

# **Multiannual Strategic Plan**

## **of**

# **Romanian National Agency for Medicines and Medical Devices**

## **(2025-2028)**

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### **Introduction**

This strategic framework sets out the guiding principles and operational plans for the National Agency for Medicines and Medical Devices for the period 2025-2028. Building on previous policies, the plan reflects current national priorities and the dynamic landscape of European regulation and health innovation.

The strategy emphasizes the importance of good governance, technological modernization and active participation in European and global networks to ensure that Romanian citizens have rapid access to high quality medicines and medical devices, even in the face of market limitations and evolving health challenges. The framework aims to adapt rapidly to the changing health environment driven by technological advances, demographic changes and international collaborations. It underlines the importance of effective regulation and active involvement in the EU network to ensure rapid access to new medicines and to better address availability.

### **Mission**

The primary aim of the Agency is to serve to protect and promote public health by ensuring the safety, efficacy and availability of medicines and medical devices. The Agency acts as a policy maker, regulator and coordinator of specialized staff, striving to shape a health ecosystem that encourages innovation while maintaining rigorous safety standards. The Agency is committed to promoting transparency and facilitating stakeholder engagement to support a resilient health system.

### **Vision**

The Agency is recognized as the leading authority in Romania for the regulation of medicines and medical devices - an organization known for its integrity, professionalism and forward-looking approach. The Agency aims to become an example of efficiency and reliability, setting standards for transparent and science-based decision-making.

In the future, the Agency aims to become an internationally recognized institution that seamlessly integrates digital and scientific innovations to protect and promote public health. It envisions a

system where medical products are universally available, safe and effective, and where stakeholders - from healthcare providers and industry, to patients and institutional partners - can rely on the Agency's expertise and leadership.

The Agency strives to be a driving force for continuous improvement, promoting continuous improvement among its employees and actively engaging in international health policy discussions. In this way, the Agency aims to influence health innovation policies and to ensure that Romania remains at the forefront of health progress worldwide.

### Values

- The priority is patient-centered public health;
- Legal and ethical independence and transparency;
- Commitment to quality based on scientific progress and high standards;
- Working collaboratively, with mutual respect and openness;
- Foster an environment of motivation, growth and commitment among staff.

### Main Strategic Objectives

**1. To protect and improve public health** by ensuring access to safe, effective and high-quality medicines and compliant medical devices while minimizing interruptions in supply.

The main objective is to ensure that all citizens have rapid and equitable access to medicines and medical devices that are safe, effective and of the highest quality. This involves not only streamlining approval and oversight processes, but also mitigating the risks of supply shortages for life-saving therapies, both innovative and classical.

Beyond availability, this objective emphasizes the development of a regulatory environment that encourages the market entry of innovative medical products, including orphan drugs and advanced therapies. The Agency aims to create an ecosystem in which new treatments can reach the market quickly without compromising safety or efficacy.

**2. Sustain and improve the quality and reliability of regulatory activities**, maintaining a high standard of the Agency's activities in line with international best practice.

High standards are essential to the Agency's operations. This objective entails adopting and exceeding international benchmarks for regulatory excellence through continuous evaluation, benchmarking and the adoption of best practices. The Agency will continuously develop procedures, improve risk assessment methodologies and modernize oversight activities to ensure safety and compliance.

In addition, the Agency will prioritize transparency, data integrity and complete documentation. Clear performance indicators and regular audits will support an environment of continuous quality improvement. The objective is to ensure a robust regulatory framework at national level.

### **3. Enhance the strategic influence, visibility and role of the Agency.**

The Agency positions itself as a prominent player in national health policy making and in health initiatives at EU level. This strategic objective entails increasing the visibility and influence of the Agency in the wider European framework, actively contributing to EU policy making and positioning Romania as a valuable partner in international health collaborations.

In addition, the Agency will promote its role as a center of expertise, sharing information and best practices. The Agency aims to promote partnerships with academic institutions, industry leaders and international organizations to influence health innovation and regulation. Strengthening its voice in public health decision making, both domestically and in the EU, aligns with Romania's broader health and economic development objectives.

### **4. Ensuring adequate resources and promoting organizational resilience** in order to effectively achieve the Agency's mission.

Achieving the strategic objectives requires sufficient human and financial capacity and infrastructure. This focuses on attracting and retaining highly qualified professionals, securing sustainable sources of funding and investing in state-of-the-art IT infrastructure.

The Agency will also develop contingency plans to respond to emerging health threats, regulatory changes and market challenges. Strengthening organizational resilience ensures that the Agency can deliver on its commitments despite changing circumstances.

### **5. Promoting digital transformation and operational efficiency.**

Exploiting digital technologies is fundamental to modernizing the Agency's operations. This objective promotes the development of a comprehensive digital ecosystem - integrating workflows, data management systems and communication channels - to ensure timely, accurate and efficient service delivery.

Priority areas include the implementation of a system for supply chain transparency, in collaboration with the Ministry of Health, and the development of e-services for stakeholders. Digitization will reduce administrative burdens, increase transparency and encourage data-driven decision-making, ultimately improving the quality and timeliness of activities.

### **6. Strengthen stakeholder involvement and public trust.**

Maintaining strong relationships with all stakeholders - patients, health professionals, industry, government bodies and international partners - is vital. The Agency aims to encourage open communication, develop user-friendly information resources and build trust through transparency and accountability.

Effective stakeholder engagement involves organized consultations, educational initiatives and the ability to respond to public concerns. In doing so, the Agency will strive to build society's trust in its operations and strengthen its reputation as a transparent authority.

## Challenges

Significant challenges include health-specific legislative complexities, outdated infrastructure, the financial politics of the Romanian pharmaceutical market, workforce retention issues, EU regulatory adjustments and resource constraints stemming from EU reforms.

The Agency operates in a complex environment marked by regulatory changes at national and EU level, budgetary constraints related to investment, recurrent expenditure and, especially, wage policies, government limitations on hiring across the public sector and workforce challenges, including staff migration to the private sector.

## Activities and priority areas

The multi-annual strategic plan takes into account the European Medicines Agency Network (EMRN) Strategy to 2025, which focuses on 6 strategic directions:

- availability and access to medicines
- digital transformation and data analytics
- innovation in health technologies
- combating antimicrobial resistance and emerging health threats
- supply chain resilience
- long-term sustainability and operational excellence.

At the national level, the Strategic Plan supports the **National Health Strategy 2023-2030**, adopted by the Romanian Government, which aims at overall improvements in health, reduction of inequalities and a balanced health system that responds to the needs of citizens.

## Concluding remarks

The strategic plan takes into account continuous monitoring and flexible adjustment of actions in order to achieve the set objectives. If the agency's progress on certain indicators shows shortcomings, the root cause analysis will guide corrective actions, ensuring that targets are ultimately achieved.

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