Committed to a Healthier Future: a report from the 2016 International Federation of Pharmaceutical Manufacturers and Associations General Assembly

Written by Tara Bracken, PhD, Sabin Vaccine Institute

Ensuring sustainable use of innovative medicines by patients in 2030

Representatives from the biopharmaceutical industry and global health experts from around the world convened to address the question of how to ensure sustainable use of innovative medicines by patients in 2030 at the 28th Assembly of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). On November 30th, more than 130 global health leaders from intergovernmental organizations, nongovernmental organizations, academia, stakeholders, partners, and the research-based pharmaceutical industry attended the event in Washington, D.C. The theme of this year's assembly was "Committed to a Healthier Future."

The primary challenges to ensuring equitable access to medicines highlighted at the Assembly included the growing global burden of noncommunicable disease, creating a space for innovation in low- and middle-income countries, the need to secure IP rights, and a lack of sufficient regulatory capacity building and understanding of regulatory frameworks. Intersectorial cooperation, innovative business models and fostering trust with the public were identified as key opportunities to address these challenges.

Over the last two years, under the leadership of outgoing President Stefan Oschmann, IFPMA has placed special emphasis on embedding sustainable health policy advocacy within the framework of universal health coverage, highlighting the importance of building strong health systems and leveraging the private sector's strengths in developing and delivering medicines. IFPMA was also an active participant in the global regulatory policy arena, collaborating with the World Health Organization on the enhanced pre-qualification program for vaccines and medicines and advocating for regulatory system convergence and harmonization to ensure steady supply chain. This year's IFPMA Assembly served as an opportunity to strategize on how to build on that foundation under the new leadership.

International journalist Riz Khan led a series of moderated discussions consisting of representatives from the biopharmaceutical industry, the World Health Organization, the World Bank, academia and the non-profit sector to identify challenges and opportunities facing the global health community in ensuring improved access to and sustainable use of innovative technologies and medicines. Dr. Peter Hotez, President of the Sabin Vaccine Institute and Dean for the National School of Tropical Medicine, Baylor College of Medicine, gave the keynote address on neglected tropical diseases.

Challenges in a Changing World: Dr. Peter J. Hotez calls for action to help take emerging and neglected tropical disease innovation to the next stage of development.

In his keynote address, Dr. Peter Hotez, President of the Sabin Vaccine Institute and Dean for the National School of Tropical Medicine, Baylor College of Medicine, highlighted the significant role the pharmaceutical industry has played in the success of the Millennium Development Goals. "It's been an extraordinary success story, and it turns out that the successes are attributed to the people in this audience through the pharmaceutical industry," said Hotez.

Hotez noted the remarkable progress to reduce child mortality and combat HIV/AIDs, malaria and other diseases of global health concern. Goals two and four of the Millennium Development Goals inspired the creation of the United States President's Emergency Plan for AIDS Relief (PEPFAR), a 30 percent reduction in global malaria cases and deaths, and a 50-90 percent reduction in childhood deaths from vaccine preventable diseases. "You did that," Hotez told the Assembly. "This is the pharmaceutical industry stepping up and producing vaccines and antiretroviral drugs and getting them out there. When the history of global health is written, I think this has to be considered an important part of it," said Hotez. He also pointed out the impact of the pharmaceutical industry on neglected tropical diseases. Donations from most of the major multinational companies have resulted in dramatic reductions in the global prevalence of diseases such as lymphatic filariasis, onchocerciasis, trachoma and leprosy.

Despite these gains, the last five years have seen the rise of new emerging and neglected diseases. These diseases tend to fall into two categories: vector-borne diseases such as dengue, Zika and Chagas disease, and zoonotic diseases such as Ebola and coronavirus infections. Hotez described the current situation as a game of "global health whack-a-mole," in

which the reduction in some diseases is followed by a rise in the vector-borne and zoonotic neglected and emerging diseases.

Hotez went on to describe the new global forces promoting the emergence of vector-borne and zoonotic diseases invoking the framework of the Anthropocene – the epoch shaped by human migrations, urbanization, climate change, global conflict and the shifting character of global poverty. For example, these diseases have risen dramatically in the conflict zones of the Middle East and North Africa and have spilled over into Southern Europe, evidenced by the return of malaria and the emergence of dengue, chikungunya, leishmaniasis and West Nile virus and even schistosomiasis in Corsica.

One effect of these Anthropocene forces is an important shift in where poverty is found. "Today, most of the poverty-related neglected diseases are found among the poor living in G20 nations," according to Hotez, a new concept he calls "blue marble health." For example, Hotez estimates that there are 12 million people living with at least one poverty-related neglected or emerging disease in the United States.

According to Prof. Hotez, dialogue between sectors will be critical to address the emerging and neglected vector-borne and zoonotic diseases. "Solving this problem will require an unprecedented dialogue between industry and academic partners, and even within the academy to have fertile cross-discussions between different academic disciplines beyond the biomedical scientists, including experts in economics, political science, sociology, climate change and geophysics. We'll need to break down traditional siloes."

Hotez concluded his address with a call for the industry to enable continued progress through investment in emerging and neglected tropical disease research and development, particularly for vaccines. Product development partnerships such as that of the Sabin Vaccine Institute have successfully brought several NTD vaccine candidates through the early stages of clinical development; however, it is unlikely they will be able to bring these vaccine candidates to market on their own. "I don't think we have the horsepower to make it through the next stage," said Hotez. "This is where we really need the multinational pharmaceutical companies to guide us through that next step. We relied on you for success in the Millennium Development Goals, and you stepped up to the plate and hit it out of the ballpark. We're going to have to call on you again. We need you and I think this is going to be a game-changer; I think we can solve these problems."

Non-communicable Diseases: the IFPMA Assembly acknowledges the growing burden of non-communicable diseases as a significant global health concern, identifies the need for investment in basic health infrastructure and improved access to existing medicines as top priority.

Hotez's keynote set the stage for a major discussion point of the IFPMA Assembly's discussion panels: the response to the growing global burden of noncommunicable diseases (NCDs). Though no one underlying cause for the increased prevalence of NCDs has been identified, it is clear that with the victories against communicable diseases stemming from the Millennium Development Goals, NCDs like diabetes and hypertension are on the rise.

The first discussion of the assembly featured Dr. Cary Adams, CEO of the Union for International Cancer Control; Dr. Anselm Harris, Director of the Department of Noncommunicable Diseases and Mental Health at the Pan-American Health Organization; Professor Kenji Shibuya, Professor and Chair of the Department of Global Health Policy at the University of Tokyo; Dr. Durhane Wong-Rieger, President and CEO of the Canadian Organization for Rare Disorders; and Dr. Andreas Seiter, Senior Health Specialist for the World Bank's Health, Nutrition and Population Global Practice.

The afternoon discussion panel included Dr. Peter J. Hotez, President of the Sabin Vaccine Institute and Dean of the National School of Tropical Medicine at the Baylor College of Medicine; Dr. Brendan Shaw, IFPMA Assistant Director General; Mary Lou Valdez, Associate Commissioner for International Programs at the United States Food and Drug Administration; Dr. Bente Mikkelsen, Head of the WHO Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases Secretariat; and Professor John Reeder, Director of the WHO Special Programme for Research and Training in Tropical Diseases.

Dr. Cary Adams, CEO of the Union for International Cancer Control, highlighted key challenges facing the global health community as it addresses this growing disease burden. "The statistics from the WHO suggest that by 2030 the number of deaths due to NCDs will increase by 12 million – NCDs will be responsible for five times the number of deaths than communicable diseases, so that's a massive growth and something that needs to be addressed by the community." Adams says the aging population due to global health improvements are key driving to NCD incidence around the world. Hotez added that NTD comorbidities are likely significant underlying causes of NCDs among poorer populations.

When asked about the role of innovation in addressing NCDs, Adams admitted that while innovative drugs are important, they are only important in context. "If you look at most low- and middle-income countries, there is no chance that they will have access to innovative drugs in the next ten to 15 years," he said. "They don't even have access to the older/generic essential medicines and the essential technologies to address the NCD burden, which is growing year by year."

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Adams explained that the global health community has set a goal of achieving 80 percent availability of essential medicines and technologies required to treat major NCDs by 2020, but that there is still a long way to go to achieve that goal even before moving to increase access to innovative drugs. One of the key challenges of using innovative drugs in this context is the lack of basic health infrastructure to administer them in the first place. "I think there needs to be a lot of investment over the next ten to 15 years in the basic health infrastructure," said Adams. "There's a whole series of challenges around understanding the nature of what is in place today and what we need to put in place in the future in order to address the diseases. We can't just deliver the drugs and hope it is going to be ok."

Partnerships: intersectorial cooperation is critical to address existing and emerging global health issues.

Adams also described partnerships and cooperation as being essential to resolving key global health issues over next decade – a theme of most of the day's conversations. "I'd say that's the most important innovation that we have to put in place over the next ten years – the ability to work cross-sector on specific areas where there will be some conflicts," said Adams. "The ambition to resolve the health issues that we're trying to address can only be achieved through partnership across sectors." Adams noted that there have been recent improvements in collaboration within the pharmaceutical industry over last five years, citing more open dialogue between competitors to work together to solve global health problems.

Dr. Durhane Wong-Reiger, President and CEO of the Canadian Organization for Rare Disorders, described improvements in intersectorial partnerships and how they work toward a common goal – healthier populations. "What's really evolved – and in rare diseases this is hugely the case – is that willingness of the companies to invest way beyond the drugs. We talk about innovative drugs, but we also need invest in everything else – the identification, the training of clinicians, raising support in terms of the community and especially the patient organizations."

Oschmann referred to an emphasis on partnerships as his personal "mantra." He noted what he considers a favorable shift in the balance between open and competitive innovation within the biopharmaceutical industry toward more intersectorial collaboration. "The world cannot accelerate global health without partnerships," said Oschmann. "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."

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Incoming President Ian C. Read echoed Oschmann's sentiments, stressing the importance of novel partnerships to solve the complex problems facing the global health community. Through these partnerships, Read hopes the pharmaceutical industry and the global health community can develop innovative health finance and risk-pooling mechanisms, remote training and health workforce retention solutions, and sustainable business models and tiered pricing strategies in order to improve access. He also hopes to leverage existing and novel partnerships to allow for improved management of infrastructure and capital investments, implementation of mechanisms for governance and accountability, development

of a sound policy environment. Lastly, he believes intersectorial partnerships will enable health system strengthening and regulatory harmonization, implementation of new access programs and enhanced data collection and analysis to inform health policies and investment decisions.

Dr. Andreas Seiter, Global Lead, Private Sector, Health Nutrition & Population Global Practice, World Bank, highlighted the need to foster trust in the private sector in order for such partnerships to thrive. In order to address that need, the World Bank is now providing an opportunity to encourage better understanding between the private sector and those critical of it by creating a neutral platform for person-to-person dialogue. "It is becoming apparent that there's no way of reaching universal health coverage without the partnership and strong participation of the private sector broadly," said Seiter.

The WHO and Pan-American Health Organization (PAHO) are similarly acting as convening forces to help identify and overcome hurdles standing in the way of inter-sector cooperation. "I represent a mechanism that is part of the solution," said Dr. Bente Mikkelsen, Head of the WHO Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases Secretariat. "Many NGOs have never been in the same room as representatives of the private sector. I think there is a lot of misunderstanding and lack of dialogue and real information exchange between the sectors." To address this problem, in 2014 the WHO organized a secretariat consisting of 350 members – of which IFPMA was one of the first – to facilitate dialogue between sectors and to aid in the realization of commitments already made by member states.

Dr. Anselm Hennis, Director of the Department of Noncommunicable Diseases and Mental Health at PAHO, emphasized that transparency is key during such dialogue, and PAHO acts to facilitate more open conversation by being as inclusive as possible. "We have convened meetings, for example around HPV tests and HPV vaccines, whereby we bring everyone to the table together, we vet them, we make sure the products they are offering meet certain standards and we have independent representation from countries to see what's available and make independent determinations."

Collaboration between stakeholders in different sectors isn't only happening at the global level, but also at a national level. Dr. Kenji Shibuya, Professor and Chair of the Department of Global Health Policy at the University of Tokyo, detailed such cooperation centered on the most recent G7 summit, hosted this year in Ise-Shima, Japan. "The Prime Minister really was keen to push the agenda of global health given the fact of health security and other issues, and he called up not only the minister of finance, the minister of health and the minister of foreign affairs, but he also approached the private sector." The result was the creation of a new pandemic emergency facility fund similar to the Coalition for Epidemic Preparedness Innovations. "So collaborating with different stakeholders to ensure the stability and also the access to those who are really in need of essential services – that is happening in global health but also in domestic health policy."

Improving Access to Innovation: strong intellectual property systems, investor confidence and markets that are open to trade and investment are essential to enable universal access to innovation.

Panelists at the IFPMA Assembly identified the need to create an environment that better enables universal access to innovation as a key challenge to address. "I think that's something that we don't really talk enough about," said Hotez. "From my perspective, just like people have a fundamental right of access to food, water, shelter and essential medicines, they have a right of access to innovation."

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IFPMA Assistant Director General Dr Brendan Shaw emphasized that intellectual property (IP) is a strong enabler, rather than a barrier, for access to both current and future innovative medicines and technologies. "There have been 500 medicines made over the last couple of decades. Pretty much all of them have come out of the pharmaceutical industry, and intellectual property has been an important precondition for the development of those medicines," he said. He explained that innovation in the pharmaceutical industry is long, complex and capital-intensive, and that intellectual property rights are necessary to make it possible for companies to reasonably embark on such a risky endeavor. "If we're going to have the next generation of vaccines and medicines available, we're going to need IP as precondition for this to occur."

In his opening address, Oschmann stressed that a focus on IP alone will not solve the problem of why access to medicines is limited in low- and middle-income countries. “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 multifactorial reasons why patients in many low- and middle-income countries do not have the access to the life-saving medicines they deserve and need.”

According to Oschmann, the right environment – characterized by strong IP systems, solid investor confidence and markets that are open to trade and investment – needs to be carefully cultivated in order for pharmaceutical innovation to thrive. “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,” said Oschmann. “However, it is a fact that innovation is getting harder and there are areas – for example neglected tropical diseases – where collaboration is key.”

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Hotez agreed with Oschmann that IP enables access to innovation but that there is much work to be done to figure out how to use it for that purpose more effectively. He believes significant opportunities lie in an organization the World Intellectual Property Organization (WIPO) created in 2011 to further the development of new medicines and technologies for NTDs, malaria and tuberculosis through innovative partnerships – WIPO Re:Search.

Tom Bombelles, Head of Global Health in WIPO’s Global Challenges Division, explained that though IP systems work in most markets, there are areas where market-driven solutions don’t apply. For example, there is no economic pull for innovation in NTD treatment and diagnostics because the primary populations that will use them cannot afford to pay for them. WIPO Re:Search was created to help fill that market gap.

“We really have to look at these access initiatives. Yes, the system works, but how does it need to be changed and adjusted?” he said. “What are the solutions to sustain the innovation that’s happening and to make sure that access also is being delivered with the same efficiency or even greater than the innovation is coming out of the pipeline?”

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One way in which WIPO is working to fill that gap is through a partnership with BIO Ventures for Global Health, led by President Jennifer Dent. At the IFPMA Assembly, Dent introduced a WIPO pilot program launched two months ago to help inventors in low- and middle-income countries navigate and benefit from existing IP systems. The industry is also already working on improving access to new medicines through strategic pricing and voluntary licensing and performance agreements.

Creating Space for Innovation in Low- and Middle-Income Countries: innovative business models are needed to improve access and create a space for research and development in low- and middle-income countries.

Bomballes noted that the global debate on improving innovation access in low- and middle-income countries has evolved over the last year to consider more than just IP. It has become increasingly clear that in order to create space for research and development in areas where market solutions don’t work, innovation is required not just around products, but also around business models.

In order to fill the research and development gap for products that don’t stand to make a large profit, novel business models will need to be developed and adopted. “The problem isn’t the technology – for the most part, the technology has outpaced our political, social and financial instruments to figure out this gap. And that’s where we need the innovation – the finance models, the economics – in order to figure out how these partnerships can be made,” said Hotez. Director of the WHO Special Programme for Research and Training in Tropical Diseases. Professor John Reeder agreed, saying research is needed not just for products but also for implementation, in order to identify how to effectively bring new products into an existing system.

Reeder suggested that changes to the research and development process that create a target-product profile that has access built into it will go a long way toward ensuring delivery of innovation to the people who need it. “This will allow us to think about the attributes of those products that would allow them to reach populations in the end,” he said. “So basically giving people what they’re asking for instead of what you think they want. It’s really important to engage with scientists and practitioners in disease-endemic countries.”

According to Shaw, this is already happening to some extent. “There are companies playing around with business models, trying new things both in the patented and generic space,” said Shaw. “We’re seeing companies come with new access strategies around pricing or delivery, and that’s really encouraging. I think that the encouraging thing is that the industry is doing this; this is actually industry innovation that’s driving this.” Shaw explained that the key to changing business models to improve access is to give companies the space and the predictability in the policy and business environment to allow that innovation to happen. For example, the regulatory barriers surrounding pricing strategies currently prevent companies from coming up with innovative tiered pricing solutions.

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Martin Bernhardt, Vice President of Relations with International Institutions at Sanofi, recounted challenges he faced while exploring a new business model due to a lack of will in-country to help to put these new systems in place. “As part of our responsibility to find new pricing approaches when it comes to going to countries with poor resources, with three other companies in this room, we ran two pilots in developing economies to improve access to NCD medicines, including an innovative one,” he recounted. In the end, it took two years working with the government to put the pilots in place, then another year to get sufficient information from the study to draw conclusions. Though according to Mikkelsen the WHO is trying to find a construct for a platform to facilitate the implementation of such programs, a dearth of data in nearly every relevant area has hindered their efforts.

Innovation and capacity building for regulatory frameworks: Fostering a better understanding of regulatory frameworks and significant regulatory capacity building are critical for improving access to innovation

In 2011, the United Nations General Assembly declared that there should be increased collaboration with the private sector to improve access to essential medicines for NCDs. However, Mikkelsen recounted that it quickly became clear that one of the main obstacles to improving access was lack of regulatory capacity building and understanding of regulatory frameworks.

“This is an essential area of this solution - to be sure we can fix the regulatory side. There is a lot of work being done to ensure regulatory capacity building,” added Greg Perry, Executive Director of the Medicines Patent Pool. The Medicines Patent Pool serves as a mechanism to facilitate these changes, and has already successfully worked with seven companies within IFPMA to accelerate the speed and supply of essential HIV products in developing countries, while simultaneously reducing prices and ensuring access.

Mary Lou Valdez, Associate Commissioner for International Programs at the United States Food and Drug Administration, added that because regulatory systems are not well understood or appreciated, the industry needs to develop innovative ways to disseminate data that will start the dialogue on the necessity of regulatory capacity and frameworks. She stressed the need to work together to make the case for investment and to contribute to economic viability of innovation in these areas. She suggested that the first step the pharmaceutical industry needs to take in this area is to work together to understand each other’s different approaches and perspectives. “Four percent of the world’s population lives in United States, which means most of the innovation to come will come from outside our borders,” she said. “It really forces us to look at other vantage points.”

Valdez also argued that an important motivation to build regulatory capacity and encourage innovation is to combat counterfeit medicines. “It’s not all about lack of access – there’s a lack of infrastructure tied to it,” Valdez said. “There is a real dollar cost and negative impacts to country growth and wellbeing if we don’t address counterfeit products.”

Vision of a Healthier Future

This IFPMA assembly marked the last event held during the tenures of IFPMA President Stefan Oschmann, Chairman of the Executive Board & CEO at Merck KGaA, and IFPMA Director General Eduardo Pisani. “I look with great pride at the

industry in its current and future state. We are spearheading a biomedical revolution that is making an enormous contribution to humanity," Oschmann said.

In his opening remarks, Pisani acknowledged the members of IFPMA for their efforts in the field of global health. "Our industry is one part of the solution to address global health challenges, and we have a crucial role to play. We are committed to improving people's lives and we intend to engage with the health community and beyond, and help find answers and take action to overcome the challenges," said Pisani.

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Since his election 2014, Oschmann led the organization through historic shifts in the global health arena, including the adoption of the Sustainable Development Goals and a renewed focus on affordability of medicines, global health security and global health governance following the Ebola epidemic. Oschmann also led IFPMA through the adoption of a strategic plan intended to bring the industry's mission of advancing global health and furthering human development.

Oschmann highlighted four key focus areas that helped IFPMA tackle existing and emerging global health challenges during his tenure as president: sustainable health policy, access to innovation and intellectual property, the development of science-based regulatory frameworks and building trust through ethical conduct of business.

Embracing Innovation for 2030

At the close of the event, incoming IFPMA President Ian C. Read, Chairman of the Board and Chief Executive Officer at Pfizer, outlined his plan for the future of IFPMA and its role in the global health community. "IFPMA is well-positioned to inform the development of public policies that promote solutions while enabling health systems to address the barriers preventing health care access," said Read. In order to accomplish these goals, IFPMA must advocate for solutions that embrace innovative partnerships with governments and market-based incentives that support the development of new medicines, promote innovative solutions for health services and delivery, ensure adequate health care access for all and emphasize the value of government investment in their health systems.