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.

Panelist

Michael Deats

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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.