EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Aims of the Workshop

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Reflecting developments since 2000

- In 2013 the IDWP decided there was a need to replace the *Points to consider on pharmacokinetics and pharmacodynamics in the development of antibacterial medicinal products* (CPMP/EWP/2655/99)
- Concept paper issued for consultation in 2014
- Draft EMA/CHMP/594085/2015 adopted 24 September 2015
- Now out for public consultation until 31 March 2016
- This workshop was planned to occur during consultation
- Plan for final Guideline by end of 2016

Approach to the Guideline

- Reflects experience from recent application dossiers and CHMP Scientific Advice and some recent publications
- For ≥ 20 years application dossiers for new antibacterial agents have included PK-PD analyses to support dose regimens and sometimes to replace dose-finding studies
- The extent of the data used to support these analyses (everything from patient PK in the POPPK models to strains used to identify PD targets) has varied
- Few dossiers have included planned CER analyses

Approach to the Guideline

- Guideline attempts to provide a basis for ensuring that the data used to support PK-PD analyses are sufficient

- Includes mention of essential microbiological data needed to underpin dose-finding, approaches to identifying PK-PD indices and PD targets, PK data collection, estimating PTA, collection of data to support CER analyses and some special considerations for BL/BLI combinations

- The focus is on using these data and analyses to select doses for further clinical evaluation and to consider how the clinical development programme could be impacted

Outline and purpose of the Workshop

- Topics by session reflect the chapters of the draft guideline
- For each topic the aim is:
  - To hear the opinions from experts in the field
  - To understand what needs revision in the draft text
  - To consider issues on which there have been divergent views expressed and/or divergent approaches taken in different drug development programme
  - To attempt to reach a consensus on what is essential
  - To agree on areas where different options should be mentioned because no single option can be considered optimal

Output from the Workshop

- A Meeting Report will be drafted and published on the EMA website along with slides (as permitted by experts)

- The proceedings of this Workshop will be taken into account when drafting the final guidance along with all the written comments we (hope to) receive