MEETING SUMMARY

Tripartite meeting held between the EMA, FDA and PMDA at the EMA, London, on 1-2 September 2016 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-facetted and that the regulatory approach for the evaluation of antibacterial agents is only one element of the total response that is required to encourage and accelerate new antibacterial drug development to meet patient needs.

These three regulatory agencies recognize that:

- It is appropriate to exercise flexibility with regard to the requirements for clinical development programmes for antibacterial agents, especially for new agents that may be used to treat patients with limited treatment options because of antimicrobial resistance;

- There is benefit in further convergence on the data requirements for the approval of antibacterial agents;

- It may be appropriate to accept a greater degree of uncertainty regarding the benefit-risk balance when developing new antibacterial agents that can be used to treat patients with limited treatment options, e.g. it may be acceptable to conduct trials in smaller numbers of patients than would usually be required;

- It is important to conduct sound analyses of the pharmacokinetic-pharmacodynamic relationship for the purposes of selecting dose regimens for study in clinical trials, including regimens that may minimize the risk of selecting for resistant organisms;

- There is value in developing clinical trial networks to facilitate the evaluation of new antibacterial agents and the development of such networks is encouraged;

- There is value in continuing the discussions that were initiated 1-2 September 2016 at the EMA; further discussions proposed for Spring 2017 will take into account not only the pre-approval clinical development programmes but also activities conducted in the post-approval period.