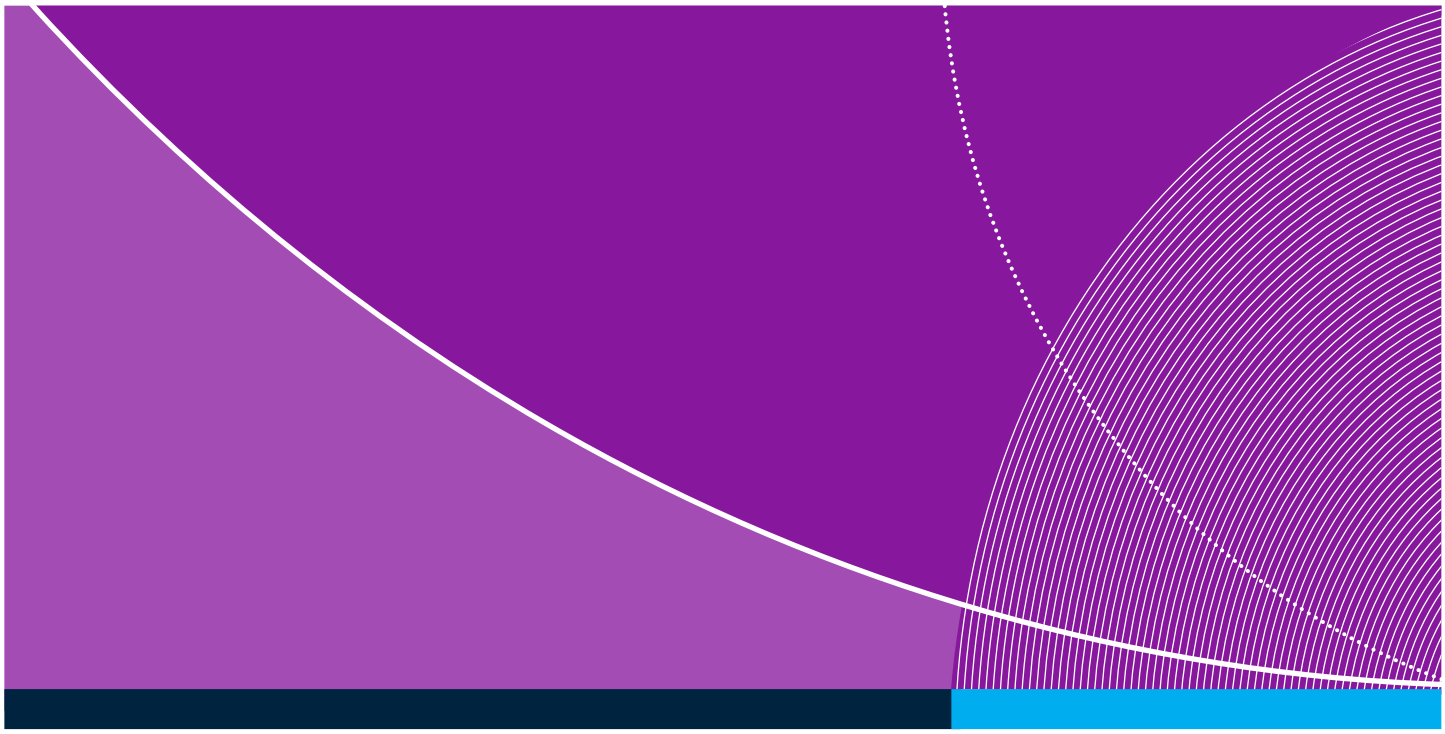

Improving Access and Affordability for Biopharmaceuticals in Emerging Markets

A briefing paper from the Biopharmaceutical Think Tank discussion at the 2019 IFC Global Private Health Care Conference

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IFC International Finance Corporation WORLD BANK GROUP

Creating Markets, Creating Opportunities

IFC's Global Private Healthcare Conference took place in March 2019, with a primary aim to spark discussion and drive action around the private health sector and its role in meeting critical challenges in emerging markets. The theme of the 2019 conference was *Disrupting the Present, Building the Future—Embracing Innovation to Deliver Results.* Alongside the main conference sessions, invited health care thought leaders, policy experts, investors, and industry representatives from around the globe gathered for a think tank session to discuss some of the most pressing challenges, trends and opportunities related to biopharmaceuticals in emerging markets. This briefing paper reflects key themes and important points from the discussion that took place, and leverages additional insights, research, and analysis to bring light to this important topic.

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This briefing paper was written by Chrissy Bishop, with guidance from Tim Gamble, both of The Economist Intelligence Unit (EIU) Healthcare team. It was written based on the expert opinions from participants of the think tank session, (in which the EIU had input on the themes being discussed, were in attendance, and engaged in the discussion) and additional desk research.

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Improving access and affordability for biopharmaceuticals in emerging markets

Over the last decade, there have been several global and regional initiatives to improve both access to medicines and affordability in low- and middle-income countries. However, marketing authorizations of needed products are often delayed as researchers and manufacturers have to work through multiple regulatory requirements to register products across countries.[1,2] These challenges are particularly relevant to the biopharma industry, which includes the use of biotechnology in medical research and development efforts to create and produce some of the most sophisticated and complex drugs on the market. Biopharmaceuticals fall into the following categories: modified human proteins, monoclonal antibodies, vaccines, products transferred by gene delivery vectors, growth factors and cytokines, hormones, and blood-plasma derived products.

Biopharmaceuticals are used for both prevention (e.g., vaccines) and treatment of diseases such as cancer, diabetes, and immunological conditions like rheumatoid arthritis. They are generally better targeted, come with fewer side effects, and can help to add more healthy years to a patient's life than other forms of treatment. Due to an intensive development process and regulatory requirements, biopharmaceuticals often come at a high price, costing an average US$10,000-$30,000 per year; they can even exceed US$500,000 for the most complex formulas.[3]

Manufacturing biopharmaceuticals reliably and at scale requires a major capital investment. Research and development infrastructure, including high-quality cell lines, assay development capabilities, and manufacturing facilities, are costly to maintain, especially in developing markets.[4] Yet, developing markets now account for one-third of global growth in drug demand, with a global, compound annual growth rate of 5-8 percent.[5]

Another contributing factor to the globalization of biopharmaceuticals across emerging markets is the implementation of the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).[6] Before TRIPs, the pharmaceutical industry was led by vertically integrated transnational corporations, with production of drugs largely restricted to their home countries, and very little investment into larger markets overseas. In addition to TRIPs, universal health coverage has also had a notable impact, as appropriate access to both medicines and vaccines are growing priorities in emerging markets.[7]

To keep up with the globalization of the biopharmaceutical industry, the players involved must revisit and fundamentally reassess many of the strategies, technologies, and operational approaches they use. For example, the pharmaceutical sector is shifting from a vertically integrated and technology-driven model to a producer-driven model for innovative biopharmaceutical

products. At one end of the scale, the industry must develop capabilities to quickly and reliably produce smaller scale batches of personalized medicines for cell therapies. However, this is usually done in developed markets due to high production cost. On the other hand, high-volume, low-cost manufacturing is needed to deliver cost effective insulin and vaccines for low- and middle-income countries.[4]

This briefing paper discusses three themes that may facilitate the sustainability, access and affordability of biopharmaceutical production in emerging markets, and aims to focus on how these concepts are embedded in the health care landscape. This paper takes insights from IFC's think tank discussion comprising investors and business leaders in biopharmaceutical production, along with recent scientific literature. These three themes include:

- *Harmonization of regulatory pathways;*
- *Collaborations to encourage research and development;*
- *Improving sustainability of pharmaceutical pricing.*

HARMONIZATION OF REGULATORY PATHWAYS FOR DRUG APPROVALS

Harmonization refers to "*improving international cooperation across participatory authorities to develop uniform technical guidelines for the registration of pharmaceuticals for human use.*"[8] Harmonization should be a priority for governments, public health bodies, and the biopharmaceutical industry alike, for a few reasons. Firstly, it reduces duplication, and creates a common set of standards that facilitate communication and information-sharing. Secondly, it enhances the suitability of locally manufactured biopharmaceutical products for export to other countries. Together, these factors broaden availability, speed up access, increase competition, and raise standards across the sector.[2] While the industry has a relatively strong track record of harmonization for small molecules, there is significant room to grow these efforts for large molecules as well.

The legal-regulatory standards and processes in the biopharmaceutical market are not uniform, meaning the regulatory standards in one part of the world differ from one another.[9] At present, very few developing countries have legal or regulatory procedures to deal with the commercialization of a new biological entity.[10] Also, changes to legal-regulatory frameworks elevate exposure to risk. As increasingly complex biopharmaceutical products such as cell and gene therapies are developed, the capacity and expertise required to carry out appropriate clinical assessments are required. In the field of biopharmaceuticals, the opportunity for regulatory authorities to collaborate, avoid duplication and allocate resources to critical areas of need remains as stark as ever, thereby improving speed of and access to new biopharmaceutical products.[9] The World Health Organization (WHO) aims to support national governments in strengthening national medicines regulatory authorities in a couple of ways: by supporting

the development of internationally recognized norms, standards, and guidelines; and by providing guidance, technical assistance and training that facilitates the local implementation of these standards and guidelines.[2] The WHO stresses that if even one of these aspects is missing, effective biopharmaceutical regulation cannot be achieved.[2] One of the consequences of the inefficient assessment of new biopharmaceutical products is sometimes referred to as the "drug lag".[11] Drug lag is a term used to describe a measure of when a drug becomes available in a country, as well as gaps in the total quantity of drugs available in different countries.[11] Drug lag is a continuing problem and particularly affects developing markets, where the regulatory-legal and institutional frameworks that govern biopharmaceuticals are comparatively new.[12] In the world's largest markets by revenue (United States, European Union and Japan), drug lag has been driven in part by the lack of government funded health care systems, vertical integration, and high unmet medical need across therapeutic areas, such as oncology.11 In emerging markets, the story is quite different. Sources of funding for biopharmaceutical innovation are typically private and often out-of-pocket. Multiple stakeholders also exist, reflecting a highly fragmented ecosystem, while the legal-regulatory framework that governs research, development and commercialization are nascent. Furthermore, each country has specific regulatory controls that govern the approval of new drugs, and these differ from country to country.[12] This can create costly and prolonged development of regulatory submissions. The drive to improve regulation across developing markets has originated predominantly from the biopharmaceutical industry rather than governments. Despite economic growth, improvements to the biopharmaceutical legal-regulatory infrastructure remain elusive, and most experts believe there is still some way to go.[11]

One study isolates the following regulatory factors as causal to the drug lag across emerging markets:[11]

- ***Requirements for western approval***—reliance on western countries to establish regulatory precedence of approval for a drug;
- ***Requirements for local clinical development***—currently required in India at Phase III, compared to Korea, which primarily requires bridging studies—these are not as extensive and are used to 'bridge the gap' between the requirements and the data Korea receives from the pharmaceutical company. China also eased local clinical development requirements at Phase III for qualifying products in 2017,[13] and more recently became the first emerging market country to approve a novel biopharmaceutical drug before the West;
- ***Certificate of pharmaceutical products***—primarily devised by the WHO as a way of enabling regulatory authorities to ascertain good manufacturing practice and quality status of the drug product;
- ***Good manufacturing practice***—most certificates of pharmaceutical products carry a good manufacturing practice statement;
- ***Pricing approval***—price certificates, which are an agreement between the pharmaceutical company and health authority, stating the price at which the drug will be sold when marketing authorization is granted;
- ***Document authentication***—authorities can request that certificates of pharmaceutical products, good manufacturing practice, and price certificates are legalized and notarized
- ***Lack of harmonization***—a lack of harmonization between countries can lead to unnecessary duplication of effort and a waste of valuable resources.

There are few examples of a biopharmaceutical product receiving marketing authorization first in an emerging market, which may largely be due to the latency of, and need for, additional clinical evidence in relevant addressable populations, as well as the commercial attractiveness of developing markets. One study looked at mapping pharmaceutical regulation in the developing world using the WHO data.[14] To do this, public and private generics markets were surveyed in 78 developing countries to investigate regulatory standardization. The results showed a strong resistance to standardization and variation in the implementation of international pharmaceutical norms, quality standards, and regulatory infrastructure. Furthermore, markets did not appear to have influenced their neighbors in establishing regional patterns.[14]

There are examples of efforts for harmonization across Europe, aiming to address these challenges. The European Medicines Agency has a long history of developing effective cooperation and sharing regulatory documentation between authorities. The European Union has signed mutual recognition agreements with third-country authorities (Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the United States) concerning the conformity of assessment of regulated products. Such agreements contain a sectorial annex on the mutual recognition of good manufacturing practice inspections and batch certification of human and veterinary medicines. In turn, medical recognition agreements allow authorities and their counterparts to rely on each other's good manufacturing practice inspection system; share information on inspections and quality defects; and waive batch testing of products on import into their territories.

Harmonization Efforts in Africa

Africa has made notable efforts toward harmonization. A few examples include the East African Community, the Southern African Development Community, and the African Vaccine Regulatory Forum. The former two work toward harmonization among participating authorities, and the latter aims to develop mechanisms and pathways for expedited regulatory review of clinical trials for products being developed to address public health emergencies and neglected diseases.[9] The Drugs for Neglected Diseases initiative published a report in 2013 on the road to regulatory harmonization for Africa. As the supply of new effective treatments are developed, a need for swift and efficient regulatory processes that deliver safe, appropriately evaluated biopharmaceutical products to patients will continue to emerge.

The main challenges in Africa include:

- Adequate legislation to address all regulatory requirements and mandates;
- Management structures and processes with good regulatory practices;
- Human resource capacity (volume and skills) and resources (financial and infrastructure);
- Lack of harmonized manufacturing requirements and inspection procedures;
- Market control, including inspection of all consignments and batches imported, and control of substandard, spurious, falsely labelled, falsified or counterfeit medical products.[15]

The WHO has been supporting regulatory cooperation and harmonization efforts across Africa to address some of these challenges. The African Medicines Regulatory

Trade agreements that facilitate market access and encourage greater international harmonization of compliance standards and safety are critical. They benefit regulatory authorities by reducing duplication of inspections, allowing for greater focus on sites that could have a higher risk and broadening the inspection coverage of the global supply chain. They also facilitate trade in pharmaceuticals because they reduce costs for manufacturers by lowering the number of inspections taking place at facilities and waiving re-testing of their products upon importation. While these models need to be replicated on a global scale, there are some encouraging signs of growth.[9]

In addition to Africa, initiatives in other regions, such as the Pan American Network for Drug Regulatory Harmonization, the Gulf Central Committee for Drug Registration, and the Pharmaceutical Product Working Group of the ASEAN Economic Community are aiming to support effective harmonization of pharmaceutical regulation. As emerging markets look to balance greater access to high-quality care with opportunities for efficiency, strengthening these efforts may be an important consideration.

Harmonization Initiative, established in 2009, has the intention to improve health across the African region by increasing access to high-quality, safe and effective medicines. Improvements are focused on strengthening the technical and administrative capacity of participating national medicines regulatory authorities. In doing so, the initiative restricts its focus to the registration of priority essential medicines (mainly generics) to help maximize near-term patient benefit and impact on the critical disease burden facing Africa.[15] Similar market control exists in Indonesia, where recent efforts to increase efficiency of medicine and supply procurement included the restriction of the number of active pharmaceutical ingredients in the national formulary.[16] This reduced both overall drug expenditures and the use of less cost-effective drugs.

COLLABORATION TO ENCOURAGE RESEARCH AND DEVELOPMENT

Sustainable development goal number 3.8 states to "achieve universal healthcare coverage, and provide access to safe and effective medicines and vaccines for all".[17] For many countries, however, it remains difficult to achieve even basic health care services, and because of weak health care systems and incoherent policies, inequalities are exacerbated rather than resolved. Collaboration between industry and health systems is essential to encourage investment in innovation and the sustainable availability of essential medicines, vaccines, diagnostics, and health technologies.[18] For example, in 2018, Beijing eliminated tariffs on biopharmaceuticals to help encourage demand and growth of the industry.[19] Additionally, the Indian government and the World Bank have recently joined efforts to accelerate biopharma development, including programs to encourage entrepreneurship and domestic manufacturing.

Beyond direct assistance, governments and the biopharmaceutical industry can work together to develop and pursue other funding options as well. Collaborations such as product development partnerships, innovative financing mechanisms, voluntary licensing and non-asset declarations across the biopharmaceutical sector have helped reach hundreds of millions of people in under-resourced settings to date. When intellectual property does not exist, the bedrock on which new treatments are developed requires new models and approaches to expand

the access for patented products. When intellectual property is insufficient to stimulate research and development for diseases of poverty, the biopharmaceutical industry has a track record of pursuing innovative partnerships and collaborative approaches to share the costs and risks of research and development, on which no financial return can be expected.[18]

A further example of collaboration includes partnerships between the biopharmaceutical industry and academia. In this kind of collaboration, research and development ventures and associated risks are often shared. In 2011, a collaboration between a drug company and several universities in the Boston area was valued at US$100 million. Other examples of partnerships occur on a more regional scale. The Innovative Medicines Initiative represents a European example of successful collaboration between the European Union and the European Federation of Pharmaceutical Industries and Associations. The Innovative Medicines Initiative is focused on accelerating the discovery of, and patient access to, the next generation of medicines, as opposed to improving chemistry, manufacturing and solving problems with controls.[20] This asymmetry in activity is a reflection of a developing market focus on concerns such as communicable disease, as opposed to cancer therapies, which require innovative biologics. These and other innovative collaborations can provide an incentive to produce biopharmaceutical products across emerging markets, as well as for potential exporting. They provide a dual benefit of both achieving public health goals, and opportunities for economic growth.[21]

In 2018, a total of 3,003 completed partnerships were identified, which featured licensing, product acquisition, commercialization, joint venture, manufacturing and supply, and research and development alliances.[22] Part of the reason that partnerships are so critical in this field is that biopharmaceutical companies do not focus on a single strategy, but are involved in multiple investment and development strategies. A common strategy to market biopharmaceuticals is collaboration between companies. These collaborations or partnerships can be used to gain access in regions where the company has less experience.

Some of the more interesting leads established by companies such as Mylan and Pfizer where multinational corporations that target the biosimilars sector, have sought tie-ups with emerging market partners:

- A 2009 agreement handed Mylan exclusive commercialization rights to Biocon biosimilars in the US, Canada, Japan, Australia, New Zealand, the European Union and European Free Trade Area. Co-exclusive rights apply elsewhere. The original deal currently covers six products (filgrastim, pegfilgrastim, trastuzumab, adalimumab, bevacizumab, and etanercept). In 2013, the two signed a separate deal covering three biosimilar insulin analogs, for which Mylan has commercialization rights in the US and Europe.

- Pfizer inherited co-marketing rights to eight Celltrion biosimilars through its 2015 acquisition of Hospira. The original deal, struck in 2009, covered the US, Europe, Australia, New Zealand, and Canada, where each party has the right to commercialize the products under its own brand name. In October 2015, Pfizer returned rights to Celltrion's rituximab and trastuzumab products, which overlapped with its existing biosimilars development portfolio. In October 2016, Teva acquired the U.S. and Canadian marketing rights for the rituximab and trastuzumab products jettisoned by Pfizer a year earlier.

- In 2013, Merck & Co acquired extensive marketing rights to Samsung Bioepis' biosimilars. Samsung Bioepis will be responsible for the development, manufacture, and registration of products subject to the deal, and will receive milestone payments and royalties on sales generated by Merck & Co. In 2014, the two companies signed a separate agreement on the development, manufacture, and commercialization of Merck & Co's biosimilar insulin glargine candidate.

Partnerships that are most successful in terms of revenue seem to include equity stakes and shared research and development expenditures, which continue to be significant components of biopharmaceutical partnerships.[22] Looking ahead, there are more opportunities for biopharmaceutical companies to continue to create partnerships that encourage research and development and enable their products to get to the market.[22]

There are a few different aspects that can help partnerships to be more effective. Real world data may be one resource that helps to equip service providers to combine knowledge and forge partnerships. Real world data can produce the kind of evidence that has the power to underpin the economic case for innovative medicines. Better use of electronic medical records, for example, could assist pharmaceutical and biopharmaceutical companies to create useful links to molecular databases with the right governance and technology frameworks.[23] Another facilitator is the government. Highly competitive pharmaceutical companies will be more likely to collaborate if governments provide the right incentives and occupy a pivotal role in supporting local firms to adapt to regulatory changes.[24] This also applies to biopharmaceutical production.

IMPROVING SUSTAINABILITY OF PHARMACEUTICAL PRICING

The total research and development cost per approved biopharmaceutical product was estimated to be US$1.4 billion in 2011 prices.[25] From the patient's perspective, out-of-pocket costs are estimated to be 14 percent higher among biopharmaceutical products than among other pharmaceutical products. The higher prices for biopharmaceuticals are mainly due to longer development times and a slightly higher cost of capital. For biopharmaceutical companies to achieve growth, they might consider holistic pricing solutions. Companies need a more systematic approach that helps identify which products might be more suitable than others in the markets they will be sold. To be successful, this approach must be grounded in a realistic assessment of how all stakeholders, including payers, value the different features of specific medicines. This also means identifying which stakeholders are most ready to embrace more collaborative pricing models.[26] Compared to small-molecules, published list prices of biologics and biosimilars are high, even across developed markets. Some researchers argue that the comparatively complex patent protection for reference biosimilars represents an entry hurdle for follow-on producers. This means that around 90 percent of the population in developing countries purchases medicines through out-of-pocket payment—medicines have become the largest family expenditure after food in these countries.[27]

The WHO and a non-governmental organization called Health Action International have identified some key areas to assist the regulation of pharmaceutical pricing in emerging markets, which also apply to the biopharmaceutical market. First is the regulation of distribution mark-ups, which can assist to reduce medicine

prices, but can also have unintended consequences. The WHO advises that to prevent complications, incentives and disincentives within a supply chain must be mapped, and potential unexpected effects considered before the controls are applied. It is also important to consider the structure of the health system and setting, which will determine how mark-ups can be applied and regulated.[27] For example, Malaysia, which has a relatively weak pharmaceutical system, is at risk of pharmaceutical manufacturers taking control of setting high drug costs. To prevent this, the WHO recommends that countries should empower relevant pharmaceutical authorities to enforce price control policies, especially regarding the regulation of distribution chain and retail chain mark-ups.[27] As part of an overall pharmaceutical pricing strategy, countries need to consider regulating distribution chain mark-ups. In order to implement mark-up regulation, there needs to be a high level of political support, as well as a strategy for enforcement.[27]

Another complication in the regulation of medicine cost is taxation. In many countries, medicines have a tax imposed, which can include importation tax applied to specific pharmaceutical ingredients. This can have a big impact on the cost of the final product and can affect capacity for local production. The WHO advises that countries should consider exempting essential medicines from taxation, and ensure any reductions or exemptions from taxes on medicines have the effect of reducing prices for the patient or purchaser.[27] In India for example, some rules have been implemented, which involve providing tax exemptions for up to 150 percent of investments in research and development, and up to a five-year tax exemption for companies involved in research and scientific projects.[12] However, implementation of reduction or abolition of taxes on medicines requires high-level political support and legislation.[27]

Cost-plus price setting can be an attractive policy option in countries where there is no other pricing regulation, as it can be straightforward to implement. However, determination of manufacturer costs can be challenging. The WHO states cost-plus pricing might, however, help stabilize medicine prices in unregulated settings, and help reduce out-of-pocket payments in less regulated markets, including for biopharmaceuticals. Implementation of cost-plus formulae requires legislation that mandates price setting for either a selection of medicines or all those ones supplied. However, obtaining this cost data for material drug prices may be difficult, and therefore time consuming.[27]

External reference pricing is also proposed as a feasible method of price setting when resources are limited, as it provides quick information to regulators and other policy makers. It might work best as a method for negotiating or benchmarking the price of a medicine, but to implement this method, legislative frameworks are required. When applying external reference pricing, using high-income countries as a reference for lower-income settings creates risks. Therefore, countries and payers should select comparator countries based on economic status, the pharmaceutical pricing systems in place, and the burden of disease.[27]

Promoting the use of generic medicines may also help manage pharmaceutical prices. However this is a complex process, and requires many different pharmaceutical sector policy components to be in place, such as establishing the kind of system that can assist the market entry of generic drugs, and having a functioning and transparent medicines regulatory agency.[27] Oncologists are also being encouraged to embrace biosimilar drugs to help control the costs of cancer care.[28] Competitive price pressure can only begin once the availability and number of biosimilars on the

market increases. Streamlining the patent approval process is suggested, applying the patent invalidation process known as the Inter Partes Reviews, and improving the process of granting patents before they reach the Food and Drug Administration, a United States government agency, for market approval.[3]

A final consideration for sustaining pricing regulation and informing decision-making is the health technology assessment process, which is often lacking or underdeveloped in low-income countries. There is increasing interest across the world in health technology assessment for use in decision-making.[27] However, this process is resource-intensive to implement in terms of the skills required and the activities involved, which is why they are often more likely to exist in developed markets.[29] The WHO advises that countries should use health technology assessment as a tool to support reimbursement decision-making, as well as price setting and negotiation.[27]

CONCLUSION

This paper has discussed three key areas for development in the biopharmaceutical industry that may assist with regulatory harmonization and improving sustainability of pricing of biopharmaceutical drugs in emerging markets. Throughout the Think Tank discussion, several ideas and recommendations, highlighted below, were raised for continued development, discussion and attention around this important topic:

1. Harmonize legal-regulatory norms, standards, and guidelines in the biopharmaceutical market;
2. Increase the capacity of medicines regulatory authorities through technical assistance and regional collaboration to improve access to new biopharmaceuticals and reduce drug lag;
3. Boost collaboration between industry, health systems, and other stakeholders to encourage investment in innovation, including product development partnerships, novel financing mechanisms, voluntary licensing, and non-asset declarations across the biopharmaceutical sector;
4. Curate high-quality, real-world data through electronic health records and other means to inform development efforts, track outcomes, and inform drivers of cost-effectiveness for biopharmaceuticals;
5. Develop workforce capacity to adequately develop, evaluate, regulate, and integrate effective biopharmaceutical products into standards of care;
6. Increase cost and pricing transparency to grow sustainability in emerging markets, such as supply and distribution chain mark-ups, incentives, taxation, and others;
7. Ensure governments are engaged in all stages of regulatory procedures to support successful approval and implementation of innovative new therapies.

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