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CORRESPONDENCE
Lence Ivceska

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POSTER COMMUNICATION · PHARMACEUTICAL INDUSTRY

European pharmaceutical legislation reform: Overview and implications for innovation, access and public health

Lence Ivceska[1]*

[1] Replek, Kozle 188, Skopje, Republic of North Macedonia
* Corresponding author: Lence Ivceska

KEY MESSAGES

1. Adapt the EU regulatory framework to support and stimulate medical innovation;
2. Increase and equalize patient access to medicines across the EU
3. Address key public health threats including antimicrobial resistance (AMR).

ABSTRACT

Introduction. 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).

Materials and methods. A descriptive review and qualitative analysis of relevant European pharmaceutical regulatory documents, EMA publications, EU legislative initiatives, and scientific literature were conducted. Official regulatory sources, including EMA guidelines, programming documents, and EU legislation, were reviewed to identify and assess the key proposed regulatory changes. Particular attention was given to accelerated assessment, conditional marketing authorisation, antimicrobial resistance (AMR), and the FAST-EU initiative. The findings were analysed and synthesised to evaluate their potential implications for pharmaceutical innovation, patient access, and public health.

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ABSTRACT (CONTINUED)

Results. Accelerated assessment: Reduction of the marketing authorisation assessment timeline from 210 to 150 days for medicines addressing major public health needs or representing significant therapeutic innovation.

Conditional marketing authorisation: Facilitation of earlier patient access to medicines addressing unmet medical needs, subject to specific conditions and continued post-authorisation data collection.

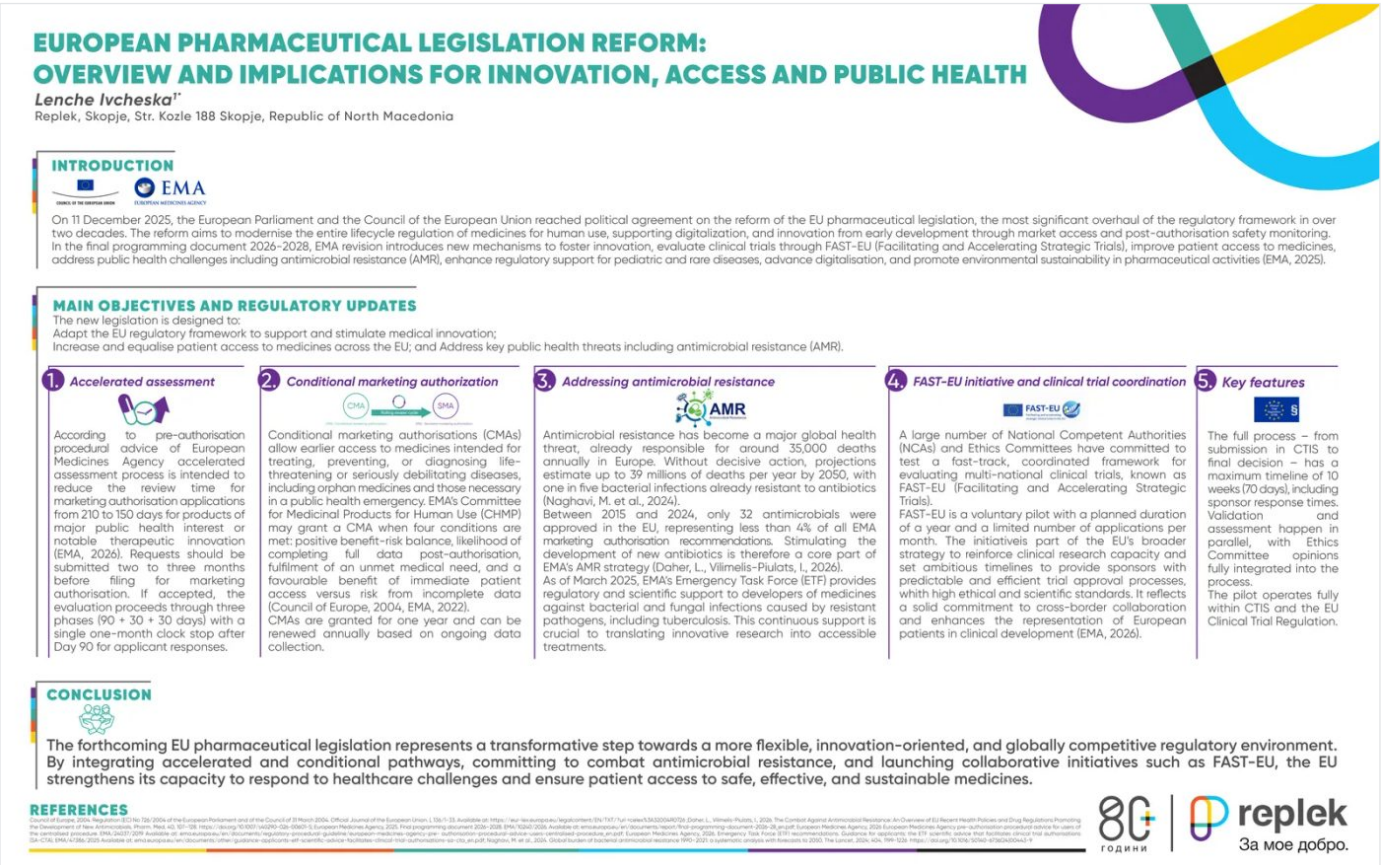
Antimicrobial resistance: Increased regulatory support for the development of new antimicrobial medicines in response to the growing global AMR threat.

FAST-EU initiative: Introduction of a coordinated clinical trial assessment framework, aiming to reduce approval timelines to a maximum of 70 days (10 weeks).

Regulatory modernisation: Greater emphasis on innovation, digitalisation, patient access, and more efficient regulatory procedures.

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.

POSTER



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