Revised guideline aims to strengthen global approach to development of new antibacterial medicines

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EMA has published a [revision of its guideline on the evaluation of human medicines indicated for the treatment of bacterial infections](https://www.ema.europa.eu/documents/scientific-guideline/draft-guideline-evaluation-medicinal-products-indicated-treatment-bacterial-infections-revision-3_en.pdf) for a six-month public consultation. Stakeholders can send their comments by 31 July 2019 to [idwpsecretariat@ema.europa.eu](mailto:IDWPSecretariat@ema.europa.eu) using the provided.

EMA plays an important role in the fight against [antimicrobial resistance](https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/antimicrobial-resistance) by supporting the development of new medicines and treatment approaches, especially for patients with infections caused by multi-drug resistant bacteria and limited therapeutic options.

Antimicrobial resistance is a global public health problem. Regulators in the European Union, the [United States](https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/united-states) and [Japan](https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/japan) have had extensive discussions over the last few years to explore and agree how to align as much as possible their respective data requirements so that medicine developers can design [clinical trials](https://www.ema.europa.eu/en/glossary/clinical-trial) that meet the evidence needs of multiple regulatory agencies. The revised guidance reflects the outcome of these discussions.

In addition, it offers clarification on the clinical development of antibacterial agents that are expected to address an unmet medical need, in accordance with experience gained from previous regulatory decisions.

Specific advice has also been added with regards to the EU regulatory requirements to develop medicines for the treatment of uncomplicated urinary tract infections and gonorrhoea.

The draft revised [guideline](https://www.ema.europa.eu/en/glossary/guideline) was adopted by EMA’s human medicines committee ([CHMP](https://www.ema.europa.eu/en/glossary/chmp)).