PMAC PRINCE MAHIDOL AWARD CONFERENCE 2018

PARALLEL SESSION 1.3

SAFEGUARDING MEDICINES IN THE ERA OF AMR: WHAT DO WE KNOW? WHAT WORKS?

| BACKGROUND

The prevention, detection and mitigation of emerging and re-emerging infectious diseases involve both applying preventive controls in animal production as well as ensuring the safety, efficacy, quality, and appropriate use of vaccines, diagnostics and medicines through secure supply chains and health delivery systems.

Complex and fragmented supply chains, especially in countries and regions with limited regulatory and quality oversight, increase the likelihood of substandard, fraudulent or adulterated medicines entering the market. Poor quality medicines ensure microbial replication in the presence of drug pressure. Substandard and falsified medicines also contribute to lack of efficacy and adverse events, undermining trust in the health system. Inappropriate use of anti-microbials is another driver of AMR. Both poor quality medicines and inappropriate use are preventable and can be addressed through the development of robust regulatory and quality assurance systems, treatment guidelines and enforcement.

While there are major limitations in evidence and best practice in the human health sector, even less is known in the veterinary sector, both with respect to use and quality of antibiotics in animals, and effective controls. Further, environmental factors are beginning to come to light.

| OBJECTIVES

- Review evidence of what is known about the links between medicines quality and AMR.
- Highlight successful efforts in, and benefits from, strengthening systems that monitor and strive to improve medicines quality.
- Address environmental impacts of antibiotic manufacturing on AMR.
- Relate frameworks for addressing medicines quality and appropriate use in the human sector to the animal sector and discern what lessons and approaches from other initiatives could be mobilized to address these drivers of infectious disease risk and AMR.

Moderator

Katherine bond

Vice President, International Regulatory Affairs

U.S. Pharmacopeia
United States of America

Katherine Bond, Sc.D., is USP's Vice President, International Public Policy and Regulatory Affairs, where she leads a new team to advance the quality of medicines, foods and dietary supplements worldwide. Dr. Bond brings more than twenty years of demonstrated public health leadership experience, in the field and in management. Dr. Bond served as Director of the Office of Strategy, Partnerships, and Analytics, Office of International Programs, U.S. Food and Drug Administration, where she advanced programs and policies to strengthen regulatory systems and supply chain analytics. Prior to public service, Dr. Bond focused her energies on priority public health issues such as health security, infectious diseases and health systems impacting Southeast Asia and Africa in senior positions with Rockefeller Foundation's Asia Regional Office and Africa Regional Office, and the Mekong Regional Office of PATH. Dr. Bond has also held many consultancies and academic appointments—as both lecturer and researcher—at universities in the United States and abroad. She additionally appears as lead or contributing author on a variety of peer-reviewed research papers and technical documents in areas of regulatory systems strengthening, global health security, health systems, and intervention strategies for specific at-risk populations. Dr. Bond earned her Bachelor of Arts degree from Swarthmore College and her Doctor of Science degree from the Johns Hopkins University Bloomberg School of Public Health.

Panelist

Damiano de Felice

Director of Strategy

Access to Medicine Foundation
Netherlands

Damiano de Felice is Director of Strategy and Member of the Management Team at the Access to Medicine Foundation. He leads the strategy of the organisation, focuses on enhancing its impact, manages the relationship with governments and investors, is responsible for fundraising and oversees finances. Damiano is an expert in the relationship between business, human rights and development, and a member of the World Economic Forum Global Future Council on Human Rights. Damiano holds a PhD in International Relations from the London School of Economics, and two Master's degrees in Political Science and International Relations (from the University of Pisa and the Sant'Anna School of Advanced Studies respectively). During his career, Damiano has advised international organizations, companies, governments and NGOs, and published several papers on human rights and development issues. To stimulate positive change within the pharmaceutical industry, Damiano often speaks publicly on access-to-medicine matters on platforms hosted by international, governmental and non-governmental organizations, including the UN and WHO.

Panelist

Margaret Hamburg

President

American Association for the Advancement of Science
United States of America

Dr. Hamburg is an internationally recognized leader in public health and medicine. As Foreign Secretary of the National Academy of Medicine, She is senior advisor on international matters and is the liaison with other Academies of Medicine around the world. She is also President-elect of the American Association for the Advancement of Science (AAAS). Dr. Hamburg is a former Commissioner of the U.S. Food and Drug Administration (FDA), where she was known for advancing regulatory science, modernizing regulatory pathways, and globalization of the agency. Before this, she was founding vice president and senior scientist at the Nuclear Threat Initiative, a foundation dedicated to reducing nuclear, chemical and biological threats. Other positions have included Assistant Secretary for Planning and Evaluation (HHS), Health Commissioner for New York City, and Assistant Director of the National Institute of Allergy and Infectious Disease. Dr. Hamburg currently sits on a wide range of not-for-profit boards including the Commonwealth Fund, the Simons Foundation and GAVI. She also serves on the Harvard University Global Advisory Council and the Scientific Advisory Committee for the Gates Foundation, among other activities. She is a graduate of Harvard College and Harvard Medical School.

Panelist

Margareth Ndomondo-Sigonda

Head of Health Programs

New Partnership for Africa's Development
South Africa

Panelist

Michael Deats

Group Lead, Substandard and Falsified Medical Products

World Health Organization
Switzerland

Michael joined the WHO in 2011 as the project manager responsible for the design and implementation of the Global Surveillance and Monitoring system for substandard and falsified (SF) medical products. The following year he was appointed Group Lead for Substandard and falsified medical products within the Essential Medicines Department where he manages a team who receive reports, provide technical support, issue Global alerts and undertake secretariat duties for the Member State Mechanism for SF medical products. Prior to joining the WHO Michael was the head of enforcement for the Medicines and Healthcare products Regulatory Agency in the United Kingdom (2005-2011), and led a team of 45 investigators, inspectors, lawyers, and analysts. He had responsibility for the investigation of all major breaches of medicines regulation, through to criminal prosecution. He led the largest successful investigation and prosecution in Europe of falsified medicines entering hospitals and pharmacies. He is the author of the MHRA's first Falsified medicines strategy and Enforcement strategy. Whilst with the MHRA Michael launched the illegal internet pharmacy campaign known as Operation Pangea, now coordinated by INTERPOL. From 1975-2005 Michael was a Police Officer in the UK, based in London but working Internationally, specialising in the investigation of organized crime. He attended the Police Staff College, Bramshill, both as a student and visiting lecturer to the Association of Chief Police Officers, and International Command Course. He retired in the rank of Detective Superintendent. Michael has worked in over 60 Countries worldwide.

Panelist

Sanne Fournier-Wendes

Senior Advisor to the Executive Director of Unitaid

Unitaid, Geneva
Switzerland

Sanne FOURNIER-WENDES is the Senior Adviser to the Executive Director in UNITAID's Executive Office. A Danish national, sanne has over 15 years of experience in Strategy and Policy Development and partnership building and programme management. She worked in the Private Sector, the Global Fund and UN System. She holds a Bachelor's and a Master's in Economics. She has been at UTD for over 2 years.

Panelist

Sasi Jaroenpoj

Head of Veterinary Medicinal Product and AMR containment Section

Department of Livestock Development, Ministry of Agriculture
Thailand

Panelist

Timothy Wells

Chief Scientific Officer

Medicines for Malaria Venture
Switzerland

Dr Timothy Wells has been the Chief Scientific Officer of Medicines for Malaria Venture (MMV) since 2007, co-ordinating the development pipeline of new medicines from discovery through to post-approval studies. During his time at MMV he has led the implementation of collaborations based on high content screening, developments in translational medicine, and open access drug discovery. With our partners we have developed a wide portfolio of new medicines in clinical trials (all discovered within the last decade) as well as 7 products, many of which are currently being used by millions of children worldwide. One of the keys to MMV's success is the development of open access agreements in drug discovery and development, for which MMV was given the Open Data Institute award from internet pioneer Tim Berners-Lee in 2015. This has helped to drive innovation in a disease area which is classically considered to be one of market failure. Prior to joining MMV, he had over 20 years experience in drug discovery and development. From 1997 to 2006, he was the Head of Research for the Swiss biotech company Serono, developing products in neurology, immunology, oncology and reproductive health. In addition to his work at MMV, he advises on a variety of infectious disease projects, including tuberculosis and schistosomiasis. He is a non-executive director at Kymab, developing next generation monoclonal antibody technologies, and an interest to their applications in neglected disease. He has 220 peer reviewed publications, and an H-index of 71, and in 2015 co-authored a book on drug design for neglected disease. Tim received his PhD in Chemistry in 1987, on the engineering of enzyme transition states from Imperial College, London; his ScD in Biology in 2009, from Cambridge University in the UK, was mainly awarded for his work on cytokine biology. He is a fellow of the UK's Royal Society of Chemistry and of the Academy of Medical Sciences.