



International Federation
of Pharmaceutical
Manufacturers & Associations

A full-page background image of a pharmaceutical worker in a cleanroom. The worker is wearing a light blue protective suit, a hairnet, glasses, and a face mask. They are holding a clipboard with a blue and white floral pattern and are looking at a pressure gauge on a piece of industrial machinery. The machinery is made of stainless steel and has various pipes, valves, and gauges. The overall scene is brightly lit and clean.

TECHNOLOGY TRANSFER:

A COLLABORATIVE
APPROACH TO
IMPROVE GLOBAL HEALTH

*The Biopharmaceutical Industry
Experience*

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Dear Reader,

Since the publication of the first version of this report in 2015, the global landscape for pharmaceutical technology transfers has only become more complex—and more important. Most notably, the COVID-19 pandemic has brought technology transfers into the spotlight. The pandemic has illustrated how technology transfers can enable rapid scaling of new health innovations, but also raised new challenges and misperceptions.

Given these developments, it is critical for countries, policymakers, multilateral organizations, and the biopharmaceutical industry to establish clear principles for successful technology transfer. By collaborating around shared goals, these stakeholders can ensure that technology transfers are a “win-win” that advance global health and drive economic development in a way that is sustainable for the broader innovation ecosystem.

The pharmaceutical industry is committed to playing a central role in these efforts. Therefore, IFPMA has updated this report to reflect the current global environment for technology transfers, especially in light of COVID-19. It includes a review of what technology transfers are and how they work, a checklist for successful technology transfers, a deep dive on COVID-19, and a list of recommendations to guide the path forward.

With this report, we aim to empower policy leaders at the global and national levels with the knowledge needed to sustainably bridge R&D gaps, increase the availability of vaccines and medicines, and stimulate investment in key industrial areas. These are critical goals for all countries at all income levels, as well as multilateral organizations like the United Nations, the World Health Organization, the World Bank, the World Trade Organization, and the World Intellectual Property Organization.

On behalf of IFPMA member companies, we look forward to engaging with these organizations and leaders to develop cutting-edge solutions. We remain confident that pharmaceutical innovation can lead the way on today’s urgent health challenges – and we will continue to both drive this innovation and maximize its impacts for people around the world.

Thomas B. Cueni
Director General



EXECUTIVE SUMMARY

Ensuring technology transfers are a “win-win”

The transfer of advanced technology is essential for economic development. It enables countries to accelerate the acquisition of knowledge, experience and equipment related to advanced, innovative industrial products and processes. This, in turn, builds the skills of the local workforce and creates new high-tech employment opportunities.

Technology transfers for medicines and vaccines can bring additional, unique benefits. These transfers not only drive economic and social development, but can also help improve the health of recipient countries’ populations by increasing access to innovative medicines and vaccines. To chart the best path forward, it’s essential to understand the current landscape for technology transfers, the factors that enable success, and how different stakeholders can work together to deliver on these prerequisites.

The evolving landscape for pharmaceutical technology transfers

The landscape for pharmaceutical technology transfers has evolved significantly in recent years. As pharmaceutical technology and production have become more complex, technology transfers have come to require a greater level of expertise, human skills, organizational and procedural knowledge, and other key tangible and intangible elements. At the same time, emerging economies and middle-income countries have developed sophisticated pharmaceutical industries, enabling more dynamic flows between countries.

The COVID-19 pandemic has also introduced new considerations, challenges, and misperceptions. Overall, the pharmaceutical industry has tapped its long track record of

technology transfers to enable the rapid scaling of COVID-19 vaccine production. In just the first year of COVID-19 vaccines, there have already been [more than 300 manufacturing and production deals around the globe](#), the vast majority of which (approx. 75%) involve some sort of licensing and transfer of technology, and at least 30 of them on mRNA vaccines.

However, there have been growing calls for even greater levels of COVID-19 technology transfer, particularly for low-income countries. While addressing COVID-19 in these countries is critically important, there is not yet broad recognition of the many complex factors that must be addressed to ensure the safe, high-quality production of these vaccines, including those related to site selection and capabilities, national regulations and licensure requirements, and workforce skills. These factors must be considered and addressed in all countries where technology transfers occur, especially for complex innovations like mRNA vaccines.

Further, technology transfers should be seen as just one tool in a larger toolbox for increasing the global availability of medicines and vaccines, rather than as a panacea. This recognition can help to ground technology transfers in reasonable goals and expectations, as well as place the needed focus on other responses and health policy measures.

A checklist for effective, sustainable technology transfers

Many biopharmaceutical companies have used technology transfers to improve a country's ability to use innovative medicines, including by strengthening the expertise of the local scientific and medical communities and, where possible, working to improve health infrastructure. This can deliver reputational and/or commercial rewards for companies, and economic development and health benefits for countries.

However, while some decisions to transfer technology may be taken on a philanthropic basis, these collaborations will ultimately be sustainable only if they are driven by commercial rationales and market conditions, which are in turn heavily influenced by policy and regulatory decisions by national governments. The decision by biopharmaceutical companies to transfer technology depends on a wide variety of factors, most of which are influenced by the local policy environment.

Technology transfer is complex. As the current pandemic is showing, it is not just a formula that can be easily shared. Instead, it's a complex equation involving many factors and steps. While an overall prerequisite for transferring technology is the existence of the rule of law, ten additional factors emerge as critical enablers for pharmaceutical technology transfers:

1. Rule of law is established and enforced;
2. Political stability and transparent economic governance;
3. A trusted partner adhering to high ethical standards;
4. A viable and accessible local market;
5. Appropriate capital markets;
6. Innovation-friendly environment with sound intellectual property rights;
7. Proper access to information;
8. Adherence to high regulatory standards;
9. Skilled workforce;
10. Clear economic development priorities.

The roles of different countries, organizations and sectors

Many different stakeholders can take action to enable effective, sustainable pharmaceutical technology transfers, including countries at every income level, multilateral organizations, and the pharmaceutical industry.

Many emerging economies and other middle-income countries are developing a suitable policy environment and are witnessing the benefits of access to advanced foreign technologies and expansion of their domestic capabilities. However, low-income countries may not always be able to offer the preconditions required for successful uptake of technology transfer. The experience of IFPMA member companies suggests that governments of low-income countries can encourage technology transfers by focusing on attracting technology for which there is already a demand from local companies, and by adopting mutual recognition of regulatory decisions, within regions and between high- and low- and middle-income countries (LMICs), which can help increase the local market and/or reduce regulatory barriers.

In addition, high-income countries can help LMIC experts to increase their technical expertise and familiarity with international standards. Public-sector institutions can also increase technical and financial assistance to LMICs to strengthen local technical competence.

The importance of transferring technologies for medicines is recognized in several of the World Health Organization's strategies and plans.

Recommendations for effective, sustainable technology transfers

The biopharmaceutical industry is committed to shaping effective, sustainable technology transfers. IFPMA member companies support technology transfers by:

- Creating new technology through research and development of innovative pharmaceuticals and vaccines.
- Delivering programs that offer a range of products and the transfer of specialized knowledge and skills, thereby contributing to economic development and public health of the recipient country.
- Transferring not only manufacturing technology but also other forms of acquired expertise.

Success also requires action from policymakers, multilateral organizations, and other stakeholders. Therefore, the IFPMA calls on:

- Governments in low- and middle-income countries to provide policy support for the development of national private sectors and implement a welcoming policy environment for global partner firms.
- Governments in high-income countries to increase aid funding for health and healthcare in the developing world as a platform for economic development. This can be innovative at the same time as affordably addressing basic needs.
- Multilateral organizations to create knowledge hubs on technology transfers, establish special trust funds to support training of scientific and technical personnel in their countries of origin, and share knowledge about management of the public-private research interface.



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01 The Basics of Technology Transfer in the Pharmaceutical Sector

What it is: The different elements of technology transfer

Simply put, technology transfer in the pharmaceutical industry is the transfer of the elements required to develop and/or produce a medicine or vaccine. However, the transfer of pharmaceutical technology and R&D typically requires far more than sharing a “recipe” or building a bricks-and-mortar factory. Especially as pharmaceutical research and manufacturing has become more complex, effective technology transfer can require a number of different elements¹:

“Techno-ware”: the transfer of physical objects such as equipment for use in research laboratories or production equipment for the manufacture of pharmaceuticals ingredients, or the formulation or packaging of final products.

“Human-ware”: the human skills required for technology management and learning, such as training for researchers or general practitioners. Technology transfer can also create positive spillover effects into associated industries and into the supporting public-sector research infrastructure.

“Info-ware”: the techniques related to knowledge, information, and technology, in the form of a technology license.²

“Orga-ware”: the organizational and procedural knowledge needed to operate a given technology, relating to a chemical or biological compound.

¹ Ramanathan, K. 1994. The polytrophic components of manufacturing technology. *Technological Forecasting & Social Change*, 46, 221-258. Sharif, M., 1995. *Technology transfer and development*, ADB, Manila

² As noted in the World Health Organization Commission on Macroeconomics and Health Report of 2001, voluntary licenses can be a valuable tool for transferring technology. Voluntary license agreements may or may not entail transfer of manufacturing know-how. To learn more about technology transfer and voluntary license programs, please visit the IFPMA website (www.ifpma.org).

How it works: Strong market mechanisms provide the starting point

Foreign direct investment (FDI) is by far the main channel for technology transfer, but other market mechanisms such as licensing agreements, royalties and joint ventures are also vital channels. Through regulation and investment, governments can help to create the right conditions for these technology markets to function. For the biopharmaceutical sector, reliance on “non-market” mechanisms is unlikely to provide a sustainable technology transfer platform for economic growth or business development.

What’s changing: The dynamic map of technology transfer

Newly industrialized countries and other middle-income countries are increasingly relying on technology transfer to access advanced foreign technologies and expand their domestic capabilities. In addition, technology transfer programs have contributed to better health, for example, in Brazil, where development of vaccines through technology transfers has been essential to the country’s universal immunization program.

Traditionally, technology transfers have typically flowed from high-income countries to low- and middle-income countries. However, more dynamic networks are now beginning to emerge, making former designations like “North-South” less relevant. In particular, there is a growing difference between middle-income countries and low-income countries.

Low-income countries may still have weak absorptive capacity for foreign technologies. This generates a particular challenge for R&D pharmaceutical technology transfer, since those parts of the world least able to benefit from it today are among those who need its products the most.



OUR COMMITMENT TO COMBAT COVID-19

GLOBAL HEALTH PROGRESS | Collaborating for a sustainable future

Check out our resources to explore examples of technology transfers:

- > IFPMA COVID-19 Information Hub
- > Global Health Progress
- > Tech Transfers Case Studies Annex

CASE STUDIES

Technology transfers in practice: IFPMA members' long track record

IFPMA members want to contribute to the sustainable development of the world economy and to the improvement of the health and living standards of people in all regions. They are committed to work with public and private institutions in low- and middle-income countries to enhance healthcare provision for the benefit of all patients.

IFPMA member companies believe the contribution of pharmaceutical industry technology transfers lies in:

Developing innovative pharmaceutical and vaccine technologies

Continuing to deliver corporate social responsibility programs that offer a range of products and the transfer of specialized knowledge and skills, which contribute to public health and economic development of the recipient country

Enabling access to appropriate therapies and technical know-how, by implementing programs to improve the health of patients and build capacity around the world

Transferring not only manufacturing technology but also other forms of acquired expertise, ranging from good clinical and laboratory practices to innovative solutions for therapy adherence and health literacy

As one means to achieve these goals, IFPMA member companies have engaged in technology transfer activities for a number of years in many emerging and developing countries, building up a substantial track record.

Manufacturing and Entrepreneurial Know-How Transfer

This may include transfer of physical material, equipment or an entire factory, provision of information, know-how and performance skills to allow recipient countries to produce medicines and vaccines locally. Voluntary licenses can also be a valuable tool for transferring technology. A voluntary license is an authorization given by the patent holder to a third party (e.g., a generic pharmaceutical manufacturer), allowing that party to make, use, sell or import the patented article, e.g., a medicine. The licensing terms usually include quality requirements and define the markets in which the licensee can make, use, sell or import the product. Voluntary license agreements may or may not entail transfer of manufacturing know-how.

Scientific Collaboration and Knowledge Sharing

Technology transfer is also performed through collaboration in the scientific field, including sharing of knowledge. Much of the research being conducted by IFPMA member companies into diseases disproportionately affecting people in low- and middle-income countries is conducted on a collaborative basis, with public- and private-sector partners.



02 A Checklist for Transferring Technologies

Commercial opportunities are paramount for the private sector when considering technology transfer. However, if the basic conditions are right, non-commercial reasons may also play a part in decision-making. This is particularly true in advanced technology sectors, especially when presented with an opportunity to open a market to a specific technology or increasing access to lifesaving technologies, such as in the case of the current COVID pandemic.

While many countries are already well-positioned to attract R&D pharmaceutical technology transfers, some low-income countries still struggle to provide the enabling conditions for technology transfer that could be expected in middle-income countries. In most cases, the concern is not so much about intellectual property enforcement as the capacity of the industrial sector to absorb advanced technology.

Pharmaceutical and vaccine manufacturers consider a variety of factors in evaluating potential technology transfer ventures. Many of these factors are influenced by government policy decisions.

The most effective role for governments, beyond guaranteeing the rule of law is to create optimal enabling conditions, linked to the country's overall economic policy objectives. A government's willingness to create optimal conditions to attract technology is a strong determinant of whether transfers will be directed towards their domestic industrial sector.

While many governments in newly industrializing and middle-income countries are taking an active role in encouraging the transfer of technology, in low-income countries, it can be difficult for their domestic industry to meet the above conditions. In these cases, governments and international development institutions need to play a greater role to determine the potential for technology transfer in the future.

Pharmaceutical and vaccine manufacturers consider a variety of factors in evaluating potential technology transfer ventures. Many of these factors are influenced by government policy decisions. Ten factors can be identified:

Biopharmaceutical companies are also looking for:

RULE OF LAW IS ESTABLISHED AND ENFORCED

INNOVATION-FRIENDLY ENVIRONMENT WITH SOUND INTELLECTUAL PROPERTY RIGHTS

POLITICAL STABILITY AND TRANSPARENT ECONOMIC GOVERNANCE

PROPER ACCESS TO INFORMATION

A TRUSTED PARTNER ADHERING TO HIGH ETHICAL STANDARDS

ADHERENCE TO HIGH REGULATORY STANDARDS

A VIABLE AND ACCESSIBLE LOCAL MARKET

SKILLED WORKFORCE

APPROPRIATE CAPITAL MARKETS

CLEAR ECONOMIC DEVELOPMENT PRIORITIES

A CHECKLIST FOR TRANSFERRING TECHNOLOGIES FOR MEDICINES AND VACCINES

- Underpinned by a predictable, stable and transparent policy and legal framework

RULE OF LAW IS ESTABLISHED AND ENFORCED



- Proven track record of receiving party
- Values and behaviors conducive to trust-based relationship



A TRUSTED PARTNER ADHERING TO HIGH ETHICAL STANDARDS

- Political and economic stability, including predictability in industrial policy-making
- Political will to address health challenges and strengthen healthcare system capacity

POLITICAL STABILITY AND TRANSPARENT ECONOMIC GOVERNANCE



A VIABLE AND ACCESSIBLE LOCAL MARKET



- Market size and/or prevalence of certain diseases
- Market equally accessible to domestic and foreign enterprises

- Sufficient resources to meet high quality and safety standards
- High-quality facilities and equipment for scientists and healthcare professionals
- Promotion of inward investment through incentives designed to encourage tech transfer from foreign companies



APPROPRIATE CAPITAL MARKETS

ADHERENCE TO HIGH REGULATORY STANDARDS



- Internationally recognized regulatory standards in place
- Efficiency in processing product registrations and other applications

- Strong legal framework and enforcement ensuring secure intellectual property rights, data confidentiality, transparency and certainty for investors, licensees, and customers

INNOVATION-FRIENDLY ENVIRONMENT WITH SOUND IP RIGHTS



- Educated workforce with engineering and management skills
- Free movement of scientists and other experts strengthen healthcare system capacity



SKILLED WORKFORCE

- Effective systems for disseminating market-relevant information for technology holders and technology demanders to identify potential partners

PROPER ACCESS TO INFORMATION



CLEAR ECONOMIC DEVELOPMENT PRIORITIES



- Promotion of technology transfer matching overall economic policy goals
- Investment in domestic healthcare systems and infrastructure as a priority in the development agenda

1. Rule of Law is established and enforced

For all investors, the rule of law is a clear prerequisite. This is a basic principle that is required for any and every sector and society to flourish, as there needs to be the underlying legal security which is only brought about through an adequate legal system and adherence to it. Without a rule of law-based system in place, foreign investments would be hardly possible, and no company would be able to undertake a technology transfer without taking on levels of risk far beyond what would be justified. This particularly applies to nascent technology sectors.

2. Political stability and transparent governance

A country's relative political and economic stability will influence the rate of inward technology transfer and can be seen as a precondition for any technology transfer. Long periods of stability also lead to stronger and more successful partnerships, as demonstrated by Brazil, where some partnerships started 30 years ago, and by Singapore, which in the recent past has secured a strong industrial base, partly as a result of stability and transparent governance. Whether a transfer generates value over the medium- and long-terms depends, in part, on a certain degree of predictability in policy-making, especially industrial policy, inflation and interest rates, and international economic and political linkages. Even when research-based pharmaceutical company technology transfers are philanthropic in nature, they need to be sustainable in order to achieve their goals.

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A technology transfer is on a certain level a constructive collaboration between two parties seeking to create a positive impact – the underlying level of trust dictates the extent to which the parties can build on their relationship and provide positive outcomes for society.

In the host countries, concerns about the impact of technology transfer on the existing industrial base may restrict the opportunities for integration and promotion of these collaborations. On occasion, it can be effective for governments to take a leadership role in communicating the need to prepare for open markets, facilitating the upgrading of local capacities, and preparing the public for the changes to the local economy that come with global integration.

Biopharmaceutical companies have found that training and education programs can help in changing attitudes. For example, programs to train and equip local researchers to carry out clinical trials or quality control to internationally recognized standards can lay the foundation for opening up a market.



There is a risk of confusing political leadership for healthcare with political leadership for local supply of healthcare goods and services. Political leadership is critical to address global and local health challenges and, more importantly, to strengthen the capacity of healthcare systems. Political leadership in promoting local production can be a different story, unless it is tempered by the views of technology providers.

3. A trusted partner adhering to high ethical standards

Trusted partners must be available for technology transfers to even begin and for any discussion over sensitive proprietary information. A proven track record is an element which institutes trust between the parties, and instills confidence in both partners. Due to the kinds of technologies and business risks involved with sharing proprietary information, there must be a certain level of trust between the parties for the technology transfer to go ahead. A technology transfer is on a certain level a constructive collaboration between two parties seeking to create a positive impact – the underlying level of trust dictates the extent to which the parties can build on their relationship and provide positive outcomes for society. Without the needed level of trust, the sharing of sensitive information through a technology transfer will not be undertaken.

4. A viable and accessible local market

The host country must feature a viable, accessible local market for the transferred technology. There is no “one-size-fits-all” formula to determine the ideal market size that ensures the economic viability of domestic production. However, the larger the country or geographic bloc, the greater the market potential and investment appeal. For pharmaceutical technology transfer, the prevalence of certain diseases will also play a role in determining the size and viability of the market, as is the case for malaria-endemic countries, for example. Biopharmaceutical companies are more likely to consider small countries when there is effective regional economic integration. All countries, large or small, benefit from ensuring that foreign enterprises have easy access to their markets and that the pharmaceutical sector is not burdened by differential treatment of domestic

and foreign investors. Technology transfer activities may also take into account other factors, such as health security at national and regional levels.

5. Appropriate capital markets

For many governments seeking to expand technological capacity, attracting direct investment is very important, but there is also the need to maximize the spillover benefits of that investment, which requires adequate capital markets. For example, a local pharmaceutical manufacturer receiving a product license must have sufficient resources to meet high standards of quality and safety controls, good manufacturing practices, sophisticated human capital, and so on. Likewise, benefits from the transfer of clinical skills increase when scientists or medical personnel have access to high-quality facilities and equipment. All of these require financing. When local private capital markets are insufficient, the public sector or global institutions may provide alternative solutions. However, in the case of healthcare and the pharmaceutical industry, the extended time horizons and high investment risks raise unique challenges for sustainable public-sector investment. Where such public-sector investments are made, whether in production capacity or in underpinning research activities, participation of foreign organizations should be encouraged.

A number of emerging economies have made strategic decisions to attract biopharmaceutical investment. This can be a natural evolution from existing chemicals or generics production capabilities. In some cases, encouragement for foreign direct investment has been coupled with government support to nurture indigenous scientific expertise. R&D-based pharmaceutical companies have on occasion been able to contribute to this process by providing training in the scientific and business disciplines relevant to strengthening research capacity and transforming scientific ideas into commercial opportunities. Governments can also promote inward investment through tax breaks and other forms of incentives designed to encourage technology transfer, in compliance with international trade rules. Global institutions, such as the International Finance Corporation and the World Bank, provide certain options geared towards medium-term investments in the private health sector.

6. Innovation-friendly environment with sound intellectual property rights

To successfully attract imported technology and to build the necessary preconditions for adapting imported technology, countries need a supportive environment that includes strong intellectual property (IP) protection. Effective implementation of any intellectual property laws and regulations already in force provides transparency and certainty for investors, licensees, and customers. The level of intellectual property protection tends to be directly and positively linked to the rate of technology transfer.

To a large extent, this was the rationale behind the negotiation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Article 7 of the Agreement addresses the relationship between intellectual

property and technology transfer, economic welfare, and the need for a balance of rights and obligations. It reads:

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

It was assumed that governments would be responsible for putting in place the proper legal environment and economic conditions to facilitate private commercial transactions, while high-income countries would introduce measures such as technical support to facilitate technology transfer (TRIPS articles 66 and 67). The sum total of private deals and government facilitation would lead to technology transfer and capacity-building.³ The TRIPS assumptions have been partially vindicated, in that technical capacity is more widely distributed around the world than was the case before TRIPS. At the same time, it has become clear that, although a robust intellectual property regime is a necessary component of a knowledge-based economy, it must also form part of a wider trade-oriented framework.

Technical support may often be needed to help build innovation-friendly frameworks. For example, a limiting factor for low- and middle-income countries can be lack of knowledge on how to manage intellectual property at the interface between academic and private sector research. Support for this critical juncture is important to assist translation from basic research to practical innovation. Technical assistance to establish an intellectual property system supports the business development of local innovators, licensees, and patentees. A country with aspirations to develop a technology base must be able to transfer technology from the public to the private sector within its own borders. It is thus important that the public domain continues to function in an open and efficient manner.

While building innovation-friendly and intellectual property frameworks entails costs, and initially benefits foreign entrants, the domestic costs of failure to advance intellectual property rights are also significant. If intellectual property protection is inadequate, firms may choose not to transact at all, offer and rely on older-generation technologies, or keep information within the firm by dealing only via subsidiaries. Disclosure of proprietary information requires a high level of confidence in both partners and the legal regimes under which they operate. Business development will also be more difficult in the absence of secure intellectual property rights and data confidentiality. Strong intellectual property protection and enforcement in LMICs benefit domestic economic development by providing an incentive for domestic entrepreneurial initiatives. Major middle-income countries such as India and China have many positive attributes sought by inward investors, but their experience also demonstrates how the pattern and rate of adoption of IP has influenced industrial development.

³ This strategy was successfully employed by the Asian Tigers and some of the Eastern European countries, which adopted the necessary legal infrastructure, followed sound economic policies, and incorporated technology transfer initiatives in their national development programs.



7. Proper access to information

Where adequate legal frameworks are in place, attention should be given to supporting access to information. This has a number of dimensions, from better documentation of available resources to the longer-term issue of addressing the complexity of the global knowledge market. In the absence of effective systems for disseminating market-relevant information, technology holders may find it difficult to identify precisely who is interested in purchasing their technology, while technology demanders face a similar challenge in finding entities willing to transfer their technology. These asymmetries can result in very high search costs, which can be reduced by improving information, networking, and other communication measures. The emergence of product development partnerships such as Medicines for Malaria Ventures, Drugs for Neglected Diseases initiatives, the Global Alliance for TB Drug Development, or initiatives like WIPO Re:Search demonstrate the point. These autonomous bodies have become knowledge hubs in which all stakeholders, including pharmaceutical companies, can provide both assets and knowledge to advance the specific goals of the partnership.

8. Adherence to high regulatory standards

The pharmaceutical industry is one of the most heavily regulated, to ensure quality, safety, and efficacy of its medicines and the well-being of patients. The ability to meet international regulatory standards, or at least those of the major markets, is a precondition for many technology transfer activities. Regulations and standards apply also in low- and middle-income countries. For example, governments require product registration and data submissions to demonstrate quality, safety, and efficacy. Governments also vary greatly in their relative efficiency in processing registrations and other applications, which can influence a technology holder's decision to make a transfer to a particular country.

When the technology transfer operation involves local production, technology holders often choose the recipients based in part on their capacity to comply with international quality standards. The ability to meet these standards has contributed to the growth of the domestic pharmaceutical industry in emerging

countries. For example, Indian companies account for a significant share of the new drug applications received by the US Food and Drug Administration (FDA) and are also major suppliers to the substantial donor-funded market for antiretrovirals (ARVs) and anti-malarial medicines.

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Improving the health of the population and healthcare delivery will presumably rank high on the development agenda of any country pursuing technology transfer and should be reflected in an appropriate level of investment in the domestic healthcare system and infrastructure.

Although building strong regulatory and administrative capacity for pharmaceuticals requires a substantial investment by governments, the failure to do so can inhibit the ability of the local industrial sector to attract technology and can isolate the country from a globalizing world. The pharmaceutical industry has undertaken initiatives to enable LMIC researchers, manufacturers, and regulators to align their practices to international norms. For example, the Japan Pharmaceutical Manufacturers

Association has worked with WHO since 1989 to provide quality control training courses for Asian government quality control personnel.

9. Skilled workforce

Human capital is an essential element of the technology transfer process. The successful absorption of technology or know-how in the recipient country and its translation into greater economic development hinge on the availability in the host country of an educated workforce with, for example, engineering and management skills. Certain low- and middle-income countries are disadvantaged because a large proportion of their highly trained workers have emigrated to more technologically sophisticated environments in higher-income countries. The healthcare sector has been particularly hard hit by this “brain-drain”.

Migration is a mixed blessing for many countries. By improving the prevailing conditions, individuals may be more inclined to return home. Flexible work structures and international fellowships can also help. High-income countries can play a major role both by providing access to the best centers of higher education, as they do now, and by supporting sustainable solutions to human resource issues. Through scholarships and other initiatives, IFPMA members have sought to strengthen the human resources available to low- and middle-income countries. One good example is the EDCTP-TDR Clinical Research and Development Fellowship. This program, developed with the help of IFPMA, offers targeted training to enhance competencies in clinical trials for medicines, vaccines and diagnostics on a broad range of infectious diseases of poverty.

Inward investment also helps create a skilled workforce, as pharmaceutical companies train LMIC nationals and transfer needed expertise from elsewhere.

Supportive government policy is crucial to ensuring the free movement of scientists and other experts.

10. Clear economic development priorities

The finite or limited resources available to governments mean that measures taken to promote technology transfer must be realistic and fit with overall policy goals. A technology transfer policy dedicated to the creation of completely new types of economic activity, and one which is as complex and as highly regulated as the pharmaceutical sector, can present a much bigger challenge than building on a sector that already exists.

Where local capacity already exists, governments must be ready to invest in support of their technology development goals. Having the right legal framework is important but countries that are successfully strengthening their technology base in a particular sector have often also committed to develop the supporting science base through public sector funding.

The impact of health and healthcare on economic outcomes makes healthcare investment a strategic priority. Improving the health of the population and healthcare delivery will presumably rank high on the development agenda of any country pursuing technology transfer and should be reflected in an appropriate level of investment in the domestic healthcare system and infrastructure.

FEATURE

Transferring Technology in a Pandemic Setting: Not Business as Usual

Technology transfer has been fundamental to the global pharmaceutical industry's ability to rapidly scale up production of COVID-19 vaccines, and it will likely remain so in the future. However, there are a number of unique challenges for technology transfer related to COVID-19 vaccines, especially for transfers to low- and middle-income countries that may have limited absorptive capacity. To continue expanding the global fight against the pandemic, these complex challenges must be understood and addressed. The COVID case has only exacerbated the need for receiving countries to be fully prepared to receive high-end, complex technologies and be equipped with proper access to information, skilled workforce, and viable partners.

The role of technology transfers in scaling COVID-19 vaccine production

IFPMA member companies' long track record and deep experience in technology transfer has enabled them to respond quickly to the SARS-CoV-2 (or, COVID-19) pandemic. Industry's current estimated capacity is almost 10 billion COVID-19 vaccines in 2021 – tripling previous annual vaccine delivery. This is an outstanding achievement after only 5 months from the first vaccine receiving emergency use authorization, especially considering that the average vaccine development timeline is 10-15 years; whereas the COVID-19 vaccine was developed in less than one year, including the development and production of innovative mRNA vaccines.

Technology transfers have played a key role in this historic success. Within the first year of existence of COVID-19 vaccines, there exist about 300 manufacturing and production deals around the globe, the vast majority of which (approx. 75% involve some sort of licensing and transfer of technology for COVID-19 vaccines and at least 30 of them for mRNA vaccines.

Remaining challenges and key considerations

However, while technology transfer has played a key role in the scaling of COVID-19 vaccine production, this process is complex and requires a high degree of expertise, managerial and technical bandwidth, and absorptive capacity. There are a number of reasons for this complexity:

- **It is critically important to ensure the safety, quality, and efficacy of vaccines.** Therefore, strong regulatory oversight is a must, and policies that allow such transfer without compromising public health must be enacted and enforced. This includes high standards of Good Manufacturing Practice (GMP) and Quality Assurance in the receiving manufacturer.
- **Vaccine manufacturing is technologically much more complex than small chemicals.** Setting up the production of an existing vaccine typically requires lengthy technology transfer, including knowledge sharing, for a newcomer to become operational. Further, there is limited understanding outside of vaccine manufacturers and regulators on the rigorous requirements leading to approval of a vaccine manufacturing facility. These challenges are magnified in the case of COVID-19 mRNA vaccines.
- **A successful transfer requires meeting a broad range of requirements.** A company seeking to transfer vaccine production capabilities must consider: a manufacturing site's existing space, technical capabilities, and capacity; national regulations and licensure requirements; and the presence of a suitably skilled local workforce.⁴ All of these requirements must be assessed and met for each case of technology transfer.
- **For these reasons, the transfer of vaccines can be an extended process.** A recent survey by McKinsey and Company highlighted that tech-transfer times for sterile dosage forms, such as injectable vaccines, range from 18 months to more than 30 months. This time extends if the transfer takes part between two different companies (i.e. half-a-year or longer)⁵, but can be expedited in situations with a trusted partner with a proven track record of production of safe, effective and high-quality vaccines. Other sources refer to up to four years for a tech transfer of new vaccines to be completed.⁶
- **The pandemic setting leads to new considerations and misperceptions.** A broad lack of understanding of the above factors

⁴ Nature, Applying lessons from the Ebola vaccine experience for SARS-CoV-2 <https://www.nature.com/articles/s41541-020-0204-7>.

⁵ McKinsey, 'Why tech transfer may be critical to beating COVID-19', July 2020. <https://www.mckinsey.com/industries/life-sciences/our-insights/why-tech-transfer-may-be-critical-to-beating-covid-19>.

⁶ Wolf et al., 'Applying lessons from the Ebola vaccine experience for SARS-CoV-2 and other epidemic pathogens', Nature, June 2020. <https://www.nature.com/articles/s41541-020-0204-7>

can lead to misperceptions of “delays,” when in fact timelines are driven by the elements required for licensure.⁷ While in normal times a vaccine tech transfer is considerably shorter than a clinical trial – leaving plenty of time to organize – in a pandemic setting, specific logistical, economic, regulatory, scientific, and programmatic considerations come into play, beyond a “business as usual” approach.

Moving ahead with clear expectations and collaborative efforts

Companies are doing their utmost to rise to these challenges through globally optimized networks of suppliers and producers. However, speeding the pace of progress will also require action from national governments and multilateral organizations.

In order to rapidly scale up access to vaccines in low-and-middle income countries, it is critical that trade barriers are removed, particularly those that are preventing export of vaccines from key manufacturing hubs in developed and developing countries. In addition, companies need to be able to rapidly source essential input supplies of raw and packaging materials, consumables, and equipment. A premature expansion in the number of manufacturers can lead to overstretch of supply chains, hoarding or outbidding of scarce raw ingredients, inconsistency in manufacturing across sites, and increased pressure on regulatory systems.

The biopharmaceutical industry is actively collaborating with policy partners to address these and other challenges. Just as global collaboration led to the development of COVID-19 vaccines on an unprecedented timeline, similar levels of collaboration are needed to scale access to these vaccines across the globe.

⁷ Ibid

03 A Path Forward for Sustainable Technology Transfers

A resilient, sustainable, and high-quality private sector in the health and life sciences industry is critical for the development, manufacturing, supply, distribution, and availability of medicines and other health technologies, such as vaccines, medical devices, and diagnostics.

Developing technical capacity in low-income countries – where tech transfer is often a critical and emotive issue – requires more than just a national endeavour.



While the international community has tried to address the situation through direct financial aid, more needs to be done for the majority of low-income countries to have the appropriate conditions for successful uptake of technology transfer. International development and financial assistance through institutions like the World Bank are intended to build local capacity, but many low-income countries, especially in sub-Saharan Africa, have yet to make significant advances. This situation may change as the COVID pandemic has refocused momentum on local production of medicines and, in particular, vaccines in low- and middle-income countries.

While this paper identifies the prevalent enablers for tech transfer, different approaches are needed for different kinds of health products and different levels of development in each country. A critical lesson from several examples is that no two pharmaceutical facilities are identical, and subtle differences – for example in the configuration of piping or the way valves open and close – can make a huge difference to a drug’s consistency and quality.⁸

⁸ WIPO Magazine, https://www.wipo.int/wipo_magazine/en/2015/02/article_0007.html



It's a very complex sector, with complicated science, very complicated manufacturing processes, we have to be very careful to whom we transfer the know-how, in particular because of the imperative of safety and quality.

Sai Prasad, Executive Director, Quality Operations, Bharat Biotech, President, Developing Countries Vaccine Manufacturers' Network (DCVMN)

For technology transfers to work for both the provider and the receiver, there need to be additional incentives for projects in which technology transfer and the associated capacity-building are the main operation (e.g., licensing, joint ventures) and a recognition of the more extensive needs of low-income countries, both in capacity-building and in external financing.

Tech transfer is only one of many options that should be considered

for increasing the availability of vaccines in the developing world. It is not a panacea. An important prevailing condition that is often missing is the need for policy coherence in host countries, with a national vision, where technology transfer and public health development are part of the same strategy and "in sync" with each other.

Across all advanced technology sectors, including pharmaceuticals, there is a large base of evidence and consensus that technology transfer is strongly influenced by the conditions in the host country described above. Adherence to international norms will positively influence the level and magnitude of technology transfer directed to a given market.

The immediate objective in policy planning should be to strengthen capacity and understanding of the appropriate framework to facilitate technology transfer. Emerging economies that are now at the point where they have a significant domestic stake in promoting innovation as part of their economic development will have a key role to play over the medium term. To this extent, South-South cooperation should also be encouraged.

Policy recommendations: Actions for host countries, source countries, and multilateral organizations

Based on IFPMA member companies' experiences, the solution for effective pharmaceutical technology transfers depends on actions from both host and sponsor countries, with the support of multilateral organizations and positive engagement from industry. This was reaffirmed by the 2021 World Health Organization's resolution on "strengthening local production of medicines and other health technologies to improve access". To optimize their national technology bases, enhance sustainability, and realize maximum benefits, the IFPMA calls on:

- Governments in low- and middle-income countries to provide policy support for the development of national private sectors and implement a welcoming policy environment for global partner firms;

- Governments in high-income countries to increase the funding available for health and healthcare in low- and middle-income countries as a basic platform for economic development. This can be innovative while also affordably addressing basic needs.

1

Policy recommendations for host countries

- Focus on technology for which there is a demand from local companies and markets. This will motivate local companies to develop innovation projects to suit local needs and markets, and it will generate spillover benefits that can be captured by the local economy.
- Institute progressive development of a national intellectual property system. This is integral to efforts to promote learning from technology transfer and follow-on innovation.
- Allow foreign companies to participate in relevant projects where public funding is being deployed to strengthen industrial capacity. This cross-sector collaboration represents an important opportunity for economic development.
- Consider mutual recognition of administrative or regulatory decisions. This approach can be applied both within regions and between high- and middle- and low-income countries.

2

Policy recommendations for source countries

- Commit to greater access to standards-setting bodies for experts from low- and middle- income countries. This will help to ensure that standards reflect the unique considerations of these countries.
- Increase technical and financial assistance for improving the ability of low- and middle-income countries to absorb technology and trade. This can both promote innovation and efficiently meet basic healthcare needs.
- Ensure that tax deductions are available for technology contributions to non-profit entities engaged in technology transfer in low- and

middle-income countries. This will provide an incentive that reflects the value of technology transfer.

- Offer fiscal incentives to encourage enterprises to employ, at least temporarily, recent scientific, engineering, and management graduates from low- and middle-income countries. This approach can help to build the skills and knowledge base of host countries' workforces.
- Develop grant programs that support meaningful involvement of research teams from low- and middle-income countries. These programs can help to stimulate innovation and build scientific skills and knowledge globally.

3

Multilateral policy recommendations

- Reduce information gaps by establishing knowledge hubs on technology transfers. These hubs can feature examples of successful technology acquisition programs that have been undertaken.
- Establish special trust funds to support training of scientific and technical personnel in their countries of origin. These funds can help to raise the global level of scientific expertise in the life sciences industry, ultimately leading to both faster innovation and faster economic development.
- Share knowledge about management of the public-private research interface. Multilateral organizations can share examples and best practices that help these cross-sector collaborations to run smoothly and maximize positive outcomes.



Check out more examples of technology transfers on our IFPMA COVID Information Hub and Global Health Progress.

IFPMA COVID HUB
www.ifpma.org/covid19

GLOBAL HEALTH PROGRESS
globalhealthprogress.org

CASE STUDIES
bit.ly/2Z3AoLr



International Federation
of Pharmaceutical
Manufacturers & Associations

Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
Email: info@ifpma.org

www.ifpma.org

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