DEVELOPMENT STRATEGY 2024–2027

November 2023

LEGAL BASIS FOR THE AGENCY'S WORK AND POWERS

The Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: the Agency) started its work on 1 January 2007 following the merger of the Agency of the Republic of Slovenia for Medicines and Medical Devices, functioning as a body within the Ministry of Health, and the Ljubljana Institute for Pharmacy and Drug Research. It was established pursuant to the Decision on the Establishment of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No 115/06).

Business address: Slovenčeva ulica 22,
1000 Ljubljana
Registration number: 2256584
Tax identification number: 24862185
User code: 27650
Sub-account number at the Ljubljana Public Payments Administration of the Republic of Slovenia: SI56 0110 0600 0020 296
Tel.: +386 (0)8 2000 500
Fax: +386 (0)8 2000 510/+386 (0)8 2000 557
Website: www.jazmp.si
Email: info@jazmp.si
Founder: Republic of Slovenia,
Government of the Republic of Slovenia
Legal and organisational form: public agency
Public agency's bodies: Director,
Public Agency Board
Responsible person: Momir Radulović, *mag. farm.*

The Agency is the competent authority in the areas of medicinal products, medical devices, blood and blood products, human tissues and cells, and the manufacture of and trade in illicit drugs in groups II and III. It performs tasks with public authorisations pursuant to the act on medicinal products, the act on medical devices, the act on blood supply, the act on the quality and safety of human tissues and cells intended for treatment, the act on the manufacture of and trade in illicit drugs, the act on pharmacy services, the act on public agencies, and the decision on the establishment of the Agency. In relation to the users of its services, the Agency works in accordance with EU and national sectoral legislation and with the regulations governing administrative procedures and administrative operations. It performs administrative, supervisory and professional/expert tasks. Its activities include active cooperation with international institutions in the listed areas of work.

TABLE OF CONTENTS

1. FOREWORD 4
2. INTRODUCTION 4
3. MISSION 6
4. VISION 6
5. VALUES 6
6. STAKEHOLDERS AND THEIR EXPECTATIONS 7
7. STRATEGIC CHALLENGES AND SWOT ANALYSIS 8
8. KEY OBJECTIVES AND STRATEGIES 8
9. STRATEGIES FOR INDIVIDUAL AREAS 12
10. STRATEGIC MANAGEMENT 13
11. REFERENCES 13

1. FOREWORD

The role of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: the Agency) as a system regulator and supervisory authority is key in protecting public health and in the system of supplying the population of Slovenia with medicinal products and medical devices. Furthermore, an independent and autonomous agency is essential for the coherent functioning of the economic sector of manufacturing and marketing of medicinal products and medical devices through regulatory mechanisms that enable and promote innovation, competitiveness, export and employment in the sector of healthcare products and services; this sector represents a large part of Slovenia's GDP (according to estimates, the three largest companies contribute 6% to Slovenia's GDP), as it is a sector of products and services with high added value.

Both roles of the Agency contribute significantly to the welfare and protection of public and animal health in Slovenia, as well as to development, economic growth and export orientation. To enhance its societal role, the Agency requires the most stable, sustainable and long-term sources of funding, along with bolstered human potential.

2. INTRODUCTION

The 2024–2027 Development Strategy of the Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices outlines the strategic guidelines for the coming period and complements previous strategies in line with its core values, taking into account changes in the international and national environments. An efficient regulatory system and equal and professional involvement in the EU network allows for rapid access to new medicinal products and better insight into shortages thereof.

Following the effective rehabilitation, in the light of the challenges of the COVID-19 pandemic and the Slovenian Presidency of the Council of the EU, the implementation of key activities was analysed and the existing 2024–2027 Development Strategy was upgraded to account for changes in both Slovenia and the EU.

Strategic planning is based on the monitoring and anticipation of change in the Agency's business environment that may significantly impact its operations and development. Our era is marked by extremely rapid changes in all areas of its operation. Digitalisation, automation, the internet, artificial intelligence, genomics, immuno-oncology, personalised medicine, cell therapy, unmet healthcare needs, new diseases and the redefinition of existing ones, and many other new approaches do not only reflect advances in technology but also shape the new mindset and influence the functioning of human society. Demographic change, coupled with political, legislative and economic changes in the EU and the rest of the world, is contributing significantly to these developments, underlining the need for inter-institutional national and intra-EU cooperation. In such an environment, it is all the more important to continuously follow the trends and to react in a timely and adequate manner based on a public health risk assessment. In this context, in November 2020, the European Commission (EC) adopted a new patient-centred Pharmaceutical Strategy for Europe, which aims to ensure access to high-quality, effective and safe medicines, while enabling the needs for medicines to be met, even in times of crisis, through robust supply chains.

The Pharmaceutical Strategy for Europe has four main objectives:

- Ensuring access to affordable medicines for patients and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, cancer and rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high-quality, safe, effective and greener medicines;
- Enhancing crisis preparedness and response mechanisms and addressing security of supply;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

Legislation governing the Agency's activities primarily consists of EU regulations. The European Medicines Agency (hereinafter: the EMA) and the Heads of Medicines Agencies (hereinafter: HMAs) identified shared challenges, goals and priorities in five-year strategy documents to give strategic direction to the work of the European medicines regulatory network (hereinafter: the EMRN), i.e. **the European Union Medicines Agencies Network Strategy to 2025**. High compatibility of the Agency's objectives with the EMRN's strategic objectives and the aforementioned Pharmaceutical Strategy for Europe is crucial for the Agency's strategy. With regard to medical devices, the CAMD (Competent Authorities for Medical Devices) joint action projects and, with respect to veterinary medicines, additionally the One Health Commission's strategic plan were taken

into account.

The European Union Medicines Agencies Network Strategy to 2025 (EMRN) outlines the following six strategic focus areas:

- Availability and accessibility of medicines,
- Data analytics, digital tools and digital transformation,
- Innovation,
- Antimicrobial resistance and other emerging health threats,
- Supply chain challenges, and
- Sustainability of the EMRN and operational excellence.

At the national level, **the Resolution on the National Healthcare Plan 2016–2025: "Together for a Healthy Society"**, is taken into account; this constitutes the foundation for the development of healthcare and for the drafting and adoption of legislation governing health insurance and healthcare services. This Resolution maintains the vision of high-quality public healthcare accessible to all.

The Agency's objectives were defined so as to provide support in terms of all four overall objectives of the Resolution:

- Improved health and wellbeing and less inequality in the health of the residents of Slovenia,
- An accessible, successful and stable healthcare system that adapts effectively to residents' needs,
- Satisfied patients and providers of services, and
- A more significant contribution of the healthcare sector to the development of Slovenia.

In the domestic and EU environment, the Agency aims to actively co-create policies and regulatory requirements, and respond to them, so as to accomplish its mission, which is characterised by the aforementioned wide-ranging social and health changes. The Agency's strategy places patients, as users of medicinal products and medical devices, at the centre. The health reform in Slovenia, the strategic guidelines in veterinary medicine and major changes in the EU's regulatory network pose new challenges for the Agency. Significant amendments to basic pharmaceutical legislation, which will be implemented at the EU level in the coming years for medicinal products for human use, as well as legislation governing the quality and safety standards for substances of human origin (SoHO) intended for human application are on the horizon. At the same time, there are challenges in meeting the timelines of revised EU legislation on medical devices and in vitro diagnostic medical devices and the implementation of the Regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. The understanding and support of the founder and other relevant stakeholders are pivotal in this respect, as their cooperation, especially in providing the appropriate legal basis and financial and human resources, is a prerequisite for the establishment of conditions enabling adaptation to change.

The strategic plan for the next four years aligns with the mission, vision and values, which are integral components of the internal culture. It also considers stakeholders and their expectations, identifies key environmental trends, and outlines strategic challenges for the future. Based on the latter, strategic areas were defined, objectives were set for the Agency and its organisational units, and a SWOT analysis was performed. In addition, activities were identified to meet these objectives, creating the basis for the development of annual work programmes.

What is regulated?	How is it regulated?
• Medicinal products for human use • Medicinal products for veterinary use • Medical devices • Clinical trials • Blood, tissues and cells	• Issuing manufacturing, marketing and distribution authorisations for medicinal products and active substances • Issuing marketing authorisations for medicinal products after assessing their safety, quality and efficacy • Supervising business entities that manufacture or distribute medicinal products and medical devices • Continuously monitoring medicinal products and medical devices in order to react swiftly to safe application and quality deviations • Publishing expert information, including on the safe application of medicinal products and medical devices and other public health measures

The Agency's other responsibilities:

- it is the national pharmacovigilance centre,
- it is the national pharmacopoeia authority,
- it is the key source of data for the Central Database of Medicinal Products,
- it sets maximum allowed prices of medicinal products for human use,
- it is a key source of data on medicinal products for veterinary use in the European Union Product Database (UPD),
- it appoints and supervises the notified bodies for medical devices,
- it supervises pharmacy services,
- it regulates and supervises homeopathic and natural medicinal products, active substances, and illicit drugs from groups II and III, and
- other professional tasks.

The development of the strategic plan takes into account, first and foremost, the fact that the aforementioned key strategic areas have a significant impact on:

- human and financial resources,
- professional competences, and
- supporting information and communication systems.

3. MISSION

In the fields of medicinal products, medical devices, blood, tissues and cells, the Agency acts in the public interest and for the common good by protecting public health and thus providing for the health of both people and animals. As a proposer of policies and a coordinator of experts, the Agency helps to shape the social environment by creating value and investing in its own capacities. With its professional procedures, regulatory activities and supervision, the Agency also enables and promotes the accessibility of products and the activities of stakeholders that contribute to advances in science and the profession to the benefit of the whole of society.

4. VISION

Health protection is effectively delivered by the Agency, a modern, reputable and internationally recognised institution ensuring the provision of safe, effective and accessible medicinal products and compliant medical devices and other products in its field of activity to all citizens. This is achieved through professionalism, an agile approach and lifelong learning, with collaboration with national and international partners for the benefit of the community.

5. VALUES

Patient-centred – We put the protection of public health and the interests of users of medicinal products, medical devices, blood, tissues and cells first.

Integrity – We act independently, lawfully, transparently and responsibly, in accordance with legally permissible objectives and moral and ethical principles, given the Agency's important role in society and irrespective of an individual's position within the Agency.

Expertise – We carry out our tasks according to the principles of quality, taking into consideration high standards and scientific and professional advances in health in a way that puts the patient first.

Cooperation – We work in a collaborative way, with mutual respect and trust and openness to diversity.

Personal development – We create an environment that provides encouragement and motivation and produces committed, determined, courageous, proactive and satisfied co-workers.

The mission, vision and values are a summarised statement of our aspirations that guide us in our daily work and help us formulate our development plans. Just like the competent authorities in other EU Member States, the respect for and international visibility of the Agency are the result of its total commitment to its mission as it pursues the principles of personal integrity, trust, ethics and quality.

In addition to intensive professional work, this vision requires continuous and self-critical evaluation of the Agency's actions, positions and decisions in terms of how beneficial they are for people and animals. Stakeholders and their goals are taken into consideration insofar as their goals are compatible with the Agency's mission, vision and values. In so doing, the Agency fully respects the fact that its independence stems from its public powers, which enable the State as its founder to realise one of the community's noblest aims, i.e. care for its citizens' health.

6. STAKEHOLDERS AND THEIR EXPECTATIONS

The Agency can efficiently perform its mission only if its activities to the greatest extent possible match the needs and meet the expectations of its stakeholders. These may be compatible with the Agency's mission and tasks or, in some cases, entirely different or even conflicting. In view of this, the Agency will review the compliance of stakeholders' expectations with its strategic objectives and take into consideration only those that are compatible and support its objectives. In developing the strategy, stakeholders' expectations were assessed based on our knowledge, participation in meetings, experience and the use of communication tools in the national and international arena. The strategy places patients, as users of medicinal products and medical devices, at the centre.

STAKEHOLDERS		EXPECTATIONS
General public	Patients or their carers, users, animal owners	High-quality, safe, effective and affordable medicinal products and medical devices on the Slovenian market; information-supported products
Expert public	Pharmacists, doctors and other health professionals, veterinarians, etc.	High-quality, safe, effective and affordable medicinal products and medical devices together with adequate information; transparent operation, information, communication, cooperation
Clients – users of the Agency's services	Applicants, clients	Speedy, efficient and high-quality procedures, transparent operations, efficient market regulation, acceptable costs/tariff
Suppliers of goods and services to the Agency	External suppliers	Compliance with contractual provisions, cooperation/coordination, regular payments
Governing institutions	Founder: Government of the Republic of Slovenia, governance: Board of the Public Agency for Medicinal Products and Medical Devices	Lawful, effective, economic and reliable (consistent) operations, provision of expert support to systemic guidelines, and responsiveness (efficient in terms of both content and cost)
Partner institutions	Health Insurance Institute of Slovenia (ZZZS), National Institute of Public Health (NIJZ), National Laboratory of Health, Environment and Food (NLZOH), Administration of the Republic of Slovenia for Food Safety, Veterinary and Plant Protection (UVHVVR), Association of Patients' Organisations of Slovenia (ZOPS), Institute for the Authentication of Medicinal Products (ZAPAZ), Medical Chamber of Slovenia (ZZS), Hunters Association of Slovenia (LZS), Ministry of Health (MZ), Ministry of the Economy, Tourism and Sport (MGTŠ), Ministry of Higher Education, Science and Innovation, academic institutions, and others	Working together in the public interest and for the common good, locally and internationally, with clearly defined rules for the advancement of society, adding professionalism and responsiveness, synergy of missions and visions
EU institutions and other international organisations	EC, EMA, HMA, CAMD, Council of the European Union, EDQM, PIC/S, WHO and others	Efficient content, implementation of the relevant EU requirements in Slovenia, lawful and reliable operations, expertise, integrity, engagement in activities, initiative (proactive)

Internal public	Employees, trade unions	Good working environment, clear rules, career development, high-quality leadership, participation in development processes, suitable remuneration

7. STRATEGIC CHALLENGES AND SWOT ANALYSIS

The key strategic challenges were defined based on our knowledge of the domestic and international environment, anticipated changes in this environment, expertise and the Agency's development so far, along with forecasts and guidelines stemming from our experience, major trends in the development of institutions, networks, initiatives and stakeholders' expectations at the level of the EU. The challenges were as a rule translated into strategic objectives of the Agency in key strategic areas. The SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) of the current situation helped to define the strategic objectives and develop activities to attain them.

Strengths	**Opportunities**
- Autonomous and independent public agency with public powers and a public service - Skilled and committed staff with appropriate experience and competences in key processes - Stable processes and procedures and an established quality system - COVID-19 experiences in national and international cooperation and crisis response - Experience in managing or participating in international projects - Close involvement in the EU network and numerous participations in international activities - Recognised agency among comparable EU Member States	- Playing an active role in shaping new EU pharmaceutical legislation - Involvement of external experts in international procedures for specific therapeutic areas - Enhanced cooperation with other national competent authorities - Competing for new EU projects - Amendment to the Agency's business model - Digitalisation with appropriate IT support for core activities - Achievement of above-average results by competent authorities in relation to size
Weaknesses	**Threats**
- Among the smallest agencies in Europe despite the importance of pharmaceutical activity in Slovenia - Shortage of staff in IT and new technologies (artificial intelligence, big data), statistics, immuno-oncology, diabetes, personalised medicine, advanced therapy medicinal products, etc. - Due to numerous EU legislative changes, the management of processes, procedures and administrative burden is not optimal without changes in national legislation - Outdated IT technologies do not allow comprehensive computerisation of business processes and integration with EU databases - Part of the public sector as a public agency	- Due to the small size of the market, there is less interest from marketing authorisation holders to bring medicinal products to the market and to keep them on the market - Disproportionality of development through innovation in the pharmaceutical industry and health needs - Lack of incentives to maintain access to medicinal products - Increase in the number of emergency entries and imports of medicinal products and extraordinary increases in the authorised prices of medicinal products - Regulatory changes at the EU level and new competences of the Agency, for which the Agency potentially does not receive the necessary human and financial resources from its founder - Loss of competent staff due to external circumstances (staff migration to the industry sector mainly due to financial conditions of work)

8. KEY OBJECTIVES AND STRATEGIES

Based on the achievements of the Agency's past development strategies, as seen in the annual reports, the key challenges and the SWOT analysis, the following main strategic objectives have been identified in the strategic plan:

1. Ensuring access to and availability of safe and effective medicinal products and compliant medical devices, thereby protecting public health
2. Maintaining the overall quality of activities based on international benchmarking
3. Visibility of the Agency – enhanced role of the Agency in policymaking and EU projects with a development orientation
4. Ensuring the necessary resources to implement the Agency's mission and vision
5. Efficient organisation and digital maturity

Described below are activities aimed at achieving each strategic objective.

1. Ensuring access to and availability of safe and effective medicinal products and compliant medical devices, thereby protecting public health

The small size of the Slovenian market poses a constant risk of disruptions in the supply of medicinal products and of access to new and expensive innovative medicinal products. This is also associated with a relatively low

level of competition between the various manufacturers of innovative, generic and similar biological medicinal products. Until the EU legislation is amended, which is expected to regulate this area, the Agency will continue its efforts to enhance the efficiency of the medicinal products supply system, regardless of whether this concerns new medicinal products with a centralised market authorisation or established medicinal products that are scarce in Slovenia because so few are sold.

Under this objective, the Agency will contribute to the implementation of the National "One Health" National Antimicrobial Resistance Strategy (2019–2024), which considers perspectives from human and animal health and from the environment. This strategy involves collaboration between the health, agriculture and environment ministries, along with experts and stakeholders in these fields. The Agency's specific contributions will focus on reducing overall consumption of antimicrobials and finding solutions to improve accessibility to both existing and new antibiotics through pull incentives.

Operational strategic objectives	Activities
1.1 Develop cooperation with partners on access to medicinal products and medical devices in order to improve coordination and prioritisation	1.1.1 Be actively involved in the Medicine Shortages Steering Group (MSSG) and other working groups – MDSSG, SPOC, TF AAM, EU4H-JA CHESSMEN, EDQM, etc. 1.1.2 Actively monitor the presence of medicinal products on the market and communication with the expert public

Operational strategic objectives	Activities
	1.1.3 Work with the competent institutions, pharmaceutical and medical professionals, and the patients' association to establish formal channels and collaborations to manage the shortage of medicinal products and medical devices 1.1.4 Participate in the establishment of measures and mechanisms in the event of crisis situations and upgrade existing regulatory activities 1.1.5 Overhaul the national list of medicinal products and increase the proportion of medicinal products with a marketing authorisation
1.2 Contribute to the responsible and prudent use of antimicrobials and to finding solutions for access to old and new antibiotics	1.2.1 Offer regulatory tools to expand therapeutic options while mitigating the impact of bacterial resistance to antimicrobials on human health and the environment 1.2.2 Develop expertise in the field of antimicrobial resistance in bacteria 1.2.3 Actively participate in the implementation of the national strategy for antimicrobial resistance management 1.2.4 Participate in EU4H-JA EU-JAMRAI 2 (pull incentives)
1.3 Strengthen pharmacovigilance and vigilance regarding medical devices so as to reduce the risk associated with medicinal products and medical devices	1.3.1 Reduce the risks associated with medicinal products, including the implementation of emergency measures 1.3.2 Inform the public and increase accessibility to vigilance information through publications on the Agency's website 1.3.3 Raise awareness among the expert and general publics of the importance of reporting adverse reactions to medicinal products and medical devices
1.4 Timely, efficient and high-quality implementation of administrative and supervisory procedures	1.4.1 Ensure and strengthen medicinal products and medicinal devices market surveillance under the Agency's competence by increasing the number of inspectors in all areas of competence 1.4.2 Establish a sufficient number of experts with relevant competences in new and existing key areas of activity and continuously upgrade regulatory expertise 1.4.3 Strengthen the application of the risk-based approach in all areas of activity
1.5 Improve the availability of medicinal products with recognised added therapeutic value through cooperation with other competent bodies and decision-makers	1.5.1 Increase cooperation with relevant institutions and researchers in academia and pharmaceutical and medical professionals 1.5.2 Improve access to innovative medicinal products, including orphan medicinal products (horizon scanning) 1.5.3 Contribute to creating conditions to make Slovenia more attractive for clinical trials and to make innovative therapies available to patients

The objectives for each year will be defined in the annual work programmes.

2. Maintaining the overall quality of activities based on international benchmarking

In a highly regulated and complex environment, the Agency is one of the smaller ones in the EU and as such faces relatively bigger challenges and burdens, but it has a unique opportunity and ambition to be among the most visible agencies in the EU network. With participation in the EU network, the Agency's goal is to accelerate access to essential innovations and gain and share the experience, knowledge and competencies necessary to effectively fulfil its mission and to benchmark internationally against various indicators and evaluations.

Operational strategic objectives	Activities
2.1 Increase the number of international procedures	2.1.1 Compete and bid in the EU market for new procedures 2.1.2 Authorisation of medicinal products in the framework of international procedures with mutual recognition (EU DCP/MRP procedures), where the Agency plays the role of Reference Member State (RMS) 2.1.3 Authorisation of medicinal products for human use (rapporteur, co-rapporteur, peer reviewer, member of multinational teams) 2.1.4 Pharmacovigilance issues (leader, co-leader), assessment of safety signals 2.1.5 Appoint and monitor notified bodies for medical devices, supervise manufacturers, authorised representatives of manufacturers established outside the EU, supervise importers and distributors, implement vigilance 2.1.6 Product- or system-specific pharmacovigilance issues (leader, co-leader) involving good manufacturing practices (GMP) on Slovenia's territory and in third countries
2.2 International audit (BEMA, JAP and others)	2.2.1 Corrective and preventive action programme 2.2.2 Regular and unannounced internal audits, including action plans to eliminate potential discrepancies 2.2.3 Training of new internal auditors, including participation in international audits

The objectives for each year will be defined in the annual work programmes.

3. Visibility of the Agency – enhanced role of the Agency in policymaking and EU projects with a development orientation

The aim is to further enhance the Agency's visibility, as the Agency's staff and external experts act as Slovenia's delegates in expert groups, committees and working bodies of EU institutions. Regular and active participation in these groups, along with cooperation with other Member States' delegates, is deemed crucial for ensuring the high quality of the Agency's activities. It is essential not only to facilitate the transfer of experience and knowledge from abroad to Slovenia, but also to actively engage in the formulation of guidelines, policies, opinions and positions. EU legislation whose application falls under the Agency's powers has recently undergone significant upgrades, with plans to further reinforce these activities in the future. Efforts must be undertaken to ensure timely and effective implementation, as the Agency is responsible for enforcing the applicable legislation. Through participation in these working groups, the Agency aims to greatly contribute towards the continuous harmonisation of relevant issues.

Based on the successful Slovenian Presidency of the Council of the EU in 2021, the Agency increased its international presence and strengthened its involvement in EU projects, particularly in Joint Actions within the EU4Health programme 2021–2027. The Agency is in charge of some activities within this programme. The projects that the Agency currently implements or takes part in, and will continue to do so in the future, upgrade its competencies, contribute to acquiring new knowledge, facilitate the recruitment of new staff and support the Agency's development, which is key given its powers.

Operational strategic objectives	Activities
3.1 Enhanced role of the Agency in policymaking	3.1.1 Proactively participate in amending new EU legislation on medicinal products for human use and others through participation in EU working bodies 3.1.2 Co-formulate opinions, positions and guidelines in working bodies of EU institutions, such as EMA, HMA, EC, CAMD, EDQM, PIC/S 3.1.3 Participate in the amendment of existing and the drafting of new laws and implementing regulations
3.2 EU projects and development orientation	3.2.1 EU4H-JA IncreaseNET 3.2.2 EU4H-JA CHESSMEN 3.2.3 EU4H-JA CT-CURE 3.2.4 EU4H-JA SAFE CT 3.2.5 EU4H11 3.2.6 EURIPID 3.2.7 EU4H-JA JAMS 2.0 3.2.8 Participate in innovative areas (e.g. EU-IN, combinations of medical devices with added active substances in support of medical devices, scientific advice by participating in working groups (SAWP, PRAC, etc.)) 3.2.9 Acquire IT skills and competences (e.g. Digital Skills Academy in the framework of the EU NTC and new digital tools, etc.)

The objectives for each year will be defined in the annual work programmes.

4. Provide resources for the implementation of the mission and vision

Creating the right conditions for employees is of paramount importance, as employees are the key to the Agency's success and development. **#greatplacetowork**

The Agency must evolve into a continuous learning organisation to stay up-to-date with the latest advancements in its field and fulfil its role in human resource management. This role is key for developing the necessary skills and competencies among staff to achieve strategic objectives and adapt to changes in the EU environment and stakeholder needs. Organisational unit design should consider factors such as size, staffing capacity and equipment and their impact on implementing the Agency's business strategy and the prospects of its activities. The Agency aims to further develop its potential and enhance its role as a professional regulator, safeguarding human and animal welfare in the field of medicinal products and medical devices while fostering scientific advancement. Through the strategic planning process, the needs for additional staff and competencies were identified; these will be prioritised with realistic timelines for realisation. The Agency requires an additional 30 experts over the next three years to address new tasks stemming from the implementation of EU legislation, with a focus on developing and retaining existing staff.

Operational strategic objectives	Activities
4.1 Human resource management	4.1.1 **#greatplacetowork** and related activities (health promotion, teambuilding, training, increasing the Agency's visibility as an attractive employer, etc.) 4.1.2 Develop a human resource strategy and investing in people 4.1.3 Prepare the basis for deviating from the general personnel plan rules and consider amending the Agency's business model, taking into account long-term economic indicators in the pharmaceutical sector 4.1.4 Targeted management 4.1.5 Systematic annual measurement of employee satisfaction
4.2 Provide financial resources	4.2.1 State budget funds for the public service 4.2.2 Tariff for medical devices 4.2.3 Obtaining new/additional financial resources – EU funding, additional fees from international procedures, etc. 4.2.4 Provision of financial resources from own resources and investing in own capacities 4.2.5 Monitor the impact of EU legislation on the fee components of the Agency
4.3 Address the space shortage	4.3.1 Examine the feasibility of acquiring real estate as an activity development

The objectives for each year will be defined in the annual work programmes.

5. Efficient organisation and digital maturity

Regardless of its sector, size, structure or maturity, an organisation must continuously upgrade its governance system or integrated business model to ensure ongoing success.

The Agency handles approximately 40,000 administrative cases annually and receives over 10,000 electronically submitted applications. Effectively managing this workload requires an upgrade of IT systems. In the modern landscape, comprehensive IT support is essential, especially for managing procedures related to the marketing authorisation of medicinal products and the surveillance of medical devices. In terms of digital maturity, the initial phase of the strategy implementation should prioritise the establishment of the Agency's central IT system, which will facilitate the realisation of the Agency's other strategic objectives.

Operational strategic objectives	Activities
5.1 Efficient organisation	5.1.1 Improve the implementation of core and supporting business processes (SOPs, DN, etc.) 5.1.2 Remove administrative barriers through changes in legislation (prices, annual fees, external experts, the Administrative Procedure Act, etc.) 5.1.3 Further develop balanced indicators at the sector level 5.1.4 Harmonise the implementation of activities in selected comparable processes in particular sectors 5.1.5 Communication strategy 5.1.6 Organise training for stakeholders

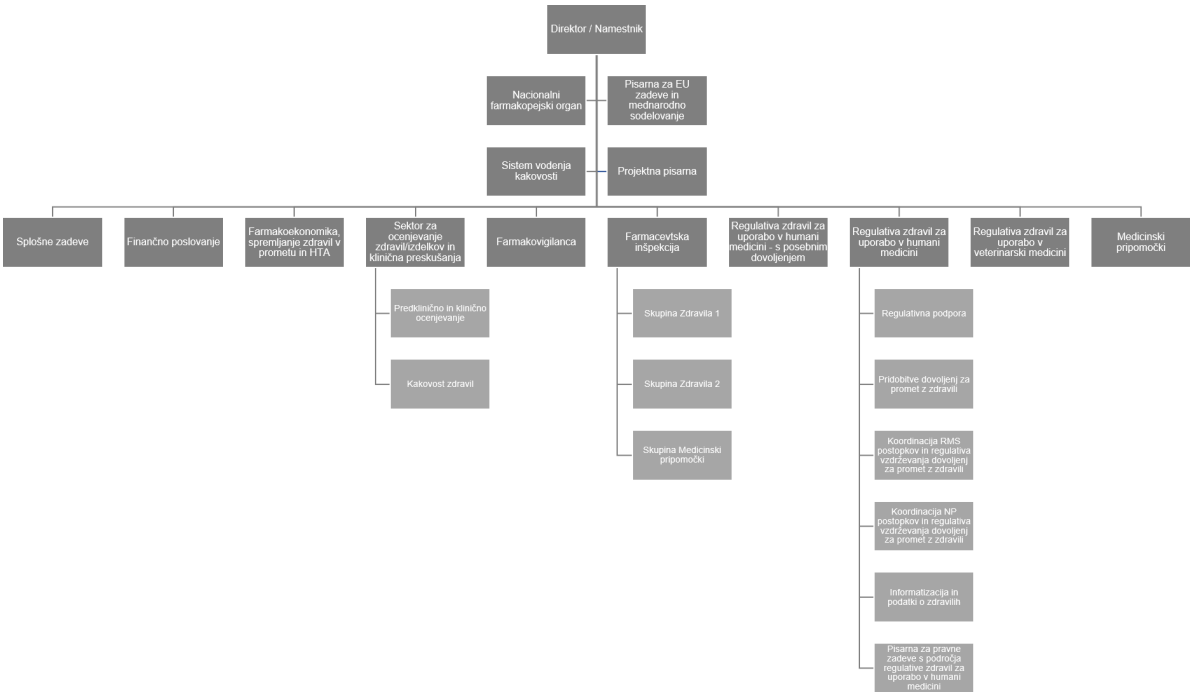
5.2 Increase digital maturity	5.2.1 Implement the CIS for core operations with transparent workflows 5.2.2 Implement ISO IDMP and ensure quality and structured input data for the central electronic health record 5.2.3 Establish links to EU databases for automatic data exchange 5.2.4 Ensure appropriate infrastructure and tools for digital business (document system, KIS, information security, SPOT, e-delivery, PaaS, etc.)

The objectives for each year will be defined in the annual work programmes.

9. STRATEGIES FOR INDIVIDUAL AREAS

The Agency's development strategy serves as the basis for compiling and implementing strategies for individual areas. This will be done by custodians of individual areas in cooperation with the heads of organisational units and project managers in respective areas. The strategies and activities for individual areas will be created in such a manner as to enable their inclusion in annual work programmes and financial plans. The attainment of annual goals will be evaluated using the relevant indicators and presented in the Agency's annual reports.

The Act on Job Classification and Organisation defines the organisational matrix according to the tasks imposed on the Agency by sector-specific laws. The matrix organisational structure is established in order to promote cooperation among employees and a more efficient organisation of work, as well as the implementation of key development activities.



10. STRATEGIC MANAGEMENT

Due to the lack of adequate IT support and sufficient competent staff, the Agency cannot respond to the most demanding challenges in the implementation of its mission and realise its ambitious plan to join the EU/EEA network of its counterparts as a full-fledged and equal partner. The EU institutions expect the competent authorities to be equally effective in all the Member States regardless of the country's size.

The Agency's 2024–2027 Development Strategy serves as the foundation for drafting the Agency's annual work and operational plans. Progress towards the set objectives will be tracked through the execution of processes and projects within specific areas and through the annual drafting of business reports. Periodically,

specific indicators will be reviewed to monitor the progress towards the attainment of objectives. In the event that the expected results are not achieved, an analysis of causes and consequences will be conducted and strategies accordingly adapted to attain the objectives.

11. REFERENCES

National Strategy of Healthcare Quality and Safety (2023–2031)
Pharmaceutical Strategy for Europe
European medicines agencies network strategy to 2025
Competent Authorities for Medical Devices
One Health Commission
Resolution on the National Healthcare Plan 2016–2025: Together for a Healthy Society;
National "One Health" National Antimicrobial Resistance Strategy (2019–2024)
Quality and safety in healthcare – MANUAL