Regulators in EU, Japan and US Take Steps to Converge on Approaches to Development of New Antibacterial Drugs

The European Medicines Agency (EMA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and the U.S. Food and Drug Administration (FDA) have agreed to align certain aspects of the clinical development of new antibacterial drugs in order to stimulate the development of new treatments to fight antimicrobial resistance and protect global public health.

Representatives from the three regulatory agencies met in Vienna on April 26-27, 2017 and discussed recommendations for the design of clinical trials that test new treatments for certain types of bacterial infections, including infections caused by multi-drug resistant organisms. They identified areas where the development approaches in the three regions could be streamlined.

EMA, PMDA, and FDA will be working to update their respective guidance documents. While the updates are ongoing, they will provide advice to individual medicine developers in line with the agreements reached.

This tripartite meeting in Vienna followed an initial meeting that took place at EMA in September 2016 where the agencies discussed regulatory approaches for the evaluation of new antibacterial agents https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/AboutMCMi/UCM519783.pdf

The EMA, PMDA, and FDA will continue to collaborate in order to facilitate the development of safe and effective antibacterial drugs.