EMA
EUROPEAN MEDICINES AGENCY

Implementation of the New Pharmaceutical Legislation (NPL)

Delivery stream 6 (Regulatory & Legal)

17th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines, 20 November 2026

Zahra Hanaizi, Senior policy specialist & NPL delivery stream lead

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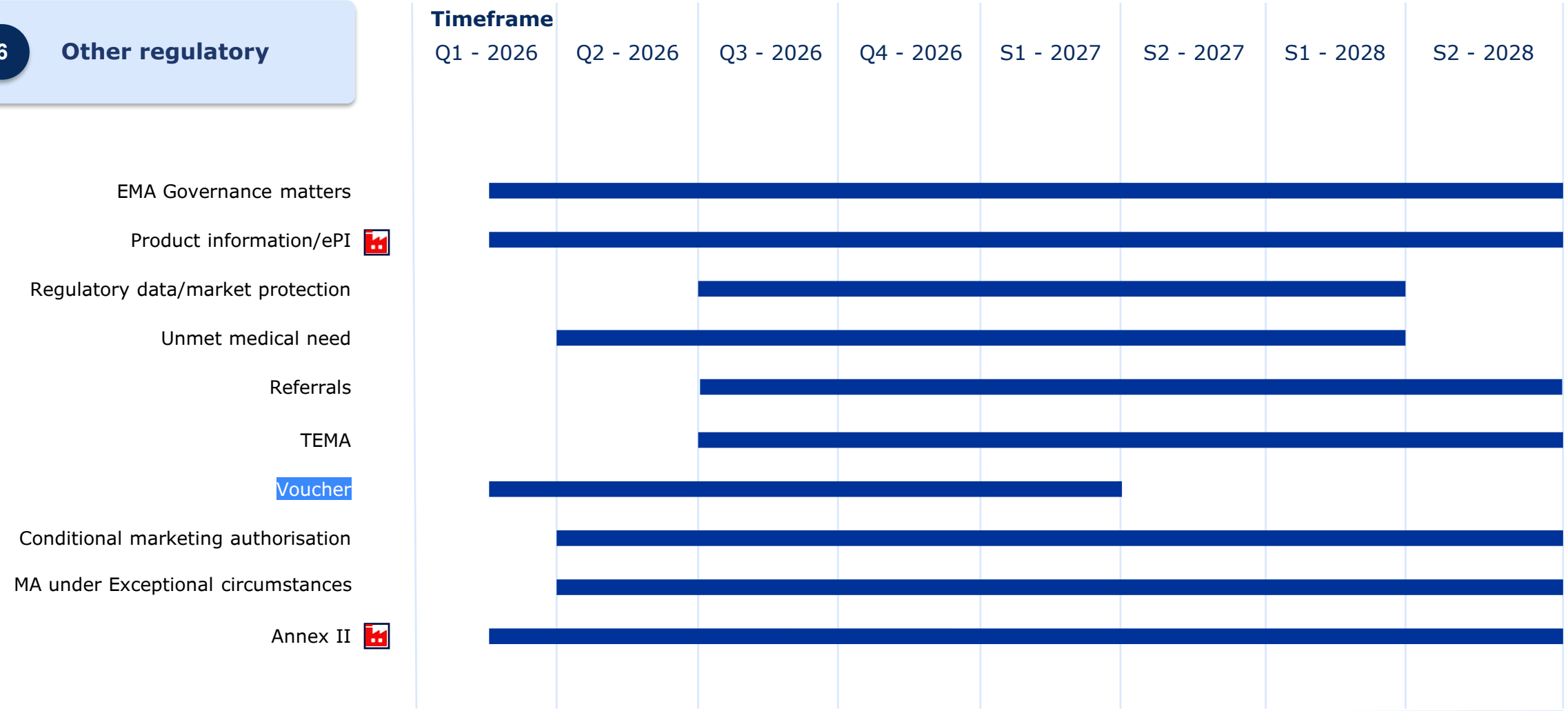
DELIVERY STREAM 6: Regulatory & legal

6 Other regulatory



Timeframe Industry priority Blue 2026 priorities

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Conditions to be eligible for a Transferable data exclusivity voucher (TEV)

iMAA to include a request with supportive documentation on:

Scientific criteria

Justification that the product meets the scientific criteria for '**priority antimicrobial**'. *

Information on additional requirements

Demonstration of **capacity to supply** **

Information on all **direct financial support received** **

Demonstration that **MAA was submitted first to EMA** or no later than 180 days after the submission outside EU

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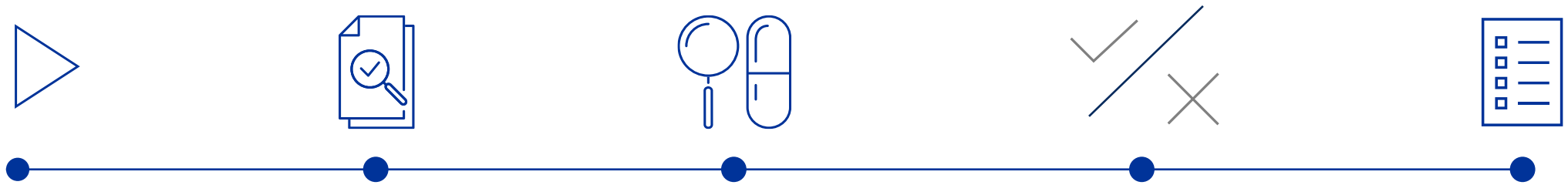
Transferable data exclusivity voucher
How will the voucher request be handled



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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TEV - Stakeholder engagement and next steps

2026

12 November

Stakeholder meeting on the TEV

Presentation of draft guidances on scientific criteria, additional requirements and procedural aspects

w/c 23 November

Publication of TEV webpage

Q&A on procedural aspects for requesting a voucher

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

Draft guidance on additional requirements (demonstration of capacity to supply, information on source of funding)

For public consultation until end January

December

New Regulation enters into force

Voucher provisions become applicable

2027

Q1 2027

Adoption and publication of final CHMP Guidance

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Annex II

Guiding principles

- ensure **harmonisation** for EU (NAPs/CAPs and different product classes)
- balance **granularity** (detail = predictability) & **flexibility** (futureproofing/innovation)
- clarify expectations for dossier content & **ensure compatibility with ICH M4Q / CTD**

Define requirements for

- Marketing authorisation dossier
- Specific dossier (e.g. generics, bio-hybrid, fixed-dose combination, conditional MA…)
- Particular medicinal products (e.g. ATMP, radiopharmaceuticals, homeopathics…)

Stakeholder engagement

- Considerations/issues can be conveyed in existing platforms
- Formal consultations foreseen during development of delegated act by European Commission

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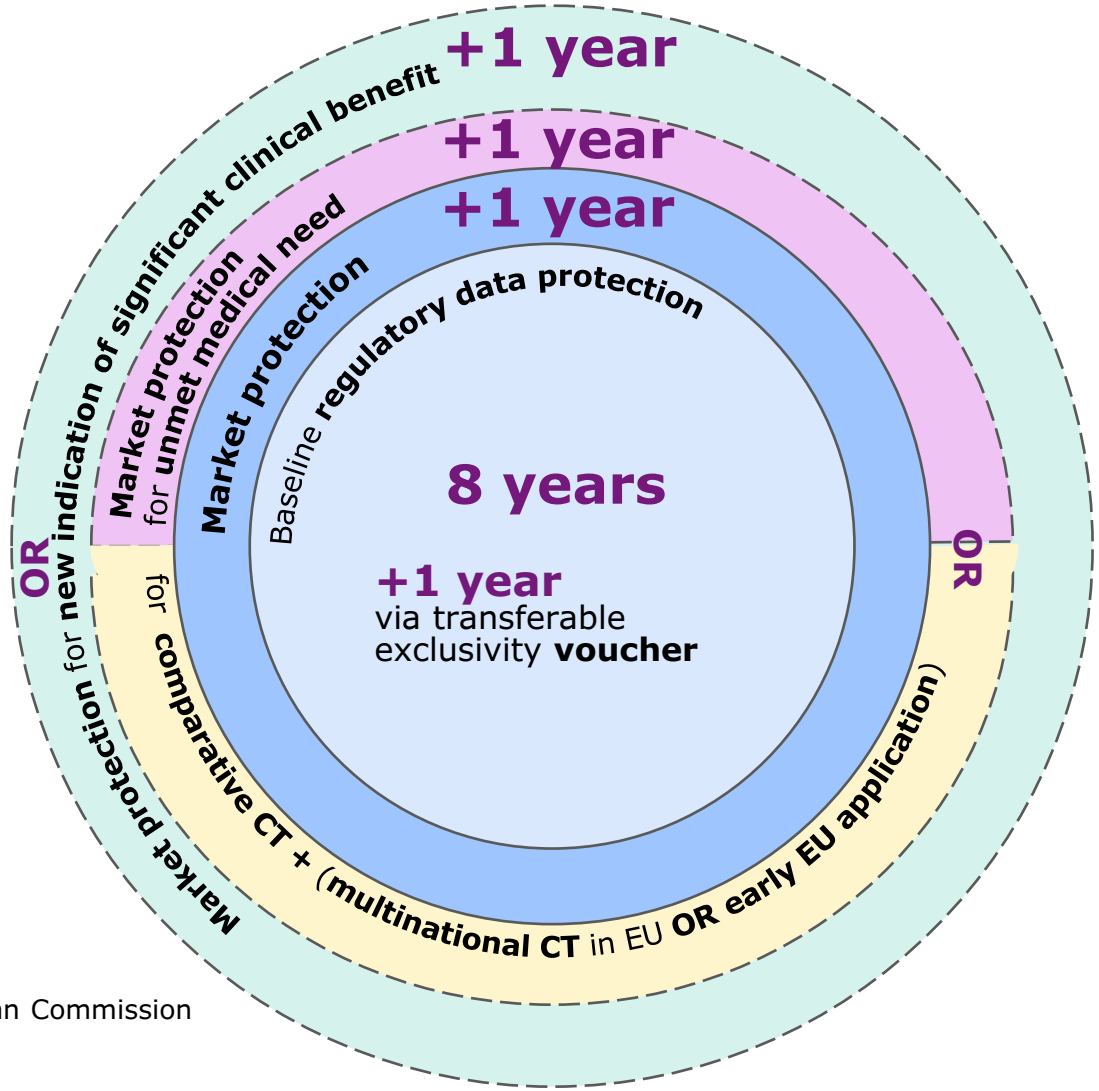
Incentives to encourage innovation



Source: European Commission

Maximum achievable market protection:

12 years

Unmet medical need:
There is no medicine authorised in the EU or the use of the medicine has to result in a clinically relevant improvement in efficacy.

'The competent authorities of the Member States shall make available on their website the list of medicinal products for which they have granted a national marketing authorisation and that are protected by regulatory data protection and regulatory market protection, indicating the applicable extension in accordance with Article 84. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.' (New directive, Article 83)

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