# EUROPEAN PHARMACEUTICAL LEGISLATION REFORM: OVERVIEW AND IMPLICATIONS FOR INNOVATION, ACCESS AND PUBLIC HEALTH

***Lenche Ivcheska*[1*]**
Replek, Skopje, Str. Kozle 188 Skopje, Republic of North Macedonia

## INTRODUCTION

COUNCIL OF THE EUROPEAN UNION

EMA
EUROPEAN MEDICINES AGENCY

On 11 December 2025, the European Parliament and the Council of the European Union reached political agreement on the reform of the EU pharmaceutical legislation, the most significant overhaul of the regulatory framework in over two decades. The reform aims to modernise the entire lifecycle regulation of medicines for human use, supporting digitalization, and innovation from early development through market access and post-authorisation safety monitoring. In the final programming document 2026-2028, EMA revision introduces new mechanisms to foster innovation, evaluate clinical trials through FAST-EU (Facilitating and Accelerating Strategic Trials), improve patient access to medicines, address public health challenges including antimicrobial resistance (AMR), enhance regulatory support for pediatric and rare diseases, advance digitalisation, and promote environmental sustainability in pharmaceutical activities (EMA, 2025).

## MAIN OBJECTIVES AND REGULATORY UPDATES

The new legislation is designed to:
Adapt the EU regulatory framework to support and stimulate medical innovation;
Increase and equalise patient access to medicines across the EU; and Address key public health threats including antimicrobial resistance (AMR).

### 1. *Accelerated assessment*

According to pre-authorisation procedural advice of European Medicines Agency accelerated assessment process is intended to reduce the review time for marketing authorisation applications from 210 to 150 days for products of major public health interest or notable therapeutic innovation (EMA, 2026). Requests should be submitted two to three months before filing for marketing authorisation. If accepted, the evaluation proceeds through three phases (90 + 30 + 30 days) with a single one-month clock stop after Day 90 for applicant responses.

### 2. *Conditional marketing authorization*

CMA — Rolling review cycle — SMA
CMA: Conditional marketing authorisation
SMA: Standard marketing authorisation

Conditional marketing authorisations (CMAs) allow earlier access to medicines intended for treating, preventing, or diagnosing life-threatening or seriously debilitating diseases, including orphan medicines and those necessary in a public health emergency. EMA's Committee for Medicinal Products for Human Use (CHMP) may grant a CMA when four conditions are met: positive benefit-risk balance, likelihood of completing full data post-authorisation, fulfilment of an unmet medical need, and a favourable benefit of immediate patient access versus risk from incomplete data (Council of Europe, 2004, EMA, 2022).
CMAs are granted for one year and can be renewed annually based on ongoing data collection.

### 3. *Addressing antimicrobial resistance*

AMR
Antimicrobial Resistance

Antimicrobial resistance has become a major global health threat, already responsible for around 35,000 deaths annually in Europe. Without decisive action, projections estimate up to 39 millions of deaths per year by 2050, with one in five bacterial infections already resistant to antibiotics (Naghavi, M. et al., 2024).
Between 2015 and 2024, only 32 antimicrobials were approved in the EU, representing less than 4% of all EMA marketing authorisation recommendations. Stimulating the development of new antibiotics is therefore a core part of EMA's AMR strategy (Daher, L., Vilimelis-Piulats, I., 2026).
As of March 2025, EMA's Emergency Task Force (ETF) provides regulatory and scientific support to developers of medicines against bacterial and fungal infections caused by resistant pathogens, including tuberculosis. This continuous support is crucial to translating innovative research into accessible treatments.

### 4. *FAST-EU initiative and clinical trial coordination*

FAST-EU
Facilitating and accelerating strategic clinical trials in the EU

A large number of National Competent Authorities (NCAs) and Ethics Committees have committed to test a fast-track, coordinated framework for evaluating multi-national clinical trials, known as FAST-EU (Facilitating and Accelerating Strategic Trials).
FAST-EU is a voluntary pilot with a planned duration of a year and a limited number of applications per month. The initiativeis part of the EU's broader strategy to reinforce clinical research capacity and set ambitious timelines to provide sponsors with predictable and efficient trial approval processes, whith high ethical and scientific standards. It reflects a solid commitment to cross-border collaboration and enhances the representation of European patients in clinical development (EMA, 2026).

### 5. *Key features*

The full process – from submission in CTIS to final decision – has a maximum timeline of 10 weeks (70 days), including sponsor response times.
Validation and assessment happen in parallel, with Ethics Committee opinions fully integrated into the process.
The pilot operates fully within CTIS and the EU Clinical Trial Regulation.

## CONCLUSION

**The forthcoming EU pharmaceutical legislation represents a transformative step towards a more flexible, innovation-oriented, and globally competitive regulatory environment. By integrating accelerated and conditional pathways, committing to combat antimicrobial resistance, and launching collaborative initiatives such as FAST-EU, the EU strengthens its capacity to respond to healthcare challenges and ensure patient access to safe, effective, and sustainable medicines.**

## REFERENCES

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