DEVELOPMENT STRATEGY 2018–2021

NOVEMBER 2017

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I. INTRODUCTION

Strategic planning is based on the monitoring and anticipation of change in an organisation's environment that may significantly impact its operations and development. Our era is marked by extremely rapid changes in all areas of our lives. Digitalisation, automation, the internet of things, 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 indeed shape the new mindset and influence the functioning of human society. Demographic change coupled with political and economic upheavals in the European Union (EU) and the rest of the world contributes significantly to these developments.

It is therefore increasingly important to continuously follow the trends so as to be prepared to provide a timely and adequate response. The Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (hereinafter: the Agency) works in an environment very much influenced by social change and responds to such change in an appropriate manner. The health reform in Slovenia, the strategic guidelines in veterinary medicine and changes in the EU's regulatory network pose new challenges to the Agency. The understanding and support of the founder and other key stakeholders are pivotal in this respect, as their cooperation is a precondition for the establishment of conditions enabling adaptation to change. To accomplish its mission, the Agency aims to actively co-create policies and regulatory requirements in its domestic environment.

The Strategic Plan for the Period 2014–2017 expired at the end of 2017. In order to define social change and assess its impact on the Agency's future work, and to prepare an adequate response, the staff and the management of the Agency compiled a new strategic plan covering the period from 2018 to 2021. In the process, the vision, mission and values, as the essential elements of an organisation's internal culture, were updated, key stakeholders designated and their expectations evaluated, major trends in the Agency's environment were taken into consideration and main challenges identified. On the basis of these challenges, the Agency redefined its key strategic areas, set its overall objectives and those of its organisational units, analysed its strengths, weaknesses, opportunities and threats, and prepared action plans to attain these objectives.

The Agency is faced with the following two main challenges:

- unsuitable IT support to the Agency's activities, its networking with domestic partners and participation in the European network of agencies and
- the Agency is understaffed in the majority of its working areas, which as a rule results in the lack of adequate competences in some areas.

Due to the lack of adequate IT support and competencies, the Agency cannot respond to the most demanding challenges in the implementation of its mission and realise its ambitious plan to join the network of its counterparts in the EU/EEA 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. In its strategy up to 2020, the European Medicines Agency (EMA) defined the crucial role of suitable IT support to processes and better utilisation of available resources as the cornerstone of international cooperation within the network. Our 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 European network, though it will not be able to deliver this unless the two challenges mentioned above are successfully tackled.

In response to the first challenge, a special project for the Agency's digital transformation was designed, enabling its smooth functioning, networking and development in the period covered. Furthermore, owing to the scope and complexity of the acquisition, development and maintenance of competences, a comprehensive project titled "KRONOS" has been prepared to close essential gaps in the area of human medicines and provide a regulatory throughput corresponding to the needs and expectations of the stakeholders, while continuously meeting the legislative and other systemic requirements. Similar projects

will also be prepared for medicinal products for veterinary use and for medical devices. A strategy for human resources development will be drawn up simultaneously. It will identify, acquire, develop and maintain competencies matching the Agency's demand in the remaining areas of its work.

The aim is to increase the visibility of the Agency as the key factor on the domestic market in the provision of reliable, uninterrupted and efficient supply of effective, safe, high-quality and affordable medicines, medical devices, and other products and services within the framework of our work and mission. In relation to this, a special communication strategy will be created, targeting the relevant publics with appropriately designed and thematically defined communication (according to the Agency's activities) delivered through modern multimedia channels.

The Agency's vision, mission, values and objectives were defined to support the mission, values, development vision, overall objectives and priority areas noted in the **Resolution on the National Healthcare Plan 2016–2025 ("Together for a Healthy Society")** and the common **EU Medicines Agencies Network Strategy** up to 2020. The Joint Action projects of the Competent Authorities for Medical Devices (CAMD) were taken into consideration in relation to medical devices, as was the Strategic Plan of the One Health Commission in relation to veterinary medicines. Current European trends in the assessment of health technologies are reflected in our strategic objective to join the EU Health Technology Assessment Network (EUnetHTA).

Based on our concern for users and providers, the Agency would like to guarantee suitable access to and provision of healthcare services within the national healthcare system. With equal participation in the European Network, the Agency would like to accelerate access to essential innovations and gain and exchange experience, knowledge and competencies needed to properly perform its mission. The decision of the Heads of Medicines Agencies (HMA) to introduce the comprehensive benchmarking of European medicines agencies in the selected areas of their operation (based on ISO 9004 guidelines) provided us with the possibility to have our work assessed objectively. Coupled with other comparative indicators, this enables us to set an ambitious objective, i.e. to become one of the most successful agencies of the network based on measurable (and comparable) indicators (and by success we mean both efficiency and quality).

The Agency's Strategic Plan will be reviewed and accordingly amended once a year or whenever any of the important circumstances for its work and organisation change. To this end, a custodian of the Strategic Plan has been appointed. A special document will govern the review and amendment procedure. At any given time, the Agency will thus have an updated Strategic Plan for the next four years, serving as a basis for drafting its annual plans of work and operations.

THE LEGAL BASIS FOR THE AGENCY'S WORK AND POWERS

The Agency started its operations 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).

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Founder: Republic of Slovenia, Government of the Republic of Slovenia
Legal and organisational form: public agency
Public agency's bodies: Director, Board
Public agency's management: Dr Andreja Čufar, Director; Dr Stanislav Primožič, Deputy Director

The Agency is the competent authority in the area of medicines, 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 medicines, 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 the regulations governing administrative procedures and administrative operations. It performs administrative, supervisory and professional/expert tasks. Its activities include cooperation with international institutions in the listed areas of work.

II. VISION

The Agency is a respected and internationally well-established authority that meets its commitment to protect health with its expertise and independence and by taking into account those stakeholders' expectations which are compatible with the Agency's objectives.

A vision is a summarised statement of aspirations that guide us in our daily work and help us formulate our development goals. Just like competent authorities in other EU Member States, the respect for and international visibility of the Agency are the result of our total commitment to its mission as we pursue the principles of personal integrity, trust, ethics and quality. Stakeholders and their goals are taken into consideration insofar as their goals are compatible with the objectives, vision, mission and values of the Agency. 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. In so doing, we fully respect the fact that the Agency's independence stems from its public powers, which enable the State as its founder to realise one of the community's noblest aims, namely care for its residents' health.

III. MISSION

In the fields of medicines, medical devices, blood, tissues and cells, we provide for the health of both people and animals, and as proposers of policies and coordinators of experts, we co-create the social environment. With our professional procedures, regulatory activities and supervision, we at the same time enable and promote the accessibility of products and the activities of stakeholders who contribute to advances in science and the profession to the benefit of the whole of society.

The Agency's other responsibilities:	*Not the responsibility of the Agency:*
• 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 covers the regulation of prices for human medicines, • it appoints and supervises the notified body for medical devices, • it carries out activities in relation to Health Technology Assessment (HTA), • it supervises pharmacy services, • it regulates and supervises homeopathic and natural medicinal products, active substances, and illicit drugs from groups II and III.	• it does not supply medicines and medical devices, blood, tissues and cells, though it does regulate and supervise the activities of entities to which it issues permits for these activities, • it does not conduct joint public procurement procedures for medicines and medical devices, though it does provide the related expert support at the systemic level, • it is not the notified body for medical devices or the body for their professional standardisation; it does not issue EC certificates or EC declarations of conformity for medical devices, • it does not issue permits for the provisions of pharmacy services, • it does not cover the fields of cosmetics, food supplements, chemicals or substances that are not medicines or active substances and additives in feedstuffs.

IV. VALUES

Integrity – we work in compliance with laws and regulations; we are committed to transparent and fair practices in accordance with legally permissible objectives and to moral and ethical principles.

Expertise – we perform high-quality tasks in an effective, diligent, unbiased and competent manner while taking into consideration high standards, and scientific and professional advances in health.

Responsibility – we work in a responsible manner in terms of our respective posts at the Agency and in terms of the Agency's place in society.

Cooperation – we play a connecting role, taking into consideration mutual respect, openness and trust.

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

V. KEY STRATEGIC AREAS

The key strategic areas of the Agency's work are defined by laws and regulations. In this document, the key strategic areas are presented not only from the standpoint of legislation governing individual fields but also from the standpoint of our clients, while taking into consideration the internal organisational needs. Each of the following key strategic areas implicitly includes many clearly defined activities with which the Agency, based on regulations, positions and guidelines, implements its mission of the competent authority at the national and EU levels. Such areas are, for example, pharmacovigilance and pharmaceutical inspections. Nevertheless, the following four areas were defined for the purposes of the Strategy's clarity:

1. **Medicinal products for human use,**
2. **Medicinal products for veterinary use,**
3. **Medical devices,**
4. **Blood, tissues and cells.**

When drafting this Strategy, we primarily took into account the fact that the definition of the key strategic areas at the level of some or all the Agency's activities has a considerable impact on:

- required professional competencies;
- human resources – number of employees;
- Communication and Information System support;
- financial resources.

The key strategic areas are addressed from the standpoint of the exercise of the Agency's public powers at the following two levels:

1. products (medicinal products and medical devices) and
2. activities of business entities;

from the standpoint of the implementation of the following three categorical functions of the competent authority:

A. regulation;
B. supervision; and
C. other professional tasks;

and from the standpoint of the following bases or results of its work:

- regulations, policies, positions and guidelines;
- procedures and decisions;
- development;
- management and communication.

	MEDICINES (H + V)	MEDICAL DEVICES	BLOOD	TISSUES AND CELLS
PRODUCTS	⬭	⬭		
ACTIVITIES	⬭	⬭	⬭	⬭

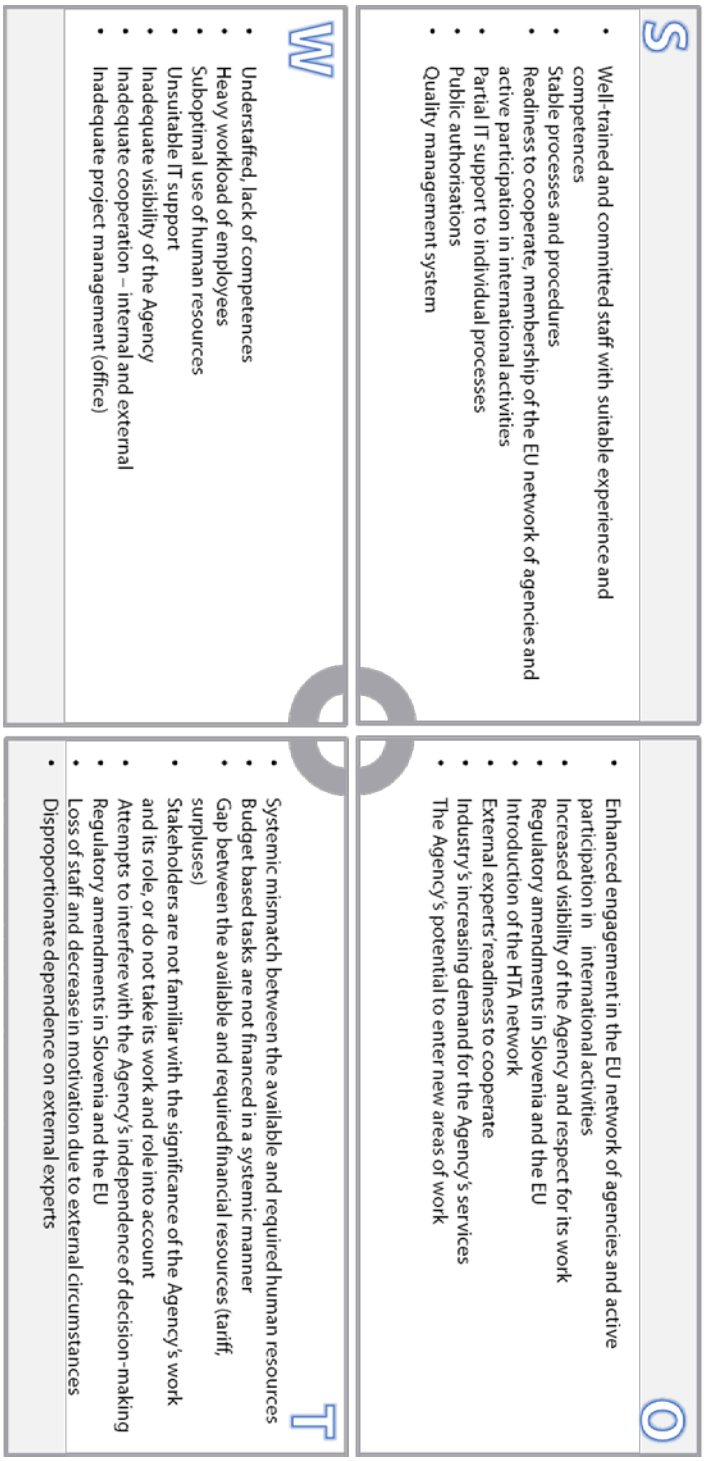
VI. KEY STAKEHOLDERS AND THEIR EXPECTATIONS

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. When drafting the Strategy, stakeholders' expectations were evaluated on the basis of our knowledge, frequent communication with stakeholders in Slovenia and abroad, and the experience gained in the communication. In the future we will monitor and review their expectations more systematically, using suitable tools, and in closer cooperation with national and European institutions.

GROUP			EXPECTATIONS
1	**Patients/general public**		high-quality, safe, effective and affordable medicines and medical devices on the Slovenian market; information-supported products
2	**Expert public**	health professionals, veterinarians	high-quality, safe, effective and affordable medicines and medical devices together with adequate information; transparent operation, information, communication, cooperation
3	**Clients – users of the Agency' services**	applicants	speedy, efficient and high-quality procedures, transparent operations, efficient market regulation, acceptable costs/tariff
4	**Suppliers of goods and services to the Agency**	external services	compliance with contractual provisions, cooperation/coordination, regular payments
5	**Governing institutions**	A. founder (the Government of the Republic of Slovenia); B. governance (the Ministry of Health, the Ministry of Agriculture, Forestry and Food, other ministries and bodies)	lawful, effective, economic and reliable (consistent) operations, provision of expert support to systemic guidelines, and responsiveness (efficient in terms of both content and cost)
6	**Partner institutions and individuals**	the Health Insurance Institute of Slovenia; the National Institute of Public Health; the National Laboratory of Health, Environment and Food; the Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection; and others	cooperation based on clearly defined rules, expertise, responsiveness, mission and vision synergies, mutual trust, coordinated values
7	**EU institutions, the Council of Europe and other international organisations**	EC, EMA, HMA, CAMD, Council of the European Union, EDQM, PIC/S, and others	efficient content, implementation of the relevant European provisions in Slovenia, lawful and reliable operations, expertise, integrity, engagement in activities, initiative (proactive)
8	**Employees**		good working environment, clear rules, career development, high-quality leadership, participation in development processes, suitable remuneration

VII. KEY STRATEGIC CHALLENGES AND SWOT ANALYSIS

The key strategic challenges were defined on the basis of 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. Challenges were as a rule translated into the strategic objectives of the management and organisational units. The SWOT analysis of the current situation helped us define the strategic objectives and elaborate strategies on how to attain them.



VIII. KEY OBJECTIVES AND STRATEGIES

On the basis of the key challenges and the SWOT analysis, we defined the strategic objectives of the leadership and wrote up strategies how to attain them:

1. **Support of the Resolution on the National Healthcare Plan 2016–2025**:
   - support for processes for the optimal supply of approved medicines through a maximum share of medicines with market authorisation and conforming medical devices;
   - supervision of and support for processes for the conformity of operations of business entities in the area of medicines, medical devices, blood, tissues and cells with respect to all the activities associated with these products within the Agency's powers;
   - timely, efficient and high-quality implementation of administrative and supervisory procedures and the elimination of the backlog of applications;
   - development of cooperation with other institutions that are important in the terms of the affordability of medicines, medical devices and other products within the Agency's powers;
   - membership of the HTA network (in Slovenia and the EU).

     STRATEGY:
     - to write up a strategy for human resources management with a detailed list of competencies required and a clear plan for the identification, selection and acquisition of competencies, motivation and training activities (for both new and existing staff and outsourced professionals);
     - to set up formal channels and methods of communication and cooperation with the selected institutions.

The Resolution on the National Healthcare Plan 2016–2025, "Together for a Healthy Society", constitutes the foundation for the development of healthcare in Slovenia over the next decade and for the drafting and adoption of legislation governing health insurance and healthcare services. The Resolution maintains the vision of high-quality public healthcare accessible to all. It defines the priority areas for the development of public healthcare, health services at all levels, and leadership, management and financing of healthcare and details the challenges, specific goals, activities, measures, indicators, financing and timeline. The Agency's objectives were defined so as to provide support to all four overall objectives of the Resolution, namely:

- 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;
- a more significant contribution of the healthcare sector to the development of Slovenia.

In relation to medicines, the Resolution on several occasions highlights the issue of access thereto while also taking into account their cost-effectiveness. Furthermore, it notes that the small size of the Slovenian market poses a constant risk of disruptions in the supply of medicines and of access to new and expensive novel medicines. This is also associated with a relatively low level of competition between the various producers of original, generic and similar biological medicines.

The Agency's Strategy hence focuses on minimising the constant risk of disruptions in the supply of medicines and the elimination of the consequences of a producer's decision to provisionally or permanently take a medical product off the market. The Resolution announces measures to increase the efficiency of the system for the supply of orphan medicines regardless of whether these are new medicines with a centralised market authorisation or old, well-established medicines that are not available in Slovenia because so few are sold.

In respect of the Agency's vision, mission and values and given the fact that the legislation governing its work is predominantly that of the EU, it is essential for this Strategy to include objectives highly compatible with the EMA & HMA Roadmap to 2020. The latter identifies the following four strategic priority areas:

- contributing to human health by encouraging and supporting the development of new medicines in response to the real health needs and guaranteeing the availability of existing medicines;
- contributing to animal health and human health in connection with veterinary medicine by increasing the accessibility of veterinary medicines and reducing risks associated with the use of antimicrobials in medicine;
- optimising the operation of the network by providing appropriate expertise within it so as to be able to effectively respond to new health challenges;
- contributing to the global regulatory environment by establishing a strong international role of the network which includes a better overview of the global supply chains and helps unify the regulatory standards, promotes the reliability and division of work between regulatory bodies, and enhances capacity-building.

In such a national and European environment, and based on the Agency's ambitious objectives in this Strategy, we would like to become one of the most visible agencies of the EU network.

2. **Total quality based on international comparison:**
   - a) annual increases in the number of initiated and completed EU DCP/MRP procedures in which the Agency is the designated RMS. The objectives for each year will be defined in the annual programmes of work;

     b) annual increases in the number of initiated and completed EMA procedures in which the Agency is engaged in the following areas:
     - authorisation of medicinal products for use in human medicine (rapporteur, co-rapporteur, peer reviewer, member of multinational teams),
     - authorisation of medicinal products for use in veterinary medicine (rapporteur, co-rapporteur, peer reviewer, member of multinational teams),
     - product- or system-specific pharmacovigilance issues (leader, co-leader)
     - product- or system-specific pharmacovigilance inspections (leader, co-leader)

     The objectives for each year will be defined in the annual programmes of work. To achieve in the next four years above-average results (i.e. to be ranked among the top half countries) compared to other competent authorities in the EU/EEA Member States in relation to at least two of the four indents under point (b) above.

     STRATEGY:
     - to write up a strategy for human resources management with a detailed list of required competencies and a clear plan of identification, selection and acquisition of competencies, motivation and training activities (for both new and existing staff);
     - Programme for the Digital Transformation of the Agency.

   - to attain above-average values of at least 10–14 key performance indicators in the BEMA IV process conducted by the EU network of agencies responsible for medicines;
   - annual increases in values of at least half of the key performance indicators from the preceding indent that are in the BEMA IV process or in the programme of the Agency's annual internal audits assessed at 3.5 (3.0) or lower.

     STRATEGY: programme of corrective and preventive measures concerning the last BEMA report and regular internal audits, including action plans to eliminate potential discrepancies.

3. **Provision of resources for the implementation of the vision and mission:**
   - provision of human resources with required competencies

     STRATEGY:
     - to write up a strategy for human resources management with a detailed list of the required competencies and a clear plan of identification, selection and acquisition of competencies, motivation and training activities (for both new and existing staff and outsourced professionals);
     - to implement the KRONOS project, which, in terms of content and dynamics, is the first coordinated project with the strategic objective of appointing a flexible team of experts in human medicines;
     - to prepare similar projects for veterinary medicines and medical devices and the HTA.

   - provision of efficient and comprehensive IT support

     STRATEGY:
     - Programme for the Digital Transformation of the Agency composed of 15 projects for computerisation of all aspects of the Agency's work;
     - to set up an adequate infrastructure for digital operations and on-line connection with European databases and IT systems of the European network of regulatory bodies;
     - to establish a core team of experts for proactive IT upgrades in order to perform the mission in the national healthcare system and in the international environment of European regulatory bodies.

   - provision of financial resources

     STRATEGY: to introduce a new tariff, preserve surpluses, acquire new/additional finances – EU funds, additional fees from the MRP, CP and GMP procedures, etc.

     STRATEGY (joint): to set up formal channels and methods of communication and cooperation with selected institutions (including the EU partner institutions).

   In respect of the envisaged strategy for human resources, mapping of the required competencies and pathways to acquire, develop and maintain these competencies will be carried out. In the process of strategic planning, the Agency assessed the needs for additional staff and competencies that in the aforementioned projects will be classified according to their importance and allotted a realistic implementation deadline.

   In the coming two to four years, the Agency will need an additional 34 experts. Special attention will be paid to the current staff and their future employment at the Agency.

4. **Making the Agency visible** (in the domestic and international environment):
   - providing systematic and proactive communication

     STRATEGY: to write up a comprehensive communication strategy, specifying target groups, communication plans with clearly set and measurable goals, channels/media and messages.
     The fact that the Agency and its work lack visibility was identified in the process of strategic planning. Considering the importance of the Agency's mission and its crucial contribution to the protection of health, we believe that in order to be able to successfully perform our tasks, the general and expert publics alike must be well familiar with our activities, understand them and take them into consideration. The reputation of Agency will thus be enhanced and the vision pursued. Increasing visibility both in Slovenia and internationally has been set as one of our key strategic objectives. A communication strategy with clearly defined target groups will help us attain this objective. The strategy will specify communication goals, key messages and communication channels. An

implementing plan, including designated providers, assessment of the required funds and deadlines, will be drawn up. As we have already been working with an outsourced partner in the area of communication, this partner, together with the heads of organisational units and management, will provide the communication strategy.

- cooperation with organisations in the domestic and international environment

  STRATEGY: to set up formal channels and methods of communication and cooperation with selected institutions.

5. **Efficient organisation:**
   - introducing a modern organisational culture based on cooperation and supported by the organisational matrix

     STRATEGY: to systematically measure organisational energy on an annual basis and subsequently write up plans of changes in organisational culture, to establish a project office to manage strategic projects, and to establish a communications office.

     STRATEGY: Programme for the Digital Transformation of the Agency.

Individual strategies can support several strategic objectives. Objectives and strategies aimed at attaining objectives are presented in the table below:

STRATEGIC OBJECTIVES / **STRATEGIES**	**Total quality based on an international comparison**	**Support of the Resolution on the National Healthcare Plan 2016–2025**	**Provision of resources for the implementation of the vision and mission**	**Making the Agency visible**	**Efficient organisation**
Programme of corrective and preventive measures concerning the last BEMA report and regular internal audits, including action plans to eliminate potential discrepancies					
To write up a strategy for human resources management with a detailed list of the required competencies and a clear plan for the identification, selection and acquisition of competencies and motivation and training activities (for both new and existing staff); KRONOS project – extended					
To set up formal channels and methods of communication and establish cooperation with selected institutions (including the EU partner institutions)					
To provide suitable and comprehensive IT support – Programme for the Digital Transformation of the Agency					
To introduce a new tariff, preserve surpluses, acquire new/additional finances – EU funds, additional fees from the MRP, CP and GMP procedures, etc.					

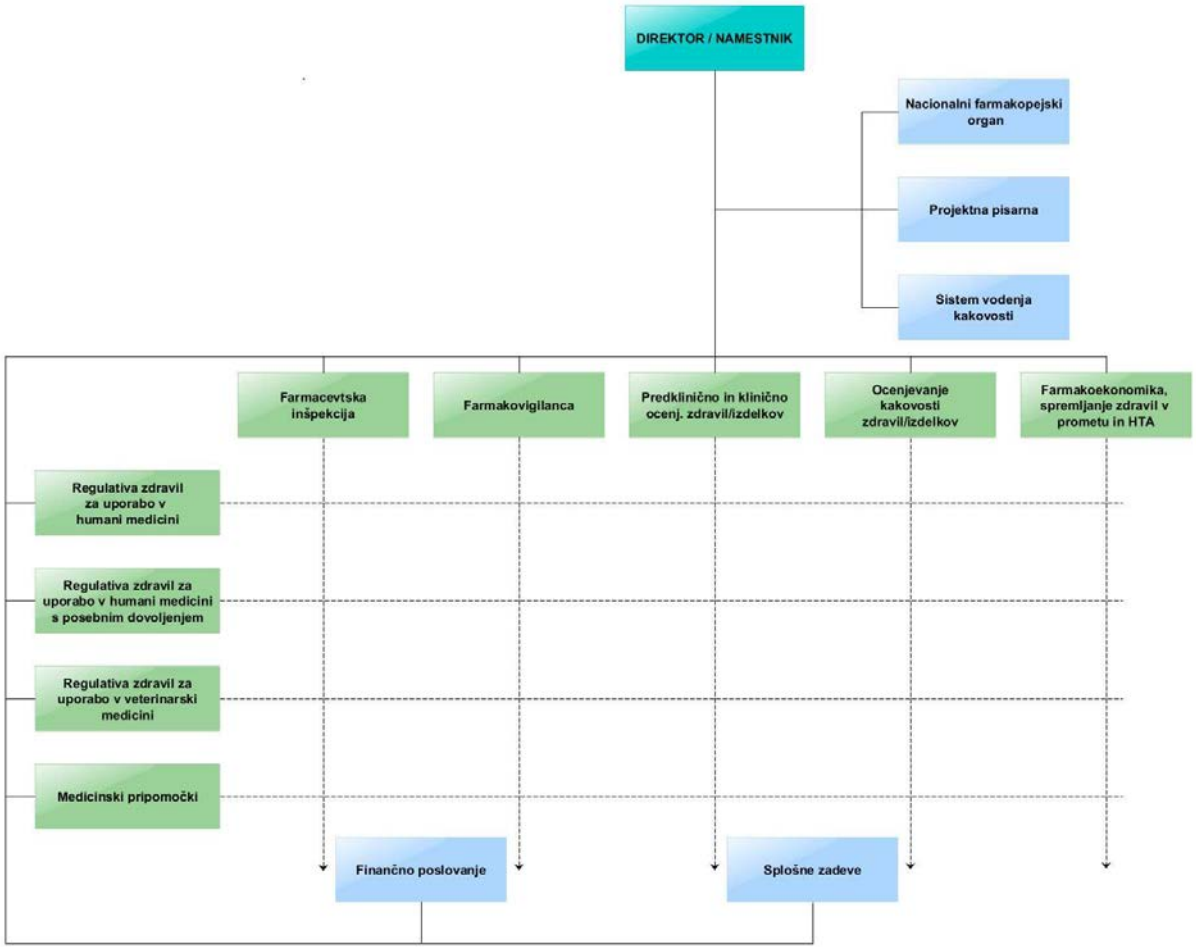
To write up a comprehensive communication strategy, specifying target groups, communication plans with clearly set and measurable goals, channels/media and messages					
To systematically measure organisational energy on an annual basis and subsequently write up plans for change in organisational culture, to establish a project office to manage strategic projects, and to establish a communications office					

NOTE: Considering the systemic changes in the legislation governing health that were mentioned in the introduction, development challenges and resulting new tasks should be highlighted as, at this point, they cannot be translated into strategic development objectives though it is highly likely that they will emerge during the implementation of this Strategy in the form of amendments to it. The health reform will most probably include amendments to the legislation on prices of medicines and criteria for public funding of medicines and medical devices. New mechanisms guaranteeing their accessibility and mechanisms assessing the quality of the healthcare system are expected to develop further and include efficiency reviews. The Agency will aspire both to intensify its cooperation with other institutions working in the field of health and to increase its participation in the initiatives of Slovenia within the EU, which is an additional challenge for the management process placing emphasis on the development of competent staff and the need to plan the allocation of resources.

IX. STRATEGIES FOR INDIVIDUAL AREAS

The Agency's strategic plan 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 for individual fields will be created in such a manner as to enable their inclusion in the annual programmes of work and financial plans. The attainment of annual goals will be evaluated using the relevant indicators and presented in the Agency's annual reports.

On 19 April 2016, the Agency adopted its new Act on Job Classification and Organisation. The Act defines the organisational matrix according to the tasks imposed on the Agency by the legislation. This new matrix will enhance cooperation among the Agency's staff and facilitate the organisation of project work, since the key activities for the development of the Agency are project-based.



X. STRATEGIC MANAGEMENT

The Agency's Strategic Plan will be reviewed and accordingly amended once a year or whenever any of the important circumstances for its work and organisation change. The heads of strategic areas, in cooperation with the heads of divisions, continuously follow developments in the Agency's environment, identify all the factors that could have an impact on its operations and organisation, and propose amendments to the Strategic Plan whenever an essential circumstance from the plan changes. To this end, a custodian of the Strategic Plan has been appointed. A special document will govern the review and amendment procedure. At any given time, the Agency will thus have an updated Strategic Plan for the next four years, serving as a basis for drafting its annual plans of work and operations.

Continuous supervision of the implementation of key projects within individual strategies and annual reviews conducted for the purposes of writing business reports will enable us to monitor progress in the attainment of objectives. At least once a month we will review certain indicators in order monitor the dynamics of our progress towards our 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.

A strategic plan so modified will serve as a basis for writing the Agency's annual work and financial plan, with detailed annual goals supporting the strategic objectives. At least once a month, we will review certain indicators to check whether the annual goals have been attained.

REFERENCES

- Resolution on the National Healthcare Plan 2016–2025 ("Together for a Healthy Society"): http://www.mz.gov.si/si/delovna_podrocja_in_prioritete/resolucija_o_nacionalnem_planu_zdravstvenega_varstva_2016_2025_skupaj_za_druzbo_zdravja/;
- One Health Initiative: http://www.onehealthinitiative.com/;
- Joint Strategy of EMA and national regulatory bodies up to 2020: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000292.jsp&mid=WC0b01ac05800293a4;
- EUnetHTA Joint Action 3 2016–2020: http://www.eunethta.eu/.