Committed to a healthier future

IFPMA

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Foreword

Resistant bacteria are threatening safe care in hospitals around the world, lifesaving vaccines still face many challenges as they travel from the initial point of delivery to the children who need them, and changing lifestyles are putting untold pressure on resource-strained health systems. So what do we need to do for society to be healthier? And who can be expected to foot the bill for ground-breaking new treatments that allow us to dream of stopping some of the world's most devastating illnesses, disproportionately affecting people living in low- and middle-income countries?

There is widespread agreement that tackling the most pressing global health challenges requires resources, experience, and capacity of all actors working together. From our offices in Geneva, the IFPMA team, together with our members from around the world, shares industry's know-how and contributes to achieving shared solutions with other global health players.

Geneva is the center of global health policy development, with key issues in both developed and developing countries often "converging" on United Nations agencies' agendas, triggering further initiatives at national or regional level. The World Health Organization (together with its regional offices) has on its agenda numerous systemic, regulatory, and disease-specific issues of major relevance to our industry. The World Intellectual Property Organization continues its work on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities, on substantive patent law issues, and proposals arising from the use of genetic resources. The World Trade Organization's Trade Policy Review of individual countries also offers opportunities to address key issues of concern to the industry in a multilateral environment.

Other stakeholders in the global health community are active on intellectual property and access to medicines, but also on other health priorities ranging from non-communicable diseases to vaccination. IFPMA and its members strive to build trust and promote dialogue with these organizations.

> *"I urge the private sector to take its place at the table and plot a path forward for the next 15 years, reaffirming once again that responsible business is a force for good."* – United Nations Secretary-General Ban Ki Moon

With partnerships mobilizing all stakeholders to deliver the goals and targets of new global 2030 agenda for sustainable development, the biopharmaceutical industry stands ready to cooperate with other sectors, as well as governments and international organizations, non-governmental organizations, and academics, to grow as a community of partners and catalyze transformational change. IFPMA and its members are engaging in some 300 partnerships across the world to prevent diseases, improve health system infrastructure, train health professionals, discover new treatments for neglected diseases, donate medicines and vaccines, and promote other measures to improve the availability and quality of treatment for patients.

Our working environment is an exciting one; we serve as representatives for a business that is involved in the discovery of new medicines and vaccines for present and future generations. We facilitate and catalyze industry's efforts to expand access to quality therapies. We are passionate about the role we have in the quest to find effective and sustainable solutions to today's most pressing health concerns.

The IFPMA team

Geneva, home to unique synergies for health

IFPMA is the industry partner for intergovernmental organizations, thanks to its consultative status with the United Nations and specialized agencies. Those institutions include the World Health Organization, UNAIDS, the Joint United Nations Programme on HIV/AIDS, the World Intellectual Property Organization, the United Nations Children's Fund, the United Nations Conference on Trade and Development, the United Nations Economic and Social Council, and the United Nations Industrial Development Organization. IFPMA also has formal relationships with the World Bank and the World Trade Organization.

IFPMA is based in Geneva, the "public health capital of the world", where many organizations are engaged in the critical interface between public health, development, and innovation. Geneva is also home to many other major actors in global health, including the Global Fund to fight AIDS, Tuberculosis and Malaria, the International Federation of Red Cross and Red Crescent Societies, Gavi, the Vaccine Alliance, the Foundation for Innovative New Diagnostics, Médecins sans Frontières, and many other non-governmental organizations, foundations, partnerships and academic institutions, innovative biotech start-ups, and biopharmaceutical companies.

Moreover, Geneva hosts permanent Missions to the United Nations for more than 140 countries.

IFPMA *in Brief*

At IFPMA we advocate policies and practices that encourage the discovery of and access to life-saving and life-enhancing medicines and vaccines, for people everywhere.

WHO WE ARE

We represent research-based biopharmaceutical companies, and regional and national associations across the world.

HOW WE WORK

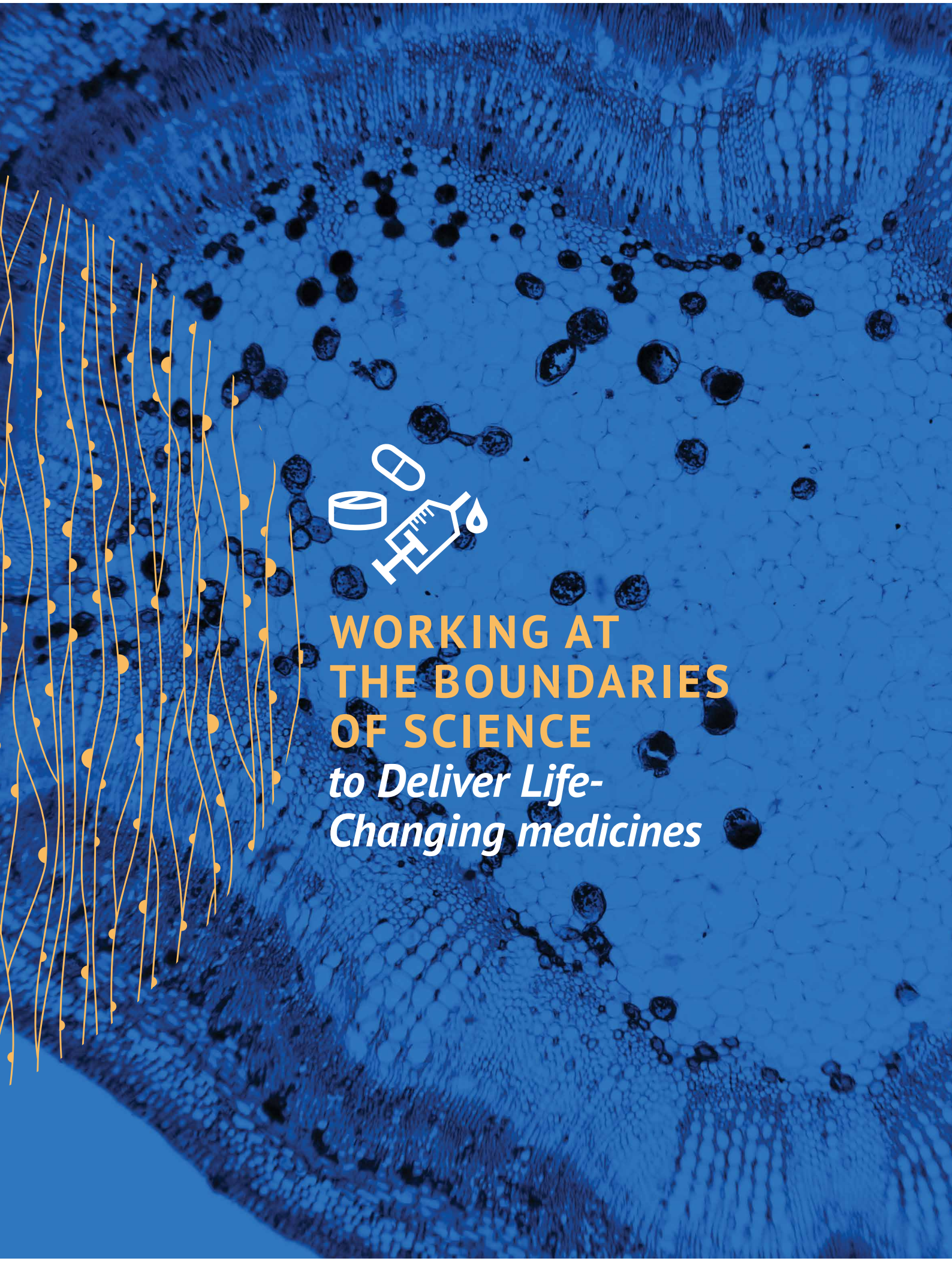
We facilitate collaboration, dialogue, and understanding within our industry and with other global players in the health community.

WHAT WE DO

We bring the industry and broader health community together to foster innovation, promote resilient regulatory systems and high standards of quality, uphold ethical practices, and advocate sustainable health policies to meet global needs.

WHY IFPMA

We are the unique, informed, and credible voice in conversation with the global health community to address the many challenges in public health policy for current and future generations.



WORKING AT THE BOUNDARIES OF SCIENCE

to Deliver Life-Changing medicines

Never have people lived longer and never have so many children been saved from dying in the first years of life. While much of this progress is due to better sanitation and improved access to medical services, medicines and vaccines have extended and improved the quality of life for millions of people.

Innovation has played a profoundly significant role in this story. The new medicines and vaccines springing from the dedicated work of biopharmaceutical scientists over decades has created a legacy from which we all benefit. Effective medicines and vaccines do more than prevent and treat diseases and patients are not the only ones who are helped by new developments. When new medicines improve a population's health, the economy benefits from a healthier workforce.

IFPMA promotes the value of innovation every day, laying out the industry's perspective on how to continue to push the limits of science to improve global health, and contribute to the prosperity of society.

BIOPHARMACEUTICAL INNOVATION: LIVING LONGER, LIVING BETTER

The research-based biopharmaceutical industry is one of the most innovative sectors in the world. Biopharmaceutical innovation – the core of our industry's work – relies on pushing the limits of scientific knowledge to advance new therapies for the benefit of patients. Our industry plays a unique role in discovering medicines and vaccines to prevent and treat diseases. Our researchers are working tirelessly to find novel ways to attack diseases and address emerging threats. They are exploring new scientific approaches while expanding their knowledge and understanding of human diseases.

Over the past century, biopharmaceutical research and development has contributed to increased life expectancy and better quality of life. Their discoveries save millions of lives and help those suffering from disease to recover and lead healthier, more productive ones. Healthier individuals are a driver for wealth; the introduction of innovative medicines has multiple benefits for society. It improves the physical and mental well-being of individuals, allows them to contribute to economic activity, and reduces hospitalization and healthcare costs.

Transforming fundamental research into viable treatments is the challenge our industry faces. Success depends on continuous innovation – for the prevention and treatment of common, as well as complex and neglected conditions, and for improvements in existing treatments. Creating new medicines is difficult, expensive, and time-consuming. A policy environment that enables medical innovation to flourish is essential for biopharmaceutical companies so that they can continue to invest in the development of new solutions that benefit humanity.

Our role is to make sure that the benefits of innovation are appreciated and accessible, but also that the conditions needed to foster research and development are well understood.

At IFPMA, we will continue to work to help the general public and policy-makers understand that medicines and vaccines are not a cost, but an investment.

Biopharmaceutical R&D and its impact on global health

Over the past century, the private sector has produced the majority of the medicines and vaccines on the market.

Vaccines are recognized as one of the most successful and cost-effective public health interventions, with positive impacts on health, productivity and well-being across the globe. Vaccines prevent 3 million deaths each year from diarrhea, pneumonia, cervical cancer and many more illnesses. Between 2000 and 2014, immunization campaigns cut the number of deaths caused by measles by 79%, with a reduction of 92% in Africa between 2000 and 2008.

Scientists have discovered and developed 19 classes of antibiotics, leading to the treatment and cure of several thousand types of infection and saving over 200 million lives.

It is estimated that the use of medicines against malaria has saved the lives of 1.14 million African children between 2011 and 2015.

Over the past 35 years, HIV/AIDS has gone from being a death sentence to a chronic, manageable disease thanks in large part to advances in biopharmaceutical research that has developed more than 20 antiretroviral therapies. The number of AIDS-related deaths worldwide peaked at 2.1 million in 2004 and has since fallen to an estimated 1.6 million deaths in 2012. This can be largely attributed to the introduction of new antiretroviral therapies combined with more patients being provided with treatment.

Today, if diagnosed early, leukemia can be driven into remission with a once-daily treatment. High cholesterol and other cardiovascular diseases, which required extensive treatment in the 1970s, can now be easily managed with oral therapy. Developments in cancer treatments in the past couple of decades have extended and improved the lives of patients and have avoided unnecessary treatments and procedures.

Since 1980, 83% of life expectancy gains for cancer patients are attributable to new treatments, including medicines.

In the last 30 years, biotherapeutics, therapies derived from living organisms, have become an integral and valuable part of modern medicine. Insulin, used by diabetics to regulate blood sugar, was the first modern medicine produced using biotechnological methods. Since then, many biotherapeutic medicines have been developed and licensed to treat serious illnesses, including cancer, heart disease, multiple sclerosis, anemia, and rheumatoid arthritis.

New paths to fight disease

Medical advances give patients one essential ingredient for survival: hope. With biopharmaceutical companies developing more than 7,000 innovative medicines worldwide and investing over USD 500 billion in research and development since 2000, there are good reasons to be optimistic.

Our researchers are continuing the fight against HIV/AIDS and, with more than 40 new medicines in the pipeline, there is a growing belief that a cure can be found. Biopharmaceutical companies are focusing on improved treatment regimens, more effective therapies, and preventive vaccines.

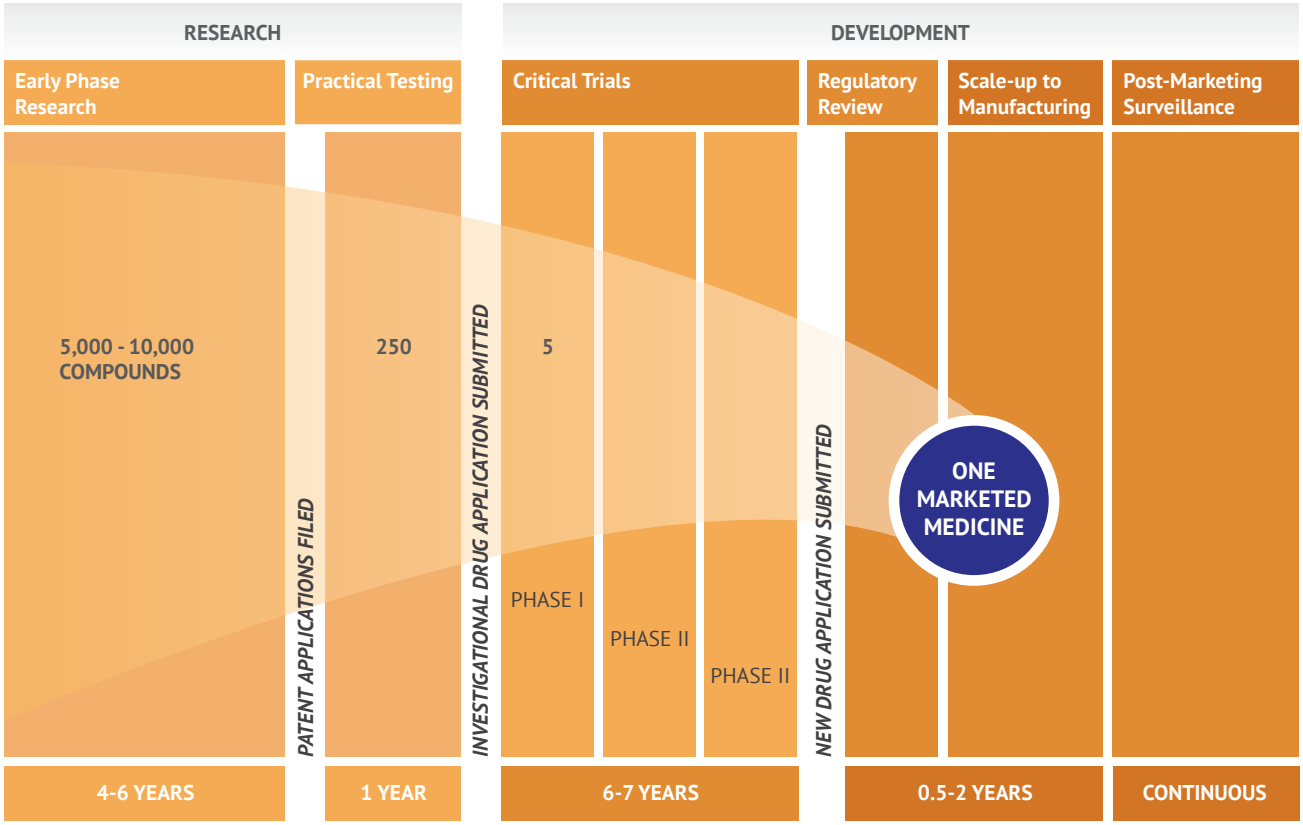
There are 3,073 projects in the pipeline for cancer treatments. These lines of research include lung, prostate, and breast cancers, but also other rare types of cancer. The fight against cancer is challenging; requiring sophisticated cutting-edge technology and pioneer approaches to medicine. Some of the latest research and development technologies include the use of nanotechnology to assist the delivery of medicines to malignant cancer cells, potentially overcoming some limitations of existing treatments, and immuno-oncology – one of the most promising and quickest-growing areas of cancer research. Immuno-oncology, which is focused on the development of therapies to improve the body's immune response against cancer, has the potential to make huge improvements to treatment outcomes across a range of cancers, including common threats like melanoma, lung, and breast cancer, as well as hematological cancers. The role of personalized medicine is also growing and holds potential to prevent disease, find the correct treatment more quickly, prevent side effects, improve patients' quality of life, and treat disease more effectively.

More than 20 of the vaccines currently in development target diseases such as HIV, malaria, tuberculosis, bacterial pneumonia, meningitis, and leishmaniasis.

DISCOVERING NEW CURES: FROM LABORATORY TO PATIENT

Risk is the fundamental element in biopharmaceutical research and development. It is not enough to discover a promising compound. Success actually depends on minimizing the time and associated costs to bring a compound forward from a scientific "idea" from basic research, to discovery of a compound, through development, to final regulatory approval. On average, it may take 10 years and about USD 2 billion to bring a new medicine from the research pipeline to patients, including the cost of failures. To help identify unmet needs, our researchers work with the scientific community to monitor epidemiological trends. The research and development begins then with screening of chemical and biological compounds with potentially useful properties. Of the thousands tested, only a few hundred are deemed promising enough for pre-clinical trials. These hundreds are further tested for efficacy and safety and a handful then selected for clinical trials. The process can take many years to arrive at this stage.

To illustrate, in 2014, 43 new medicines were launched globally, while in 2013 more than 3,400 compounds were at different stages of development.



BOOSTING THE GLOBAL ECONOMY

The research-based biopharmaceutical industry is one of the most innovative sectors in the world. Of all industrial sectors, ours has consistently invested the most in research and development, even in times of economic turmoil and financial crisis. Compared with other high-technology industries, the annual spending by the biopharmaceutical industry is five times greater than that of the aerospace and defense industries, 4.5 times greater than that of the chemicals industry, and 2.5 times greater than that of the software and computer services industry.

The biopharmaceutical industry, one of the world's largest industries, plays a major role in boosting the global economy. The industry has a total economic footprint of USD 437 billion in terms of Gross Value Added (global Gross Domestic Product). It is also a major global employer, employing over 2 million people worldwide.

SUSTAINING BIOPHARMACEUTICAL INNOVATION

Innovation is the driving force for progress in healthcare. Leading edge science and competition have given birth to a revolution in new health technologies. These are transformed through rigorous testing into medicines, vaccines, devices and diagnostics that offer great hope to patients. The role that health innovation plays is even more critical today, as global demographic changes challenge health authorities with a double burden of chronic non-communicable diseases and the rise of new infectious pathogens resistant to established therapies. The biopharmaceutical research and development process is characterized by significant risks. Success is never guaranteed; biopharmaceutical companies face ever growing challenges in research and development of new treatments for patients.

Innovation cannot happen without a number of enabling conditions, such as access to world-class researchers, political and financial stability, efficient and resilient health systems, and a regulatory framework that protects and rewards innovation. A robust ecosystem that supports and encourages innovation is critical to allow companies to continue to make progress, absorb the investments that do not make it to market, learn from every setback, and eventually come up with new treatments to fight against diseases.

Innovation must be encouraged by sound intellectual property protection. An intellectual property regime incorporating patents, copyrights, and trademarks remains the best and most effective way to allow inventors to focus on research and development, and to allow significant contributions to public health to leave the drawing board and see the light of the day. It is largely due to these protections that the private sector has been able to produce the majority of life-saving medicines and vaccines we rely upon today.

EXPANDING ACCESS TO HEALTHCARE

Having the right medicines is just one step in improving public health. Increasing access is also vital, but doing so can be complex and difficult. The factors that might impact a patient's potential access to a given medicine or vaccine include the distribution system within a community or country, the quality of the healthcare system itself, general infrastructure, access to insurance, and government policies on import tariffs and taxes.

There are many gaps in healthcare systems that have an unequal impact on populations. However, countries have proven that with targeted efforts and political will, improving quality and tackling inequities within systems can yield enormous improvements in public health.

Expanding access to care in low- and middle-income countries requires a structured, collaborative effort that ensures health systems use resources effectively and efficiently. Governments, payers, and clinicians need to consider a range of decision-making tools to prioritize health care interventions and ensure patients have access to quality health care products and services to prevent, diagnose, and treat diseases. Some governments and payers use health technology assessment to help inform health policy decisions. Health technology assessment should focus on assessing the effectiveness and efficiency of healthcare interventions, including the use of medicines and medical devices, within the whole health system and informing the prioritization of health care services. IFPMA is working with its members on these issues to develop policies and standards, and represent industry views at international fora.

Improving access to health services requires cooperation between the public and private sectors. IFPMA companies have taken a flexible approach to further enhance access to treatments in less developed economies. These initiatives do not always depend on waiving intellectual property rights. Differential pricing and capacity building can help promote access even if patents exist on the medicine or vaccine. This is especially applicable in least developed economies. In many cases where patents do exist, IFPMA companies have allowed generic manufacturers to produce protected medicines through programs of voluntary licensing, technology transfer and non-assert policies.

Our industry is committed to improving public access to medicines and vaccines. To that end our members are involved in 300 health partnerships, with thousands of on-the-ground operators in the field. Many of these programs facilitate access to treatments, strengthen health systems by addressing issues of infrastructure and capacity building, and raise awareness, along with delivering better treatments.

ACCELERATING ACCESS TO SAFE, HIGH QUALITY

Medicines and Vaccines

We believe that patients everywhere should be treated with medicines and vaccines that conform to high quality standards. Science-based guidelines provide clear direction for the development, manufacture, and supply of medicines. They help to assure that medicines and vaccines are safe, effective, and of quality. What's more, they provide a common platform to help regulators and industry alike to build a shared understanding of what quality means and how to achieve it.

ENSURING PATIENT SAFETY

Quality guidelines provide practical and pragmatic direction to those involved in the development, manufacturing, and supply of medicines and vaccines. They help to assure that medicines and vaccines are safe, effective and of quality. They ensure that regulators and the biopharmaceutical industry have a shared understanding of the necessary requirements.

Pharmacovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects, is key to monitoring the safety of medicines and vaccines. Critical, reliable, and balanced input of safety information provided by all stakeholders is essential in this area to ensure that pharmacovigilance systems work. In such context, IFPMA believes that greater engagement in and support for pharmacovigilance practices are needed to empower all stakeholders to help deliver effective safety reporting on a global basis. Good practices exist in many countries, but in too many settings patients, healthcare professionals and other stakeholders do not understand the role that they should play.

In order to anticipate, identify, record, and report side effects, stakeholders need to have a good understanding of the medicines themselves. In the context of biotherapeutics medicines for instance – more complex and unique compounds – IFPMA helps explain the different issues at stake for such medicines and how pharmacovigilance practices can address such challenges, providing Good Pharmacovigilance Principles and considerations. IFPMA also takes an active role participating in exchange platforms, to provide views on how best to maintain a robust pharmacovigilance system that relies on consistent and accurate data. To achieve this, IFPMA works closely with the World Health Organization Advisory Committee on Safety of Medicinal Products.

STRENGTHENING REGULATORY SYSTEMS AND PROMOTING CONVERGENCE

Strong regulatory systems are needed to ensure that people around the world have timely access to quality medicines and vaccines that are both effective and safe. Such systems operate through a mix of directives and regulations, standards, and procedures aimed at keeping availability of treatments and prevention of diseases on track.

A comprehensive system of regulatory supervision with expertise in inspections, product assessment, and monitoring of quality, including possible side effects, is paramount. Such systems should be in place and operational before medicines or vaccines are introduced and throughout their life cycle.

Today, only 20% of the World Health Organization's Members States have well developed pharmaceutical regulatory systems. This is partly due to considerable human and financial resources that such systems entail.

In a globalized world, the regulatory landscape is changing every day to address both old and new challenges. With regulatory systems increasingly under pressure globally, the most promising solution in the journey to make regulatory systems work more efficiently is through regulatory convergence and harmonization. Aligned regulatory systems will also lead to enhanced safety, in particular helping to prevent the introduction of lower quality or fake medicines and vaccines, as well as to address any shortages in supply.

Achieving regulatory convergence requires cooperation among governments, international and non-governmental organizations, healthcare professionals, industry, and patient groups.

IFPMA is committed to regulatory system strengthening and puts particular emphasis on regulatory convergence and harmonization as well as capacity building efforts. Together with partners, IFPMA regularly co-organizes regional regulatory conferences to provide platforms for dialogue and expertise sharing. This, alongside speeding up local review and authorization, are critical measures to make the best use of limited resources while at the same time supporting essential regulatory oversight on quality, safety, and efficacy.

Fighting fake medicines

Fake medicines pose a major threat to global health. IFPMA has been active in campaigning for recognition of the issue at all levels of the health community. It urges collaborative action to develop policies that recognize, prioritize, and address effectively the problems created by fake medicines.

IFPMA regularly organizes workshops to promote an integrated approach to fight fake medicines. At these meetings, best practices are shared on a broad agenda: current regulatory and legislative landscapes and initiatives; supply chain integrity; practices and technologies for prevention, detection, and monitoring of fake products; and fostering collaboration within and between countries.

Fake medicines have evolved into a global threat. They are found in nearly every country and across all disease treatment areas. Up to 30% of medicines in some areas of Asia, Africa, and Latin America are at high risk of being fake, and worldwide more than 50% of medicines sold via illegal online pharmacies worldwide are fake.

'Fight the Fakes' is a unique campaign to raise awareness and promote responsibility from the beginning to the end of the biopharmaceutical supply chain. It involves every level of the health community, from nurses and pharmacists to manufacturers. Becoming a partner of 'Fight the Fakes' means joining a unique global movement leveraging existing networks to combat this very serious problem.

'Fight the Fakes' has garnered recognition from industry and patient representatives alike for its effectiveness in highlighting the threat and in demonstrating how collaboration can help deal with the serious threats to patient health.

IFPMA is one of the founding partners of 'Fight the Fakes'.

MAINTAINING ETHICAL STANDARDS AND *Earning Patients' Trust*

Advancing medical knowledge and expertise is a priority for IFPMA members. A continuous dialogue between healthcare professionals and the research-based biopharmaceutical industry is essential to ensure that patients have access to the medicines they need, and that these professionals have up-to-date, comprehensive information about the diseases they treat and the medicines they prescribe. IFPMA members remain committed to not only providing the latest scientific and educational content to healthcare professionals and to the broader health community, but doing so with integrity and the highest professional standards. Only in this way can we ensure that all interactions between our industry and the healthcare community are ethical, responsible and made in the best interest of patients.

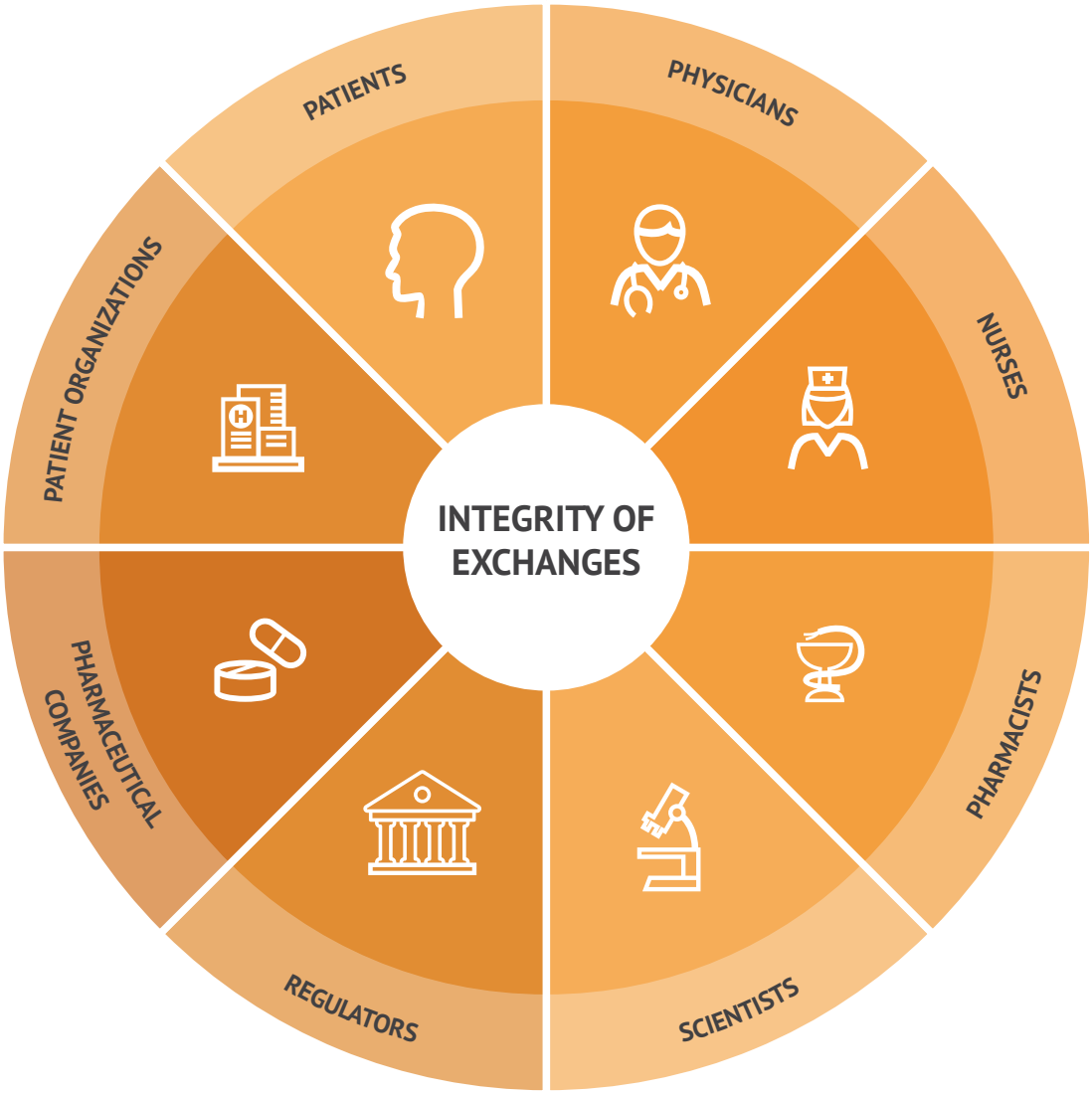
IFPMA CODE OF PRACTICE

An efficient healthcare system depends on mutual trust between all parties. As companies are the point of origin for much of the information on medicines and their application, they have a responsibility to share this scientific knowledge with governments, doctors, nurses, scientists, and patients in regulated conditions. The healthcare community and the public must be confident that biopharmaceutical companies and their employees, wherever they operate, communicate and act in an ethical and professional manner. Patients need to trust that their doctor is making informed, independent decisions about their treatment, and that the prescription given is in their best interests.

As regulatory requirements, technological developments, community expectations, and evolving business models require enhanced approaches to business ethics, IFPMA is working with its members to implement ethical business practices.

IFPMA member companies have agreed to share the same high standards of integrity, and have designed a self-regulating system in which they can be held to account. They do this not only by keeping each other in check, as healthy self-regulation dictates, but also by making widely known the standards that governments, the healthcare community, and the public at large can expect. These standards are conveyed through the IFPMA Code of Practice, as well as a recent Framework for Ethical Collaboration with healthcare stakeholders.

The fast pace of medical innovation and the continuing drive to improve global public health is reliant on proper communication throughout the entire medical community – from researcher to attending physician, from nurse to patient. Trust remains the crucial bedrock of these exchanges, regardless of the form they take – be it leaflets, academic articles, or continuing medical education.



In all contexts, information shared by IFPMA members must be to the highest possible ethical standards. The IFPMA Code of Practice sets binding standards for member companies and associations to operate in accordance with the agreed rules and regulations. Supplementary to existing national and regional legislation, ethical criteria set by the World Health Organization and other international agreements, the Code provides assurance of exchanges with the healthcare community that are appropriate, transparent, and in the best interest of patients.

The IFPMA Code is regularly updated to keep abreast with the increasing complexity of healthcare systems: in addition to providing standards for promotional materials, its current iteration details appropriate interaction with patient organizations, the disclosure of clinical trial research data, and healthcare professional participation in industry-sponsored events and meetings. IFPMA communicates the Code requirements to its members and supports training to help ensure its correct application, including an online training program accessible to everyone. The IFPMA Code Compliance Network has been formed to exchange best practices in Code implementation, and guide members in their own outreach and training efforts.

Across IFPMA's national associations, global research-based biopharmaceutical companies, and the near 2 million employees, the Code is a tangible example of the research-based biopharmaceutical industry's commitment to making a strong contribution to public health while adhering to the highest standard of practice.

IFPMA encourages others – doctors, pharmacists, nurses, academics, patients, and consumers – to become aware of this benchmark. The better other stakeholders understand the standards, the easier it will be for them to join us in living up to the pledge of high ethical practices throughout the healthcare sector.

The Consensus Framework for Ethical Collaboration

The Consensus Framework for Ethical Collaboration is a multi-stakeholder platform outlining the shared principles that should guide the conduct of the various actors in the healthcare sector. These are:

- *Putting patients first;*
- *Supporting ethical research and innovation;*
- *Ensuring independence and ethical conduct in all interactions;*
- *Promoting transparency and accountability.*

Signed by the international-level organizations representing patients, healthcare professionals, and the pharmaceutical industry, the Framework codifies a shared commitment to ensure safe and appropriate treatment for patients and transparency across all organizational operations.

It is also designed to be replicable at the national level. IFPMA facilitates the implementation of the Framework platform for its members, providing assistance in fostering dialogue with national-level healthcare stakeholders and other relevant collaborators.

As a living document, the Framework is also open to endorsement by other key partners in life-sciences and healthcare delivery.

The Framework is one example of how IFPMA is working in collaboration with governments and the healthcare community to build trust among patients and continually improve global health.

PIONEERING NEW APPROACHES TO *Boost Innovation*

Over the past century, medical innovation has transformed human lives by curing disease, lessening suffering, and extending life spans worldwide. The global health community managed to vanquish scourges like polio, vaccinate populations to prevent measles, mumps, rubella and other ailments, and turned HIV/AIDS from a death sentence into a manageable condition.

Yet, some of the greatest challenges lie ahead. The threat from antibiotic resistant bacteria is growing; at the same time neglected tropical diseases continue to deeply affect emerging economies. The biopharmaceutical industry is facing ever-harder scientific challenges. Making inroads against these problems demands that we expand our arsenal of cures through ongoing innovation and an unprecedented degree of global cooperation.

The research-based biopharmaceutical industry is thinking creatively about its innovation and business models to meet these new challenges. Our industry is working in collaboration with different players from academia, public research institutes, product development partnerships, to small, medium and large biopharmaceutical companies. This improved collaboration, which is taking place in many different ways, facilitates the dissemination of technologies and know-how across a much wider scientific community.

ACCELERATING INNOVATION TO FIGHT NEGLECTED TROPICAL DISEASES

One person in seven suffers from neglected diseases. Each year neglected diseases disproportionately disable or kill millions of poor people primarily in tropical and subtropical areas of the world. Despite this, neglected tropical diseases did not receive, until recently, as much collective attention as needed, given the global health community's focus on other priorities.

Increased leadership from the World Health Organization and other key partners, including our industry, helped revert the above trend in recent years, generating significant efforts to help relieve populations from these devastating yet preventable conditions. Addressing these diseases means giving a possibility to endemic populations to break the cycle of poverty and move towards sustainable development.

For decades, the research-based biopharmaceutical industry has been committed to the fight against diseases affecting vulnerable populations.

Today, IFPMA companies are involved with 186 separate research and development projects in neglected tropical diseases. Most of these projects are collaborative efforts between biopharmaceutical companies and more than 80 partners from universities, public and private sector institutes, and non-governmental organizations. These product development partnerships facilitate exchange of expertise and scientific knowledge to develop new treatments and vaccines.

IFPMA also supports the WIPO Re:Search consortium. This program provides a searchable, public database of intellectual property assets that are available for license or collaboration in the fields of tropical diseases, tuberculosis and malaria. These intellectual property assets might be new compounds, technologies, know-how and data. The aim is to speed up research for treatments that will ultimately improve the lives of those living with these diseases.

TRANSFERRING TECHNOLOGY TO FOSTER LOCAL SOLUTIONS

Transfer of technology from originator to new users is a key component of economic development. It is one means by which low- and middle-income countries can accelerate the acquisition of knowledge, experience, and equipment needed for advanced, innovative industrial products and processes.

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 sustainably increasing access to innovative medicines and vaccines. In an increasingly globalized world, creating the right conditions for the transfer of technology is an important consideration for all countries at all income levels. Based on their experience, IFPMA member companies have drawn up a list of policy recommendations that could be used by national and international institutions to encourage and facilitate transfer of technology.

RETHINKING THE WAY WE FIGHT BACTERIA

Antibiotics have been critical to medicine and public health for over seventy years. They have helped wipe out conditions that killed people in the past and are essential in managing bacterial infections today as well as making modern surgery possible. However, antibiotic resistance is one of the most pressing health threats facing the world today.

Seventy years after their introduction, we now face the possibility of a future without effective antibiotics for several types of bacteria that cause life-threatening infections. It is estimated that a continued rise in drug resistance could lead to 10 million additional deaths a year by 2050 and a reduction of 2% to 3.5% in Gross Domestic Product.

World leaders are calling for global action to fight against antimicrobial resistance. This call has considerably increased international awareness of the threat of antimicrobial resistance. The World Health Organization has called for change at national level, calling for increased presence of antimicrobial resistance policies in national health plans.

As an association, IFPMA is well positioned to drive efforts in boosting innovation as well as in important areas such as education, prevention, and optimized use.

MAINTAINING THE VACCINES INNOVATION EDGE

Vaccines have proven to be one of the most effective preventative technologies in the fight against infectious diseases, with an almost unparalleled impact on public health. Vaccines prevent 3 million deaths each year from diphtheria, tetanus, pertussis, and measles. Immunization not only saves lives and improves health, it also unlocks the potential of the community. A vaccinated community is healthier, stronger, and more productive. Our new generation of vaccines, incorporating smart technologies, is already making the same kind of public health impact as their pioneering predecessors, dramatically reducing the burden of pneumococcal disease and rotavirus disease – two of the biggest killers of children.

Our members, together with our partners, are united by a common challenge to save lives, improve health, and ensure long-term prosperity through life-saving vaccines. We support the Decade of Vaccines Global Vaccine Action Plan, a framework to prevent millions of deaths by 2020 through more equitable access to existing vaccines for people in all communities. The vaccine technologies that have driven the public health and economic gains from immunization would not be possible without sustained investment in innovation and the unwavering ambition of dedicated scientists. Investment in innovation not only helps to prevent the re-emergence of infectious diseases but also helps to ensure that the global community is prepared when new threats emerge.

IFPMA is a unique platform for representing vaccine manufacturers, including influenza vaccines. We share insights, experience, and proven paths to advance vaccine technologies and ensure reliable supply to extend the benefit of vaccines to more people and provide better protection from life-threatening infectious diseases.

One of IFPMA's roles in this conversation is to explain why the vaccine manufacturing chain is so complex, why the right conditions and incentives to support confidence around sufficient, durable supply of high-quality vaccines are important, and why the policy and regulatory environment can have a critical impact on the timely and secure supply of vaccines.

Global Vaccine Action Plan (GVAP)

The IFPMA report "Innovation for a Healthier World" provides an overview of the collective effort and contribution of the biopharmaceutical industry to the Global Vaccine Action Plan (GVAP). It reports on the industry's innovation beyond the traditional research and development model to work in partnerships to optimize production, improve the supply chain to reach people in remote areas, and support strong national commitments to immunization.

PARTNERING TO
Tackle Global Health Challenges

Improving public health is a collaborative process requiring solutions that go beyond medicines or vaccines. Everybody needs good sanitation. People need primary care. Patients need access to well-trained doctors and nurses. Hospitals require functioning equipment, fresh water and reliable electricity.

Solving global health problems starts with a shared commitment to improving lives. The expertise and contributions of the global health community – nurses, doctors, governments, foundations, NGOs, academic institutions, and industry – have dramatically increased access to quality care, reaching the farthest corners of the world. Fighting disease in developing countries continues to pose enormous challenges due to the increasing burden of disease and growing populations, often requiring better infrastructure for health service delivery.

While the research-based biopharmaceutical industry has a crucial role to play in promoting global health, it remains only one part of the solution. IFPMA is a key player in helping put the public-health puzzle together, able as it is, to share the biopharmaceutical innovation sector's experience in those discussions that are engaging the global health community and beyond.

IFPMA HEALTH PARTNERSHIPS DIRECTORY

IFPMA hosts the Health Partnerships Directory, a continuously expanding online database that allows users to view, in depth, health partnerships from across the world that involve the research-based biopharmaceutical industry. Users of the Directory can learn the stories of people working to implement partnerships on the ground and also read the testimony of people who have had their lives impacted by these initiatives.

The collaborations detailed in the Health Partnerships Directory bring together governments, intergovernmental and non-governmental organizations, private sector companies, universities, and foundations. Broadly, they aim to improve the lives of people suffering from HIV/AIDS, malaria, tuberculosis, neglected tropical diseases, and non-communicable diseases as well as tackling cross-cutting challenges such as women's and children's health.

Partnerships can improve a health program's effectiveness by reducing both risks and duplication of investment activities. The 300 active partnerships in the Directory go beyond corporate social responsibility or the model of a donor and beneficiary; they seek transformational engagement, addressing systemic issues to have a lasting impact. The biopharmaceutical industry, through these programs, is taking the lead in developing shared value for communities. The collaborations are designed around the core competencies and assets of each partner, and leverage existing systems to foster local ownership.

'Transformational' health partnerships

Business Social Responsibility (BSR), a global business network and consultancy focused on sustainability, has conducted an independent review of the contributions the health partnerships featured in IFPMA Health Partnerships Directory make to the health of people in low- and middle-income countries. IFPMA members' health partnerships help to:

Build stronger health systems and improve healthcare access, health awareness, and training

Pioneer innovative tools and approaches

Improve scientific knowledge in low- and middle-income countries to aid discovery of new medicines and vaccines

Help economies grow by improving health in developing countries

This report summarizes the contribution of global health partnerships to meeting global health needs, with a focus on low- and middle-income countries, and provides perspectives on how to increase the impact and scale of these partnerships going forward.

Based on BSR research and discussions with industry and stakeholders, certain approaches lead to practical and significant improvements to help global health partnerships improve and expand their impact:

- *Adopt a health needs-based approach;*
- *Engage in broad-based partnerships and multi-company partnerships;*
- *Ensure aligned partnerships to maximize shared resources and expertise;*
- *Use existing country systems and promote local ownership;*
- *Establish more comprehensive measures to track outcomes and impacts.*

ACHIEVING SUSTAINABLE AND INCLUSIVE DEVELOPMENT

The United Nations Millennium Development Goals, the ambitious strategy launched in 2000, provided governments and other stakeholders with a set of clear, concrete and achievable targets to adopt in order to improve the lives of citizens, wherever they live. Tremendous progress has been made toward achieving these goals; our industry being one of the driving forces within the private sector. In the last 15 years child mortality rates have dropped dramatically, while targeted investments in fighting malaria, and notably HIV/AIDS and tuberculosis have saved millions of lives. These achievements have come as our industry worked alongside with governments, international organizations, public-private institutions such as Gavi, the Vaccine Alliance, and philanthropic institutions such as the Bill and Melinda Gates Foundation.

The Millennium Development Goals provided the impetus for increased international investment and collaboration to improve global health. Today, global health holds a more central place in the international agenda. Governments and the private sector are coordinating more to address global health needs. The Sustainable Development Goals, the successor of the Millennium Development Goals, mark the start of the widest-ever conceived and concerted global effort to transform our world by 2030. Reflecting the reality of an integrated world, the new Sustainable Development Goals take a holistic and multifaceted approach, interweaving health considerations into all of the goals.
The Sustainable Development Goals, and in particular Goal #3 and its targets, offer an opportunity to inject a new vision that recognizes health as a driver of global economic growth.

Our comprehensive efforts to fight neglected tropical diseases

Stopping neglected diseases is achievable. Success relies on a multi-stakeholder approach to not only drive further research but also integrate environmental improvements, boost capacity-strengthening efforts, improve health policies, provide better screening and broaden availability of quality, safe and effective medicines.

Adding to their research and development efforts, IFPMA member companies are also involved in over 40 partnerships to support capacity-strengthening projects in developing economies. These programs aim to bolster local health systems, provide safe water and sanitation, and raise public awareness on disease prevention.

Moreover, the biopharmaceutical industry continues to deliver on its 2012 pledge of 1.4 billion annual treatments for tropical diseases through to 2020. The treatments work to control or eliminate the nine diseases responsible for more than 90% of the global neglected diseases burden. These donated medicines help underpin the World Health Organization's mass drug administration programs for neglected diseases. This industry's commitment is valued at more than USD 17.8 billion, making it the largest public health medicine donation program in the world.

Each year, IFPMA releases a report that captures our industry's pipeline for neglected diseases, listing projects where companies are working alone and ones where they are working with non-industry partners. These reports help keep track of our engagement and help us build a constant dialogue with the neglected tropical diseases community.

ADVANCING UNIVERSAL HEALTH COVERAGE

With 400 million people lacking access to essential health services, such as family planning, prenatal care, skilled birth attendance, child immunization, antiretroviral therapy to combat HIV and AIDS, tuberculosis treatment, and access to clean water and sanitation, governments are progressively placing emphasis on the promise of Universal Health Coverage. This has become an increasingly salient issue for developed and developing countries alike in the context of the global economic crisis, increasing healthcare demands, and still unmet medical needs. There is increasing recognition that expanding health coverage is an investment in socio-economic well-being and a key contributor to the wealth and economic productivity of countries.

While every country is unique and tailored approaches will be required, there are common challenges and opportunities faced by countries at all stages of Universal Health Coverage. Universal Health Coverage goes beyond mere supply of medicines: it addresses physical accessibility, financial affordability, and acceptability of health services by populations. As an industry, it is critical that we actively contribute to innovative thinking and responses that expand access to care issues for disadvantaged populations. We believe the business community and the biopharmaceutical industry in particular have an unprecedented opportunity to contribute to this debate and present the vision and the value that industry brings towards achieving healthier societies around the world.

Responding to crises

IFPMA supports the World Health Organization and other global health agencies in responding to crisis situations and in efforts to improve future responses. We share our expertise in finding solutions for managing disease outbreaks and other humanitarian emergencies, and in promoting global health security.

During disasters such as earthquakes or tsunamis, our member companies provide significant emergency aid, both in financial donations and donation of medicines and other medical supplies. To ensure that the assistance provided is appropriate and coordinated, our members are partnering with a range of expert medical and disaster-relief organizations.

During the 2014/15 Ebola outbreak, the R&D-based biopharmaceutical industry played an integral part within the overall response. IFPMA has engaged with the World Health Organization and contributed knowledge and expertise. The scientific community, our industry, and regulators have worked with the World Health Organization at a record pace, shaving years off usual timelines to develop Ebola vaccines, medicines and rapid diagnostics tests.

During the 2009/10 H1N1 influenza pandemic, IFPMA members responded by broadening access to vaccines and biopharmaceuticals, through commitments to research and development, large-scale donations, tiered pricing and expanded production. IFPMA is working with the World Health Organization and other stakeholders to plan and put in place the infrastructure and resources needed to ensure an appropriate response to future influenza pandemics.

ACHIEVING HEALTHY LIVES AT ALL AGES

A high-functioning health-care system is one that is able to meet health needs at all stages of a person's life, through prevention, screening, diagnosis, treatment, and care. To achieve healthy lives at all ages requires the commitment to prioritize health in all relevant policies and to involve all stakeholders, including academia, civil society, and the private sector. IFPMA calls for continued dialogue and constructive engagement involving all stakeholders to build better, durable health-care systems. There is no sector – government, civil society, or industry – that can alone drive the system-wide changes required to address the most intractable health challenges. It also requires a parallel commitment to foster an ecosystem for innovation in life sciences that will continue to enable the research, development and scientific partnerships to flourish. It is this innovation that will lead to new, patient-centered medical interventions, and health services.

Achieving healthy lives at all ages starts from combating non-communicable diseases. These conditions account for 63% of all deaths globally, claiming lives as a result of genetic or lifestyle factors. The four types of non-communicable diseases – cardiovascular disease, cancers, diabetes, and chronic respiratory disease – are responsible for 80% of deaths in low- and middle-income countries. In those countries one third of deaths occur before the age of 60. Moreover, they are a scourge of premature death and disability that not only takes lives but also cripples economies, slowing down development, and often contributing to continuing a cycle of poverty.

The biopharmaceutical industry has a key role to play by researching and developing solutions to prevent, treat, cure, and manage chronic diseases. Our industry can point to tremendous contributions to human health through its research and development of successive generations of new medicines to safely and effectively treat chronic diseases. Our industry is hard at work on the next generation of therapies. There are currently more than 4,000 new medicines in the pipeline to treat cancer, diabetes, heart disease, asthma, and mental disorders.

Besides investing in research and development of new medicines, biopharmaceutical companies are also actively involved in ensuring that medicines for these diseases are appropriate for, and made available in, resource-poor settings. Our experience and skills can be useful in many areas of the fight against non-communicable diseases, including in promoting healthy lifestyles. This is why we are involved in many partnerships addressing prevention, as it is a crucial component in tackling the non-communicable diseases challenge.

Partners in shaping healthier societies - IFPMA partnerships

As an association, we have instigated a number of innovative collaborations to strengthen health systems across low- and middle-income countries and improve the quality of care for patients. We have started several partnerships with a regional or global reach, many with a focus on the prevention of chronic diseases, which are already responsible for 63% of deaths globally.

For example, we teamed up with the International Federation of Red Cross Red Crescent Societies to develop, pilot and scale-up the implementation of '4HealthyHabits', a tool to help people in the Federation's volunteer network reduce the prevalence of chronic diseases in their community. Behavioral change in four key areas – unhealthy diet, excess alcohol, tobacco use, and physical inactivity – dramatically reduces an individual's risk of developing the four most prevalent chronic diseases: cancer, cardiovascular disease, chronic respiratory disease, and diabetes. Through a worldwide collaboration of volunteers that connect with communities on a daily basis, we have the potential to reach 3 million people with relevant information that helps them adopt healthier lifestyles.

Recognizing the huge potential mobile technology has to leap-frog and overcome barriers, IFPMA joined forces with the International Telecommunications Union's multi-stakeholder partnership 'Be He@lthy, Be Mobile', sharing with national governments best practices for mobile health strategies and providing important information on disease prevention and management direct to mobile phone users.

To save lives and stem the rising tide of cancer across Latin America and Caribbean countries, PAHO Foundation and IFPMA have entered into a pioneering partnership to strengthen prevention capacity focused on the biggest women killers – breast and cervical cancer – as well as on supporting national cancer policies and planning with improved collection of reliable data.

IFPMA is continuously looking for opportunities for productive new public-private partnerships to improve global health.

OUR MEMBERS

Founded in 1968, IFPMA is a global, non-profit, non-governmental organization. IFPMA represents the research-based biopharmaceutical industry. Our members comprise leading international companies as well as national and regional associations across the globe, and organizations who are supportive of our industry's goals.

OUR GOVERNANCE AND LEADERSHIP

IFPMA governing bodies are the IFPMA Council, a group of elected representatives from member companies and associations, and the IFPMA Assembly, which comprises the entire membership. The President is elected by the Council for a two-year term and is chosen from among the Chief Executive Officers of member companies.
Two Vice Presidents are also elected for a period of two years.

OUR EXPERT GROUPS

IFPMA has several expert committees and working groups which leverage industry expertise to develop effective approaches to health issues. Members have the opportunity to join a range of expert networks focused on their interests and expertise.

OUR COMMITTED TEAM

At the core of our daily operations an international and multidisciplinary team leads on and supports our global programs and activities.

OUR RESOURCES

IFPMA in-house publications are key tools in advocacy outreach on different topics. We also commission third party research to support our advocacy programs with extensive empirical evidence.

The IFPMA corporate website is a comprehensive information resource. We regularly publish a wide range of position papers, news releases, articles, blogs, infographics, animations, and video interviews to inform policymakers, media and the general public.

Additionally, the IFPMA Health Partnerships Directory is the most comprehensive international database for health development programs involving the research-based biopharmaceutical industry. Each partnership profile offers valuable insights into why a specific program was developed, and the ways in which it is helping to make a difference to communities around the world. Content can be filtered by disease area, program type, country and partner organizations.

STAY CONNECTED

Learn more and stay connected **www.ifpma.org**

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