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 / Panelist

Margaret Hamburg

President

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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.