



Innovating Together for Global Health

The role of pharmaceutical innovation in improving public health took center stage during the 26th IFPMA Assembly, which was attended by over 200 participants from the public and private sectors.

Under the theme "Innovating Together for Global Health," the biennial global pharmaceutical industry conference held in Geneva on 31 October 2012 focused on essential biopharmaceutical contributions to public health, the industry's continued commitment to innovation, and the importance of effective health partnerships in meeting the world's most pressing health challenges.

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Director General Eduardo Pisani opened the proceedings, highlighting the industry's commitment to innovation despite new and increasingly complex challenges.

"Innovating today is becoming harder – serendipitous discovery of 'one size fits all medicines' has become extremely difficult and costly, patients demand safer and more effective treatments and this is reflected in regulatory requirements becoming more and more stringent. As an industry, we need to change and adapt in order to meet the new challenges we are faced with," Mr Pisani said.

Additionally, Dr John C. Lechleiter, Chairman, President and CEO of Eli Lilly and Company, and newly elected President of IFPMA, gave his inaugural address, setting the industry direction for the next two years. In particular, he called for policies that encourage innovation, a continued commitment to building trust with stakeholders, and a strengthening of health partnerships.

High-level stakeholders from public policymaking, global health organizations, research, and industry discussed various aspects of innovation during three panel sessions. Internationally renowned journalist Riz Khan, who has worked for the BBC, CNN, and Al Jazeera, moderated the panel discussions.

Other conference elements included dynamic videos, filmed interviews, and the "Innovation Hub," which allowed participants to discover cutting edge examples of some of the latest examples of health solutions.

Fostering an Innovation Ecosystem

Newly elected IFPMA President, Dr John C. Lechleiter, Chairman, President and CEO of Eli Lilly and Company

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Fostering an Innovation Ecosystem



“When it comes to healthcare policy, we need to speak up for policies that sustain and encourage innovation and against those that would undermine it.”

As the newly elected IFPMA President, Dr John C. Lechleiter, Chairman, President and CEO of Eli Lilly and Company, gave an inaugural address that focused on the essential role of medical innovation and the importance of encouraging sustained biopharmaceutical innovation in the years ahead. He also called on the entire global health community to “do your job” in finding much-needed health solutions while promising the industry would continue doing its part.

“The cumulative impact of medical innovation is nothing short of mind-boggling,” said Dr Lechleiter. From the number of lives saved and lives prolonged to economic and societal benefits, the total contribution of innovative medicines is difficult to calculate.

Since 1928, more than 200 million lives have been saved from antibiotics; in the last decade, an estimated 2.5 million children’s lives have been saved from measles, polio, and diphtheria, pertussis, and tetanus (DPT) vaccines; and in recent years, treatments for HIV/AIDS has led to a dramatic decline in mortality rates from the disease.

The average life expectancy at birth has increased by more than 50 percent in less than a century and, in terms of economic benefits, biopharmaceutical innovations have allowed for healthier, more productive societies the world over. Despite these monumental gains, Dr Lechleiter cautioned that such progress should not be taken for granted.

“We need ongoing innovation to tackle diseases that range from those that come with little warning—such as the H1N1 virus—to infections caused by resistant microorganisms to those associated with

people living longer and longer—like cancer and Alzheimer’s, to name a few. Without new breakthroughs, we risk a human and economic catastrophe.” he said. While the biopharmaceutical industry has hundreds of potential medicines for both noncommunicable and infectious diseases in development, companies face increasing challenges in bringing new medicines to market. In this context, Dr Lechleiter called on pharmaceutical industry leaders to “stand up for innovation”.

“When it comes to healthcare policy, we need to speak up for policies that sustain and encourage innovation and against those that would undermine it. What I call an ‘ecosystem’ of innovation has several important elements—among them sound intellectual property protection and a regulatory system that keeps pace with 21st century science,” he explained.

Placing medical innovation at the top of the industry’s priority list, Dr Lechleiter said that it was also essential to continue building trust among key constituents and to continue working in partnership with public health stakeholders in addressing today’s most pressing global health problems.

Panel 1 – Innovation today: treading new ground to meet global health needs

Health experts from academia, a leading regulatory agency, global advocacy, diagnostics, and the pharmaceutical industry identified a common need to adopt a more collaborative approach to health challenges in order to deliver the most effective health solutions today.

Working in isolation to take on global health challenges is not going to cut it in the 21st century. That was the conclusion reached by experts from very different sectors during the first Assembly panel, “Innovating today: treading new ground to meet global health needs.” In order to make a real impact in public health, joining forces on common issues through innovative partnerships is decidedly the new world order.

Cary Adams is CEO of the Union for International Cancer Control and the Chair of the NCD Alliance. Founded in 2010, the NCD Alliance groups four international federations tackling the world’s biggest killers—cancer, diabetes, cardiovascular and chronic respiratory diseases—under one umbrella.

Mr Adams called the initiative an innovative example of how different groups can be more effective by working together. “We do not ignore our differences, but we accept them in order to get together in a common space. What holds us together is that we have risk factors in common, palliation in common, and improvement in primary care in common,” he said.

Professor and Head of Medical Oncology at Pitié-Salêtrière Hospital, David Khayat called the rapidly growing prevalence of cancer as much of a political problem as a medical and scientific one. According to the WHO, in 2020, there will be 20 million new cases worldwide which will cause the death of 10 million people that year. Given the enormity of this disease burden, he said, “If we—the pharmaceutical industry, the government, the NGOs, and the doctors—are not

working together, we will not be able to defeat this very complex and very costly disease.”

Regarding the global availability of treatment, Dr John Lechleiter said that innovative partnerships are needed to improve delivery systems. “We collectively need to innovate around the services, the information, and the infrastructure that are necessary to ensure that ultimately the patients achieve good health,” he said.

Founded in 1906, the US Food and Drug Administration (FDA) is also broadening its vision, moving from a domestic focus to working increasingly with global partners. Mary Lou Valdez, Associate Commissioner for International Programs at the FDA, explained, “We are recognizing that we cannot do it alone and that we really must work together and move toward the kind of leadership that will be required to ensure the safety and quality of products.”

With new scientific and technological advancements in diagnostics, Dr Nigel Darby, Vice President of BioTechnologies and Chief Technology Officer of GE Healthcare, highlighted new opportunities to improve healthcare efficiency by coupling diagnostics with therapeutics.

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John C. Lechleiter, Chairman, President and CEO, Eli Lilly and Company

Cary Adams, CEO, Union for International Cancer Control

Nigel Darby, Vice President of BioTechnologies, Chief Technology Officer, GE Healthcare

David Khayat, Professor and Head of Medical Oncology at Pitié-Salêtrière Hospital

Mary Lou Valdez, Associate Commissioner for International Programs, US Food and Drug Administration (FDA)

abilities to tailor treatments to individual patients starts to become much greater. We see diagnostics as a partnership with therapeutics as really a way to make sure that therapeutics going forward are used in the best possible way,” Dr Darby said.

“We are recognizing that we cannot do it alone and that we really must work together...”

Mary Lou Valdez, Associate Commissioner for International Programs, US Food and Drug Administration (FDA)

Discussion

Additional interesting topics were raised throughout the first panel session. Here are just a few participant questions and speaker responses:

Q: What kind of innovation is necessary in order to improve access to innovative medicines to people in developing countries?

A: Dr Lechleiter said that as getting medicines to patients is a complex process that requires well-working, robust infrastructure, more work needs to be done in the area of capacity building. He suggested supporting local companies to meet international standards such as the Good Manufacturing Practices.

Q: The treatment of the four NCDs becomes much more difficult when coupled with another condition, for example diabetes with depression. Is the fact that mental and neurological diseases

have not been included as a major NCD an impediment to really addressing the problem?

A: Mr Adams said that mental health is a fundamental issue when it comes to NCDs and that the NCD Alliance is about to conduct a search to find a global mental health federation to join its steering group.

Q: The world deals with co-morbidity but the healthcare community does not seem very well equipped in dealing with disease combinations. How can we start to treat diseases more holistically?

A: Mr Darby said that the solution starts with understanding disease in the clearest and most detailed way and that with the development of technologies which allow physicians to understand and interpret disease at the molecular level, the future for a more holistic diagnosis and treatment of disease is bright.

Panel 2 – Creative innovation: addressing key research gaps

Key gaps in research today are pushing some health and policy experts to search for the most practical solutions to achieve the greatest public health impact possible with limited available resources.

While cutting edge science, new technologies and inventions are exciting and can draw lots of attention, sometimes what is most needed are practical, affordable and concrete interventions that can be deployed quickly and effectively. During the second session, six experts discussed where they see possible solutions to unanswered health needs during the panel, "Creative innovation: addressing key research gaps."

Neglected tropical diseases, malaria, and tuberculosis affect more than one billion people, many of whom live in the world's poorest countries. With limited market drivers, addressing these diseases is one of the world's most urgent health challenges. "In this area, if we want to encourage the capacity to innovate where the market is failing, then we need to use different forms of organization in order to do so," said Francis Gurry, Director General of the World Intellectual Property Organization (WIPO).

Launched last year, WIPO Re:Search, a consortium of pharmaceutical companies and research institutions, aims to accelerate drug discovery through the sharing of intellectual property for pharmaceutical compounds, technologies, know-how and data. Mr Gurry said that the partnership is a good example of social innovation for concrete results: "We think it's taking advantage of the networked world. It's focused and it's concentrated and will deliver real capacity building with scientists moving around from institution to institution."

Dr Trevor Mundel is president of the Global Health Program at the Bill and Melinda Gates Foundation. He leads the foundation's efforts in R&D of health solutions, including vaccines, drugs and diagnostics. Before he will put the organization's support behind a health innovation, he closely examines its practical implications. "The final intention is the outcome and the impact we are going to have. So as much as it's interesting and nice to do these innovative ideas, let's put that against what practically is going to be impactful at the end of the day," Dr Mundel said.

In terms of field research, Dr Ama de-Graft Aikin, Visiting Fellow from the London School of Economics and Senior Lecturer at the University of Ghana, closely examines the impact of disease on different population segments and what that means in terms of treatment needs.

"Looking at patients who live with diabetes in Ghana suggests that we need to look at how people manage co-morbid conditions. For instance, if you've got diabetes and hypertension, how do you re-orient yourself to the fact that you live with two conditions, which have two separate medical strategies you need to employ? And how do you even make sense of the medicines you take? Most rural people in Ghana, for instance, don't know the names of the medicines they are taking," Dr Aikin explained.

The Novartis Institutes for Biomedical Research (NIBR) are taking into account some of these field realities with the development of drugs that are better adapted to meet patient needs. Dr Dhavalkumar D. Patel, Head of NIBR Europe, said that the Novartis Institute for Tropical Diseases in Singapore is developing a malaria drug that can be delivered in one rather than three doses, limiting the risk of drug hoarding, virus resistance, and other issues.

Dr Bernard Pécoul, Executive Director of the Drugs for Neglected Diseases Initiative (DNDi), a non-profit public-private partnership for research, also highlighted the need to involve endemic countries from the start of the drug development process. "We need to think access from the beginning. So we need to secure the guarantee that at the end of the day, if we are successful, we have a product that will be accessible at an affordable price," Dr Pécoul said.

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Francis Gurry, Director General, World Intellectual Property Organization (WIPO)

Trevor Mundel, President, Global Health Program, Bill and Melinda Gates Foundation

Dhavalkumar D. Patel, Head of Novartis Institutes for BioMedical Research Europe

Ama de-Graft Aikin, Visiting Fellow, London School of Economics; Senior Lecturer, University of Ghana

Bernard Pécoul, Executive Director, Drugs for Neglected Diseases initiative (DNDi)

Ulf Wiinberg, President and CEO, H. Lundbeck A/S

The need for pragmatism was also expressed from the biopharmaceutical industry. Ulf Wiinberg, President and CEO of H Lundbeck A/S, a company that specializes in disorders of the central nervous system (CNS), said that budget constraints can be a hindrance to the potential of biopharmaceutical innovation capacity.

"Clearly there are general pressures on the industry right now and more uncertainty means that it is more important to pick safer products and projects and know earlier if they are going to work and that very much handicaps research in the brain. It is difficult to do research in the brain due to a lack of biomarkers and clinical markers," Mr Wiinberg said. He said that research is needed to better understand the biology of the brain in order to make greater strides in CNS personalized medicine.

"We need to think access from the beginning."

Dr Bernard Pécoul, Executive Director of the Drugs for Neglected Diseases Initiative (DNDi)



Discussion

Additional interesting topics were raised throughout the second panel session. Here are just a few participant questions and speaker responses:

Q: In areas where the market incentive structure is not lined up to support private sector research, should the public sector step in?

A: Dr Pécoul said that the issue is more a question of leadership and priority setting. He suggested that in the area of neglected diseases that the public sector should move in that direction.

Q: What should be done about the irrational use of drugs and in changing behavior on the patient side of the equation?

A: Dr Aikin said that when experts talk about irrational use of drugs, it's actually rational in the world of people who live with illness under difficult psychological, social, and economic circumstances. She suggested that more research should be conducted to understand what rationality and irrationality means in the life of someone that lives with a mental health condition, infectious disease, or chronic disease in poverty.

Q: How can the use of technologies help to address budget constraints that limit the time physicians have to communicate effectively with patients?

A: Dr Mundel said that he has seen how mobile phone-based technologies are backing up traditional caregivers in poor communities and is convinced that these kinds of interventions will be impactful in addressing health challenges in the future.

Panel 3 – Societal partner: ensuring innovation serves societal and business needs

When it comes to doing business in healthcare, there are significant opportunities for creating innovation and growth where there are the greatest social needs.

The third Assembly panel, “Societal partner: ensuring innovation serves social and business needs,” looked at the compatibility of business and social needs in the healthcare sector. Experts working in different segments of socially responsible investment, shared examples of how biopharmaceutical innovation is aligning with society’s needs today and opportunities for value-sharing in the future.

“The idea of creating shared value is that companies can contribute to their profitability at the same time as they’re solving social problems,” explained Mark Kramer. The Co-founder and Managing Director of FSG, a nonprofit consulting firm specializing in business solutions that address social needs, sees vast opportunity for value-sharing in the biopharmaceutical space.

“Pharmaceutical companies need to be willing to address and overcome what they see as market failures today. That reaching low-income populations requires innovations in distribution, in packaging, in partnerships, to enable companies to get past what seem to be market failures,” Mr Kramer said.

The GAVI Alliance, a public-private partnership focused on increasing access to immunization in poor countries, exemplifies the value-sharing approach. Dr Seth Berkley, CEO of the organization, explained that GAVI has offered a new model in global vaccination outreach.

“This is not about charity. This is about trying to change the curve, change the way we market, change the way we think of things. . . . Of course, as one begins to produce vaccines from the beginning at much larger quantities, you reduce the cogs.

You actually increase profits in your primary markets, so you are doing good and doing well at the same time,” Dr Berkley said.

Working in Responsible Investing at PGGM Investments, Rogier Snijdewind said that socially responsible investments make good business sense. “We try to be more of a long-term investor and taking this into account, we consider it to be a part of the long-term viability of a company’s business,” Mr Snijdewind said.

Additionally, Mr Snijdewind encourages all companies to expand the scope of where they are doing business. “Geographical innovation and looking beyond the markets that are known, going into new territories, is key. I think for long-term value that is something that not only pharmaceutical companies but all companies that we invest in, and there are quite a few of them, should look into and should be prepared to do,” Mr Snijdewind advised.

Caroline Roan, President of the Pfizer Foundation and Vice President of Corporate Responsibility and Reputation at Pfizer, said that responding to public health needs is at the core of their business. “When I am asked what Pfizer’s social purpose is, I say that it’s our business purpose: to discover,

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Seth Berkley, CEO, GAVI Alliance

Rogier Snijdewind, Head of Responsible Investing, PGGM Investments

Caroline T. Roan, President, The Pfizer Foundation; Vice President, Corporate Responsibility & Reputation Pfizer Inc.

Mark Kramer, Co-founder and Managing Director, FSG

develop, and bring to market, life saving, life enhancing medicines that really allow you to live your life to its fullest capacity,” Ms Roan said.

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Mark Kramer, Co-founder and Managing Director, FSG

Discussion

Additional interesting topics were raised throughout the third panel session. Here are just a few participant questions and speaker responses:

Q: When it comes to accessing public funds to finance drug research and innovation, is it ethically appropriate to ask the public to pay twice for pharmaceutical innovation, especially when it becomes profitable?

A: Mr Kramer said that the public good generated by the creation of powerful, new drugs and effective distribution systems is of great value to society and is a worthwhile public investment.

Q: Does the pharmaceutical industry have a role in preventing the risks associated with advances in biotech research that could be misused deliberately or accidentally?

A: Ms Roan said that pharmaceutical companies spend a lot of time managing risk, as there is a lot of risk associated with bringing medicines to market. Therefore, she envisioned many opportunities for partnerships in this area as industry has the expertise to take on such additional challenges.

Q: Are investments in non-traditional partnerships sustainable or a passing trend?

A: Dr Berkley said that while there are many different forms of partnerships emerging, some more successful than others, the only way to solve big health challenges today is through the collaboration of many different sectors.

A Look Back at IFPMA Leadership 2010-2012

William Charnetski, Vice President of Global Government Affairs and Public Policy at AstraZeneca, shared IFPMA's accomplishments over the past two years, emphasizing trust building initiatives and public health partnerships.



From the importance of preventing and controlling noncommunicable diseases (NCDs) to the urgency of developing treatments of neglected diseases, the global healthcare community is facing a number of formidable challenges. In this context, Mr

Charnetski underscored "the need for public and private stakeholders to combine skills, strengths and resources has become more apparent than ever."

Citing several key achievements made when AstraZeneca's former CEO, David Brennan, was IFPMA President, he pointed to the revision of IFPMA's Code of Practice, which was expanded to include all interactions with healthcare professionals, medical institutions, and patient organizations. He called the Code update an "important milestone" for the industry and said that stakeholder feedback has been "very positive."

Focusing on trust building behaviors, the IFPMA has made other significant contributions to tackling complex public health issues over the past year. In particular, Mr Charnetski cited WIPO Re:Search, a public-private partnership aimed at fostering R&D for the treatment of neglected tropical diseases, malaria and tuberculosis, and the London Declaration,

an initiative to control or eliminate 90 percent of the global burden of neglected tropical diseases (NTDs).

Finally, Mr Charenetski highlighted IFPMA leadership shown in understanding the barriers that are preventing the prevention, control, and treatment of NCDs through the Framework for Action on NCDs. Looking ahead he applauded the IFPMA's focus on innovation and encouraged the industry to focus the conversation on benefits to patients, healthcare systems, and society as a whole.

"The need for public and private stakeholders to combine skills, strengths, and resources has become more apparent than ever."

William Charnetski, Vice President of Global Government Affairs and Public Policy at AstraZeneca

"I am Innovation"

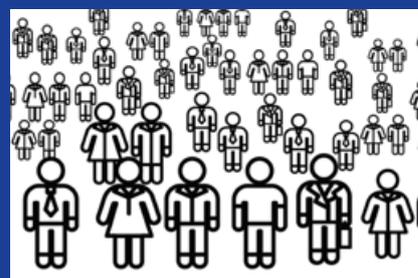
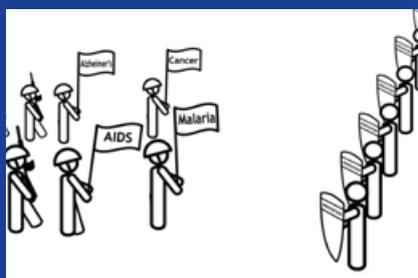
Innovation came alive in a short film, taking participants on a journey that began with the earliest of inventions, its major achievements, and the challenges it faces on the road ahead. The voice of innovation asked some big questions – some which could be answered and others, which had to be left open.

How has innovation made strides in global health?

From the eradication of smallpox to the near defeat of polio, over the past century, biopharmaceutical innovation has led to the development of lifesaving medicines and vaccines that allow people to live healthier and longer lives, supporting the growth and progress of societies worldwide.

Can innovation win the fight against life-threatening diseases?

Major health challenges requiring innovation is still needed in order to address public health threats including HIV/AIDS, malaria, Alzheimer's, cancer, and drug-resistant strains of Tuberculosis. To view "I am Innovation," visit: <http://www.youtube.com/watch?v=kwo4d5Ywwk>



Cutting Edge Healthcare Solutions

For the first time this year, Assembly participants were able to discover tangible examples of innovation in healthcare. The “Innovation Hub” showcased several organizations from the private and public sectors, which displayed their latest research, technologies, strategies, and solutions that are advancing global health today.



Drugs for Neglected Diseases Initiative (DNDi) specializes in new treatments for neglected diseases, such as an improved combination therapy for sleeping sickness and a child-adapted dosing of a Chagas disease medicine. In a policy brief, Why an essential health R&D convention is needed, the non-profit organization called for improved coordination of international efforts in addressing neglected diseases through a binding agreement under the WHO. For more information, visit: www.dndi.org

GE Healthcare is developing a wide range of systems and tools to improve the detection and diagnosis of diseases through molecular imaging systems. For example, using innovative hardware, software and imaging agents, the company is developing Alzheimer’s disease biosignature tests for early detection. For more information, visit: www.gehealthcare.com

IBM Institute for Business Value is examining how extensive collaboration between technology and the life sciences industry could improve health outcomes. In an executive report, Fade or flourish, IBM suggests the industry moves toward a more integrated and collaborative business approach with an emphasis on data mining, sharing, and analysis. For more information, visit: www.ibm.com/iibv

Novartis Institutes for Biomedical Research demonstrated how the genetic signature of microorganisms is being used for the identification of natural products as candidates for drug development. For more information, visit: nibr.com

Roche Personalized Healthcare aims to offer patients more effective treatment options by understanding the sub-categories of diseases to improve diagnostics, optimize medicine administration, and better monitor the success of a therapy. For more information, visit: www.roche.com/personalised_healthcare.htm

Sproxil is helping diabetic patients in Nigeria to avoid counterfeit medications. Patients can text the PIN codes printed on anti-diabetic medication packs to a toll free number to quickly verify authenticity. For more information, visit: www.sproxil.com

WIPO Re:Search aims to facilitate the research and development of new treatments for neglected tropical diseases, malaria, and tuberculosis. One year since its launch, the consortium, run in partnership with BIO Ventures for Global Health, today has over 60 partners including pharmaceutical companies, academic institutions, and research organizations. For more information, visit: www.wipo.int/research

In addition, **Charles River Associates (CRA)** featured its recently released study, Policies that encourage innovation in middle-income countries, commissioned by the IFPMA. The report analyzed key political and economic factors that support innovation in the biopharmaceutical sector across eight geographically diverse countries. One of the key findings showed that consistent long-term government policies are essential for sustainable innovation. For more information, visit: www.ifpma.org

For more information on the event:
www.26ifpmaassembly.org

For information on innovation, global health and the pharmaceutical industry:
www.ifpma.org