6 November 2019
European Medicines Agency

Meeting Summary

Tripartite meeting held between the EMA, and FDA and PMDA in Tokyo, Japan to discuss convergence on approaches for the evaluation of anti-infective products

At the fourth tripartite meeting, significant progress was made in our discussions on recommendations for clinical development of new anti-infective products, acknowledging that considerable convergence has been achieved so far.

- Taking into account the previous tripartite activities, the three agencies discussed further alignment on clinical trial designs for key indications for antibacterial drugs for which convergence has not yet been reached. It was reflected that data from contemporary clinical trials would be pivotal in defining the most suitable way forward.
- Paediatric development is an important aspect in the development of anti-infective products. Methods to facilitate obtaining paediatric clinical data and utilization of modelling and simulation were discussed.
- Test methods and derived interpretive criteria for susceptibility testing are often different in EU, Japan and US. To facilitate multi-regional anti-infective drug development, communication and collaboration among scientific and public health bodies involved in such activities are key and options for harmonization are strongly encouraged.
- Clinical trial considerations for new treatment modalities such as monoclonal antibodies and other non-traditional therapies for the treatment and/or prevention of infectious diseases were discussed. The need to work together to facilitate new approaches and to aim for convergence was recognized.
- The three Agencies will continue to discuss in 2020 to further advance their work on regulatory convergence.
- The three Agencies plan to publish the outcome of the discussions e.g. in a scientific journal to inform stakeholders details of the work done so far.
- The discussion has been expanded to include antifungal agents which is an area affected as well by growing antimicrobial resistance and where clinical development programs can be challenging.

See websites for contact details

U.S. Food and Drug Administration: www.fda.gov
European Medicines Agency: www.ema.europa.eu
Pharmaceuticals and Medical Devices Agency: www.pmda.go.jp