

MEETING SUMMARY

Tripartite meeting held between the EMA, PMDA and FDA in Vienna, on 26-27 April 2017 to discuss regulatory approaches for the evaluation of antibacterial agents

The EMA, FDA and PMDA consider that a robust response to the problem of antimicrobial resistance must be multi-faceted and that the regulatory approach for the evaluation of antibacterial agents is one element of the total response that is required to encourage and accelerate new antibacterial drug development to meet patient needs. Following on from the meeting of September 2016, representatives of the three agencies met for the second time.

Progress was made as follows:

- EMA, PMDA, and FDA discussed in detail clinical trial recommendations for respiratory tract, urinary tract, intra-abdominal, and skin infections, as well as for drugs intended to treat patients with multi-drug resistant infections.
- A number of areas of similarity were identified with regard to clinical trial design recommendations, such as patient selection criteria, and endpoints for certain types of infections.
- Areas were identified where a move to convergence was agreed. For example, criteria for patient selection and response in urinary tract and intra-abdominal infection trials.
- Some aspects of clinical development programs for drugs intended to treat patients infected with multi-drug resistant bacteria were agreed.
- EMA, PMDA, and FDA will be working to update guidance documents to reflect the agreed areas of convergence. In the meantime, EMA, PMDA, and FDA will provide advice to drug developers that is consistent with the agreements reached. Prior advice on drug development is not impacted.

- Areas were identified where currently differences remain. For example, which endpoints should be regarded as primary in community-acquired bacterial pneumonia and skin infection trials. Further scientific discussion and sharing of information may help to achieve convergence in those areas.
- Where there are areas of difference, EMA, PMDA, and FDA will continue to work together in order to minimize the impact on clinical development programs.
- EMA, PMDA, and FDA will continue their work on recommendations for clinical trials to facilitate antibacterial drug development leading to the availability of safe and effective drugs for patients. A next meeting is proposed for October 2017.