

Inaugural DIA- CoRE Conference shines spotlight on pandemic diseases

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Singapore – The first DIA-CoRE Conference, held on 29 and 30 January 2018 in Singapore, opened with a series of keynote addresses by senior members and subject matter experts from the industry, focusing on pandemic diseases and innovation in this area. Drug Information Association (DIA) and the Centre of Regulatory Excellence (CoRE) of Duke-NUS Medical School, Singapore co-organized this inaugural conference in Mandarin Oriental, Singapore.

The conference started with the opening messages from Joseph Scheeren (Chair-Elect DIA and Senior advisor, Bayer) and John Lim (Executive Director, CoRE). Opening day of the conference saw various experts sharing their perspectives and experiences on the topic. They gave valuable insights on the global impact of infectious diseases, its management, issues on expediting research and product development, and also barriers to accessibility of healthcare products during a pandemic situation.

Keynote speaker, Mark Pearson (Deputy Director of Employment, OECD) gave a presentation on antimicrobial resistance and pandemic infectious diseases that impact on global healthcare systems and patients, while emphasizing the size of the problem. In his keynote speech, he said, "AMR (anti-microbial resistance) is growing at the global level and increasing resistance to 2nd line antimicrobials. From economic standpoint, 38K USD per patient is needed due to AMG (anti-microbial growth) and 2.1 million labour force death by 2050 amongst working age population."

The theme was chosen such that it is not only presently relevant, but also helps draw attention and awareness on an important issue for the healthcare industry. Focus on access to health products for managing pandemics further highlighted the urgent intervention and response required by a range of stakeholders across the sector. The audience was equally diverse, comprising of government representatives, regulators, industry players, healthcare providers and academia.

Other speakers also shared challenges they faced on pandemic treatment, meeting needs of infectious diseases, vaccine

development and more. The session ended with a panel discussion on related topics such as resource limitations, predictability of regulatory outcomes and aligning practices for pandemic management.

On the second and closing day of the conference, audience learnt about some good regulatory practices from the World Health Organisation. Some other topics were also touched upon, such as – the role of precision medicines in managing pandemics, and the use of Real World Evidence as a tool to support early access to pandemic healthcare products. Ideas to accelerate patient access to innovative products were shared by regulatory authorities from Japan, Taiwan and Singapore, as well as from two companies representing pharmaceutical and medical devices sectors.

Samvel Azatyan, Group Lead, WHO gave a talk about good reliance practices as key to regulatory efficiency. In his presentation, he reminded the audience that: "Access to essential medicines is a part of right to health. However, WHO has estimated that one third of population does not have that access." He highlighted that making medicines is no longer a "local" business and the era of locally operating regulators is coming to an end, further adding that the future of medicines regulation is in convergence/ harmonization, collaboration and networking with regulators is already happening, as they being to operate more as a functional network rather than individual players, while still individually focussed on where they can add the most value.

A few other highlights of the program were discussions and knowledge sharing sessions that covered a plethora of relevant topics, such as:

- · Global impact of infectious diseases
- Increasing antimicrobial resistance and challenges to treatment management
- Experiences from recent and current pandemics in Asia
- Accelerating product research and development for infectious and tropical diseases
- Emerging roles of Real World Evidence and Precision Medicine in pandemics
- Initiatives to enhance timely accessibility to necessary health products
- Regulatory pathways and initiatives in Asia to expedite availability of health products
- Developing a cross-cutting framework for pandemic responses

The conference ended with a grand panel discussion that discussed the elements required for managing a pandemic, which started the momentum for deeper thinking in this area.

The conference was well represented by senior members from across the industry, academia, healthcare professionals, regulatory bodies and funders. Some of the prominent speakers in the conference were-

Hiromichi Shirasawa (Vice President & Head of japan Development, MSD KK)- spoke on the role and the current challenges the industry is facing in meeting needs of infectious diseases as well as sustaining a market for niche diseases.

Melvin Sanicas (Regional medical expert, Sanofi Pasteur, Asia & JPAC)- gave a comprehensive overview on how to successfully navigate the current development & regulatory landscape in a pandemic setting.

Jorge Villacian (CMO, J&J)- spoke during a grappling session on enablers for successful management of health products during pandemics. He emphasized on the emerging role of precision medicines in pandemics.

Anuradha poonepalli (Senior Regulatory Specialist, HSA)-drew attention of the audience on the registration process of dengue vaccine, thereby accelerating access to health products.

Lorenz Scheppler (Director, Global Regulatory Affairs, J&J)- piqued the expert's interests in his talk by providing some informative focus on how to bring innovation to patients. He also talked about the Industry perspective on how to expedite access to health products.

This first DIA-CoRE Singapore Conference set the stage for an industry-relevant dialogue on ensuring and accelerating product access, successful product management during a pandemic outbreak; and managing a pandemic's global impact. The need for such forums cannot be over emphasized, as they enable access of new knowledge and bring together interested stakeholders. Through conferences like this, it is hoped that learning experiences are able to help address relevant key issues, enhance understanding of significant scientific issues, and encourage useful networks to advance health products development.