

Committed to a Healthier Future 2016 IFPMA General Assembly 30 November 2016

Opening address by Dr. Stefan Oschmann President, IFPMA,

Chairman of the Executive Board and CEO, Merck KGaA, Darmstadt, Germany

Thank you, Eduardo for your kind introduction.

Good morning Partners, Colleagues, Ladies and Gentlemen. I'd like to warmly welcome all of you to the 28th IFPMA General Assembly.

I am pleased to give this morning's opening address. It has been a great honor for me to serve as IFPMA's President over the past two years. I took great pride in representing an industry that is spearheading the biomedical revolution and that is making an enormous contribution to humanity. This contribution is shown for example by our ability to better treat or, in some cases, even cure diseases such as AIDS, rheumatoid arthritis, hepatitis C or cancer.

These successes have bolstered the expectation that we will not only live longer but will also be able to enjoy old age in better health.

Let me start my address by thanking those who have supported me during my tenure: my two Vice-Presidents, Isao Teshirogi and Robert J. Hugin, all of the company representatives serving on IFPMA committees and of course the staff of the IFPMA Secretariat. Thank you all for your dedication and your hard work – whether you played a public role or were active behind the scenes.

I want to especially thank Director General Eduardo Pisani, who will be leaving his role at the end of January.

Eduardo, over the past seven years, you have significantly strengthened IFPMA and turned it into the respected and credible voice of the biopharmaceutical industry that it is today. It has been a true pleasure to work with you. Thank you for your leadership and all the best for the future.

Today, our industry faces a dynamic and increasingly complex environment. The global health landscape is continuously evolving. Let me briefly emphasize four key trends that have shaped our industry over the past two years:

Firstly, the UN Sustainable Development Goals that were adopted in September 2015 go beyond the traditional focus on vertical programs. The SDGs emphasize universal health coverage and the need to focus on non-communicable diseases. They explicitly underscore the need to build 'fit-for-purpose' partnerships with multiple stakeholders to advance sustainable development.

Secondly, global health security is now a key item on many governments' agendas. The Ebola epidemic triggered a major shift in the world's attention on the need to strengthen health systems.

Political leaders realized that building strong and resilient health systems in the context of universal health coverage is necessary in order to tackle outbreaks of this scale. The growing threat of antimicrobial resistance and the Zika outbreak further emphasize the significance of global health security.

Thirdly, global health governance has become an important topic. The Ebola crisis has brought the role of WHO in global health into focus. Key to the debate were WHO's policies for engagement with non-state

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actors. As an industry, we welcome the constructive rules agreed upon in the Framework for Engagement with Non-State Actors.

The framework continues to allow for private public partnerships. This is critical, because, let me reiterate: The world cannot accelerate global health without partnerships. The problems are too complex for any one group to address. This requires the private sector, civil society, and patient organizations to all strengthen their voices and contribute to global health. I am particularly sensitive to this topic since I know that there are many negative perceptions regarding the private sector – including the industry. But let us not judge each other based on preconceived notions, but rather by what we contribute to global health.

That also holds true for my fourth point: Various stakeholders are increasingly expressing concerns about the affordability of medicines. Voices such as the UN High Level Panel, WHO's fair pricing initiative, the recently launched Lancet Commission on Access to Medicines in the context of Universal Health Coverage and OECD's focus on high price medicines all address this issue. As an industry, we must not shy away from discussions about drug prices. Especially given the fact that these discussions so far have been rather one-sided and not always evidence-based. The UN High Level Panel, for example, entirely ignored the role of health systems in improving access to medicines and only narrowly focused on IP. But more on this later.

When I assumed the office of IFPMA President two years ago, one central question was on my mind: How can we as an industry contribute to accelerating access to health for people globally, and particularly in low-and middle-income countries?

I believe that improved access to health services is core to sustainable economic and social development. But improving access to health is complex and multifaceted – so partnerships are key.

When we adopted the strategic plan for IFPMA two years ago, we recognized the need to work with partners from government, civil society, philanthropy and the private sector. To tackle existing and emerging global health challenges, IFPMA has focused on four key areas:

- Sustainable health policies,
- access to innovation and IP.
- science-based regulatory frameworks, and
- trust and ethics.

There have been so many great accomplishments in all of these fields that it would exhaust this Assembly's timeframe to name them all. Let me concentrate on a few critical issues.

During the past two years, IFPMA has made progress with major health policy initiatives. We have furthered sustainable health policies around the world and addressed some of the most pressing needs.

We put a special emphasis on embedding our sustainable health policy advocacy within the framework of universal health coverage.

The joint industry principles on UHC embody our views on the importance of quality and accessible healthcare for all populations. We especially highlight the importance of building strong health systems and of leveraging the private sector's strengths in the development and delivery of medicines. IFPMA has identified and mapped multiple industry programs that are already contributing to UHC and provide a solid basis for scaling up our efforts.

Another key element of our work has been the mounting global challenge of non-communicable diseases. There still is a lot of work to be done in this area:

NCDs already are the world's number one killer. Worldwide, they account for 60 percent of deaths.

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- Low- and middle-income countries bear the largest burden as four out of five global deaths occur there. Therefore, already today, NCDs present an urgent development issue.
- And the problem continues to grow: Globally, the NCD burden will increase by 17 percent in the next 10 years. Africa will see an increase of 27 percent.
- Over the next 20 years, NCDs will cost more than 30 trillion US-Dollars that is about half of global GDP in 2010.

Our NCD framework is the solid foundation which guides us. It addresses key issues such as innovation, availability, patient empowerment, and capacity building. Based on this foundation, we have launched several projects.

We are partnering with the PAHO Foundation for the Women's Cancer Initiative in the Americas to raise awareness of breast and cervical cancer and to improve the quality of national cancer registries in the region.

We can make a real impact in this field: Many of the 120,000 deaths from breast and cervical cancer in the Americas each year could be prevented. This is precisely our goal. Our Women's Cancer Initiative in the Americas aims at empowering women and health care professionals to improve the prevention, screening and treatment rates of breast and cervical cancer. Moreover, many health systems do not have the data necessary to develop effective national cancer policies. We are working to improve the quality and completeness of cancer data and reporting. And we are making tangible progress – for example on cervical cancer screenings or with regard to improving the quality of cancer data.

Breast and cervical cancer also pose a huge problem in Africa. Therefore, we have teamed up with WHO's regional office to initiate the "AFRO Comprehensive Cervical Cancer Prevention and Control Initiative". Just like in Latin America, we are working to raise awareness and help to improve prevention, screening and treatment rates.

Furthermore, IFPMA is working with partners to help contribute to the WHO Global Action Plan for the Prevention and Control of NCDs.

With our partners of the International Federation of Red Cross and Red Crescent Societies, we have helped thousands of people in low-income countries understand the major risk factors for NCDs and change behavior towards healthier choices. We have engaged in a cutting-edge initiative with the International Telecommunication Union and other partners called "Be Healthy, Be Mobile", which applies to NCD prevention the benefits of mobile technology.

Yet, our commitment is by far not limited to NCDs. Rather, IFPMA member companies and associations play a vital role in combating infectious diseases.

We support efforts to strengthen pandemic preparedness across the globe. The Ebola outbreak in West Africa was a case in point. Early in my presidency, I participated in high-level discussions within the G7 forum to examine ways that the health sector, including the pharmaceutical industry, can respond to pandemic emergencies such as this in the future. I had the chance to raise this issue with political leaders such as Angela Merkel. These discussions helped frame the G7 statement on pandemic preparedness in 2015.

Moreover, through the Private Sector Roundtable of the Global Health Security Agenda, our industry together with other sectors is making an important contribution to detecting, preventing and defending the public against emerging health crises.

Finally, in January of this year, our industry signed the Joint Industry Declaration on Combating Antimicrobial Resistance. The industry is committed to encouraging more appropriate use of antibiotics. We are willing to extend collaboration with academia and public agencies and to improve how R&D is done in the field.

International Federation of Pharmaceutical Ch. Des Mines 9 P.O. Box 195 1211 Geneva 20 Switzerland

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And we support initiatives aimed at affordable access to antibiotics. I am very pleased that IFPMA will be the hosting secretariat for the industry's AMR declaration.

Access to health depends not only on the broad availability of innovative drugs but on the availability of health services in general. And it is obvious that a narrow focus on IP, as was the scope of the UN High Level Panel, will not do justice to the multi-factorial reasons why patients in many low- and middle-income countries do not have the access to the life-saving medicines they deserve and need.

To tackle the problem, for example by accelerating access to drugs for non-communicable diseases, we all have to leave the trenches, analyze the real hurdles to access, and work in partnership to overcome them. Over the past few years I have seen a number of encouraging examples where partners from different segments of society have moved from ideological conflict to pragmatic collaboration. For example, I strongly believe that the industry's traditional business model based on strong IP and adequate reward for the successful innovator is still by far the best driver of future innovation. However, it is a fact that innovation is getting harder and there are areas – for example neglected tropical diseases – where collaboration is key.

Personally, I have noticed that the borderline between open innovation and competitive innovation has shifted. We now see multiple collaborations and partnerships in all areas of R&D – between academia, small and medium sized enterprises but also large companies. From an IFPMA perspective, our engagement for the AMR Initiative and the collaboration with WIPO Re:search are examples of how the private sector engages with international agencies and researchers to promote innovation and access to medicines in new ways.

At the same time, pharmaceutical innovation needs the right environment to thrive. IFPMA has rightfully advocated for strong IP systems for innovation and actively engaged in a constant dialogue with various interest groups on this issue. I had the opportunity to help drive the creation of the International Chamber of Commerce's cross-industry principles for creating and nurturing innovation ecosystems. They were launched last year in Geneva.

The principles recognize that to make innovation thrive, it takes efforts to build investor confidence. It takes skilled workers and markets that are open to trade and investment.

And it takes adequate IP systems to incentivize investments. In the light of these principles, the UN High Level Panel's recommendations seem rather misguided. The panel failed to advance a solutions based approach together with the industry and other key stakeholders. In my opinion, this was a missed opportunity.

To fully realize the goal of accelerating access to health, we need an effective and appropriate regulatory framework. Over the past several years, IFPMA has become more visible in the global regulatory policy arena.

A critical regulatory issue we worked on is supply chain assurance. Globalization has led to increasingly complex supply chains. For these, integrity and resilience are critical. Disruptions can lead to drug shortages. To make supply chains run as smoothly as possible, IFPMA has advocated for regulatory system convergence.

This is critical to provide timely and reliable access to medicines for patients around the world. For example in Africa, IFPMA's Africa Regulatory Network is actively engaging with relevant authorities and other stakeholders to encourage greater harmonization and convergence of regulatory requirements.

Furthermore, IFPMA collaborated with WHO on the enhanced pre-qualification program for vaccines and medicines. WHO supported the industry's proposed funding models, stating that they meet overall objectives of fairness, transparency, and sustainability.

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As a result, WHO announced the new funding arrangements last September and the new fee scheme will be implemented in January 2017.

Ladies and Gentlemen,

All the initiatives I have just outlined will be meaningless if our stakeholders lose their trust in us. Trust must be earned through transparency, engagement with key stakeholders and through the ethical conduct of business on our side. Persistent ethical conduct builds trust.

But just one incident of unethical business practice can destroy it. The importance of ethics therefore cannot be underscored enough.

Over the last two years, IFPMA took the global lead in strengthening ethics across the global pharmaceutical industry.

We helped to build industry capacity through workshops and training sessions in many parts of the world. Let me just give one example: Members of IFPMA's code compliance network helped engage with associations around the world to provide training and advice to member associations and companies.

Ladies and Gentlemen,

I share the view of Gro Harlem Brundtland, who once emphasized: "Health is the core of human development."

It reaffirms the very mission of our industry: to advance global health and to further human development. IFPMA has contributed to this end in the last two years. We have addressed some of the most pressing medical needs. We have worked hard to accelerate access to health. And we are ready to make further contributions. That includes taking into account affordability based on differential or tiered pricing. But these efforts will only be possible if two conditions are met. Firstly, intellectual property rights must be respected. Secondly, drugs sold at differential prices reach those for whom they are destined.

Considering the major global health challenges I just outlined, there still is a lot of work to do. With this in mind, I have been working to reshape the scope and focus of IFPMA. This is reflected is our new strategic plan. That plan includes a strong focus on topics such as universal health coverage and NCDs and a reinvigorated IFPMA governance framework to prepare it for the future.

We must build on these foundations. Today, I hand over the office of IFPMA President. And under lan Read and the new IFPMA leadership, I am confident that this organization will continue to work hard in order to accelerate access to health for everyone.

Although my tenure comes to an end, you can count on me in the future. I will continue to vigorously support our industry's efforts to join our partners in enhancing healthcare for the benefit of patients worldwide. Thank you.

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