EMA
EUROPEAN MEDICINES AGENCY

TEV: scientific assessment of the criteria for a priority antimicrobial

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Criteria for priority microbial as presented in the NPL

The criteria are presented in Article 41(3) of the new Regulation

An antimicrobial shall be considered a 'priority antimicrobial' if it **addresses a multi-drug resistant organism**, if the preclinical and clinical data **demonstrate a significant clinical benefit** with respect to antimicrobial resistance and if it has at least one of the following characteristics:

a) its **mechanism of action** is distinctly different from that of any authorised antimicrobial in the Union;

b) it contains a **new active substance** that, when used either alone or in combination with other active substances, addresses a serious or life threatening infection.

In the scientific assessment of the criteria referred to in the first subparagraph, the Agency shall take into account the 'WHO bacterial priority pathogens list', or an equivalent list of priority pathogens established at Union level.

Justification expected from applicants for scientific assessment by CHMP

Draft CHMP guidance on scientific considerations governing the criteria for eligibility as a priority antimicrobial

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Scope of guidance and legal context

The aim of the TEV is to reward applicants who successfully develop a new 'priority antimicrobial' by granting an **extra year of regulatory data protection,** which can be applied to the priority antimicrobial itself or transferred to another medicinal product under certain conditions.

Definitions

Described in Article 4(1)

Antimicrobial

Any medicinal product with a direct action on microorganisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and antiprotozoals.

Antimicrobial resistance

The ability of a microorganism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually or was previously sufficient to inhibit or kill that microorganism.

Guidance

- The guidance document sets out the **scientific considerations** that will be considered when examining if a medicinal product meets the criteria to qualify as a 'priority antimicrobial' within the meaning of the relevant definition in Article 41(3) for the granting of a TEV
- Guidance pertains to antibacterial agents – Applications for other types of antimicrobials than antibacterials may be discussed with the Agency with respect to the possibility of being eligible for a TEV.

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Key criteria

Addressing a multi-drug resistant organism

Demonstrating a significant clinical benefit

Novelty: new MoA or NAS

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Addressing a multi-drug resistant organism

1 Identify the target pathogen(s)

The applicant should identify the target pathogen(s) that the antimicrobial addresses.

2 Show the pathogen is multi-drug resistant (MDR)

A microorganism is MDR if the isolate is non-susceptible to at least one agent in three or more antimicrobial categories.

A bacterial isolate will be considered non-susceptible to an antimicrobial agent or antimicrobial category, when it is found to be non-susceptible by using available interpretative criteria established by **EUCAST**.

For pathogens for which there are **less than three agents** available, a microorganism is MDR if it is resistant to most or all agents.

3 Show it is a priority pathogen

The applicant should provide evidence that it is listed as **critical- or high-priority** in the WHO bacterial priority pathogen list, or in any equivalent list of priority pathogens established at Union level.

This could be substantiated by **Union-specific epidemiological data** (e.g. from ECDC/EARS-Net) documenting the burden, resistance trends and public-health impact of the pathogen(s), thereby confirming that it represents a priority target for the Union considering the current epidemiological situation in the Union.

Note: when **assessing a submission** for eligibility for a TEV, the EMA may consult the **ECDC**.

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Addressing a multi-drug resistant organism

Demonstrating a significant clinical benefit

Novelty: new MoA or NAS

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Significant clinical benefit with respect to antimicrobial resistance

The new agent is expected to have a characterised **pre-clinical (microbiological), PK/PD and clinical profile** that demonstrates that it provides significant clinical benefit in the context of treatment of infections caused by multi-drug-resistant pathogens.

- **Pre-clinical data** are needed to establish that the candidate antimicrobial addresses a multi drug resistant organism and overcomes resistance mechanisms currently driving clinical treatment failure:
  - in vitro/in vivo;
  - PK/PD;
  - animal models;
  - emergence of resistance.

- **For non-traditional agents**, the microbiological expectations set out above cannot be transposed *in extenso*. Specific microbiological evaluations that differ from current practices for traditional antimicrobials are required and should be discussed with EMA during the development.

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Significant clinical benefit with respect to antimicrobial resistance

Clinical data are needed to establish that the candidate antimicrobial has the ability to provide adequate efficacy and an acceptable safety profile when treating the infection(s) caused by the target pathogen(s) and **demonstrate a significant clinical benefit with respect to AMR in the indication(s) applied for, whether pathogen or site of infection specific.**

- The syndrome(s) investigated in clinical trials should be representative of the type of serious infections caused by the target pathogen(s), e.g. hospital-acquired and ventilator-associated pneumonia (HAP/VAP) for Enterobacterales.
- It is recommended that the clinical data package includes direct demonstration of efficacy in treating patients harbouring multidrug resistant infections, at least in a subset of treated patients.

If duly justified, the options for a **streamlined clinical development pathway** for addressing unmet needs described in the EMA guideline on the evaluation of medicinal products indicated for treatment of bacterial infections could be considered in demonstrating that the agent is a 'priority antimicrobial', if it brings sufficient evidence to fulfil the criteria of 'significant benefit with respect to AMR'.

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Significant clinical benefit with respect to antimicrobial resistance

- Resistance selection should be characterised before and during clinical development.
- It is emphasised that the eligibility for an unmet need clinical pathway as stated in the EMA *Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections*, may not be sufficient to meet the criteria of priority antimicrobial.
- Minor incremental advantages in the antibacterial spectrum will not suffice for qualifying as a 'priority antimicrobial'.



CHMP may consult the ETF with respect to the scientific aspect related to the ability to meet the criteria of priority antimicrobial.



Developers can seek scientific advice with regard to the design of preclinical and clinical studies that would be relevant to substantiate a claim of 'priority antimicrobial'.

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Addressing a multi-drug resistant organism

Demonstrating a significant clinical benefit

Novelty: new MoA or NAS

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New Mechanism of Action (MoA)

To be considered as a new MoA, substantial differences versus authorised medicinal products in the Union must be demonstrated.

- This cover exclusively different pharmacological target(s) and different primary pharmacodynamic effect.
- *A contrario*, other differences such as secondary pharmacodynamic effect **or** differences in pharmacokinetics would not be considered as different MoA.

The applicant should take into consideration the following document by analogy with respect to the determination of a new MoA:

- Guideline on aspects of the application of Article 8(1) and (3) of Regulation (EC) No 141/2000: Assessing similarity of medicinal products versus authorised orphan medicinal products benefiting from market exclusivity and applying derogations from that market exclusivity

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NAS and serious or life-threatening infection

- Applicants should provide evidence on the **severity of the infection**. This includes but is not limited to requirements for hospitalisation.
- Other type of **long term sequalae** such as infertility should also be considered as part of the spectrum.
- **Documented mortality** in the presence or absence of adequate antimicrobial therapy should be submitted to characterise the severity of the infection.



The applicant should take into consideration the following documents by analogy with respect to the determination of a NAS:

- Chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances - Scientific guideline
- Criteria to be considered for the evaluation of new active substance (NAS) status of biological substances (draft)

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Thank you

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