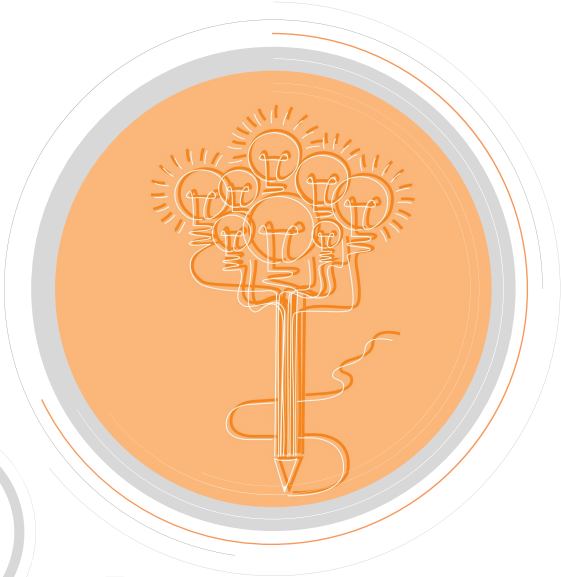
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Continue to support development of new antibacterial agents and their alternatives



Underlying actions

EMA's Regulatory Science Strategy to 2025 – Human Stakeholder Workshop

Chaired by Cesar Hernandez Garcia, HMA on 19 November 2019
Presented by Marco Cavaleri, Head of Anti-infectives & Vaccines, EMA

Disclaimer

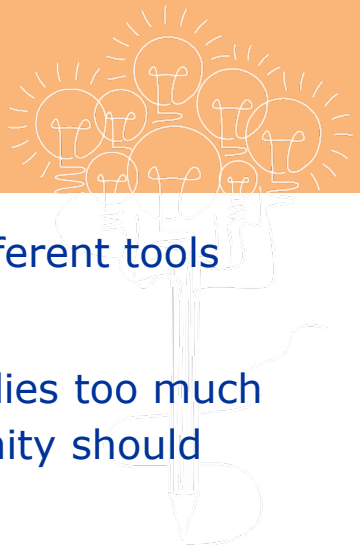
Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

The fact that these comments from stakeholders are displayed in the presentation does not mean we endorse them or commit to fulfil them in any way.

Continue to support development of new antimicrobials and their alternatives

- Evolve regulatory guidance and support alternative approaches to antimicrobial drug development
- Support initiatives, such as the clinical trials network, to facilitate and accelerate clinical development
- Encourage new business models that provide “pull” incentives beyond the current “funding research” strategy in the EU
- In collaboration with HTAs and payers, define the evidence requirements for new antibacterial medicines
- Support the development and application of rapid diagnostic tools

Encourage new business models that provide "pull" incentives beyond the current "funding research" strategy in the EU, including mechanisms for sustained availability for new and old antibiotics



- The strategy so far adopted is not leading to the expected results. Different tools could be explored.
- AMR is a dramatic example reflecting the pitfalls of a system which relies too much on the outputs of an industry-based model. The international community should support independent public research infrastructures.

Encourage new business models that provide "pull" incentives beyond the current "funding research" strategy in the EU, including mechanisms for sustained availability for new and old antibiotics

- Consider the reinforcement of arrangements which ensure that essential medicines are maintained on the market, in particular for old antibiotics that are being utilised in new ways.
- Optimise the regulatory pathway for older antibiotics that have previously been unavailable and provide incentives by means of a reduction in regulatory fees.
- Prevent future market exit by providing targeted regulatory relief for MAHs of critical antibiotics.

Encourage new business models that provide "pull" incentives beyond the current "funding research" strategy in the EU, including mechanisms for sustained availability for new and old antibiotics

- Develop an evidence-based list of critical off-patent antibiotics with a multi-sector stakeholder group?
- Work with the European Commission and member states to create a framework of procurement incentives for off-patent and generic antibiotics such as multi-winner tenders and non-price selection criteria, to ensure a stable supply of highly-effective antibiotics.

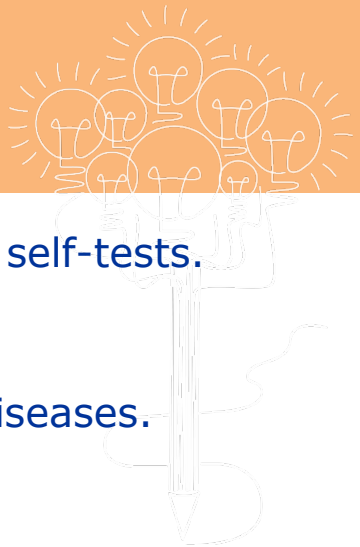
In collaboration with HTAs and payers, define the evidence requirements for new antibacterial medicines

- The unique development challenges of antibiotics are poorly understood by many stakeholders, and industry would welcome partnership with EMA to better explain the evidentiary standards and basis for assessment.

Evolve regulatory guidance and support alternative approaches to antimicrobial drug development and innovative approaches for prevention and treatment of infections

- Further regulatory support for antibiotic development, which offers the support and potential to expedite assessment along the lines of PRIME.
- Industry continue to advocate for collective action to address AMR.
- Existing emerging health threats regulatory procedures should be summarized in a comprehensive way to give guidance and quick answers for developers.

Support the development and application of rapid diagnostic tools



- Support the development and application of both PoC diagnostics and self-tests.
- This would best serve, patient and the healthcare system as a whole.
- Development of better diagnostics to improve stewardship and limit diseases.

Any questions?

Further information

RegulatoryScience2025@ema.europa.eu

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
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Send us a question via www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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