# ANTIMICROBIAL RESISTANCE

A call to action against the silent pandemic

## How developers can engage with EMA

Antimicrobial resistance (AMR) is a growing **silent pandemic that demands immediate and decisive action.**

In Europe, at least **35,000** people die from antibiotic-resistant infections every year, with **1 in 5** bacterial infections already resistant to antibiotics. Without immediate action, annual deaths could rise to **390,000 by 2050**.

Academia and pharma industry, big and small, must prioritise innovation, research & development of novel antimicrobials, alternatives to antimicrobials and quick diagnostics.

**1 in 5** bacterial infections already resistant to antibiotics.

> In the last 10 years, we have seen a worrisome decrease of new antibacterial and antifungal agents approved in the EU that are able to make a difference regarding treatment of drug resistant infections. This is not enough. AMR is a public health crisis and our Emergency Task Force stands ready to support the development of new medicines to address it.

**Marco Cavaleri**
Head of Public Health Threats

> EMA is ready to engage in early dialogue and provide systemic support to companies to facilitate medicine development. We are committed to exploring alternative treatments to antibiotics, such as bacteriophages, monoclonal antibodies, vaccines and leveraging artificial intelligence to discover new solutions.

**Francesca Day**
Head of Therapeutic Areas Department

Over the last 10 years, **32** antimicrobials were approved in the EU, which **is less than 4%** of the total EMA recommendations.

EMA
EUROPEAN MEDICINES AGENCY

EMA's Innovation Task Force offers a unique opportunity to discuss groundbreaking ideas and developments directly with the regulator. In the past 10 years we accelerated 15 AMR-related developments with pharma companies, big and small, and academia. We need more. Do engage with us early, you don't need a mature project.

**Falk Ehmann**
Head of Innovation and Development Accelerator

Globally, small and medium-sized enterprises (SMEs) lead in antimicrobial research and development. However, only 3% of EMA's registered SMEs develop and market anti-infectives. We encourage start-ups and academic groups to engage with our SME Office early on to receive regulatory and scientific support.

**Constantinos Ziogas**
Head of SME Office

## EMA's regulatory tools to support developers of antimicrobials

**Emergency Task Force**
Helps EMA prepare adequate and robust responses to health threats such as AMR by engaging with developers and providing scientific recommendations.

**Innovation Task Force**
Facilitates early dialogue between EMA and developers on scientific, legal and regulatory issues linked to innovative therapies and technologies.

**Scientific advice**
EMA's guidance to developers on the best methods and study designs to generate robust evidence on how well a medicine works and how safe it is.

**PRIority MEdicines (PRIME)**
Allows for early and enhanced scientific and regulatory support from EMA to medicines that may address patients' unmet medical needs.

**Conditional marketing authorisation**
Medicines are approved on less comprehensive data than normally required. Developers will submit additional data post-authorisation.

**SME Office support**
Provides advice, guidance and assistance to SMEs who want to develop and market medicines in the EU.

EMA
EUROPEAN MEDICINES AGENCY