EMA
EUROPEAN MEDICINES AGENCY

Claim for transferable data exclusivity voucher

Procedural aspects

Presented by Alex Correia on 12 November 2026
Regulatory Affairs Office



Procedural considerations for a TEV claim (1/2)

A claim for a transferable data exclusivity voucher (TEV) can be submitted:

When

From the **entry into force** of the new Regulation
(expected Dec 2026 – Jan 2027)

Which route

In the context of a **centralised procedure** only (i.e. to EMA)

At what stage

At the time of an **initial marketing authorisation application** (iMAA) only

In addition, note that:

- **Eligibility** for the centralised procedure granted under the current Regulation (EC) No. 726/2004, until the revised eligibility criteria apply.
- It is the **responsibility of the applicant** to provide an **appropriate substantiation** of the claim.

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Procedural considerations for a TEV claim (2/2)

Request highlighted in the application form

An **updated electronic application form (eAF)** is under development and expected in the coming months.

Justification/evidence in the dossier

Justification/evidence that the product meets the **scientific criteria for a "priority antimicrobial**", in accordance with the draft *CHMP/EMA Guidance on scientific considerations governing the criteria for eligibility as a priority antimicrobial* and the **additional requirements** is expected at submission.

Procedure

No change in the applicable timelines of the procedure, including for EMA validation and/or CHMP assessment.

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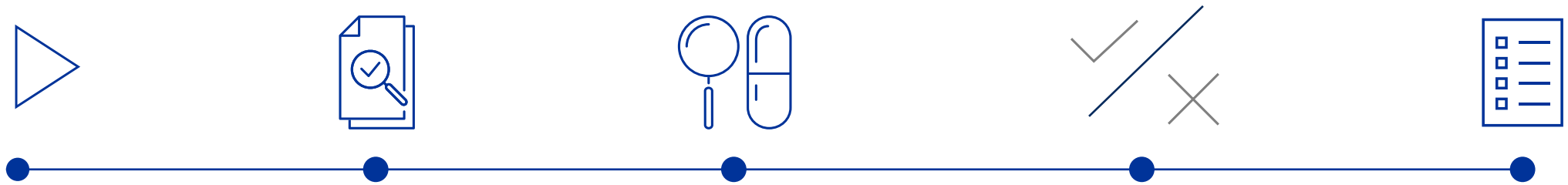
How will the voucher request be handled



Request submitted with initial MAA

EMA validation of application, including evidence on scientific criteria and additional requirements

CHMP* **assesses** scientific criteria based on the respective Guideline

EC decides on granting the TEV based on CHMP opinion and the evidence on the additional requirements

Outcome published in **EPAR**

Key message: EMA timelines and procedures unchanged, CHMP assessment of scientific criteria in parallel and as part of the iMAA assessment, CHMP opinion on the consideration of a “Priority Antimicrobial” also subject to re-examination. Outcome published in the EPAR after the EC decision.

** With involvement of ETF and/or other WPs, as appropriate.*

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Next steps



EMA webpage

With information on the TEV



Publication of specific procedural guidance

on considerations for a TEV claim



Updated eAF

including section for the voucher request



Consultation on Draft guidance documents

on scientific considerations governing the criteria for eligibility as a priority antimicrobial and on the additional requirements.

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Take-home messages

- Applicants should **collect/generate the necessary evidence to meet the requirements to claim a voucher** and **consider the timing of a regulatory submission in EU**.
- Applicants are strongly encouraged to **discuss the procedural aspects** of their application containing a claim for a voucher **with the Agency** e.g. in the context of a Pre-submission interaction.
- The **CHMP opinion on the classification** of a priority antimicrobial is **without prejudice of the opinion on the B/R of the application**.

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