Tackling Antimicrobial Resistance

EMA activities across the lifecycle of antimicrobial medicines, with a focus on human AMR

PCWP and HCPWP joint meeting
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WHY THIS MATTERS

AMR: a slow-moving pandemic

Antimicrobial resistance (AMR) is when bacteria stop responding to the antibiotics meant to kill them.

It quietly threatens routine care — surgery, cancer chemotherapy, transplants and intensive care all rely on antibiotics that still work.

"The effectiveness of antibiotics is a shared public-health resource we are spending faster than we replace it."

35,000+

deaths each year in the EU/EEA from resistant infections

Source: ECDC

1.27 M

deaths worldwide attributable to bacterial AMR (2019)

Source: Lancet / GRAM

~€1.5 bn

annual cost to EU health systems and lost productivity

Source: European Commission

Acting across the whole antimicrobial lifecycle

1

Stimulate & support

Help promising new antimicrobials reach patients via ETF scientific advice, PRIME and other incentives.

2

Evaluate & authorise

Rigorous benefit–risk assessment, including tailored paediatric pathways.

3

Promote responsible use

Clear modernised and harmonised product information, supporting prescribing and stewardship to keep antibiotics working.

4

Monitor & protect

One Health surveillance activities across humans, animals and the environment (together with sister EU Agencies).

Helping new antimicrobials reach patients

The pipeline of genuinely new antibiotics is thin — a market failure, not a science failure. EMA uses all available regulatory tools to facilitate the development of new antibacterials

- **ETF/CHMP scientific advice** — early, often fee-reduced guidance on study design.
- **PRIME** — enhanced support and possible faster review for unmet need.
- **Adapted guidelines** — PK/PD and limited treatment option pathway for areas of unmet medical need.
- **Paediatric development** — more extrapolation embedded in the agreed Paediatric Investigational Plan

Why a 'pull' reward? no new antibiotic classes in decades, and Achaogen won FDA & EMA approval for plazomicin — then went bankrupt. EMA's Emergency Task Force works together with the European Commission on the technical details on how TEVs will be granted.

NEW INCENTIVE

Transferable Exclusivity Voucher

EU pharmaceutical reform creates a 'pull' reward for priority antimicrobials.

EMA does the scientific assessment; the Commission grants 12 months extra data protection.

Safeguards: supply duty, public-funding transparency, €490 m 'anti-blockbuster' cap.

INNOVATION

Beyond traditional antibiotics

New tools demand new regulatory thinking. EMA is actively adapting pathways for non-traditional approaches

Bacteriophage therapy

EMA-EC expert workshop (Amsterdam, Oct 2026) building a regulatory framework, with participation of the US FDA, Health Canada, PMDA and other regulators.

Prevention & new modalities

Vaccines and monoclonal antibodies that prevent infections — WHO: better vaccine use could avert ~106,000 AMR deaths/year.

Regulatory innovation

Regulatory sandboxes in the new legislation to test novel products in a controlled, science-led way.

One Health: humans, animals, environment

Resistance crosses between people, animals and the environment — so the response must too. EMA monitors and advises across all three.

Humans

Joint ECDC–EFSA–EMA analyses (JIACRA) link antibiotic use to resistance trends.

Animals

Veterinary antimicrobial sales tracked and down sharply; key classes reserved for human use.

Environment

New rules require assessing the AMR-selection risk from manufacturing and disposal.

EMA’s Antimicrobial Advice Expert Group (AMEG) guides prudent use and which antibiotics to keep in reserve.

Working globally: convergence, monitoring & access

AMR is a global problem — EMA works beyond the EU to speed access, watch how antibiotics are used, and help new ones reach patients.

Global convergence

The EMA–FDA–PMDA–Health Canada AMR cluster meets quarterly; with TATFAR, ICMRA and parallel scientific advice — toward a single global development programme.

Real-world monitoring

DARWIN EU (since 2022) tracks how antibiotics are used — e.g. WHO AWaRe 'Watch' agents — together with ECDC, to guide policy.

Value & access

Antibiotic trials show non-inferiority, but payers want superiority and rarely consider AMR benefit. EMA works with HTA bodies so new antibiotics reach patients.

TATFAR: Transatlantic Taskforce on Antimicrobial Resistance; ICMRA: International Coalition of Medicines Regulatory Authorities

RESPONSIBLE USE

Protecting the antibiotics we still have

An antibiotic only helps if it is used wisely — and available when needed. New rules strengthen both.

Prescription-only, everywhere

All antimicrobials become prescription-only across the EU — with an AMR ‘awareness card’, right-sized packs and clearer patient information.

Stewardship built into approval

Companies must submit an antimicrobial stewardship plan with their marketing-authorisation application.

Safeguarding availability

Stronger shortage monitoring, supply obligations and a Union list of critical medicines.

EU target: cut human antibiotic use 20% by 2030 (Council Recommendation, 2023) · World AMR Awareness Week, 18–24 November

YOUR ROLE

Patients & healthcare professionals are partners

This work is stronger when you shape it. Where PCWP and HCPWP add the most value:

Make information usable

Help ensure leaflets and stewardship messages are clear and patient-friendly.

Bring your expertise in

Contribute to committees, guidelines and public consultations on AMR products.

Champion prudent use

As trusted voices, reinforce responsible-use messages with patients and peers.

Share lived experience

Real-world tolerability and impact data strengthen benefit–risk decisions.

KEY MESSAGES

Taking AMR forward, together

- **AMR is a present threat** — it endangers patients and the everyday foundations of modern medicine.
- **EMA acts across the lifecycle** — from stimulating innovation to evaluating, guiding use and monitoring One Health.
- **New legislation, new tools** — incentives, mandatory stewardship, supply safeguards, environmental rules — and better diagnostics to target therapy.
- **Partnership is essential** — patients and healthcare professionals make the response credible and effective.

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Thank you

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