

Transferable data exclusivity voucher for priority antimicrobials in the new pharmaceutical legislation

12 November 2026, 14:00 – 17:00 (CET)
EMA, Amsterdam, live broadcast

A transferable data exclusivity voucher (TEV) is an incentive rewarding the development of priority antimicrobials. The voucher gives its holder the right to extend by 12 months the regulatory data protection period of one centrally authorised medicinal product, either the priority antimicrobial itself or another medicinal product of the same or a different marketing authorisation holder.

The reform of the EU pharmaceutical legislation introduces the TEV as part of its objective to address antimicrobial resistance, which is also a strategic priority of the European medicines regulatory network. The voucher is among the first provisions of the new legislation to be implemented, and the European Medicines Agency (EMA) and the European Commission (EC) are preparing relevant guidance documents to support applicants.

During this meeting, EMA and the EC will provide industry stakeholders with an overview of the practical implementation of the provisions related to requesting and granting a TEV. In particular, the objectives of this meeting are to:

- Present the TEV concept as laid out in the revised pharmaceutical legislation
- Discuss key elements for the implementation of the TEV, specifically:
    - Scientific assessment of the criteria for a priority antimicrobial, including upcoming guidance
    - Other requirements for granting and procedural aspects for submitting a request

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Co-chaired by Barbara Mentré (EC) and Alberto Ganan Jimenez (EMA)

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14:00	**Welcome and opening**	
	Barbara Mentré (EC)	**5 min**
	Alberto Ganan Jimenez (EMA)	**5 min**
14:10	**Session 1: Introducing the concept**	
	The TEV in the new pharmaceutical legislation *Barbara Mentré (EC)*	**30 min**
14:40	**Session 2: Scientific assessment**	
	Scientific assessment of the criteria for a priority antimicrobial *Marco Cavaleri (EMA)* Including Q&A with Miriam Fuerst-Wilmes (IDWP member, BfARM, DE) and Filip Josephson (CHMP and ETF member, MPA, SE)	**60 min**
15:40	**Coffee break**	
		15 min
15:55	**Session 3: Other requirements and procedural aspects**	
	Other requirements and procedural aspects for requesting a voucher *Pietro Erba (EC) and Alex Correia (EMA)* Including Q&A.	**55 min**
16:50	**Closing remarks**	
	Barbara Mentré (EC) and Alberto Ganan Jimenez (EMA)	**10 min**