL REPORT: COVID-19 & PANDEMIC PREPAREDNESS

The COVID-19 pandemic has had enormous consequences globally, not least in low- and middle-income countries (LMICs). It has shown the pharmaceutical industry's capacity to quickly bring products to market, but has also highlighted the inequitable distribution of new vaccines and therapeutics.

The Index analyses data about 'coronaviral diseases,' a category that covers all coronaviruses including COVID-19, Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome (SARS). However, during the period of analysis for the 2022 Index, the overwhelming majority of products developed for coronaviral diseases targeted COVID-19.

This Special Report looks at how companies responded in the initial phase of the COVID-19 pandemic by rapidly engaging in research and development (R&D) to develop products targeting COVID-19. It also analyses how companies perform in terms of registration and applying equitable access strategies for COVID-19 vaccines. Additionally, the report outlines how some companies engaged in voluntary licensing agreements and technology transfers to enable generic supply of COVID-19 vaccines and therapeutics. Finally, the Index looks forward towards how companies are preparing for future epidemics and pandemics.

## CONTEXT

## Where we are now: the impact of the COVID-19 pandemic in LMICs

The COVID-19 pandemic has had a devastating effect in LMICs. It placed a huge burden on weak health systems and disrupted other important public health services, such as routine childhood immunisation campaigns. For example, in 2020, an additional 3.7 million children did not receive their DTP (diphtheria, pertussis, and tetanus) vaccine.<sup>1</sup> Further, the World Health Organization (WHO) estimates that the COVID-19 pandemic resulted in an additional 14 million cases of malaria and 69,000 deaths from malaria in 2020.<sup>2</sup> Alongside the direct effects on people's health, lockdowns and COVID-19 prevention measures have prevented individuals from conducting their usual social and economic activities, thereby increasing poverty and inequality.

In LMICs, lack of access to COVID-19 vaccines and treatments has exacerbated the effects of the pandemic. According to one study, an estimated 600,000 deaths in LMICs could have been prevented in the period up to December 2021 if WHO vaccination targets of 40% had been achieved.<sup>3</sup>

The inequitable distribution of vaccines has been observed in previous pandemics, such as during the H1N1 pandemic in 2009. This resulted from the greater purchasing power of high-income countries in comparison to LMICs, and also due to the lack of global vaccine production capacity.<sup>4</sup> Despite efforts from global health organisations, a similar situation has been observed during the COVID-19 pandemic.

### What is the role of pharmaceutical companies in ensuring equitable access to COVID-19 products?

Several factors have contributed to the inequitable supply of COVID-19 vaccines globally, including a lack of capacity to immediately scale up production, poor supply chain infrastructure and weak health systems.

Furthermore, early large-scale buying of most available stock by high-bidding high-income countries left little for international procurement for LMICs. Donation programmes, while important, were not sufficient to bridge the gap in access and ensure sustainable global supply. When public investments are made in R&D, as they have been during the COVID-19 pandemic, conditions for future investments could include obligations to reserve part of the early production capacity for people in LMICs to help increase access and limit health inequities.

Pharmaceutical companies have a public health responsibility to ensure people have equitable access to COVID-19 products by taking steps both during drug development and after products are launched on the market. Examples of important steps for the future include investing in innovative R&D projects to target diseases with epidemic or pandemic potential. Planning ahead for access during the R&D stage, or 'access planning,' is also necessary to ensure products can be made rapidly and universally available.

On the supply side, companies can engage in technology transfers and voluntary licensing with local manufacturers to scale up production in LMICs. Additionally, they must ensure that these products are affordable in LMICs. These steps are needed not only to ensure equitable access to COVID-19 products, but also to ensure all countries have the necessary knowledge, infrastructures, strategies and tools prepared for inevitable future pandemics.

RESEARCH & DEVELOPMENT

### R&D for COVID-19 accelerated in response to urgent need

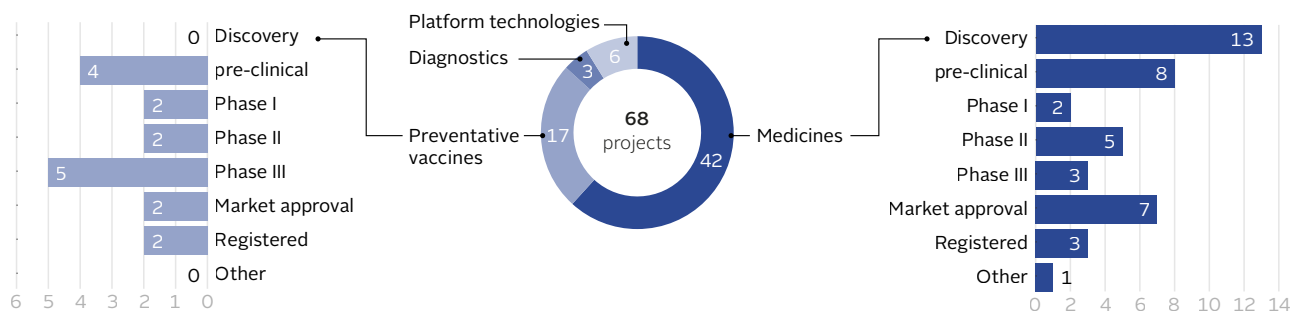
During the period of analysis,\* four preventative vaccines and ten medicines were registered or received regulatory approval.\*\* Several of these products received US Food and Drug Administration (FDA) Emergency Use Authorisation (EUA) or European Medicines Agency (EMA) conditional marketing authorisation, which are mechanisms designed to facilitate availability during a public health emergency. Such provisional authorisations enabled products targeting COVID-19 to be accelerated through the pipeline, indicating that companies can rapidly respond to urgent R&D needs and dedicate resources and investments towards finding solutions.

In addition to new innovations, some companies in scope of the Index invested resources into researching whether they could repurpose products that were already approved for other diseases and conducted trials to test products from their portfolios against COVID-19. For example, Roche's tocilizumab (Actemra®/RoActemra®) and Eli Lilly's baricitinib (Olumiant®), both of which were originally indicated for rheumatoid arthritis, received FDA EUA for the treatment of COVID-19 in hospitalised patients.

Of the 20 companies in scope, 17 were engaged in projects targeting COVID-19 during the period of analysis. During this two-year period, the companies collectively had 68 R&D projects in the pipeline targeting coronaviral diseases, including vaccines, medicines, diagnostics and platform technologies. This represents the second highest number of R&D projects in development for any disease in scope, after cancer. The number of projects in development surpasses those of other diseases including malaria (55 projects), HIV/AIDS (46 projects) and tuberculosis (34 projects). Unsurprisingly, the number of projects correlates with investment in R&D; in 2020, USD 3.87 billion was quickly made available for COVID-19 R&D.<sup>5</sup>

FIGURE 11 Multiple R&D projects targeting COVID-19 have already resulted in approved\*\* and/or registered products

Of the 68 R&D projects devoted to COVID-19 or unspecified coronaviral diseases during the period of analysis, 42 were medicines and 17 were vaccines.



\*Period of analysis for the 2022 Index: 1 June 2020 to 31 May 2022.

\*\*This number includes vaccines that received emergency use authorisation or conditional marketing approval during the period of analysis

PRODUCT DELIVERY

## Companies launched key vaccines and therapeutics targeting COVID-19

Pharmaceutical companies have been key stakeholders in the fight against COVID-19, having quickly developed vaccines, treatments and diagnostics for the virus and brought them to market. Due to the rapid progression from development to product launch during the two-year period of analysis, several projects/products are not only included in the Index's scope of analysis as R&D projects, but are also already assessed as products in the companies' portfolios. To be included in the Index portfolio, a product must have received regulatory approval (or EUA), the first necessary step to ensure a product is available.

The Index found that eight of the 20 companies in scope had COVID-19 products in their portfolios, with a combined total of 17 products – including vaccines, therapeutics, diagnostics and platform technologies. Three COVID-19 vaccines are included in the portfolio: AstraZeneca's COVID-19 vaccine ChAdOx1-S [recombinant] (Vaxzevria), Pfizer's BioNTech's COVID-19 mRNA vaccine (nucleoside-modified) (Comirnaty®) and Johnson & Johnson's COVID-19 vaccine (Ad26.COV2-S [recombinant]). Of these three, Johnson & Johnson's was filed most widely for registration in countries in scope of the Index (41), followed by Pfizer's COVID-19 vaccine (37) and AstraZeneca's COVID-19 vaccine (14). Furthermore, for both Johnson & Johnson and Pfizer, their COVID-19 vaccines were the most widely registered of any the products selected from their portfolio for analysis.

This suggests that, despite weak regulatory capacity in many LMICs, pharmaceutical companies were still able to successfully file their COVID-19 vaccines for registration, although much of this was facilitated through EUA in response to the urgency of the pandemic. Going forward, however, companies can explore other facilitated registration pathways to overcome regulatory barriers in order to file other products in their portfolios for registration in LMICs with weak regulatory capacity.

### What access strategies were used to ensure COVID-19 vaccines and therapeutics reach LMICs?

Pharmaceutical companies should use access strategies to expand access to key products in their portfolios so that they reach people across LMICs, including those at the base of the income pyramid. Such strategies can include equitable pricing, voluntary licensing, product donations and technology transfer. When setting pricing strategies, companies are expected to aim for affordability, and to integrate a payer's ability to pay for the product in their pricing approach. The Index identified three key mechanisms that companies have used to increase access in LMICs for COVID-19 products: non-exclusive voluntary licensing (NEVL), technology transfers, and supranational procurement agreements.

FIGURE 12 How many companies have COVID-19 products?

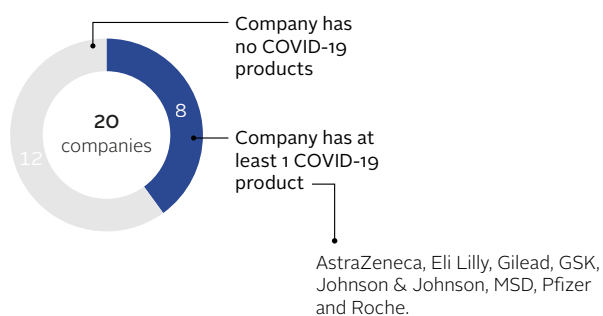
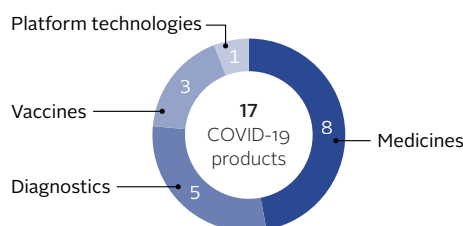


FIGURE 13 What types of COVID-19 products are in companies' portfolios?



## PRODUCT DELIVERY

## Companies engage in voluntary licensing to enable generic manufacturing, but with limitations

Pharmaceutical companies can engage in voluntary licensing by transferring intellectual property (IP) rights to a licensee, enabling them to produce generic versions of their product under certain terms and conditions. Voluntary licensing agreements can expand availability and affordability by facilitating generic supply, and are particularly valuable for expanding access in countries where the originator company does not intend to market the drug that it has patented.

For companies that hold patents for COVID-19 products, one approach has been to engage in direct licensing agreements to build global manufacturing networks. Another approach has been to agree to voluntary licences through an intermediary such as Medicines Patent Pool (MPP). When a licence is between a company and multiple sub-licensees (generic manufacturers), it is deemed to be a NEVL.

Of the eight companies with COVID-19 products in their portfolios, five (AstraZeneca, Eli Lilly, Gilead, MSD and Pfizer) have engaged in licensing agreements to facilitate access to COVID-19 products.

### Voluntary licences for COVID-19 products

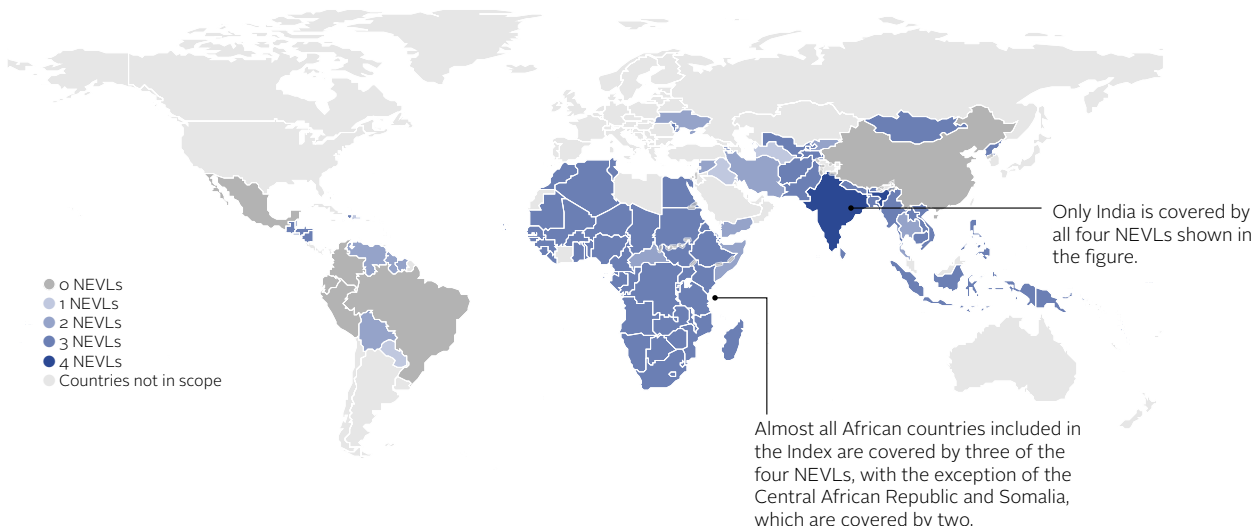
- AstraZeneca pursued a sequence of exclusive voluntary licences with Serum Institute of India, among others, for its COVID-19 vaccine (Vaxzevria). Details of these licences remain private.
- Eli Lilly signed royalty-free voluntary licensing agreements for baricitinib, an oral COVID-19 therapeutic, with three Indian pharmaceutical companies: Cipla, Sun Pharmaceuticals and Lupin.
- Gilead signed a royalty-free voluntary licensing agreement for its injectable antiviral medication remdesivir (Veklury®) with technology transfer included.
- MSD's product molnupiravir (Lagevrio®) was the first oral antiviral to be included in WHO treatment guidelines for COVID-19. MSD signed a NEVL with the MPP when the drug was still in development, before it reached regulatory approval.
- Pfizer signed a NEVL with MPP for nirmatrelvir, one of the compounds in its COVID-19 antiviral nirmatrelvir/ritonavir (Paxlovid®). The company will not receive royalties from sales of nirmatrelvir while COVID-19 is considered a public health emergency of international concern by WHO. After that period, sales to low-income countries will remain royalty free.

Three of the licences analysed (for molnupiravir, nirmatrelvir and remdesivir) include a large number of countries in scope. However, a consistent finding is that upper-middle income countries, such as Colombia, Ecuador and Peru are not included in voluntary licences. This means sizeable low-income populations in these countries will only have access to the more expensive branded version of the drug, without the option of a more affordable generic version.

Furthermore, inclusion of a country in the geographic scope of a licence does not guarantee that generic medicine manufacturers will choose to make use of the licence to manufacture the product and market it in that country. Additional follow-up is required to monitor the uptake and impact of these licences.

**FIGURE 14 Which LMICs are covered by NEVLs for COVID-19 products?**

This map highlights the number of NEVLs per country in scope of the Index for the four COVID-19 licensing agreements analysed (baricitinib, molnupiravir, nirmatrelvir and remdesivir), showing the countries in which generic medicine manufacturers are able to produce and market the companies' COVID-19 products. Three of these agreements cover at least 80% of the countries in scope of the Index.\*



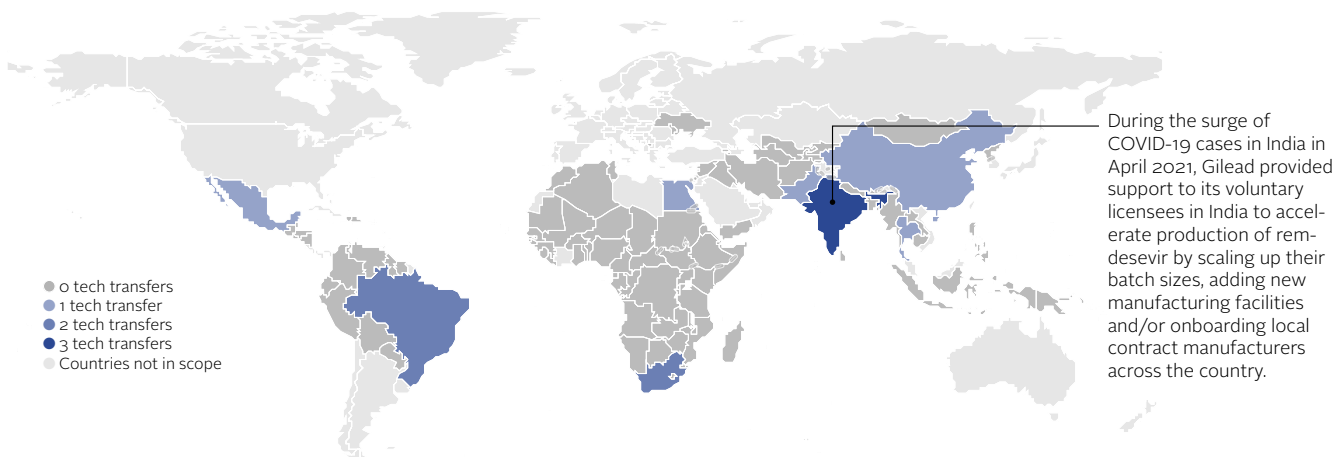
**Key developments in transferring technology for COVID-19 products**

Technology transfers – i.e., the transfer of manufacturing processes and expertise from the pharmaceutical company to local manufacturers – are a valuable tool in expanding access. The approach boosts the capacity of generic medicine manufacturers to efficiently and effectively manufacture quality-assured medicines and vaccines.

Four companies have transferred technology for COVID-19 products during the period of analysis: AstraZeneca, Gilead, Johnson & Johnson and Pfizer. For example, Gilead transferred technology as part of its NEVL agreement for remdesivir,

**FIGURE 15 Technology transfers for COVID-19 are focused in India, Brazil and South Africa**

Ten technology transfers were conducted for medicines (1) and vaccines (9) to treat COVID-19. Technology transfers are concentrated in India, Brazil and South Africa.



\*Companies submitted information regarding the NEVLs and/or non-assert declarations to the Index for analysis. AstraZeneca's sequence of exclusive voluntary licences was not shown in the graph, as details remain private. Eli

Lilly's licence (baricitinib) is only reported for India.

while AstraZeneca transferred technology to manufacturers in LMICs in combination with its private licensing agreements across a selection of LMICs. AstraZeneca reports technology transfers with more than 20 partners across more than 15 countries, including countries in Asia and Latin America.

The Index finds that technology transfers for COVID-19 vaccines and therapeutics are concentrated in a select few countries, particularly in India, South Africa and Brazil. Within these countries, the third-party manufacturers that receive the know-how to produce these products often have a high level of capacity for manufacturing vaccines and medicines already (e.g., Bio-Manguinhos/Fiocruz, Serum Institute of India and Dr. Reddy's Laboratories).

These technology transfers can help improve the supply of COVID-19 products. They can also help ensure resilience in supply chains in LMICs for future production, including production of other healthcare products. Therefore, companies can do more to ensure that more LMICs with an industrial base have access to these technologies – for example in Senegal, which is already producing COVID-19 vaccines via its Pasteur Institute, or in Algeria, which received a technology transfer to facilitate the production of the Russian COVID-19 Sputnik V vaccine.<sup>6</sup>

## PRODUCT DELIVERY

**Some – but not enough – company action to ensure procurement and supply of COVID-19 vaccines in LMICs**

When participating in pooled procurement, companies supply their products through organisations (supranational procurers), which in turn distribute them internationally to LMICs. Previously, these supranational agreements have been successfully used to improve access to antiretroviral medicines for HIV and products for other diseases of public health concern, such as tuberculosis.

During the pandemic, COVID-19 vaccines have been supplied in LMICs through supranational agreements. The Index analysed the sale of the three COVID-19 vaccines in scope through the COVID-19 Vaccines Global Access (COVAX) programme, a global initiative co-led by WHO, Gavi, the Vaccine Alliance (GAVI) and the Coalition for Epidemic Preparedness Innovations (CEPI), which aimed to accelerate the development and distribution of COVID-19 vaccines.

Despite COVAX's aim to facilitate an equitable global vaccine supply, a disparity in access to vaccines between high-income countries and LMICs persists. Moreover, this pandemic has also shown that the world cannot rely on such procurement programmes alone. Because of this, bilateral agreements are an additional step that companies should take to facilitate access.

AstraZeneca and Johnson & Johnson engaged in technology transfers and licensing agreements to increase supply of their vaccines with local partners. Although Pfizer transferred technology to bolster manufacturing capacity of its vaccine in some countries in scope, the Index did not find evidence that it had engaged in licensing agreements to enable generic supply of its COVID-19 vaccine.

AstraZeneca performs best in the field of technology transfer and licensing, with technology transfers of its vaccine across more than 15 countries, perhaps reflecting the sources of funding for the vaccine; it is reported that 97% of the funding for R&D behind AstraZeneca's vaccine came from public and charitable funds.<sup>7</sup>

In the event of a future pandemic, governments must work with companies to ensure that the terms of supranational procurement agreements are transparent and consider equitable pricing and global access. This could help to reduce disparities and ensure that people globally get the vaccines and treatments they need. However, companies should especially engage in technological transfers and knowledge sharing, as a step in fighting against a pandemic.



TABLE 1: **Supranational procurement for vaccines in LMICs**

Company	Vaccine	Supranational procurement for LMICs*	Price via COVAX
AstraZeneca	COVID-19 vaccine (Vaxzevria)	<ul style="list-style-type: none"> <li>• One agreement via COVAX facility: COVAX Advance Market Commitment (AMC)**</li> <li>• Four regional sub-licensing agreements, including with the Serum Institute of India</li> </ul>	Cost-based price: 4 USD per dose. Information is available on UNICEF website. Price applies in 91 countries funded by the COVAX Advance Market Commitment.
Johnson & Johnson	COVID-19 vaccine	<ul style="list-style-type: none"> <li>• Three agreements via COVAX facility: COVAX Advance Market Commitment; Procurement agreement; COVAX Humanitarian Buffer***</li> <li>• Procurement agreement with the African Vaccine Acquisition Trust (AVAT)</li> </ul>	Not-for-profit price: USD 7,50 per dose. Information is available on UNICEF website.
Pfizer	COVID-19 vaccine (Comirnaty®)	<ul style="list-style-type: none"> <li>• One agreement via COVAX facility</li> </ul>	Not-for-profit price; price is not disclosed.

TABLE 2: **Examples of national procurement for vaccines in LMICs**

Each of the three companies provided an example to the Index about an access strategy being used to expand access to their vaccine in one of the 108 LMICs in scope, outside of the COVAX programme and any other supranational agreements.

Company	Vaccine	Specific country example
AstraZeneca	COVID-19 Vaccine (Vaxzevria)	<b>Brazil</b> <ul style="list-style-type: none"> <li>• Licence and technology transfer to a local manufacturer, the Oswalda Cruz Foundation (Fiocruz).</li> <li>• Brazil is also covered by a COVAX supply agreement, and received 9,122,400 doses of AstraZeneca's COVID-19 vaccine via COVAX in 2021.</li> </ul>
Johnson & Johnson	COVID-19 vaccine	<b>South Africa</b> <ul style="list-style-type: none"> <li>• Vaccines were provided via two advance procurement agreements at a not-for-profit price.</li> <li>• Technology transfer agreement with local manufacturer Aspen Pharmacare Limited.</li> <li>• Drug substance supply agreement with Aspen SA Operations (Pty) Ltd.†</li> <li>• Collaboration with local government to make vaccine doses immediately available to healthcare workers via the Sisonke study in South Africa.</li> <li>• Health systems strengthening initiative, including cold chain strengthening initiatives.</li> <li>• While disaggregated bilateral data about patient reach in South Africa has not been made available, the company reports it has shipped approximately 270 million doses to the African continent.</li> </ul>
Pfizer	COVID-19 vaccine (Comirnaty®)	<b>Rwanda</b> <ul style="list-style-type: none"> <li>• Supply agreement at not-for-profit price.</li> <li>• Health systems strengthening initiative focused on country delivery readiness.</li> <li>• Covered by COVAX supply agreement.</li> <li>• 7.4 million doses supplied in support of both COVAX and the Rwandan government's vaccination programme.</li> </ul>

\*The data in this table is not comprehensive, but is based on publicly-available information and data provided by the companies to the Access to Medicine Index.

\*\*The AMC is one strand of COVAX, that finances the supply of COVID-19 vaccines

to LMICs. The AMC is funded by voluntary contributions from richer countries and private donors.

\*\*\*The Humanitarian Buffer is a novel additional initiative established within the COVAX Facility to act as a measure of 'last resort' to ensure access to COVID-19 vac-

cines for high-risk and vulnerable populations in humanitarian settings.

†The agreement enables Aspen SA Operations (Pty) Ltd, using COVID-19 vaccine drug substance supplied by Johnson & Johnson, to produce Aspen-branded finished vaccine and make doses avail-

able to the public sector in Africa, including all 55 Member States of the African Union and key multilateral entities supporting Africa's COVID-19 vaccination drive, inclusive of the African Vaccine Acquisition Trust (AVAT), and the COVAX Facility.

RESEARCH & DEVELOPMENT

## R&D for pandemic preparedness has not increased, despite COVID-19

In July 2022, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) released the Berlin Declaration, in which the pharmaceutical industry pledged to draw on lessons learned from the COVID-19 pandemic to ensure equitable access to vaccines and medicines in future pandemics.<sup>8</sup> This includes provisions for manufacturing, sustainable supply and accelerating R&D to develop new health products. Collaboration between actors and their awareness of responsibilities is a key component to prepare for the next pandemic. Although it is too soon to measure the impact such a declaration may have on access, the Index has analysed the pipelines of companies in scope to see what products they are developing to target other diseases with the potential to cause a pandemic.

Investment in R&D is important for the development of products which target diseases with epidemic potential. To encourage innovation, the WHO has compiled a list of priority emerging infectious diseases (EIDs) that pose the greatest public health risk due to their epidemic potential and/or lack of measures to counter them. The Index analyses R&D projects for 17 EIDs, based on the priorities identified by WHO and Policy Cures Research.

Among these is 'Disease X', a term which WHO adopted to refer to a pathogen that is currently unknown to cause human disease but could cause a serious international epidemic in the future. In 2020, the emergence of the SARS-CoV-2 virus (COVID-19) was deemed to be the first example of Disease X, since the inception of the term in 2018. The 'Disease X' designation seeks to incentivise cross-cutting R&D that can be easily adapted for emerging strains of infectious diseases, for example, platform technologies or diagnostics. The development of such underlying technologies could facilitate a rapid response to counteract an outbreak should one arise. The Index found that none of the companies in scope have R&D projects in development to target Disease X. This suggests that despite the rapid R&D response to COVID-19 (68 projects for coronaviral diseases), companies in scope are not investing in R&D for projects that could limit the spread of future unknown infectious diseases.

When no product is currently available on the market to sufficiently treat, diagnose or prevent a priority disease, this is defined as a 'product gap.' These products may be medicines, vaccines, diagnostics, medical devices or vector control products. Every company, regardless of size or therapeutic focus, can play a role in addressing these gaps.

FIGURE 16 While significant products have reached the market for some EIDs, the companies in scope have nothing in the pipeline for the majority of priority EIDs

Even though the number of Ebola projects in the pipeline has decreased over the last years, improvements have been made. In July 2020, the Johnson & Johnson preventative two-shot vaccine regimen Zovavira<sup>®</sup> and Mvabea received EMA marketing authorisation for the prevention of Ebola (*Zaire ebolavirus*) species.

Zika is the only disease for which a positive trend can be seen, excluding COVID-19. R&D projects devoted to this infectious disease have increased over the years. In 2020, the WHO prequalified Bayer's Fludora<sup>®</sup> Co-Max. This vector control product, a space spray for indoor and outdoor, can not only prevent the spread of Zika, but also that of dengue and chikungunya by targeting *Aedes* mosquitos.

Disease flagged as an epidemic/pandemic risk	R&D projects			Active companies		
	2018	2021	2022	2018	2021	2022
Arenal haemorrhagic fevers (incl. Lassa fever)	0	0	0	0	0	0
Chikungunya	3	4	5	3	4	3
Criean-Congo haemorrhagic fever (CCHF)	0	0	0	0	0	0
Ebola virus disease (EVD)	7	5	4	5	4	1
Emergent non-polio enteroviruses (incl. EV71, D68)	1	1	0	1	1	0
Marburg viral disease (MVD)	1	1	0	1	1	0
Middle East respiratory syndrome coronavirus (MERS-CoV)	0	0	0	0	0	0
Nipah	0	0	0	0	0	0
Bunyaviral diseases (other than CCHF, RVF and SFTS)	0	0	0	0	0	0
Filoviral diseases (other than EVD and MVD)	0	0	0	0	0	0
Henipaviral diseases (other than Nipah)	0	0	0	0	0	0
COVID-19 and other coronaviral diseases (other than SARS and MERS-CoV)	0	63	68	0	17	17
Rift Valley fever (RVF)	0	0	0	0	0	0
Severe acute respiratory syndrome (SARS)	0	0	0	0	0	0
Severe fever with thrombocytopenia syndrome (SFTS)	0	0	0	0	0	0
Zika virus disease	3	4	7	3	4	4
Disease X*	0	0	0	0	0	0

\*Disease X', added to this list in 2018, represents the knowledge that a serious epidemic or pandemic could be caused by a pathogen currently unknown to cause human disease. COVID-19 can be seen as a first example of Disease X.

Out of the 20 companies in scope, only five – Bayer, Johnson & Johnson, Merck, MSD and Takeda – engage in R&D efforts for EIDs other than COVID-19. There are currently no projects in development for 13 of the 17 priority EIDs analysed by the Index, meaning that many product gaps remain unaddressed. For example, for Lassa fever, G-FINDER and WHO recommend a preventative vaccine to be developed which can protect for at least three years in healthy adults and children, against all four strains.<sup>9</sup> Unfortunately, no such vaccine exists and no companies in scope of the Index target this EID.

This disparity indicates that, although companies responded quickly to develop COVID-19 products, the world remains ill-equipped to prevent future epidemics caused by other priority diseases. For companies in scope, the number of projects targeting some EIDs has remained relatively stable since the last Index.

Despite R&D gaps for most priority EIDs going unaddressed, companies have made some important advancements in addressing two diseases with epidemic potential during the period of analysis. Both products are accompanied by a robust plan to overcome barriers to access in LMICs.

### **What access issues should companies consider when developing products to prevent future epidemics and pandemics?**

When developing products to combat infectious diseases, companies should consider factors that may hinder the supply, storage and administration of vaccines or therapeutics in LMICs. As observed with the COVID-19 vaccines, there are many factors which can impede vaccination campaigns. This includes complicated multi-dose regimens, ultra-cold chain storage requirements and routes of administration that require skilled health workers. To overcome such obstacles, a product should ideally be easily administrable and heat stable. For example, despite having a lower efficacy than mRNA vaccines, the single-dose Johnson & Johnson COVID-19 vaccine offered advantages in terms of ease of use and storage in LMICs.<sup>4</sup> The Index identified one sublingual vaccine in development for COVID-19 during the period of analysis, i.e., a vaccine that could be dissolved under the tongue; this route of administration offers many advantages to people living in LMICs with weak health systems, as it does not need to be administered by health professionals.

To address these challenges and the development of health products, WHO lists target product profiles (TPPs) and product profile characteristics (PPCs) in its R&D Roadmaps. These outline the desired 'profile' or characteristics of a target product that is aimed at a particular EID, including potential new vaccines for MERS-CoV and Zika virus disease.<sup>10</sup>

### **How can industry contribute to pandemic preparedness?**

The COVID-19 pandemic has shown that companies have the capacity to rapidly shift R&D focus to quickly develop new products when required. While urgent investments to develop COVID-19 vaccines and therapeutics were necessary, companies should now use this opportunity to work with global health stakeholders and shift focus to develop products for other infectious diseases with the potential to cause outbreaks.

Furthermore, companies need to put the lessons learned in the COVID-19 pandemic into practice and consider barriers to access during R&D and beyond. This includes developing heat-stable formulations, easily administrable products and planning for access in the early stages of development. Pricing, procurement and supply must also be considered to ensure equitable access. With infectious diseases with pandemic potential, the issue of equitable access is even more pertinent because “no one is safe until everyone is safe”.

## Conclusions

The rapid development and authorisation of medicines and vaccines for COVID-19 indicates that the pharmaceutical industry is willing and able to respond quickly to public health emergencies. However, the disparity in vaccination rates between high-income countries and low-income countries highlights the inequitable supply of COVID-19 vaccines in LMICs. Although there are multiple obstacles to the supply of vaccines in LMICs, some companies work to improve access by engaging in equitable access strategies for their products.

The industry can also build on its successful approaches to equitable access during the COVID-19 pandemic and expand these approaches to other products and countries. This includes engaging in more non-exclusive voluntary licensing and technology transfers.

Although the COVID-19 pandemic is still ongoing, companies must address gaps that exist for the prevention and treatment of other potential EIDs by engaging in more R&D. Even when no public investment in R&D is involved, pharmaceutical companies should plan early on to ensure any innovations are easily accessible in LMICs.

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