

Portfolio Objectives 2026–2028

Human Medicines

2

Clinical Trials Authorisation

By 2028, improve clinical trial authorisation, oversight and transparency capabilities; modernise and simplify to reduce operational costs, while supporting the EU's attractiveness as a location for clinical research.

6

Medicines Shortages

Strengthen EMA capacity to monitor, prevent, and manage medicine shortages across the European network as required by the Agency's extended mandate, the new pharmaceutical legislation and the Critical Medicines Act, enhancing coordination and data integration to improve shortage prevention and response.

Human and Veterinary Medicines

4

ISO-IDMP Master database

Establish comprehensive ISO-IDMP master data management for medicines and substances to ensure consistent, high-quality information throughout the regulatory lifecycle, supporting electronic submission and import of regulatory submissions, enhanced decision-making and seamless information exchange across the EMRN.

5

Medicines life cycle mngmt

Modernise and expand the Agency's medicines lifecycle management and transparency capabilities to support the requirements of new pharmaceutical legislation while advancing digitalisation of regulatory processes, enhancing information security, and improving operational efficiency.

7

BI, AI & Analytics

Strengthen evidence-based decision-making by enhancing the Agency's ability to generate, analyse, and utilise data - including AI and advanced analytics - to improve medicines regulation, support implementation of new pharmaceutical legislation across the European regulatory network and increase efficiency.

Vet Medicines

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Vet medicines information

By 2028, enhance veterinary medicines information management capabilities ensuring adequate veterinary medicinal product data availability across the European regulatory network.

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1 Cybersecurity

Strengthen information security capabilities supporting delivery of new pharmaceutical legislation and ensuring compliance with evolving EU regulations while enhancing cyber resilience and adopting modern security frameworks.

9 Critical legacy systems

Ensure continuous and reliable operation of all critical legacy systems by implementing robust business continuity strategies to enable secure digital transformation and phased modernisation of legacy applications.

8 Corporate back office

Modernise corporate back-office systems to enhance operational efficiency, user experience and automate manual processes, ensuring continuity and security of essential business functions including finance and human resources management.