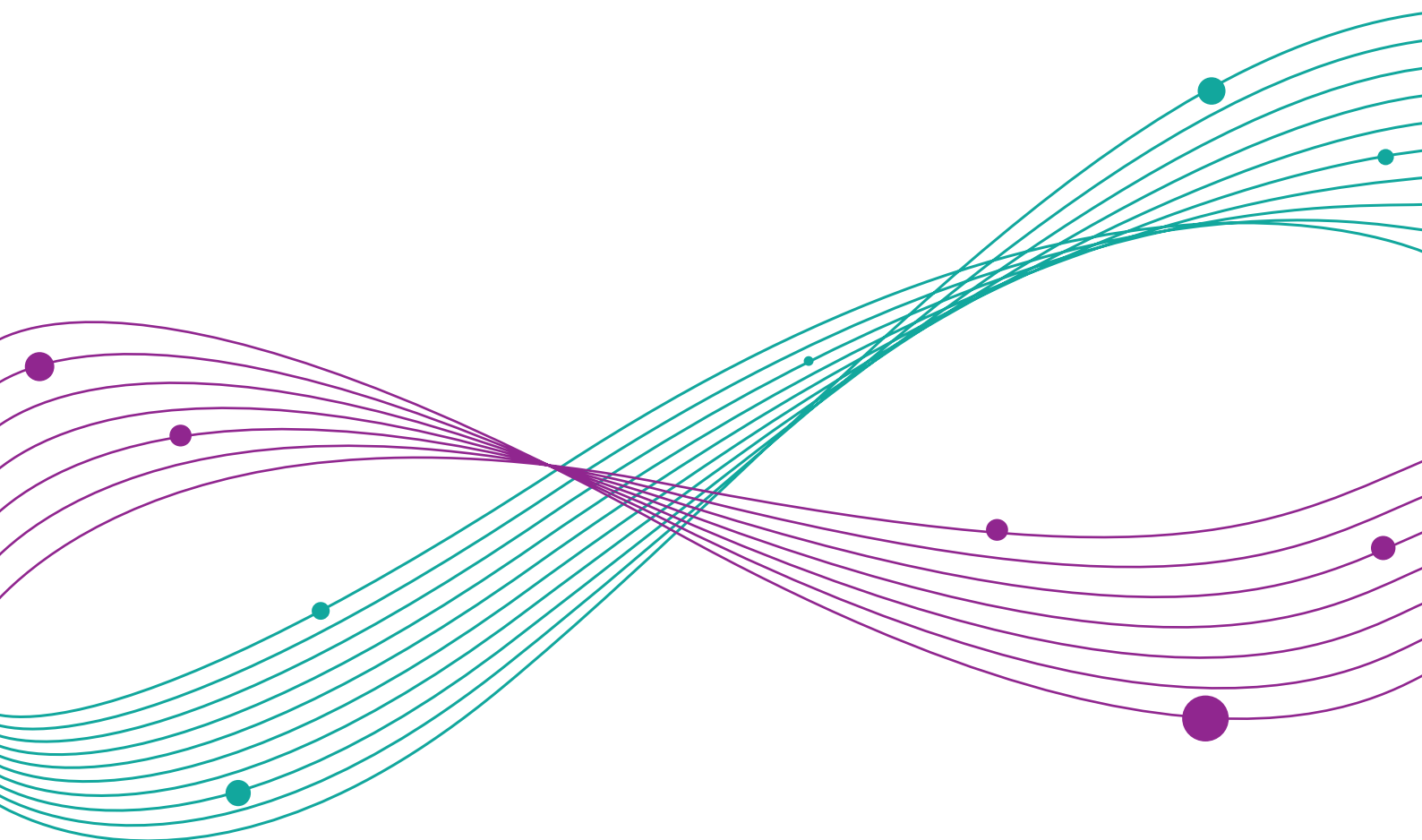


Technology Transfer: a Collaborative Approach to Improve Global Health

The Research-Based Pharmaceutical Industry Experience



International
Federation of
Pharmaceutical
Manufacturers &
Associations

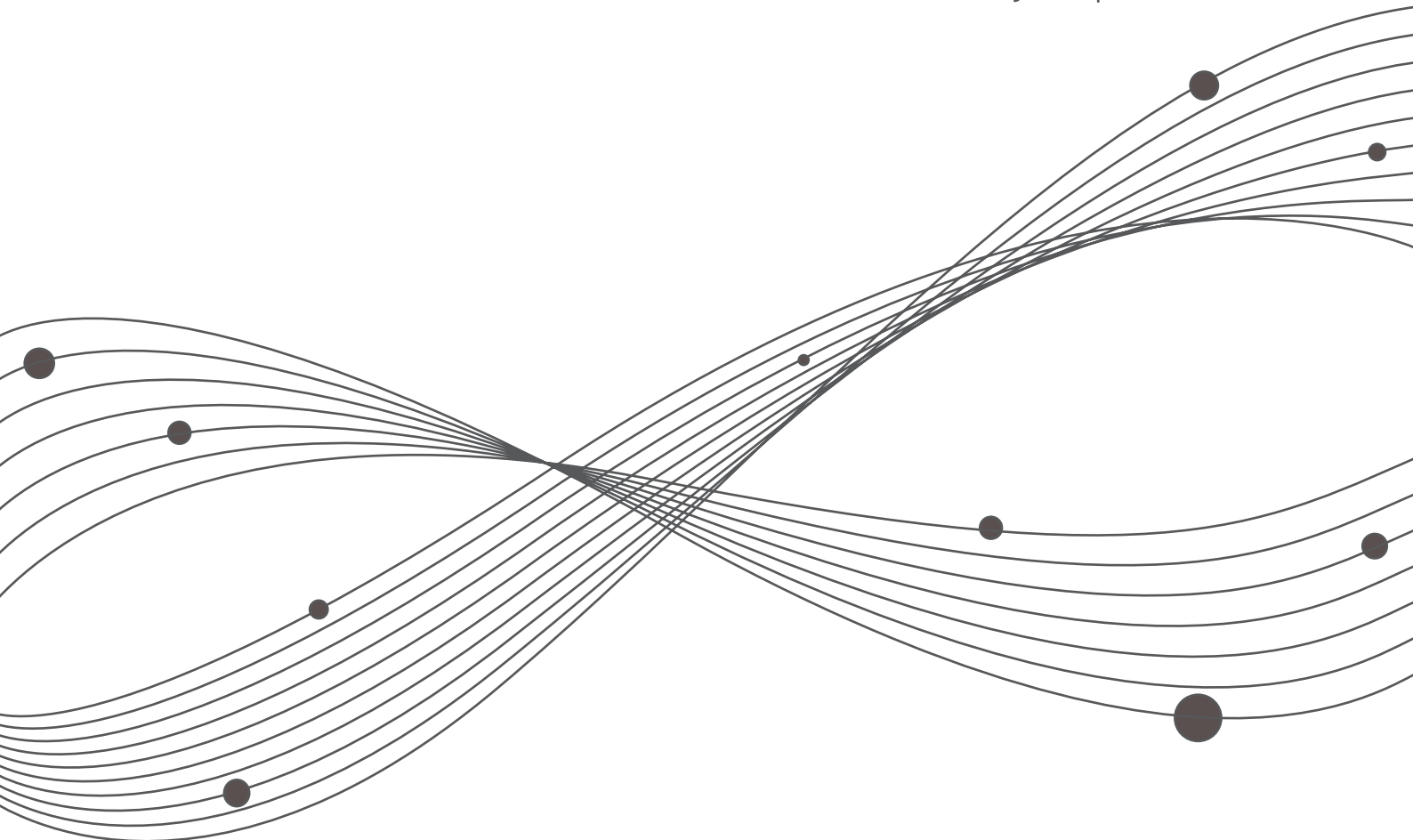
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Research-Based Pharmaceutical Industry Technology Transfer Policy Considerations

Foreword

Dear Reader,

Technology plays a central role in the economic and social transformation of countries. The wide use of technology in an economy tends to lead to improvement in the quality of production, generation of new knowledge, improvement in living standards and productivity or efficiency of exports¹. The technology transfer process results in investment in the production of food, medicines, steel, cars, electronics as one party gains access to a second party's technology, successfully learning and absorbing it, and implementing it in production.



While technology transfer of medicines and vaccines shares many of the challenges of other advanced industries, in addition, the research-based pharmaceutical industry strives to factor into the mix a commitment to global health. The aim is to devise sustainable ways to bridge the research-and-development gaps but also to increase the availability of vaccines and medicines in the developing world. Recent years have seen the research-based pharmaceutical industry engaged in pushing forward with this unique type of technology transfer, which is at the cutting edge of business practices today.

In an increasingly globalised world, the promise of technology transfer is a key consideration for all countries whether in low, middle and high income countries and many multilateral organizations, including the UN, World Bank, WTO, WIPO, have a role to play in creating the necessary conditions for global growth and poverty reduction. For the WHO and the broader public health policy making community, technology transfer as it applies to medicines and vaccines is of major importance. To contribute to these discussions and with a view to informing the debate, we have brought together in this publication over 50 examples of successful pharmaceutical technology transfers.

Building on this experience, IFPMA member companies have identified the main considerations for a country's attractiveness for transferring technology and compiled a list of policy recommendations for the relevant institutions at national and international levels.

Eduardo Pisani
Director General

¹ Torlak, E. (2004), Foreign Direct Investment, Technology Transfer and Productivity Growth in Transition Countries: Empirical Evidence from Panel Data, Center for Globalization and Europeanization of the Economy (CeGE). Discussion Papers 26, University of Goettingen, Germany - Yasar, M. and Paul, M.C.J. (2005), Foreign Technology Transfer and Productivity: Evidence from a Matched Sample, Emory Economics 0514, Department of Economics, Emory University, Atlanta, US.

Executive Summary

Creating a win-win process

Transfer of advanced technology is essential for economic development - It is one means by which low- and middle-income countries can accelerate the acquisition of knowledge, experience and equipment related to advanced, innovative industrial products and processes. It has been credited with the potential to help improve health; increase the reliability of supply and decrease reliance on imports; raise the competence of the local workforce; and reverse the “brain drain” from low and middle income countries, by increasing local “high-tech” employment opportunities.

Over and above the beneficial impact on economic and social development normally credited to technology transfer, in the field of pharmaceuticals, transferring technology can help improve the health of recipient countries’ populations by increasing access to innovative medicines and vaccines. Research-based pharmaceutical companies, members of IFPMA², make a unique contribution to improving global health through the innovative medicines that they develop. In addition, they have a strong track record of sustaining programs to improve the health of patients in low and middle income countries, by strengthening local healthcare capacity, by educating patients and populations at risk, and by conducting research and development (R&D) in diseases of the developing world. This booklet provides IFPMA’s insight into the factors influencing technology transfer in the pharmaceutical sector.

Research-based pharmaceutical industry programs provide insights for policy makers - As technology transfer is poorly captured in official statistics, this booklet seeks to inform the policy discussions by providing an overview of recent technology transfer programs in the pharmaceutical and vaccine sectors. The examples demonstrate that many research-based pharmaceutical companies have built up a credible track record using technology transfer to help improve a country’s ability to use innovative medicines, by strengthening the expertise of the local scientific and medical communities; and, where possible, with the goal of improving the health infrastructure. The rewards to companies transferring pharmaceutical technology to emerging countries are often reputational as well as commercial. So, although IFPMA member companies’ decisions with regard to transfer of technology are sometimes taken on a philanthropic basis, to prove sustainable, these collaborations are usually also driven by commercial rationales and market conditions, which are heavily influenced by policy and regulatory decisions made by national governments.

² The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 26 leading international companies and 45 national and regional industry associations covering low, middle and high income countries. The industry’s R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA’s Ethical Promotion online resource (www.ifpma.org/EthicalPromotion) and its Developing World Health Partnerships Directory (www.ifpma.org/HealthPartnerships) help make the industry’s activities more transparent. The IFPMA supports a wide range of WHO technical activities, notably those relating to medicine efficacy, quality and safety. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The importance of transferring technologies for medicines is recognized in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights of the World Health Organization (WHO). An agreed action is “to promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate”³. IFPMA insights into how the research-based pharmaceutical companies go about creating a win-win process are intended to contribute to policy making that is looking to encourage this type of activity.

The decision by research-based pharmaceutical companies to transfer technology is based on a wide variety of factors, most of which are influenced by the local policy environment. IFPMA member companies share the view that a suitable local partner is a prerequisite for transferring technology.

Critical factors - Eight factors are critical in terms of creating favorable conditions for pharmaceutical technical transfers:

1. A viable and accessible local market;
2. Political stability, good economic governance;
3. Clear development priorities;
4. Effective regulation;
5. Availability of skilled workers;
6. Adequate capital markets;
7. Strong intellectual property rights (IPR) and effective enforcement;
8. Quality of the relationship between industry and government, and the extent they are able to work together effectively for long periods of time.

Enabling conditions for low income countries - While many newly industrialized countries and other middle-income countries are developing a strong experience and seeing the benefits that access to advanced foreign technologies and growing their domestic capabilities can bring; low income countries may not always be able to offer the preconditions required for successful uptake of technology transfer. In these conditions, IFPMA member companies’ experience of transfers suggests that:

- Governments can encourage technology transfer by focusing on attracting technology for which there is already a demand from local companies and by considering using mutual recognition of regulatory decisions within regions and between high and middle and low income countries, which can help increase the local market and/or reduce regulatory barriers.
- High income countries can help by giving low and middle income country experts greater access to international standard setting bodies, which will help to increase those individuals’ technical expertise and familiarity with such standards. Public sector institutions can also increase technical and financial assistance to low and middle income countries to strengthen local technical competence.

³ World Health Assembly Resolution 61.21 which includes the WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, Element 4, Sub-Element 4.1 c.

IFPMA member companies continue to support technology transfers by:

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

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.
- High income countries to increase aid funding available 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.

I. The Anatomy of Technology Transfer in the Pharmaceutical Sector

It's much more than simply handing over technology - The transfer of R&D pharmaceuticals is more than a question of “bricks and mortar” or providing a “tool box”. It occurs through many channels, all of which result in improving the economic capabilities of the recipient. What is transferred may be a physical object or pure knowledge. Following one definition⁴, we identify the following elements;

- “Techno-ware”: for the pharmaceutical industry this would include the transfer of physical objects such as equipment for use in research laboratories or production equipment for manufacture of pharmaceuticals ingredients, or formulation or packaging of final products;
- “Human-ware”: skills and human aspects of technology management and learning, such as a training course for researchers or general practitioners across the world (page 50, 55, 57). Technology transfer can also create positive spillover effects into associated industries and into the supporting public sector research infrastructure;
- “Info-ware”: all techniques related to knowledge, information and technology; in the form of a technology license⁵;
- “Orga-ware”: organizational and procedural knowledge needed to operate a given technology relating to a chemical or biological compound.

Strong market mechanisms provide the starting point - Foreign Direct Investment (FDI) is by far the main channel of technology transfer, but other “market-mechanisms” such as licensing agreements, royalties and joint ventures are necessary channels for transferring R&D pharmaceutical technologies. Through regulation and investment, governments can help to create the right conditions for technology markets to function. Reliance on “non-market” mechanisms for the research-based pharmaceutical sector exclusive reliance is unlikely to provide a sustainable technology transfer platform for economic growth or business development.

Complex map of technology transfer - The research-based pharmaceutical industry,

⁴ Sharif (1995, 1997) and Ramanathan (1994).

⁵ 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 licenses 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).

like most other industries, is seeing the newly industrialized countries and other middle-income countries increasingly relying on technology transfer to access advanced foreign technologies and grow their domestic capabilities. The twenty five year partnership between Brazil's Oswaldo Cruz Foundation and GSK has resulted in technology and manufacturing agreements have led to the development of vaccines that were essential to Brazil's universal immunization program. The research-based pharmaceutical industry's track record is proof that in the public health arena, the historical demarcation lines such as "North-South" are being replaced by more complex networks of technology transfer. The above trend is not always shared by low income countries, and is therefore sometimes characterized by an exposure to foreign technologies and weak absorptive capacity. This creates a particular challenge for R&D pharmaceutical technology transfer and means that those parts of the world least equipped to benefit today from technology transfer are among those who need its products the most.

II. The Right Conditions for Pharmaceutical Technical Transfers

The Right Conditions for Pharmaceutical Technical Transfer

Commercial opportunities are paramount for the private sector when considering technology transfer, but if the basic conditions are right, non-commercial reasons may also play a part. This is particularly true in advanced technology sectors, especially when this might provide an opportunity to open a market to a specific technology. Many countries are already well positioned in terms of R&D pharmaceutical technology transfers; the booklet provides insights into projects not only in BRIC countries (Brazil, Russia, India and China), but also Bangladesh, Ghana, Kenya, Malaysia, South Africa, Tanzania and Thailand. Pharmaceutical and vaccine manufacturers consider a variety of factors in evaluating potential technology transfer ventures. Many of these are influenced by government policy decisions.

For all investors, political stability and the rule of law are prerequisites. What research-based pharmaceutical companies are looking for in prospective recipient countries includes:

1. Promising market scale and accessibility;
2. Political stability and good, transparent governance;
3. Appropriate capital markets;
4. Innovation-friendly environment with adequate intellectual property rights and effective enforcement;
5. Proper access to information;
6. Adherence to high regulatory standards;
7. Skilled workforce;
8. Clear economic development priorities.

The most effective role for governments is one of creating 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. Indeed today, some governments are taking an active role in encouraging the transfer of technology.

However, for low income countries, it is still difficult for their domestic industry to meet the above conditions and hence attract technology transfers. In these cases, the role of government and international development institutions is greater and policy will play an important role in determining the potential for technology transfer in the future.

1. Promising Market Scale and Accessibility

While it is not easy to define the market size or type that will make for viable economic production, it is generally the case that, the larger the country or geographic bloc, the greater the market potential and investment appeal. The prevalence of certain diseases will also play a role in determining the size of the market; this is for example the case for malaria-endemic countries. Research-based pharmaceutical companies are more likely to consider small countries when there is effective regional economic integration. All countries, large or small, benefit from ensuring their markets are easily accessible to foreign enterprises and the pharmaceutical sector is not burdened by differential treatment of domestic and foreign investors. Recent technology transfer activities, related to the production of pandemic influenza vaccines, have also taken into account other factors, such as health security issues at national and regional levels.

2. Political Stability and Good, Transparent Governance

A country's relative political and economic stability will influence the rate of inward technology transfer and can be seen as a pre-condition for any technology transfer. Long periods of stability also lead to stronger and more successful partnerships, as demonstrated by transfer partnerships in Brazil, some of which started 25 years ago. Over the recent past, Singapore has secured a strong industrial base, partly as a result of these factors. Whether a transfer generates value over the medium and long term is, in part, dependent on a certain degree of predictability in policy-making, in particular in relation to 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.

In the host countries, concerns about the impact on the existing industrial base may restrict the opportunities for integration and promotion of inward technology transfer. On occasion, it can be effective for a government 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. Research-based pharmaceutical companies have found that training and education programmes can achieve this. For example, programs to train and equip local researchers to carry out clinical trials or quality control to internationally recognized standards can sow the seeds 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, healthcare system capacity strengthening. Political leadership in promoting local production can be a different story unless it is tempered by the views of technology providers.

3. Appropriate Capital Markets

For many governments seeking to expand technological capacity, attracting direct investment is very important, but there is also a question of making the most of the spillover benefits of investment. This can reveal a need for adequate capital markets. For example, a local pharmaceutical manufacturer that receives a product license needs sufficient resources to meet high standards of quality and safety controls, good manufacturing practices, sophisticated human capital, etc. 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 will 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 long time horizons and high risks raise unique challenges for sustainable public sector involvement. Where such public sector investments are made, whether in production capacity or in underpinning research activities, participation of foreign organisations should be encouraged.

A number of emerging economies have made strategic decisions to encourage research-based pharmaceutical investment. This can be a natural evolution from existing chemicals or generics production capabilities. In some cases, as well as encouraging direct investment, resources have been established to nurture indigenous scientific expertise. IFPMA members 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 (see page 48).

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.

4. Innovation-Friendly Environment with Sound Intellectual Property Protection and Enforcement

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 protection and enforcement. Effective enforcement 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 TRIPS 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”.

This assumed that governments would be responsible for putting in place the proper legal environment and economic conditions that would facilitate private commercial transactions while high income countries introduced measures such as technical support to facilitate technology transfer (TRIPS articles 66 and 67). The sum total of those private deals and government facilitation should lead to technology transfer and capacity building⁶. 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.

There are many ways in which technical support can help to build the intellectual property framework. For example, it is reported that for low and middle income countries, lack of knowledge of how to manage intellectual property at the interface between academic and private sector research is a problem. This is where the translation from basic research to practical innovation takes place. It is important that the public domain continues to function in an open and efficient manner. Establishing the right legal framework has contributed to the growth of new industries built on innovation. Technical assistance in establishing 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.

Critics have noted that building the intellectual property framework entails costs and primarily benefits foreign entrants, but have often failed to recognize that there are also domestic costs involved in not advancing intellectual property rights. In an environment of inadequate intellectual property protection, firms may choose not to transact at all, to offer and rely on older-generation technologies, or to keep the information within the firm by dealing only via subsidiaries. Disclosure of proprietary information requires a high level of confidence in partners and in the legal regimes under which they operate. Business development will also be more difficult in the absence of secure property rights and confidential data. The existence of strong intellectual property protection and enforcement benefits domestic economic

⁶ 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.

development by providing an incentive for domestic entrepreneurial initiatives in low- and middle-income countries. Major middle income countries such as India and China have many positive attributes sought by inward investors, but also show that the pattern and rate of adoption of IP has influenced industrial development.

5. Proper Access to Information

Where adequate intellectual property systems 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 to some extent be reduced by improved information, networking and other communication measures. The emergence of product development partnerships such as Medicines for Malaria Ventures, Drugs for Neglected Diseases Initiatives, Global Alliance for TB Drug Development, provides a case in point and many examples of these can be found in this booklet. 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.

6. Adherence to 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 and this 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 apply international quality standards. The ability to meet these standards has contributed to the growth of 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.

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 a country from a globalizing world. The pharmaceutical industry has undertaken initiatives to enable low and middle income country researchers, manufacturers and regulators to align their practices to international norms. For example, JPMA has worked with the WHO since 1989 to provide Quality Control training courses for Asian government quality control personnel (see page 61).

7. 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 hinges on the availability in the host country of an educated workforce with, for example, engineering and management skills. Certain low- and middle-income countries suffer a deficit in this regard because a large proportion of highly-trained workers have emigrated to more technologically-sophisticated environments in higher-income countries. The healthcare sector has been particularly 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 in their existing role of providing access to the best centers of higher education and in 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 example, more extensively described in the annex (page 57), is the IFPMA/TDR/Gates Clinical Research Career Development Fellowship.

Inward investment also creates benefits with pharmaceutical companies training nationals from low and middle income countries and providing inward transfer of needed expertise from elsewhere. Supportive government policy is crucial to ensuring the free movement of scientists and other experts.

8. Alignment with Economic Development Priorities

The finite or limited resources available to governments imply that measures taken to promote technology transfer need to both be realistic and to 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 exist.

Where local capacity already exists, governments must be ready to invest in the

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.

As governments factor in the impact that health and healthcare has on economic outcomes, healthcare investments should be a strategic priority. To take an example close to the pharmaceutical industry, enhancement of the health of the population and the delivery of healthcare 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 infrastructures.

The Case of Low Income Countries

Low income countries may struggle to provide the enabling conditions for technology transfer that could be expected in middle income countries. In most cases, the concern in low income countries is not so much about intellectual property enforcement as the capacity of the industrial sector to absorb advanced technology. Developing technical capacity in low income countries requires more than just a national endeavor.

While the international community has tried to address the situation through direct financial aid, many low income countries still do not 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 those in Sub-Saharan Africa, have yet to make significant advances. This has led some commentators to suggest that the international aid model itself is flawed.

There is a need to provide additional incentives to undertake projects in which technology transfer and the associated capacity-building are the main operation (e.g., licensing, joint ventures) and to recognize the more extensive support needs of low income countries, both in capacity-building and in external financing, to encourage technology transfer on both the provider and the receiver side.

III. Policy Recommendations

Across all advanced technology sectors, including pharmaceuticals, there is a large base of evidence and consensus that supports the contention that:

- Technology transfer is strongly influenced by conditions in the host-country. These include background conditions such as political stability, efficient governance, infrastructure and human capital, together with economic and legal requirements;
- Adherence to international norms will positively influence the level and magnitude of technology transfer directed to a given market;
- Adequate intellectual property protection in host countries will increase technology transfer.

The immediate objective in policy planning should be to strengthen capacity and understanding of the conditions that facilitate technology transfer. The newly industrialized countries 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 optimize their national technology bases, enhance sustainability and realize maximum benefits from globalization, the IFPMA calls on:

- Governments in low and middle income countries to provide policy support for the healthy development of national private sectors and implement a welcoming policy environment for global partner firms;
- High income country governments 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 at the same time as affordably addressing basic needs.

The WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property Rights contains ambitious proposals to map research capacity and the research being undertaken. This could be valuable if supported by sustainable funding.

Based on IFPMA member companies' experience, the solution for effective pharmaceutical technology transfers depends on actions at host and sponsor country

level, with the support of multilateral organizations and positive engagement from industry.

1. Policy Recommendations for Host Countries

- Focus on technology for which there is a demand from local companies and markets as this will motivate local companies to develop innovation projects to suit local needs and markets, and will generate spillover benefits that can be captured by the local economy;
- Progressive development of a national intellectual property system 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;
- Consider using mutual recognition of administrative or regulatory decisions, 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;
- Increase technical and financial assistance for improving the ability of low and middle income countries to absorb technology and trade;
- Ensure that tax deductions are available for technology contributions to non-profit entities engaged in technology transfer in low and middle income countries;
- Offer fiscal incentives to encourage enterprises to employ, at least temporarily, recent scientific, engineering and management graduates from low and middle income countries;
- Develop grant programs that support meaningful involvement of research teams from low and middle income countries.

3. Multilateral Policy Recommendations

- Reduce information gaps by establishing knowledge hubs furnished with 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;
- Share knowledge about management of the public/private research interface.

IV. The Role of the IFPMA and its Member Companies

IFPMA members want to contribute to the sustainable development of the world economy and the improvement of the health and living standards of people in all regions, and are committed to work with public and private institutions in low- and middle-income countries to enhance healthcare provisions to 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 and public health of the recipient's 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. Examples include:
 - Sharing of know-how through clinical trials training and management;
 - Screening/sharing of compound libraries;
 - Scientific knowledge transfers via research collaborations;
 - Building public health capacity through training and education;
 - Imparting management skills/expertise;
 - Diffusing knowledge through direct investments;
 - Raising local production quality through joint ventures and licensed manufacturing;
 - Training in regulatory and quality standards;
 - Education in supply chain / logistical management;
 - Training of local health workforces;
 - Communication and advocacy training;
 - Sharing of intellectual property and other knowledge.

**Research-Based Pharmaceutical
Technology Transfer
Track Record**

Manufacturing and Entrepreneurial Know-How Transfer



This section includes programs which transfer manufacturing technology and know-how. This may include transfer of physical material, equipment or an entire factory, to allow production in a recipient country of specific products – in our industry’s case, medicines or vaccines. Such products are difficult to make without a good understanding of the related production process, so transferring know-how is also an important form of technology transfer.

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).

Biken (The Research Foundation for Microbial Diseases of Osaka University)

PT. Bio Farma (Persero)

Indonesia

2007

Influenza

This program consists of an agreement with Bio Farma for licensing Biken's manufacturing know-how for egg-based inactivated influenza vaccine. In line with the licensing agreement, the technology transfer project aims to support Bio Farma's efforts to establish "human-ware", "info-ware" and "organ-ware" to develop domestic production capacity for egg-based inactivated influenza vaccine, which involves Biken providing technical training for Bio Farma's personnel in production and quality management. The project is divided in two phases. In the first, Bio Farma gained downstream-process know-how, including blending, filling, and packaging of egg-based influenza vaccine antigen bulk-produced by Biken. In the second phase, which is currently underway, Bio Farma will acquire upstream-process know-how which will allow it to bulk manufacture egg-derived influenza antigen. Bio Farma is building a local manufacturing plant, with design work and procurement of "Techno-ware" being undertaken by external consultants.



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Bristol-Myers Squibb

Emcure; Aspen Pharmacare

India; South Africa

2006

HIV/AIDS

In February 2006, Bristol-Myers Squibb concluded royalty free technology transfer agreements with generic companies Aspen Pharmacare (South Africa) and Emcure Pharmaceuticals (India), for its newest antiretroviral, atazanavir (sold as Reyataz® in the US). The technology transfer agreement seeks to expand access to this medicine for people living with HIV/AIDS in sub-Saharan Africa and India by ensuring access to a high quality product supported by local expertise, supply and infrastructure. Bristol-Myers Squibb has transferred intellectual property and technical know-how related to the manufacturing, testing, packaging, storage and handling of the active pharmaceutical ingredient and finished dosage form, including training their personnel at Bristol-Myers Squibb facilities as well as their respective manufacturing sites in Africa and India.



©Bristol-Myers Squibb

**Bristol-Myers Squibb; Johnson & Johnson;
Merck & Co., Inc.; ViiV Healthcare**

International Partnership for Microbicides (IPM)

Global

2008

HIV/AIDS

Johnson & Johnson's Tibotec affiliate established a first-of-its-kind public-private partnership with the non-profit International Partnership for Microbicides (IPM) in 2004, providing a royalty-free license and technology transfer to develop, manufacture and distribute TMC120 as a topical vaginal microbicide to reduce sexual transmission of HIV in developing countries. IPM is conducting safety trials of TMC120 as a vaginal gel in Belgium, South Africa, Rwanda and Tanzania. Following two successful safety studies, IPM is now researching dapivirine's use in an innovative vaginal ring delivery system which could offer women extended HIV protection.

In October 2005, Bristol-Myers Squibb announced that it had granted a royalty-free license to IPM to develop, manufacture and distribute their new antiretroviral compound as a microbicide to protect women from HIV in resource poor countries. The compound was an "entry inhibitor", some of which bind directly to the HIV itself, others to the CCR5 receptor. The compound is designed to prevent HIV from entering host cells efficiently, thus preventing infection.

In 2005, Merck granted a no-cost license to IPM for development, manufacture and distribution as a microbicide for use in developing countries. Most recently, in March 2008, Merck granted a non-royalty-bearing, non-exclusive license to IPM to develop, manufacture and distribute a novel antiretroviral compound for use as a potential vaginal microbicide. The compound is the fourth Merck has granted to IPM since 2005.

In January 2008, Pfizer agreed to give IPM a royalty-free license to maraviroc, its newly-approved HIV treatment, as a microbicide for the prevention of HIV infection. Maraviroc is one of a new class of antiretroviral drugs known as CCR5 blockers. Under this agreement, IPM will work to develop maraviroc as a vaginal microbicide with the right to develop, manufacture and distribute it in developing countries. Pfizer granted these rights to IPM without a royalty. Pfizer's contribution now falls under ViiV Healthcare.

Chemo-Sero-Therapeutic Research Institute (KAKETSUKEN)

Government Pharmaceutical Organization

Thailand

2010

Influenza

In Thailand, the Governmental Pharmaceutical Organization (GPO) is establishing domestic influenza vaccine manufacturing facilities in order to prepare for the possibility of a pandemic. Kaketsuken accepted a request from the Japanese government and decided to support the GPO on a voluntary basis. This influenza vaccine technical assistance project started in 2010. Kaketsuken thinks it is very important to establish infrastructure based to provide the Thai people with sustainable local production of influenza vaccine. Thai influenza vaccine projects are driven by the Thai government and GPO, and Kaketsuken will support them only in the area of technologies needed for large-scale production.

Daiichi Sankyo

Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd.; Inter Thai; Olic (Thailand) Ltd.

China; Thailand

2004; 2005

Hypertension; Anti-bacterial; Antihemorrhagic

Under this technology transfer operation Daiichi Sankyo has granted the right to its subsidiary in China to produce and sell combination products containing Olmesartan Medoxomil as a principal active ingredient. The company has also granted Olic Ltd. and Inter Thai, contract manufacturing organizations in Thailand, the right to produce oral forms and IV of products containing extended dosage forms of Levofloxacin (New formulation project) and Tranexamic Acid. Daiichi Sankyo has transferred intellectual property and technical know-how related to the manufacturing, testing, packaging and storage of the active pharmaceutical ingredient and finished dosage form, including training recipient companies' personnel at Daiichi Sankyo headquarters in Japan.



© Daiichi Sankyo

Eisai

Eisai China Inc (Suzhou plant); Eisai Pharmatechnology and Manufacturing Pvt. Ltd.; GlaxoSmithKline Pharmaceuticals Limited ; Interthai Pharmaceutical Manufacturing Ltd.; M & H Manufacturing Co., Ltd.; PT Eisai Indonesia (Bogor plant); Taqaddom Pharmaceuticals Industries; Unichem Laboratories Ltd.; Wockhardt Limited

China; India; Indonesia; Jordan; Thailand

2004; 2005; 2006; 2007; 2008; 2009; 2010

Chronic diseases

Eisai's basic policy for global manufacturing is that each regional factory should be responsible for manufacturing and packaging the products distributed in that region. Based upon this policy, various tech transfer activities relating to Eisai's proprietary products have been carried out from Eisai Japan to regional factories around the world. This concept of a "seamless value chain" within regions allows Eisai to realize its corporate mission ("human health care") by which it contributes to patients and their families through localization of operations.

Technology transfer and local manufacturing in low and middle income countries helps Eisai to implement its Affordable Pricing Policy, which seeks to "supply products in a sustainable manner at prices affordable to the patients in need of our drugs". As a result, prices of Eisai's products are generally lower in low and middle income countries compared to those in high income countries.

GlaxoSmithKline

Oswaldo Cruz Foundation (Fiocruz)

Brazil

1985; 2010; 2007

Polio; Haemophilus influenzae type b (Hib); Measles; Mumps; Rubella; Rotavirus; Pneumococcal disease; Pneumonia; Meningitis; Bacteraemia

GlaxoSmithKline has been partnering with Brazil's Oswaldo Cruz Foundation (FioCruz) since 1985 to manufacture vaccines for public health priorities in Brazil including polio, Haemophilus influenzae type b (Hib), measles, mumps, rubella, rotavirus and, most recently, pneumococcal disease.

To address pneumococcal disease in Brazil, GlaxoSmithKline will provide FioCruz with access to the technology behind its Synflorix™ vaccine which protects against life-threatening pneumonia, meningitis and bacteraemia infections. GlaxoSmithKline will supply Synflorix™ to FioCruz until the technology transfer is completed. The Brazilian government will incorporate the vaccine into its national immunization program.

Since 2007, GlaxoSmithKline (via FioCruz) has supplied 50 million doses of Rotarix® rotavirus vaccine in Brazil. The vaccine was included in the National Program of Immunizations in March 2006 and, on 17 December 2007, a technology transfer between GlaxoSmithKline Biologicals, FioCruz and the Brazilian Ministry of Health was agreed. From 2012, FioCruz will produce Rotarix® for the Brazilian domestic market and also manufacture this vaccine under contract for GlaxoSmithKline for export. The deal benefits both GlaxoSmithKline and FioCruz and is helping to ensure that around 17 million babies in Brazil will be protected by GlaxoSmithKline's Rotarix® over five years.

GlaxoSmithKline
Shenzhen Neptunus Interlong Bio-Technique Co. Ltd (NIBT)
China
2008; 2009
Influenza

GlaxoSmithKline
Walvax
China
-
Pediatric diseases

GlaxoSmithKline has agreed to form a Joint Venture with Shenzhen Neptunus Interlong Bio-Technique Co. Ltd (Shenzhen Neptunus) to develop and manufacture seasonal, pre-pandemic and pandemic influenza vaccines for the Chinese market, including Hong Kong and Macau. The Joint Venture is expected to benefit from the differing expertise that both companies have in developing vaccines. Specifically, GlaxoSmithKline will provide access to its proprietary adjuvant system which helps to improve efficiency and optimize production by increasing the number of vaccine doses that can be produced from a given amount of antigen. Shenzhen Neptunus will provide local manufacturing capacity and R&D expertise. Both companies will provide further investment in manufacturing capacity.

GlaxoSmithKline has agreed to form a long-term joint venture with the Chinese biotech company Walvax, to develop and manufacture pediatric vaccines, including Priorix®, GlaxoSmithKline’s measles, mumps and rubella vaccine, for use in China. GlaxoSmithKline will transfer the necessary technology to allow the joint venture to manufacture the vaccines locally. GlaxoSmithKline is investing nearly GBP 30 million in the collaboration.

Eli Lilly and Company

Hisun Pharmaceuticals; Shasun Chemicals and Drugs; SIA International; Aspen Pharmacare

China; India; Russian Federation; South Africa

2003

Multi-drug resistance tuberculosis

Eli Lilly and Company initially helped the WHO Green Light Committee to address the growing threat of multidrug-resistant tuberculosis by providing second-line TB medicines at discounted prices. It then set up the Lilly MDR-TB Partnership in 2003, donating USD 135 million in cash, medicines and technology to increase access to treatment and focus global resources on prevention, diagnosis and treatment of patients with MDR-TB. The public-private partnership provides access to medicines, transfers manufacturing technology to the developing world, trains healthcare workers, raises awareness and promotes research and prevention, while providing support for communities and advocating on behalf of patients.

To date, the Partnership has transferred the technology, expertise, formulas and trademarks to manufacture Lilly's two antibiotics for MDR-TB, capreomycin (Capastat®) and cycloserine (Seromycin®) to manufacturers in South Africa, China, India and Russia — some of the world's highest-burden countries. This approach provides lower-priced medicines and also supports local economies. Lilly supplies manufacturing know-how, financial assistance to purchase manufacturing equipment and training in Good Manufacturing Practices, to ensure medicine quality. Purdue University helps provide manufacturing partners with safety, quality and business management training.

Meanwhile, Lilly continues to supply both capreomycin and cycloserine at concessionary prices to WHO-approved DOTS programs (Directly Observed Treatment, Short-course) for MDR-TB. These medicines are supplied through the WHO's Global Drug Facility. To date, Lilly has shipped some 1.3 million vials of capreomycin and 5.5 million capsules of cycloserine through the WHO DOTS program to patients in 42 countries.

Johnson & Johnson (Tibotec)

Hetero Drugs Limited; Matrix Laboratories Limited (a Mylan company); Aspen Pharmacare

India; South Africa

2011

HIV/AIDS

Tibotec Pharmaceuticals, an affiliate of Johnson & Johnson, has granted multiple non-exclusive licenses to Hetero Drugs and Matrix Laboratories of India, and Aspen Pharmacare of South Africa, to manufacture, market and distribute generic versions of its investigational non-nucleoside reverse transcriptase inhibitor rilpivirine hydrochloride (TMC278), subject to its approval for use with other antiretroviral agents in the treatment of treatment-naïve HIV-1 infected adults. The two Indian companies will have rights to market the product in sub-Saharan Africa (SSA), low income countries and India. Aspen will have rights to market the product in SSA, including South Africa. The generic manufacturers will be able to produce TMC278 as a single agent medicine and to include it in fixed-dose combination (FDC) products.

Tibotec will provide the generic manufacturers with the technical information and knowledge to allow them to manufacture the single agent product. The generic manufacturers will pay royalties ranging from two to five percent. They will be responsible for timely regulatory filing for generic TMC278 and for seeking pre-qualification from the World Health Organization (WHO) and FDA ANDA generic drug approvals. To keep medicines affordable, they are required to limit their gross profit margin on the sale of TMC278. Prior to the signing of these agreements, Tibotec submitted TMC278 for regulatory approval in the USA, Europe, Canada, Switzerland, Australia, Russia and South Korea.

Tibotec plays a key role in the Johnson & Johnson Global Access & Partnerships Program, which is committed to improving and saving lives by addressing unmet medical needs and ensuring the availability of HIV medicines. The Program is already working, through existing agreements with generic manufacturers Aspen Pharmacare and Emcure Pharmaceuticals in India to broaden access to the medicines darunavir and etravirine in SSA and LDCs and to darunavir in India.

Merck & Co., Inc. (Nobilon)

Government Pharmaceutical Organization in Thailand; Serum Institute of India; Zhejiang Tiayuan Biopharmaceuticals in China

China; India; Thailand; WHO

2009

Influenza

Live Attenuated Influenza Vaccine (LAIV) is a novel vaccine technology developed by BioDiem and licensed in 2004 to Nobilon International B.V. (now part of Merck & Co, Inc.). As part of the World Health Organization's Global Pandemic Influenza Action Plan to Increase Vaccine Supply in developing countries, BioDiem and Nobilon agreed to allow the Institute of Experimental Medicine (IEM) in St. Petersburg to supply the WHO with LAIV reassortants. Together with know-how supplied by Nobilon, these have been made available to the WHO for sub-licensing to private companies or governmental or non-governmental organizations for public sector use in developing countries. To date, sub-licenses have been granted to the Government Pharmaceutical Organization in Thailand, the Serum Institute of India Ltd and Zhejiang Tiayuan Biopharmaceuticals in China, allowing them to produce LAIV vaccine in eggs.

Merck KGaA

Local authorities and local waste industry; Merck Thailand; Merck Indonesia; Merck Philippines; GIZ (Gesellschaft für internationale Zusammenarbeit/German International Cooperation)

Indonesia; Philippines; Thailand

2010

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Merck KGaA formed a strategic alliance with the German Government's Deutsche Gesellschaft für internationale Zusammenarbeit GmbH (German International Cooperation - GIZ) intended to improve laboratory chemicals waste management in Thailand, Indonesia and the Philippines. Within the scope of a public private partnership with the GIZ, Merck will be introducing over the next three years environmentally friendly, safe waste disposal systems for used packaging and chemicals from laboratory customers. These systems will be based on Merck's Retrologistik® expertise in waste management.

In Thailand, Indonesia and the Philippines, differing logistic requirements and technical infrastructure have developed for returning and eco-friendly disposing of laboratory waste. Waste and raw materials are often disposed of through the sewer system and normal household waste. Frequently, people lack the knowledge to handle hazardous substances. The joint public private partnership project aims both to promote the development policy goals of the GIZ and to facilitate the transfer of Merck know-how and technology. The closed-loop systems established in Europe for used chemicals - in particular the international Merck standard known as Retrologistik® - constitute the master plan for introducing a safe disposal alternative into these countries. Tools are being developed to suit the regional circumstances and to provide a foundation for determine optimal disposal and recycling methods. The project has been launched in 2010 and will continue over a three-year period. Plans include on-site training on how to safely handle, store and dispose of laboratory chemicals.

Merck KGaA (MerckSerono)

MerckSerono Mexico

Mexico

2007

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Novartis

Advanced Bio Extracts (ABE)

Kenya; Uganda; Tanzania

2005

Malaria

Controlled and guided by a Global Manufacturing Execution System (MES) Project Program, a paperless shop floor management system will be deployed to pharma sites, which guides the operator through the manufacturing process. Interfaces with other IT systems on global (e.g. SAP) and local level (e.g. DCS, Scales) are part of the Global Program. Manufacturing Execution System will be installed and operated always locally, following a core approach controlled by a Center of Expertise (e.g. Global Change Control).

As the leading global supplier of artemisinin-based combination therapies (ACTs) to treat multi drug-resistant forms of malaria, Novartis has established a partnership with East African Botanical (EAB), a subsidiary of the private Kenyan company Advanced Bio-Extracts, to cultivate artemisia annua in Africa and extract artemisinin. Artemisinin is used to produce artemether, one of two active ingredients in Coartem® (artemether-lumefantrine), a highly effective anti-malarial that Novartis provides on a not-for-profit basis to the public sector in malaria-endemic low and middle income countries. With Novartis' financial and technical support, EAB expanding the cultivation of artemisia annua in Kenya, Tanzania and Uganda.

Novartis
Brazilian Ministry of Health
Brazil
2010
Leprosy

Novartis
Various Chinese API manufacturers
China
1994
Malaria

In 2010, Novartis and the Brazilian government signed a technology transfer agreement that will see production in Brazil of the leprosy medicine Lamprene (clofazimine), for use by the Brazilian national health system (SNS). The agreement will help Brazil to address this disease and to reduce its dependency on foreign suppliers, by strengthening the local pharmaceutical industry. The not-for-profit technology transfer will involve only clofazimine, which will be strictly for government use and exclusively within Brazil. The Brazilian health ministry has yet to choose which state-owned pharmaceutical company will manufacture the medicine. Clofazimine is on the government’s list of medicines, which are of strategic importance to the national health system, and which the government would like to see manufactured locally.

Since 1994, Novartis has been working intensively with its Chinese suppliers of artemether and lumefantrine, the active pharmaceutical ingredients (API) for the first WHO prequalified Artemisinin Combination Therapy (ACT) to treat malaria – Coartem®. The main activities involved the enlargement of the supply chain for the production of artemisinin with high quality standards, as well as supporting the companies involved in the extraction, purification and manufacturing of the APIs. The improvement of the manufacturing processes included the optimization of the purification steps, the development of appropriate quality control techniques, the qualification of production and the upgrade of the production and analytical equipment.

The transfer of know-how to reach international GMP standards involved the improvement of chemical processes, new analytical skills, quality assurance and validation standards as well as the production of regulatory documentation. The integration of quality standards also allowed a control of costs. That collaboration continues today with a focus on maintaining the required high quality standards while meeting the expanded demand for ACTs.



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Novartis

Ezequiel Dias Foundation (Funed), Brazilian government

Brazil

2009

Meningitis

In September 2009, Novartis Vaccines & Diagnostics signed a strategic alliance with the Ezequiel Dias Foundation (FUNED) to supply Menjugate® meningococcal C conjugate vaccine for Brazil's National Immunization Program (PNI). Novartis Vaccines & Diagnostics will supply the vaccine during phases I and II of the project, while subsequent phases will involve a complete technology transfer to FUNED. This will allow FUNED to supply 10 to 12 million doses per year and make Brazil self-sufficient in meningococcal C conjugate vaccine. The project duration is 5 years, with the option to extend it, if justified.

The process first began in September, 2009, when Novartis began supplying the vaccine to Brazil in the state of Minas Gerais. In January 2010, negotiations began with the Ministry of Health to include the vaccine in the National Immunization Program.

Roche

Beximco Pharmaceuticals; Radiant Pharmaceuticals ; Cosmos; Universal Corporation; Regal Pharmaceuticals; Aspen Pharmacare; Adcock Ingram; Addis Pharmaceutical Factory; Varichem; CAPS Pharmaceuticals; Shelys Pharmaceuticals; Zenufa Laboratories; Muhimbili University

Bangladesh; Ethiopia; Kenya; South Africa; Tanzania; Zimbabwe

2006

HIV/AIDS

Roche has committed not to file any new patents or enforce existing patents for any of its medicines in the UN-defined Least Developed Countries. Nor will it enforce existing patents for its antiretrovirals in sub-Saharan Africa. As a result, generic versions of its ARVs can be produced in these countries, encompassing 88% of all people living with HIV.

In 2006, Roche committed to an "AIDS Technology Transfer Initiative", to help local firms in countries with limited resources (low income countries and sub-Saharan Africa) to manufacture generic versions of second-line HIV medicines. This increases local capacity to provide treatment and reduces reliance on wealthier nations. Roche does this by sharing its know-how for manufacturing saquinavir and providing hands-on guidance to local manufacturers in eligible countries. A dedicated Roche team spends much of its time sharing knowledge and skills at local manufacturers' production facilities. Roche reviews requests from manufacturers on a case-by-case basis, working with companies that have the manufacturing capacity and capability to reach the right levels of quality and efficacy.

Roche expanded its program in 2008 to include training seminars for local manufacturers across sub-Saharan Africa, focused on the development of good manufacturing practices to improve locally-produced essential medicines – not just ARVs. The first two training seminars were attended by 56 delegates from 21 organizations.

Roche

State Pharmaceutical Laboratory of Pernambuco (LAFEPE)

Brazil

2003

Chagas disease (American trypanosomiasis)

To assist Brazil's efforts to reduce the impact of Chagas disease (American trypanosomiasis), Roche donated to the Brazilian government in 2003 all the rights and technology needed to manufacture Benzonidazole, a medicine to treat this tropical disease, which is endemic to much of the country. Following Roche's donation, the Brazilian government set up a manufacturing plant in the state of Acre, in the Amazon region, and started producing this drug with the help of know-how supplied by Roche. The organization manufacturing Benzonidazole in Brazil is now known as the State Pharmaceutical Laboratory of Pernambuco (LAFEPE).

Roche

Shanghai Pharmaceuticals; HEC Group; Hetero Pharmaceuticals; Aspen Pharmacare

China; India; South Africa

2005; 2006

Influenza

In 2005, Roche granted sublicenses to three generic pharmaceutical manufacturers, Shanghai Pharmaceuticals and HEC Group in China and Hetero Pharmaceuticals in India, to produce generic Tamiflu® (oseltamivir) for pandemic use in China, India and developing countries. In 2006, Roche also provided information to a South African generic pharmaceutical manufacturer, Aspen Pharmacare to allow it to produce oseltamivir for pandemic use in Africa.



© Roche

Sanofi-aventis

Sanofi-aventis

Brazil

2004

Leishmaniasis

Sanofi-aventis is transferring most of its production of Glucantime injectable (meglumine antimoniate), a first line treatment for leishmaniasis, to Suzano, Brazil. From 2004 onwards, the manufacturing facilities were improved to meet the latest Global Quality Requirements. In 2009, the Suzano Site was accredited by the French Regulatory Agency AFSSAPS, allowing it to become a major production site, serving most of Europe and rest of the world. Meanwhile, the local team has developed its formulation expertise and implemented innovative control methods.



© Sanofi-aventis

Sanofi-aventis

Sanofi-aventis Morocco

Morocco

2006

Malaria

In April 2005, sanofi-aventis signed an agreement with Drugs for Neglected Diseases initiative (DNDi) to develop a new medicine against malaria, in response to a call from the World Health Organization (WHO) for malaria to be treated by drug combinations to combat resistance.

DNDi and sanofi-aventis have developed a fixed-dose combination (FDC) of two antimalarial compounds, artesunate and amodiaquine (ASAQ) that is easier to use and more affordable than any other combination currently available. DNDi developed the formulation combining the two active ingredients in a single tablet and carried out the initial pharmaceutical and clinical development, before choosing sanofi-aventis as its industrial partner for further development. Sanofi-aventis developed the product at industrial level, carried out additional clinical studies, prepared the dossier for regulatory authorities and applied for WHO prequalification. The medicine is produced in one of the Group's plants in Morocco.

Sanofi-aventis has launched this new FDC in malaria endemic countries and is embarking on a large follow-up clinical trial program ('ASAQ field monitoring program') with DNDi and Medicines for Malaria Venture to collect good efficacy and safety data on this new medicine in 'real life' conditions, in several countries including Côte d'Ivoire, Liberia, Uganda and Senegal. This program is being set up in close coordination with the WHO.

Sanofi Pasteur

Birmex (Laboratorio de Biológicos y Reactivos de México)

Mexico

2009

Influenza

Sanofi Pasteur signed an agreement in 2009 with the Mexican government to build a EUR100 million facility to manufacture influenza vaccine in Mexico. This facility will be built and operated by Sanofi Pasteur, the vaccines division of sanofi-aventis Group, which will manufacture influenza vaccine there in collaboration with Birmex (Laboratorio de Biológicos y Reactivos de México), a vaccine manufacturer owned by the Mexican federal government. Birmex will perform certain stages of manufacturing and will distribute influenza vaccines within Mexico. The new facility, which will have an annual capacity of up to 25 million doses of seasonal influenza vaccine, will be able to switch to pandemic vaccine production, if required.



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Sanofi Pasteur

Butantan Institute

Brazil

2009

Influenza

Sanofi Pasteur has partnered with the Butantan Institute in Brazil since 1999 to deliver seasonal influenza vaccines to the Brazilian Government, with the possibility of shifting to pandemic vaccine should the need arise. Bulk antigen has been supplied by Sanofi Pasteur to Butantan, which has been performing final vaccine formulation, filling and packaging at its Sao Paulo facility. The long-term goal is for Butantan also to manufacture bulk antigen. In 2009, Sanofi Pasteur signed an agreement with the Butantan Institute in Brazil for the production and supply of A(H1N1) 2009 influenza vaccine to the Brazilian Ministry of Health, which ordered 18 million doses of the new A(H1N1) influenza virus vaccine.



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Sanofi Pasteur

Chinese authorities

China

2007

Influenza

In 2007, Sanofi Pasteur concluded an agreement with the Chinese Government, to build a facility to manufacture seasonal and pandemic influenza vaccines in Shenzhen, where Sanofi Pasteur already operates a facility. Sanofi Pasteur started the construction of the new vaccine manufacturing facility in 2008 with the goal of producing seasonal influenza vaccines for the Chinese market by 2012. It is designed for easy expansion to keep pace with the anticipated growth of the Chinese vaccine market.

Takeda

Tianjin Takeda Pharmaceuticals Co., Ltd.; P.T. Takeda Indonesia

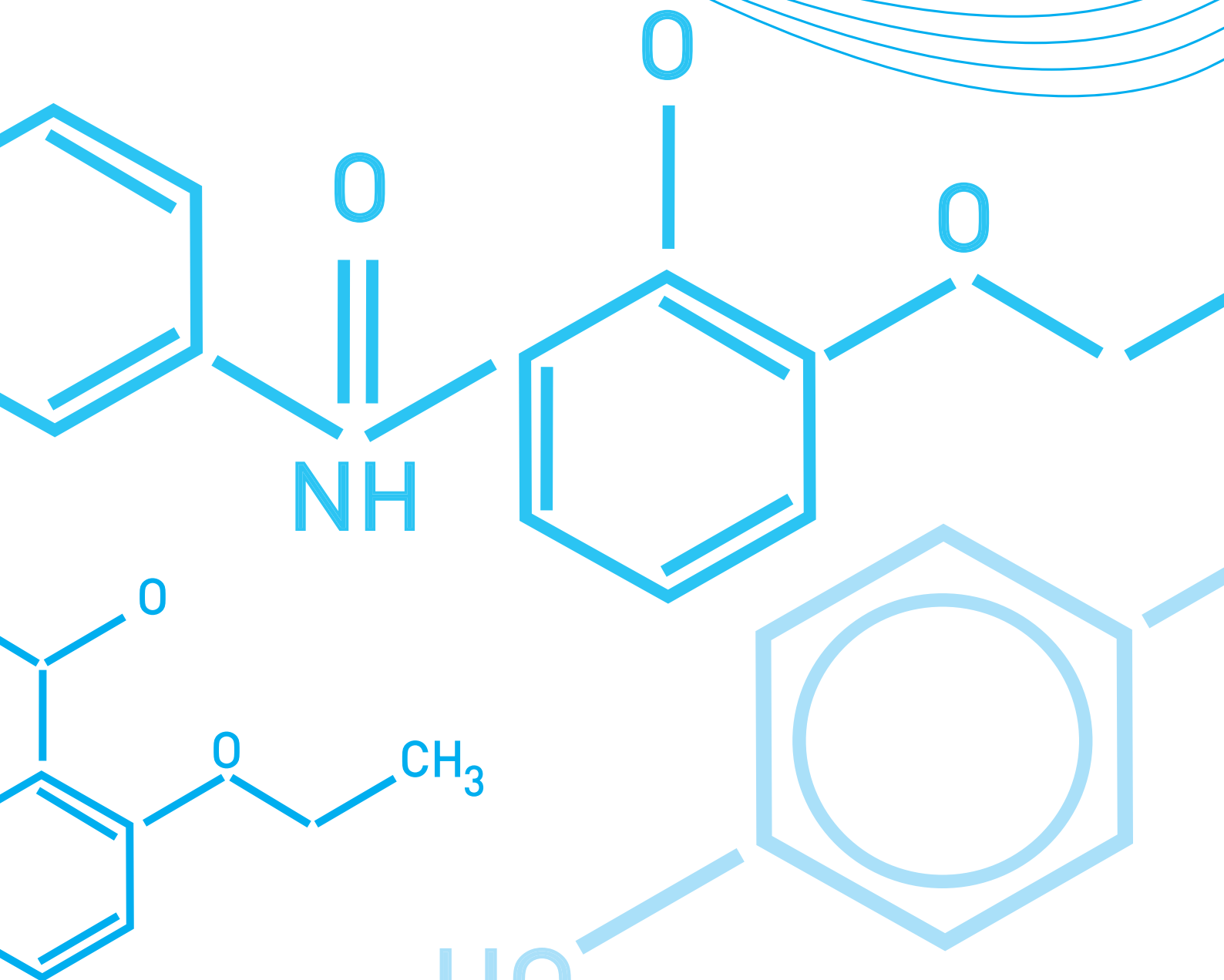
China; Indonesia

1999; 2002; 2003; 2004

Hypertension; Diabetes

Takeda's parent company in Japan transfers a range of know-how to subsidiaries in developing countries. It sends Candesartan Cilxetil tablets and Pioglitazone Hydrochloride tablets which are made in Japan to Tianjin Takeda in China. To prepare these products for marketing, Tianjin Takeda then performs locally a series of processes from blistering to packaging. Takeda also sends bulk pharmaceuticals of Candesartan Cilxetil and Pioglitazone Hydrochloride to Takeda Indonesia, which undertakes remaining production steps, from drug preparation to packaging. When Takeda transfers its production technology to each country, its engineers in Japan go there to execute technical guidance for a constant period.

Scientific Collaboration and Knowledge Sharing



Technology transfer is also performed through collaboration in the scientific field, including sharing of knowledge. Selected examples of this type of transfer have been included in this section. Much of the research being conducted by IFPMA member companies into diseases of the developing world is being conducted on a collaborative basis, with public and private sector partners, in high and low and middle income countries. For more information on R&D in ten major developing world diseases please visit the 2010 "IFPMA Status Report on Pharmaceutical Industry R&D for Diseases of the Developing World". More information on collaborative research can also be found in the IFPMA website (www.ifpma.org).

Abbott

Drugs for Neglected Diseases initiative (DNDi)

Global

2009

Tropical diseases

In 2009, Abbott initiated a partnership with the Drugs for Neglected Diseases initiative (DNDi) to identify existing molecular compounds in Abbott's research library that may offer promise in addressing neglected diseases. One class of Abbott compounds already shows potential impact on parasitic diseases and Abbott is working with DNDi on a plan to further investigate this discovery. Abbott also encourages its scientists to provide pro bono consulting to DNDi on projects of mutual interest.

Astellas

Standards and Industrial Research Institute of Malaysia (SIRIM); TropBio

Malaysia

2001

-

Astellas has conducted new drug discovery based on exact screening of micro-organisms for nearly 40 years and has accumulated fundamental technologies for biological research with microbial products. Astellas has focused on tropical rainforests where biological diversity is the greatest in the world. In December 2000, Astellas established a partnership with the Standards and Industrial Research Institute of Malaysia (SIRIM), a Malaysian state-owned enterprise, and TropBio, an Australian biotech company, for collaborative research based on micro-organisms. This partnership is in accordance with the spirit of the Convention on Biological Diversity and incorporates redistribution of benefits to the country of origin. The partnership contract contains a clause which stipulates that Astellas provide biological research technologies to Malaysia and share the rewards of any joint successes. Astellas has accordingly agreed to provide 8 trainees from Malaysia with hands-on training in its own research laboratories. The training program covers the isolation, culture, and screening of targeted micro-organisms. In addition, Astellas is supporting the construction and development of research infrastructure in Malaysia for new drug discovery based on micro-organisms. This partnership helps Malaysia to introduce advanced technology from abroad, while Astellas is able to broaden its research efforts.

AstraZeneca

Tuberculosis research centre in Bangalore

India

2003

Tuberculosis

Backed by its skills and experience in infection research, AstraZeneca joined the global effort to find new TB therapies in 2003, with the opening of a USD 20 million dedicated TB research centre in Bangalore, India. More than 80 scientists work there, with full access to all AstraZeneca's platform technologies, such as high throughput screening and compound libraries. They also work closely with the company's infection research centre in Boston, USA, as well as with external academic leaders, to capture and share best practice. The company continues to invest more than USD 5 million each year in this research effort, which is focused on finding new therapies that will act on drug-resistant strains, shorten the duration of treatment, eradicate disease (including the latent form) to reduce the chances of relapse, and be compatible with HIV/AIDS therapies (TB and HIV/AIDS form a lethal combination, each speeding the other's progress).

Development research will be done principally in countries with high rates of infection and AstraZeneca will work with external partners with relevant skills and expertise. AstraZeneca will apply for patent protection in the normal way and will seek partnership arrangements with the appropriate global and local organizations to make its TB treatment widely available in low and middle income countries through supply strategies that minimize cost of manufacture and delivery.

2009 was a year of considerable progress: In December 2009, AstraZeneca's first candidate TB drug, AZD5847, started phase I clinical trials, having showed potential in pre-clinical studies to

treat MDR-TB. If phase I testing is successful, the company will conduct further clinical development with external partners; In collaboration with the European Framework 6 consortium, AstraZeneca researchers in Bangalore have identified a new class of compounds with potential as novel TB treatments. The findings were published in *Science*, a leading academic journal, and the company continues to explore their potential; Researchers at the National Institute of Health (NIH) in the USA discovered that meropenem, AstraZeneca's marketed antibiotic for hospital-acquired infection, is also active against MDR-TB. The company donated supplies of meropenem for an NIH-sponsored research project in South Korea, combining meropenem and clavulanic acid (a component of another marketed antibiotic) to assess the combination's potential as a treatment for MDR-TB.

AstraZeneca is also part of the European Union Framework Program VI collaboration (NM4TB – New Medicines for Tuberculosis) that will enable it to work with academic leaders in TB research. AstraZeneca is the only major pharmaceutical company involved in this project, which began in 2006. Funded by a grant from the EU Framework VI program and consisting of around fifteen groups of prominent EU researchers, this consortium seeks to combine academic and pharmaceutical skills to further the discovery of new therapies for TB.

Boehringer Ingelheim

Government of Botswana and private healthcare professionals in Botswana

Botswana; South Africa

2005

HIV/AIDS and co-morbidities; Acute myocardial infarction; Hypertension; Asthma

Opened in 2005, the Boehringer Ingelheim Training and Facilitation Unit in Gaborone, Botswana trains general practitioners, physicians, occupational health specialists, nurses, pharmacists, pharmacy technicians, medical store managers, healthcare managers and health ministry officials. Since its foundation in 2005, some 7,100 attendees have taken part in training activities at the unit. Working with partners such as Harvard University, the US Centers for Disease Control & Prevention and the WHO, it provides continuing medical education workshops, courses and lectures on the management of acute myocardial infarction, hypertension, diabetes, asthma and HIV/AIDS, along with Good Clinical Practice, leadership training, customer relations, pediatric care, biopharmaceuticals and pharmacovigilance. It also undertakes public health awareness and education programs and hosts meetings of the Botswana Medical Society, the HIV Clinician Society, the Pharmaceutical Society of Botswana and other associations.

The Boehringer Ingelheim Endowed Chair in Clinical Pharmacology was set up in 2009 and helps to raise the status of health professionals and facilitates the provision of vital training to young interns and doctors, helping to advance the fight against HIV/AIDS in Botswana. It helps to lay the foundations for the Botswana Medical School, scheduled to open in 2013.

In 2006, the first pharmacy student from Botswana started at Rhodes University, Grahamstown, South

Africa under a Botswana government program funded by Boehringer Ingelheim. Beneficiaries are required to work in the public sector after completing their studies.

HIV/AIDS has a major impact on health in Botswana and Boehringer Ingelheim currently runs two clinical trials there for its nevirapine ARV. A new extended release mechanism for this ARV is being evaluated which will hopefully benefit women suffering from HIV/AIDS in Botswana. The first HIV study was initiated in 2008. Boehringer Ingelheim's ongoing clinical trial work in Botswana also addresses hypertension, diabetes, myocardial infarction and stroke, which are major causes of morbidity and mortality in the country. Boehringer Ingelheim was the first company to identify and train private practitioners to conduct clinical trials in Botswana, while at the same time bringing important research work to the Princess Marina Hospital and other medical centers.



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GlaxoSmithKline

Research centre in China

China

2007

Neurodegeneration diseases

GlaxoSmithKline

Oswaldo Cruz Foundation (Fiocruz)

Brazil

2010

Dengue

GlaxoSmithKline setup a global R&D center in Shanghai, China in 2007. This new center focuses on research into neurodegeneration to create new medicines for such profound medical needs as multiple sclerosis, Parkinson's disease, and Alzheimer's disease. The center will eventually direct the global discovery and development activities within its therapeutic area, from drug-target identification to late-stage clinical studies, while collaborating with research institutions elsewhere in China and other countries. The talent pool is enhanced continuously by a large number of scientists educated and/or having gained experience overseas who are eager to return to their home land. The goal of R&D China is to become a fully integrated center for drug research and development. Starting with the Neurology R&D group and now joined by the China Medicines Development group, R&D China has grown from a single employee at the outset in July 2007 to almost 500 staff. It is hoped that up to a thousand high skilled jobs will be created at the site by Year10 of the project.

GlaxoSmithKline has extended its vaccine partnership with the Oswaldo Cruz Foundation (FioCruz) in Brazil, to create a joint R&D initiative to develop a vaccine for dengue fever, a mosquito-borne disease that places 2.5 billion people at risk of infection globally. Scientists from GlaxoSmithKline in Belgium, where GSK's vaccines division is headquartered, and FioCruz in Brazil, will be involved in the new partnership which should help to enhance Brazilian vaccine R&D capacity.

Johnson & Johnson (Tibotec)

Global Alliance for TB Drug Development (TB Alliance)

Global

2009

Tuberculosis

Tibotec, a subsidiary of Johnson & Johnson, and the non-profit Global Alliance for TB Drug Development (TB Alliance) share their expertise and resources in the development of TMC207, which could become the first TB drug with a new mechanism of action in 40 years. Under the terms of the agreement, Tibotec is developing TMC207 for the treatment of MDR-TB and, on approval, will establish an access program to ensure the compound reaches those in low and middle income countries who are in need. The agreement grants the TB Alliance a royalty-free license for the worldwide development and access to TMC207 in the field of drug-susceptible TB. Costs for the development of TMC207 will be shared.

In addition, Tibotec collaborates with the TB Alliance in a discovery research program to identify other new compounds for the treatment of TB. The rights for the newly discovered compounds for the treatment of tuberculosis will belong to the TB Alliance under a royalty-free license.

Merck & Co., Inc.

MSD Wellcome Trust Hilleman Laboratories

India

2009

Multiple diseases

In September 2009, the Wellcome Trust and Merck & Co., Inc. announced the creation of the MSD Wellcome Trust Hilleman Laboratories, a research and development joint venture with a not-for-profit mission to focus on developing affordable vaccines to prevent diseases that commonly affect low-income countries.

The joint venture is the first in which a research charity and a pharmaceutical company have jointly created a separate entity with equally shared funding and decision-making rights. The heart of this concept is the creation of a sustainable R&D organization that operates like a business, but with a not-for-profit operating model, to address the vaccine needs of low-income countries. As well as developing new vaccines in areas of unmet need, the Hilleman Laboratories will also work on optimizing existing vaccines, an important and powerful way of increasing the impact of vaccination in resource-limited settings.

The Hilleman Laboratories will work on optimizing existing vaccines, an important and powerful way of increasing the impact of vaccination in resource-limited settings, as well as developing new vaccines in areas of unmet need. The Hilleman Laboratories, based in India, will engage and partner with a broad range of experts in vaccine research, policy and manufacturing to develop and mature its R&D pipeline. While an initial portfolio of projects is being selected only after consultation with the international community and careful technical assessment, examples of the kind of programs being considered include developing formulation innovations which affordably enhance shipping, storage, administration and disposal of vaccines, all key issues which currently limit the impact of vaccines in low-income countries.



Novartis
Thai National Center for Genetic Engineering and Biotechnology (BIOTEC)
Thailand
2005
Infectious diseases

In 2005, Novartis established a partnership with the Thai National Center for Genetic Engineering and Biotechnology (BIOTEC) in Bangkok, to transfer technological know-how for the isolation of actinomycetes bacteria – the most important source of antibiotics. This includes on-site education for BIOTEC staff provided by Novartis experts in drug discovery and infectious diseases, as well as technical training in the use of modern instruments and in the cultivation, isolation and purification natural products. In addition, BIOTEC scientists are trained at the Novartis laboratories in Switzerland in microbiology, chemical profiling and high throughput drug and animal pathogen screening. BIOTEC has quickly acquired specialist expertise and is now fully operational and autonomous.

Novartis
Ifakara Health Institute
Tanzania
2009
Tuberculosis

This collaboration between the Novartis Institute for Tropical Diseases and the Ifakara Health Institute (IHI) in Tanzania aims to develop a comprehensive molecular tool for large scale TB drug resistance surveillance, to help improve TB management strategy and to establish a TB genotyping center of excellence to track disease transmission. Validation of the molecular tool was accomplished by Novartis in Singapore, before the technology was transferred to IHI. A TB genotyping reference center has been set up at IHI-Bagamoyo, Tanzania, where local infrastructure for biomedical research already existed. The reference center has just started accessing an extended cohort centralized by the Tanzania National Tuberculosis and Leprosy Program, and will ultimately serve the entire Southern Africa region.

Novartis

NEHCRI laboratories (Collaboration between NITD, Hasanuddin University and Eijkman Institute)

Indonesia

2006

Tuberculosis; Dengue

NEHCRI is a joint clinical research initiative undertaken by the Novartis Institute for Tropical Diseases, Indonesia's Hasanuddin University and the Eijkman Institute, also in Indonesia. The collaboration aims to create value by bringing together know-how, expertise, technologies and financial resources to serve the needs of tropical, rural populations exposed to certain neglected, tropical diseases. Current activities include diagnosis of TB and Dengue cases, epidemiological and operational research, TB molecular epidemiology research and development of dengue diagnostic kits. For the last 3 years, the NEHCRI laboratory at Makassar, Indonesia has passed the external quality assurance evaluation conducted by the WHO Supranational TB Reference Laboratory Institute of Medical and Veterinary Science.

Novartis

Shanghai Institute of Materia Medica

China

2001

Multiple diseases

In 2001, Novartis established a partnership to help the Shanghai Institute of Materia Medica (SIMM) with drug discovery focused on purified natural compounds derived from plants and fungi used in traditional Chinese medicine. Novartis has provided SIMM with technological know-how, as well as modern analytical devices, computer systems and material-preparation equipment. Novartis is also providing technical and scientific training for SIMM personnel, both on-site and in Novartis laboratories in Switzerland. There has been a significant increase in scientific publications by SIMM scientists since the project started and promising compounds identified by this research will be evaluated by Novartis for licensing opportunities.

Novartis

MSc Students/Postdoctoral students from developing countries

Various developing countries

2003

Tuberculosis; Dengue; Malaria

The Novartis Institute for Tropical Diseases (NITD) has linked up with the Biozentrum of the University of Basel (BZ-UB) and the Swiss Tropical and Public Health Institute (Swiss TPH) to create a Master of Science program in infectious diseases, vaccinology and drug discovery. Launched in early 2005, this provides a high-quality MSc-level research-based training in novel approaches to tackle major communicable and emerging disease problems. A course lasts 18 months, split between Basel, Switzerland and Singapore, and includes lectures at NITD. To date, the program has enrolled 13 students, ten of whom are from low and middle income countries – Kenya, India, Indonesia, Malaysia, the Philippines and Zimbabwe.

In addition, since 2003, NITD has been providing training in drug discovery to PhD and postdoctoral students (both in-house and through external attachment). As of today, a total of 108 postgraduate students have completed the training program, with about 70 coming from low and middle income countries, such as Ethiopia, India, Indonesia, the Philippines and Zimbabwe.



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Pfizer

Drugs for Neglected Diseases Institute (DNDi); Griffith University in Brisbane, Australia; Institut Pasteur Korea

Global

2009

Human African trypanosomiasis; Visceral leishmaniasis; Chagas disease

In 2009, Pfizer expanded its collaborative research by signing an agreement with Drugs for Neglected Diseases initiative (DNDi), whereby DNDi will have access to the Pfizer library of novel chemical entities, in order to screen it for compounds that have the potential to be developed into new treatments. At this stage, Pfizer owns the IP rights and no licenses have been issued to date. Scientists in institutes affiliated with DNDi will test at least 150,000 compounds in the Pfizer library against *Trypanosoma brucei*, *Leishmania donovani* and *Trypanosoma cruzi*, the parasites that cause human African trypanosomiasis (HAT or sleeping sickness), visceral leishmaniasis (VL) and American trypanosomiasis (Chagas disease), respectively. Researchers are seeking compounds that show initial activity against the various parasites, and thus might form the basis for novel drug discovery programs to treat the diseases. Screening will be undertaken by the Eskitis Institute for Cell and Molecular Therapies at Griffith University in Brisbane, Australia, for HAT, and by the Institut Pasteur Korea, for VL and Chagas disease.

Pfizer

Medicines for Malaria Venture (MMV); London School of Hygiene and Tropical Medicine (LSHTM)

Global

2006

Malaria

Pfizer and Medicines for Malaria Venture (MMV) have entered into an agreement for the development, access and delivery of a fixed-dose combination (fdc) treatment consisting of azithromycin dihydrate (AZ) and chloroquine phosphate (CQ) for the intermittent preventive treatment of *P. falciparum* malaria in pregnancy (IPTp). A product development team comprised of representatives from Pfizer, MMV and the London School of Hygiene and Tropical Medicine (LSHTM) are coordinating the trials and an external independent data monitoring committee of malaria experts is overseeing them. Phase III clinical trials began in Africa during the summer of 2010, which should enroll up to 5,000 participants. Under the agreement, Pfizer plans to seek marketing authorization in selected malaria-endemic African countries where, with MMV, it is expected to seek to introduce the use of this important potential therapy to improve pregnancy outcomes and neonatal survival. Additionally, MMV is expected to provide several levels of support and advocacy on behalf of the project, including the development of a patient education campaign and recommendations on registration strategies in malaria-endemic countries.

Sanofi-aventis

Drugs for Neglected Disease Initiatives (DNDi); Medicines for Malaria Venture (MMV)
2010

-

2010

Malaria; Human African Trypanosomiasis; Leishmaniasis

In 2010, sanofi-aventis granted DNDi access to screen its compound library for potential new medicines showing activity against malaria, human African trypanosomiasis and leishmaniasis.

In 2008, MMV signed an MoU with sanofi-aventis for discovery work, including early-stage molecule testing, and screening, plus clinical development of ferroquine, SAR97276 and trioxaquine.



TDR Clinical Research Career Development Fellowship program: Astellas; Boehringer Ingelheim; Eisai; GSKBio; Johnson & Johnson; Merck & Co., Inc.; Novartis; Pfizer; Roche; Sanofi-aventis/Sanofi Pasteur; Sigma Tau

Developing countries researchers

Various developing countries

2009

Cancer; Chagas disease; Dengue; Hepatitis; Malaria; Sleeping sickness; Tuberculosis

The goal of the Clinical Research Career Development Fellowship program, which is coordinated by the UNICEF-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases (TDR), is to provide practical clinical experience for promising low and middle income country researchers and promote high quality clinical research and development (R&D) on medicines, vaccines and diagnostics in disease endemic countries. Upon completion of their 12-month fellowship with a research-based pharmaceutical company, the low and middle income country researchers should be equipped to return to their home countries and institutes to assume leading research roles and become valuable resources in the global effort on R&D for infectious diseases that disproportionately impact low and middle income countries. This program, which began in 2009, is supported by the Bill & Melinda Gates Foundation. Since its inception, 12 Fellows have been placed in training programs with 7 IFPMA member companies – Eisai, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche and sanofi-aventis – working primarily on diseases which disproportionately affect low and middle income countries. Additional IFPMA member companies have agreed to host Fellows in 2011 – Astellas, Boehringer Ingelheim, Merck & Co., Inc. and Sigma-tau.

Capacity Building



IFPMA members are involved in a broad range of capacity building activities which help to equip recipient countries to manage better the health challenges they confront. Specific activities include provision of physical infrastructure, training for healthcare workers, and help with the education of patients and populations at risk. Details of such activities can be found in the “IFPMA Developing World Health Partnerships Directory” at www.ifpma.org/healthpartnerships. Many aspects of healthcare capacity building can be considered a form of technology transfer. Programs in this section include skills transfer in areas such as general management, regulatory affairs, information technology, clinical trials and supply chain management (www.ifpma.org).

Boehringer Ingelheim

action medeor; Muhimbili University Dar-es-Salaam

Tanzania

2008

-

Boehringer Ingelheim

University of Cape Town; University of Stellenbosch

South Africa

Prior to 2005; 2007

Chronic obstructive pulmonary disease; Idiopathic pulmonary fibrosis

For years, Boehringer Ingelheim has been involved in health educational activities and training of health personnel in the field of HIV/AIDS and other diseases in various parts of the world. Since 2008, the company has worked with the Muhimbili University of Health and Allied Sciences (MUHAS), Dar es Salaam, Tanzania, helping to strengthen the capacity of its staff in a wide range of areas, including clinical trials skills, galenic laboratory technology, dispensing, executive management, information technology, supply chain management and regulatory affairs.

The Boehringer Ingelheim Lung Institute at the University of Cape Town was set up as a centre of excellence to support clinical trials in infectious and respiratory diseases. Officially opened on 26 April 2000, it is dedicated to the improvement of the understanding of lung health and diseases relevant to the needs of Africa. Located on the campus of the Faculty of Health Sciences, it provides clinical services as well as conducting research that is focused on epidemiology, allergy diagnostics, lung physiology, clinical pharmacology, evaluation of novel treatments and community-based interventions for improving disease management and improving health. Eight active clinical trials in asthma, COPD and tuberculosis are underway. The knowledge transfer unit was established to educate South African healthcare workers in tuberculosis and will be extended to workers in sub-Saharan Africa. Doctors from universities/public sector are trained on clinical trial related activities, including clinical trial design, performance and reporting.

Through its Student Education Program, run in collaboration with the University of Cape Town, South Africa, Boehringer Ingelheim provides full financial support for medical students from disadvantaged backgrounds. In 1992, the company pledged to fully finance ten students from disadvantaged communities to study medicine at universities in South Africa. The sponsorship included all academic fees, subsistence allowances, books, equipment and residence fees (where applicable) for the duration of their seven-year studies with no obligation to the company after graduation. Each year, two additional students join the program. To date, 20 students have graduated as general practitioners. There are currently six students in the program at the University of Cape Town and further six at the University of Stellenbosch.



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Japan Pharmaceutical Manufacturers Association (JPMA)

Regulators in ASEAN countries; Cambodian local manufacturers

ASEAN countries

1989

Multiple diseases

The Japan Pharmaceutical Manufacturers Association (JPMA) helps developing countries in Asia to establish efficient pharmaceutical distribution and quality control systems, via the following activities: Training in Japan: Since 1989, the JPMA has worked with the World Health Organization to provide annual Quality Control training courses in Japan for Asian government quality control personnel. JPMA provides practical training in medicines quality control at research laboratories and manufacturing plants, with the help of its member companies. This training strengthens the professional competence of Asian regulatory personnel and helps improve the quality of medicines in developing countries in Asia. To date, JPMA has provided training for 73 regulators.

Contracted training in third countries: JPMA also provides training for government personnel from countries such as Bhutan, Cambodia and Laos in a third country, such as Thailand. This approach is used when there may be big differences between the standard of technical equipment in Japan and in the countries concerned. JPMA started in-country training in 2001 and has trained 24 regulators so far via this type of course.

Donation of analytical instruments and Good Manufacturing Practice (GMP) training: JPMA has provided analytical instruments free-of-charge and also on-site guidance from technical and quality specialists, aiming to strengthen local quality control in Cambodia. In addition, JPMA has been providing GMP training to Cambodian

pharmaceutical manufacturers, to promote the supply of safe medicine to patients in Cambodia.

Supply of Reference Substances to ASEAN Countries: Reference substances are extremely pure active ingredients of drugs that are indispensable for assaying the content of pharmaceutical substances in medicine. Since 1992, JPMA has provided free reference substances to support a WHO program which helps ASEAN countries to assay commercially available medicines. This project is now managed by the Bureau of Drugs and Narcotics (BDN), Thai Ministry of Public Health. JPMA now funds acquisition of substances from within the ASEAN region.



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Merck KGaA (MerckSerono)

Local subsidiaries of MerckSerono in China

China

2009

Oncology; Multiple sclerosis; Fertility & other

This program is building an organization to conduct local clinical trials and allow Chinese participating in Merck's global clinical trials. The related functions are clinical operations, which includes clinical trial management and monitoring, biostatistics, medical writing, data management, drug safety, quality assurance, Regulatory Affairs, project management, medical science and evaluation of collaboration with external clinical research organizations.

Novartis

Ministry of Health in Tanzania; Roll Back Malaria Partnership

Tanzania

2009

Malaria

To help ensure that malaria patients have access to treatment even in the most remote areas of Tanzania, Novartis teamed up with the Roll Back Malaria Partnership, Vodafone, IBM and the Ministry of Health in Tanzania to develop and implement the "SMS for Life" pilot project in September 2009. "SMS for Life" uses a combination of mobile phones, Short Messaging Service (SMS) technologies and easy-to-use websites to monitor stock levels of artemisinin-based combination therapy (ACT) drugs and quinine injectables around the country.

The 21-week pilot, which covered 226 villages and 129 public health facilities in three rural districts in Tanzania (involving over one million people), significantly reduced stock-outs and expanded access to malaria treatments. At the start of the pilot, 25% of all health facilities did not have any ACTs in stock, but by the end, 95% had ACT dosage form in stock. SMS for Life is now being implemented in all 131 districts of Tanzania, comprising more than 5,000 public health facilities. Expansion to other countries is under discussion.



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Pfizer

Global Health Fellows skills-based volunteerism partnerships

Botswana; Burundi; Cambodia; China; Dominican Republic; Ethiopia; Ghana; Guatemala; Guyana; Honduras; India; Kenya; Kazakhstan; Lesotho; Macedonia; Malawi; Mexico; Morocco; Mozambique; Namibia; Nepal; Nigeria; Panama; Russia; Rwanda; Senegal; South Africa; Tanzania; Thailand; Turkey; Uganda; Ukraine; Vietnam; Zambia

2003

HIV/AIDS; Malaria & other

Pfizer's Global Health Fellows Program (GHF) is an international skill-based volunteerism program that places Pfizer colleagues in three to six month volunteer assignments with non-profit and international development organizations designed to improve health care for underserved populations. During assignments fellows transfer their professional expertise in ways that promote access, quality or efficiency of health services. More than 250 Pfizer colleagues have served in GHF assignments with 30 non-profit and international development organizations since 2003.

Sanofi-aventis

Malaria-endemic countries; Drugs for Neglected Disease Initiatives (DNDi); Medicines for Malaria Venture (MMV)

Benin; Burkina Faso; Cameroon; Cote d'Ivoire; Gabon; Kenya; Liberia; Madagascar; Mali; Mozambique; Senegal; Uganda; Zambia

2008

Malaria

Sanofi-aventis has helped to set up an innovative ASAQ (fixed-dose combination of artesunate (AS) and amodiaquine (AQ)) field monitoring program, with studies covering a range of African countries, conceived in close collaboration with the National Malaria Control Programs of the concerned countries. With more than 20,000 episodes of malaria treated with ASAQ, it is the most ambitious proactive pharmacovigilance program ever launched in Africa, for any type of medicine. Through this initiative, sanofi-aventis is helping to build pharmacovigilance capacity in Africa, adapted to needs and to resources of countries. This initiative is financially supported by Drugs for Neglected Diseases initiative (DNDi) and Medicines for Malaria Venture (MMV).

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Ilaria Capalbo.



The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical industry, including the biotech and vaccine sectors. Its members comprise 26 leading international companies and 45 national and regional industry associations covering low, middle and high income countries. The industry's research and development pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion) and its Developing World Health Partnerships Directory (www.ifpma.org/HealthPartnerships) help make the industry's activities more transparent. The IFPMA supports a wide range of WHO technical activities, notably those relating to medicine efficacy, quality and safety. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).



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