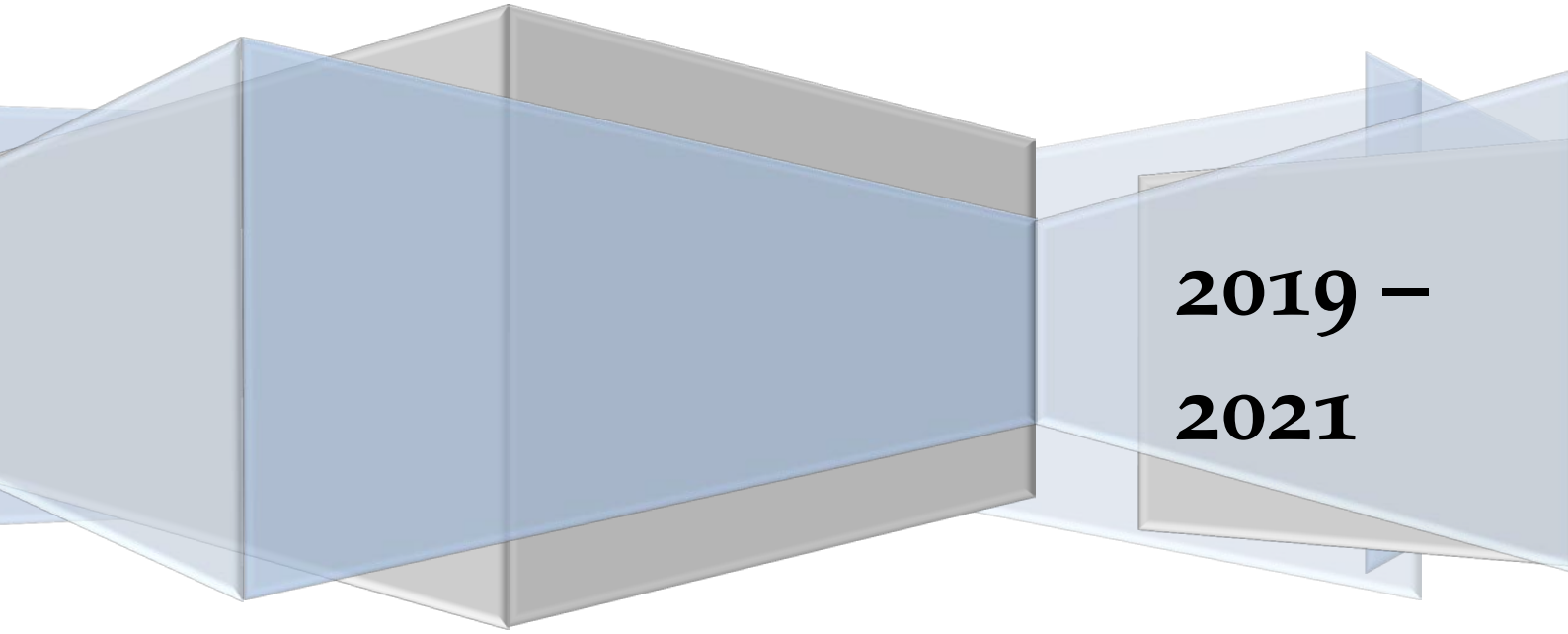
HALMED

Agencija za lijekove i medicinske proizvode

The Strategic Plan of the Agency for Medicinal Products and Medical Devices



Zagreb, 2018

CONTENT

1. FOREWORD

This Strategic Plan determines strategic priorities and development guidelines for the Agency for Medicinal Products and Medical Devices (in Croatian, *"Agencija za lijekove i medicinske proizvode"* or HALMED) as the public body in the Republic of Croatia for a three-year period from 2019 to 2021, while taking into account dynamic surroundings and circumstances within the Republic of Croatia (RC) and the European Union (EU).

The process of planning and drafting the Strategic Plan includes involvement of leaders at all levels and particular employees as well as feedback received by HALMED from interest groups in order to ensure a multi-disciplinary approach in the management and development of HALMED.

During the drafting of the 2019 - 2021 Strategic Plan, HALMED took into account the goals of national strategies from HALMED's scope of work: The 2012-2020 National Healthcare Development Strategy, 2018-2020 Strategic Plan of the Croatian Ministry of Health, 2015-2020 Public Administration Development Strategy and the 2020 e-Croatia Strategy. Furthermore, valid European regulatory requirements for medicinal products and medical devices were also considered.

Besides the goals directed towards development of core business activities, the plan also includes goals directed to the development of supporting activities. The expectation of achieving the set goals depends on suitability of available resources and HALMED's ability to fulfil requirements from national and EU legislation.

The Strategic Plan defines the general and particular strategic goals which are guidelines for devising annual business plans. Annual business plans define specific tasks and activities, deadlines and responsibility, and accordingly implement the Strategic Plan in practice. Annual plans are developed according to particular activities, providing all employees insight into the contribution of their work in achieving the organisation's general and particular goals.

Public health protection

HALMED is the independent and competent national body in RC regulating medicinal products and medical devices. The role of HALMED is to ensure that medicinal products and medical devices on the Croatian market are of a proper quality, safe and effective, thus contributing in the greatest possible measure to increasing safe usage and mitigating possible factors which pose a risk to the health of citizens where such risks relate to the mentioned products.

HALMED does this by:

- Mobilising highly-qualified and experienced experts and healthcare professionals with the aim of achieving high quality assessments of benefits and risks in administering

medicinal products and use of medical devices, supporting research and development programs, as well as providing clear and useful information to the public and healthcare professionals

- Developing effective and transparent procedures with the aim of providing patients with timely access to medicinal products based on decisions made in the interest of public health
- Supervising the safe use of medicinal products and medical devices on sale in RC, throughout the entire lifecycle monitoring side-effects and quality of medicinal products, as well as harmful incidents related to the use of medical devices
- Cooperating with international bodies competent for medicinal products and medical devices in the EU and at the global level, and
- Developing close cooperation with interest groups, including competent national bodies, healthcare professionals, scientists and researchers, patient associations, as well as research (innovation) and production industries, for the purpose of increasing availability of medicinal products and medical devices in line with a positive benefit-risk ratio.

The pharmaceutical industry is an important contributor to developing the Croatian economy. The Croatian Government has identified the pharmaceutical industry as one of the most important industries contributing to a future exports-based economic growth. Accordingly, HALMED provides strategic support to competition in the pharmaceutical industry by giving regulatory and technical advice directly related to new discoveries in the respective field and ensuring compliance with all good practice standards.

Achievements to date

HALMED has in recent times worked on achieving goals of the 2014-2018 Development Strategy which identified priorities in the period following Croatia's accession to the EU. The 2014-2018 Development Strategy has five general goals:

1. Contribute to the safety and quality of medicinal products and medical devices through effective risk management and market supervision
2. Improve services which we provide within the high-quality regulatory framework and based on risk assessment
3. Enable transparent, relevant and timely communication with patients, the public and healthcare professionals
4. Strengthen expert capacities in response to the development of regulatory requirements as well as scientific and technological achievements
5. Participate in the development of policies and legislation in the area of medicinal products and medical devices for the benefit of public health at national and EU levels.

The 2014-2018 Development Strategy was drafted within the framework of the IPA 2009TAIB project. Given that the goals related to the development of HALMED's activities have largely

been fulfilled, in general, the strategy has been successfully implemented. In line with the general goals, the main achievements are as follows:

General Goal 1

- Raising awareness and education of healthcare professions and patients on the importance of reporting side-effects from medicinal products; inclusion of patients in the pharmacovigilance system and introducing a smartphone application for reporting suspected side-effects from medicinal products
- Establishment of active cooperation and exchanging information on adverse incidents with other relevant bodies in EU member states and the European Commission, as well as with national institutions and bodies in the area of vigilance of medical devices
- Establishment of a stable quality assurance system for medicinal products on the Croatian market to assess risks along with regular sampling of medicinal products on sale for the purpose of determining compliance of medicinal product quality with approved quality requirements; continued cooperation with police and customs in protecting the market from illegal and counterfeit medicinal products
- Establishment of the Pharmacopeia Commission

General Goal 2

- Active participation in European procedures for assessing medicines after Croatia's accession to the EU, and continual growth in the number and level of complex requests in which HALMED has assessed documentation on medicinal products for the purpose of giving approval via the route of the mutually recognition procedure (MRP) / centralised procedure (DCP) or centralised procedure (CP)
- Development of an IT system for electronically reporting suspected adverse reactions to medicinal products for healthcare professionals (OPeN), enabling rapid processing of reports on possible adverse reactions, as well as facilitating reporting of suspected adverse reactions and communications between healthcare professionals and HALMED employees

General Goal 3

- Regularly and promptly informing the public of issues relating to safety, effectiveness and quality of medicinal products and medical devices, including all other important information and news from HALMED's scope of work on HALMED's website and other available communication channels
- Adapting the design and content of HALMED's website to provide more transparent, comprehensive and up-to-date information to professionals and the general public
- Implementation of standards for transparency and publicity of work
- Prompt and adequate replies to requests for access to information from HALMED's area of work
- Continued cooperation with all of HALMED's interested groups

General Goal 4

- Continued education of employees, including postgraduate specialist and doctorate programs, which has been reflected in the competency of employees for active participation in requests and enquiries sent from interest groups, in the education of

associated specialists as well as professional gatherings from HALMED's scope of work
- Continued development of the IT system

General Goal 5
- Active participation in preparing and drafting proposals for bylaws, primarily in the area of medicinal products at the national level and for the purpose of further compliance of legislation at the EU level
- Active participation in the process of adopting new EU regulations on medical devices as well as commencing preparations for implementing them at the national level

In recent time, significant organisation changes have been implemented, professional and IT capacities have also been strengthened enabling HALMED to face challenges in the coming period:
- Medicines Authorisation Division has been reorganised, and instead of the current two organisational units, four were formed in accordance with processes for approving medicinal products; special attention is given to assessing the safety and effectiveness of medicinal products
- Official Medicines Control Laboratory Division (OMCL Division) retains a high standard in implementing quality control, based upon which the European Directorate for the Quality of Medicines (EDM) again certified HALMED's laboratory in accordance with the ISO/IEC 17025 standard
- Within the Directorate, a separate organisational unit called the Inspectorate was formed and which is recognised by the international Pharmaceutical Inspection Co-Operation Scheme (PIC/S). The Inspectorate at HALMED has fulfilled its conditions and has been placed on the list of regulatory bodies covered by the mutual recognition agreement between the European Commission and Canada. Equally so, the Inspectorate at HALMED was chosen for evaluation in the first group of eight inspectorates from EU member states and which has been recognised by the U.S. Food and Drug Administration (FDA).

History

HALMED was founded on 1 October 2003 pursuant to the Act on Medicinal Products and Medical Devices by the Government of the Republic of Croatia as the legal successor of the Croatian Institute of Medicines Control and Croatian Institute of Immunobiological Preparations Controls, with a broader scope of work. Supervision of the legal compliance of HALMED's work is undertaken by the Croatian Ministry of Health.

Looking forward

In the subsequent three-year period, HALMED will support its own mission and vision, which are completely directed towards the protection of public health.

Aware of the paradigm changes in pharmaceutical research and development, where the increasing application of technology and personalised medicine is expected, as well as a

decrease in new chemical entities in favour of new biological entities and new advanced treatments, combination products of medicinal products and medical devices, and the like, HALMED will continue its cooperation with other competent national bodies within the EU and the European Medicines Agency (EMA). To become an important and reputable participant within the EU regulatory network in the area of marketing authorisation, and for the purpose of obtaining a more competitive position in the centralised procedure for approval of medicinal products, HALMED will strengthen its expert capacities and through the internal and external network of its experts, actively participate in providing healthcare advice. Equally so, HALMED will expand its cooperation in supervising implementation of good manufacturing practices (GMP) at the global level, as well as pharmacovigilance and continue developing its process of monitoring adverse reactions in quality inadequacies in order to contribute to building a safe and effective public healthcare system. Efforts will be increased in supervising marketing authorisation, as well as monitoring counterfeit medicinal products in cooperation with national healthcare, police and customs services.

Development of its proprietary internal quality management system will be continued in order to achieve the highest standards as defined in the principles for the Benchmarking of European Medicines Agencies (BEMA) and complete the building of its integrated IT system which will facilitate planning, tracking and undertaking all of HALMED's activities. Furthermore, a strong risk management system will be established which will include all of HALMED's key processes and professional obligations, while keeping in mind to strengthen its own capabilities for continued operations, as well as implemented activities in the area of pharmacovigilance and inspections which are based on risk assessment.

HALMED's interest groups are at the core of its operations, therefore communicating with them is very important. HALMED will establish new ways of communicating and improve those that have already been well established.

Its activities will contribute to reforming the Croatian regulatory system for medicinal products and medical devices, especially related to implementation of safety labels for medicinal products, implementation of new European legislation for medical products, as well as related to the area of clinical trials, which will result in a stronger and more effective legal framework for medicinal products and medical devices. For the purpose of achieving all the goals, HALMED will continue to develop its capacities and direct them to strengthening professionalism, scientific knowledge and the necessary skills essential for effective and sustainable functioning of the Croatian regulatory system in the EU region.

Zagreb, 25 September 2018

President of the Administration Board

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Prim. Stanko Belina, MD

2. PRINCIPLES OF THE ORGANISATION

HALMED was founded and commenced operating in 2003 pursuant to Article 125 of the Act on Medicinal Products and Medical Devices (Official Gazette, no. 121/03).
The operational activities of HALMED are defined in Article 122 of the Medicines Act (Official Gazette, no. 76/13 and 90/14).

Mission

HALMED's mission is as follows:

- Always be in the centre of regulatory procedures for medicinal products and medical devices
- Be recognised for the quality of its decisions and cooperation with all stakeholders
- Be a desirable employer, one who takes care of its employees
- Strengthen and develop its own capacities for the purpose of improving effectiveness

Vision

HALMED's vision is to develop as an effective, sustainable and socially conscious regulatory body.

Values

During the last fifteen years, HALMED in line with its values:

- Gravitates towards **excellence** in its work, adopting best practices and continually improving regulatory procedures for medicinal products and medical devices with the aim of protecting public health
- Is orientated towards **patients** as the end user and acts in the interest of their health by promptly responding to their needs
- Provides **information** as well as monitors and undertakes all measures for effective and rational pharmacotherapy, including measures in mitigating and eliminating possible risks relating to the use of medicinal products and medical devices
- Is open to **cooperation** with all stakeholders at the national, European and global level, and its activities provide a personal contribution to building the European regulatory network
- Establishment of **transparent** procedures and consulting with interested parties for the purpose of having a quality management system
- Actively tracks and **accepts** new scientific discoveries and new technologies, not only those in modern production, control and use of medicinal products and medical devices, but also those belonging to the digital age
- Encourages the development of its employees by investing in their ongoing education and training of competencies in line with the most modern rules of the profession and highest ethical principles.

Legislative framework

Prior to Croatia's accession to the European Union, HALMED participated in preparing the transposition of EU legislature requirements for medicinal products and medical devices to the national Medicines Act and Medical Devices Act. HALMED also participated in preparing a series of appropriate ordinances based on the mentioned acts which were approved by the health minister. HALMED's experts will be involved in preparing the draft of the other ordinances in cooperation with the Croatian Ministry of Health.

HALMED will continually monitor all changes to EU legislation in the area of medicinal products and medical devices, and also contribute to drafting all the necessary documents for their transposition into the national legal framework.

The role of HALMED

HALMED is a legal person with public powers and today undertakes its activities in accordance with the currently valid Medicines Act (Official Gazette, no. 76/13) and the Medical Devices Act (Official Gazette, no. 76/13).

Since 2003, HALMED's activities have been altered a number of times. Pursuant to Article 212 of the Medicines Act, HALMED undertakes the following tasks:

- Provides market authorisation for drugs and homeopathic drugs
- Implements the procedure for registering traditional herbal and homeopathic drugs
- Provides authorisation for parallel importing of drugs
- Provides professional assessments of quality, effectiveness and safety in administering drugs
- Conducts laboratory testing of medicinal products
- Performs official laboratory tasks in quality control for the Republic of Croatia
- Conducts quality control of drugs and homeopathic drugs, and provides its opinion on performed quality controls
- Analyses and assesses adverse reactions and the safety of respondents in clinical trials
- Drafts the Croatian Pharmacopeia
- Publishes the Croatian Pharmacopeia and other professional publications in the area of its work
- Implements pharmacovigilance activities
- Grants manufacturing authorisation to manufacturers and importers of medicinal products, i.e., tested medicinal products
- Maintains a register of manufacturers, importers and wholesale of active substances and excipients
- Grants marketing authorisation for the wholesale of medicinal products
- Grants marketing authorisation for retailing medicinal products in specialised retail stores
- Grants authorisation for mediating in the sale of medicinal products
- Grants consent for the entry and importing of medicinal products
- Grants consent for the urgent entry and importing of medicinal products

- Monitors adverse reactions and inadequacies in medicinal products
- Initiates procedures for halting marketing authorisation and the withdrawal of medicinal products from the market
- Monitors the supply of medicinal products
- Monitors the consumption of medicinal products and promotes their rational use
- Recommends to the minister supervisory measures for the consumption of medicinal products
- Performs waste management tasks (for its own needs)
- Performs the task of informing and educating about medicinal products
- Provides expert advice in the area of its business
- Provides professional guidelines from the area of its business
- Recommends the harmonisation of regulations in the area of medicinal products with the regulations of the European Union as well as regulations and guidelines from international institutions
- Establishes international cooperation in the area of medicinal products
- Performs inspection audits of the production of medicinal products, tested medicinal products, active substances and excipients as well as inspection audits of pharmacovigilance
- Maintains a register of manufacturers of medical devices, register of medical devices and register of the wholesale of medical devices
- Analyses and assesses adverse incidents in clinical trials of medical devices
- Grants marketing authorisation for the retail sales of medical devices in specialised stores
- Maintains records on medical devices sold in the Republic of Croatia
- Monitors the vigilance and safety of medical devices
- Conducts the procedure for classification of medical devices
- Issues the free sales certificate for medical devices
- Performs tasks in informing and educating about medical devices
- Establishes international cooperation in the areas of medical devices
- Proposes harmonisation of regulations in the area of medical devices with EU regulations as well as regulations and guidelines from international institutions
- Performs other tasks in the area of medicinal products in accordance with this Act and regulations passed on the basis of this Act, as well as in the area of medical devices in accordance with the Medical Devices Ac and regulations passed in accordance with this Act.

Organisational structure

HALMED is managed by the Administration Board and comprises five members. The president and members of the Administration Board are appointed by the Croatian Government at the recommendation of the minister responsible for healthcare.

The daily management and running of HALMED's operations have been transferred to the director, who is assisted in work by assistants, advisors and managers at all levels. The director appoints the following committees:

- Committee for Medicinal Products

- Committee for Medical Devices
- Committee for the Safe Use of Medicinal Products
- Committee for Pharmacopeia

Members of the respective committees are experts from HALMED and external independent experts (people with doctorates in medicine and stomatology, holders of master's degrees in pharmacy, etc.). Members of the respective committees provide expert opinion on quality, effectiveness and safety in the administering of medicinal products, i.e., quality or compliance and safety of medical devices.

The Head of the Agency also appoints the Scientific Council as the advisory body comprising the president and four members, experts from HALMED.

HALMED performs tasks in the following organisational units:

- Directorate
- Official Medicines Control Laboratory Division (OMCL)
- Medicines Authorisation Division (OZOL)
- Division for Safe Use of Medicinal Products and Medical Devices (OLIMP)
- Division for Legal, Financial, IT and General Affairs (PEI)

Structure of qualified employees

The structure of qualified employees at HALMED is closely tied to tasks and activities for which HALMED is authorised and responsible. Employees and co-workers at HALMED possess specific knowledge in the area of medicinal products and medical devices.

HALMED employs 220 employees, of which 72% have a master's or higher degree, 9% of employees have a bachelor's degree, and 18% have completed secondary school.

Furthermore, 14 employees have gained a doctorate in the sciences, six employees have gained a master's degree in the sciences, and 15 employees have a degree in medicine or pharmaceutical specialisation.

The structure of qualified employees at HALMED in the period from 2019 to 2021 should be adapted to the new conditions under which HALMED operates as described in the section Financing and based on the forecast shown in Table 1.

Table 1. A forecast of the required number of experts with specific knowledge in HALMED's organisational units for sustainable self-financing during the period 2019 to 2021.

Organisation units	Forecast of the number of experts with specific knowledge for the period 2019–2021		
	2019	2020	2021
OZOL – assessors for documentation on the quality of medicinal products	13	17	19
OZOL – assessors for non-clinical documentation on medicinal products	1	2	2
OZOL – assessors for clinical	9	11	11

documentation on medicinal products			
Total for OZOL	23	30	32
PhV – assessors for documentation on safe administering of medicinal products	11	13	14
INSPECTORATE – inspectors	10	11	12
Scientific advice – assessors for scientific advice	4	5	5
Total number of experts with specific knowledge (OZOL+PhV+INSPECTORATE)	**48**	**59**	**63**

OZOL = Medicines Authorisation Division; PhV = Department for Pharmacovigilance and Rational Pharmacotherapy.

Notes to Table 1:
According to the forecast for achieving planned revenue from European activities, an additional number of experts with specific knowledge in the area of assessing documentation on medicinal products, pharmacovigilance and inspections should be employed.

Financing

Since Croatia's accession to the European Union on 1 July 2013, HALMED's business has been harmonised with European regulatory activities in the area of medicinal products and medical devices. HALMED has become part of the European network of regulatory bodies for medicinal products with limited national activities and open opportunities for achieving revenue through European activities.

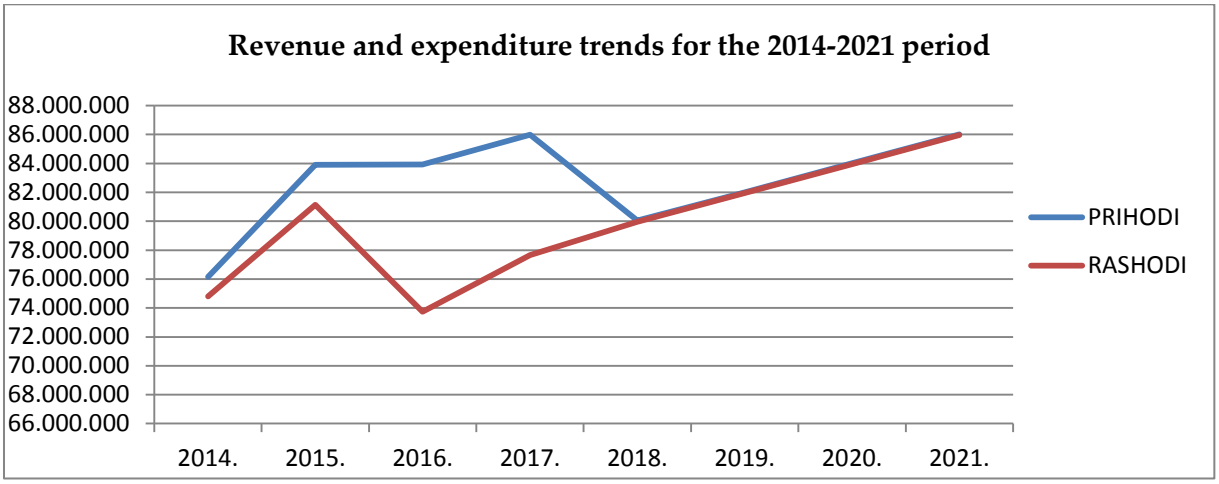
In the new business environment, and in the period from 2013 to today, HALMED has completely financed itself from its own revenue achieved from regular services, projects and other operating revenue. Operating revenue has gradually stabilised, whereas operating expenses have varied cyclically, depending on scheduled activities, requirements and increasing employment, and also related to measures and methods for monitoring and managing financial effectiveness (Figure 1).

Financing with an emphasis on sustainable self-financing is defined by the goal in section 8.3 of the Strategic Plan, and the goal is to adapt HALMED's operations to the new business environment.

Analysing achieved revenue and expenditure from its activities indicates that HALMED must undertake certain adjustments in operations due to regulatory changes in national and European legislation, and also measures by the Croatian Government for reducing so called untaxable contributions. This latter results in a reduction of the price of HALMED's services in 2018, where HALMED provided its contribution to the program of reform measures for public administration with the aim of unburdening businesses.

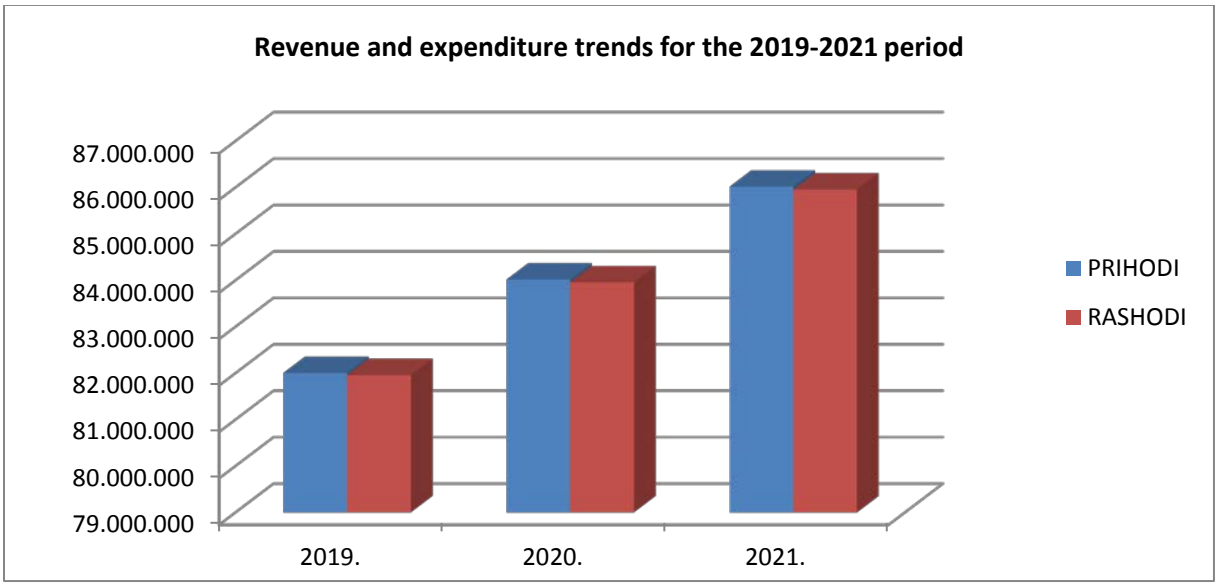
The stated operating adjustments will be reflected in the financial stability and autonomy of HALMED (Table 2 and Figure 2), under the assumption that the announced Agencies Act does not foresee different solutions or a different legal status for HALMED.

Figure 1. Revenue and expenditure trends for the 2014-2021 period, expressed in Croatian kuna



Note accompanying Figure 1:
PRIHODI = REVENUE
RASHODI = EXPENDITURE
The mentioned trend is particular present in 2018 and, on the one hand, are the result of a reduction in revenue from national activities, due to changes in HALMED's Pricelist for services and, on the other hand, an increase in costs mostly due to employing more people and the need for training experts possessing specific knowledge, which are requirements for participating in European activities. In 2018, the value of revenue and expenditure was almost equal, after which the expectation is that the two will experience proportional and harmonised growth.

Figure 2. Revenue and expenditure trends for the 2019-2021 period, expressed in Croatian kuna



Note accompanying Figure 2:
PRIHODI = REVENUE
RASHODI = EXPENDITURE
The graph shows a balance of revenue and expenditure trends while achieving minimal profit given that the goal of HALMED's operations is not to generate profit, but instead improve and protect public health. The balancing of revenue and expenditure is based on an increase in revenue from EU activities, whereas costs (for minimal wage and salary growth) are subject to material rights for employees and he average but necessary increase in IT

investments for similar systems, as well as the assumption that other functional costs and operations will remain at the 2018 level.

Table 2. Forecast of operating revenue and expenditure for the 2019-2021 period, expressed in Croatian kuna

CATEGORY	YEAR OF OBSERVATION						
	2019	INDEX 019/018	2020	INDEX 020/019	2021	INDEX 021/020	INDEX 021/019
REVENUE							
NATIONAL ACTIVITIES	69,087,436	100	69,087,436	100	66,277,902	96	96
EUROPEAN ACTIVITIES	10,967,100	122	12,977,100	118	17,787,100	137	162
OTHER OPERATING REVENUE	1,950,000	100	1,950,000	100	1,950,000	100	100
TOTAL REVENUE	82,004,536	102	84,104,436	102	86,015,002	102	105
TOTAL EXPENDITURE	81,955,404	102	83,955,404	102	85,955,404	102	105

Note accompanying Table 2:

The table shows revenue and expenditure trends and their mutual balanced growth, as well as necessary growth of revenue from European activities. This is like a compensation measure for reducing revenue from national activities due to the already mentioned changes to the Pricelist for services. Expenditure trends are subject to the existing level of functional costs, as well as the result of further employment and costs associated with it (education and professional training). Given the existing employment plan, the greatest increase in these costs are expected in 2019. In the stated period, approximately an additional HRK 2,000,000.00 revenue from European activities will be necessary. For 2020, the increase in revenue should amount to an additional 18%, whereas in 2021 due to an expected fall in some revenue from national activities by 4% which is subject to changes in regulatory provisions for medicinal products, a further necessary increase in revenue by 37% from European activities is expected.

Overall, in the period for which this Strategic Plan is adopted, HALMED should increase its revenue from European activities by about 62% or approx. HKR 7,000,000.00, whereby these activities would contribute by 21% to total operating revenue.

The adjustment of operations and "restructuring of revenue" is not possible at once but should be undertaken gradually over a number of years, using some of the funds from retained profits for the need to make additional investments in resources for staff development and equipment, as envisaged in the Statute.

One of the possible and significant savings for operational costs is a more permanent solution to the need for additional business premises, by making the decision to purchase or construct commercial premises. This measure and business decision in line with significant savings for leasing of premises and utilizing accumulated funds from profit from previous years (retained profit) for the task, would ease the pressure on controlling the pace of revenue growth from European activities.

Networking and communication

Multilateral cooperation is an important factor in HALMED's activities in the EU and wider international community. HALMED has established intensive cooperation with the European Commission, Council of the European Union – European Directorate for the Quality of Medicines and HealthCare (EDQM), European Medicines Agency (EMA), the World Health Organisation (WHO) and the WHO cooperation centre that maintains the global database for ADRs (Uppsala Monitoring Centre), heads of medicines agencies (HMA), as well as the competent national bodies for medical devices from the EU/EGP. In the future, HALMED plans to expand this cooperation and continue with active membership through the use of its experts in committees and working groups, which will enable cooperation in joint professional decision making and informing about new discoveries, good practices and interpretation of European legislation, as well as exchanging acquired experiences in the area of medicinal products and medical devices in Croatia and the EU. The Memorandum of Understanding has been signed with the Dutch Medicines Evaluation Board, and regarding Croatia presiding over the Council of the European Union in the first half of 2020, HALMED will preside over meetings at a high expert level, which includes meetings between heads of medicines agencies from member states and a meeting between the relevant bodies for medical devices.

In terms of the future expansion of the EU, HALMED has concluded a number of bilateral agreements on cooperation with neighbouring states, and there is the plan to conclude memorandums of understanding with particular agencies from EU member states.

HALMED will continue to actively participate in the e-Medicines project for setting up a system to establish a central database for medicinal products with a mechanism for exchanging data between different information systems, i.e., the Central Health Information System of the Republic of Croatia (CEZIH), application in primary healthcare protection, which also includes support to pharmacies and hospital information systems with HALMED's medicinal product database. This will enable networking of national stakeholders that have at their disposal data in medicinal products (Ministry of Health, Croatian Health Insurance Fund, Croatian Institute for Public Health, HALMED), and in the future, possibly even manufacturers, wholesale and pharmacies, which will increase productivity of the public sector and lead to savings.

Today, patients and users to a great extent are included in the process of deciding on their therapy. This trend has led to a partnership between patients and healthcare professionals in selecting a particular therapy, in which exchanging information on benefits and risks in administering therapy is key. The increased use of communication channels, such as websites and social media, has meant that the public requires access to reliable and proper information. Accordingly, healthcare professionals and agencies for medicinal products and medical devices are the primary source of information for medicinal products and medical devices.

Therefore, HALMED continues to use appropriate tools to ensure access to clear, available, transparent and easily accessible information on the regulatory system for medicinal

products and medical devices as well as information for all interest groups, such as healthcare professionals, patients, industry representatives and the general public.

HALMED is conscious of the fact that only a proper selection of communication channels for disseminating information on medicinal products and medical devices can ensure prompt dissemination of new and future information on their advantages and risks to healthcare professionals and the public.

Accordingly, HALEMD will improve its risk management system and adapt it to European requirements which are set for it. Furthermore, HALMED will continue to monitor the latest policy on transparency, while keeping in mind that the requirements for transparency in time are continually increasing.

Sustainable competitive advantage

Based on previous experience, we believe that HALMED's sustainable competitive advantage are its employees, dedicated to development and continual improvement of HALMED's operations, and who are ready to acquire new knowledge and interactively share their expertise and undertake all tasks relating to the regulatory network for medicinal products and medical devices.

3. STRATEGIC GOALS

Taking into account the achievements during implementation of the 2014-2018 Development Strategy, as well as recognised opportunities and advantages in the future, including results of the SWOT analysis of current strengths, weaknesses, external opportunities and threats in HALMED's key responsibilities, general strategic goals have been set with a clear direction for development in the coming three-year period from 2019 to 2021 for the purpose of achieving HALMED's vision and mission.

Particular strategic goals elaborate individual general strategic goals and identify a series of specific activities directed towards achieving the general goals.

General and particular strategic goals for HALMED are:

1. Access to new medicinal products on the European market

1.1. Active participation for approval of medicinal products in the centralised procedure
1.2. Active participation in simultaneous approval of medicinal products in a number of states in the decentralised procedure and mutual recognition procedure
1.3. Active participation in providing scientific advice in European procedures

2. Safe administering of medicinal products and protection of public health

2.1. Managing risks in administering medicinal products
2.2. Active participation in European procedures in the field of pharmacovigilant activities for the approval of medicinal products and for medicinal products in use
2.3. Active role in challenges to the protection of public health

3. Strengthening the regulatory framework for medical devices

3.1. Ensuring prompt and appropriate implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
3.2. Strengthening the system of monitoring harmful incidents relating to the use of medical devices

4. Strengthening supervision of the market

4.1. Monitoring the quality and safety of administering medicinal products on sale in Croatia
4.2. Active contribution to application of European regulatory GMP standards in the EU and third countries
4.3. Undertaking activities for the purpose of increasing availability of medicinal products on the market

5. Optimising regulatory processes

5.1. Optimising internal processes
5.2. Reducing administrative burdens on users of services

6. Strengthening international cooperation

6.1. Implementation of programs originating from common HMA and EMA Strategies for the 2016-2020 period

6.2. Positioning HALMED as a globally recognisable competent body

6.3. Preparing for Presidency of the Council of the European Union in the first half of 2020

7. Development of a communication strategy

7.1. Strengthening transparency of work as a public body

7.2. Strengthening HALMED's national recognisability as an important factor in the protection of public health

8. Development of internal resources

8.1. Human resources management

8.2. Improving telemetric systems

8.3. Drafting the information management strategy

8.4. Sustainable self-financing

1. Access to new medicinal products on the European market

1.1. Active participation for approval of medicinal products in the centralised procedure

Strategy for the goal:
Ensure participation in approving medicinal products through the centralised procedure in the role of Rapporteur, Co-Rapporteur and Peer-Reviewer before the EMA.
Action steps:

- Regularly applying (tendering) in the approval of medicinal products through the centralised procedure in the role of rapporteur, co-rapporteur and peer-reviewer
- Regularly applying (tendering) in the approval of medicinal products through the centralised procedure in a multinational team in which the other member state is the rapporteur or co-rapporteur
- Active expert commentary of the assessment in the approval of medicinal products through the centralised procedure currently in progress
- Training of HALMED's assessors to acquire specific knowledge, establishing cooperation with external experts from certain scientific and expert areas
- Establishing cooperation with the network of European national agencies for the purpose of exchanging experience and joint participation in centralised procedures for approval
- Active contribution to the work of committees and working groups before EMA

Prerequisites:

- Successful implementation of goal 8.1

Responsibility:

- Head of the Medicines Authorisation Division

Key performance indicator:

- Number of centralised procedures in the role of rapporteur/co-rapporteur

Unit: number of commenced procedures

- Number of centralised procedures in the role of peer-reviewer

Unit: number of commenced procedures

Time for realisation:
2019

- At least two commenced centralised procedures in the role of rapporteur/co-rapporteur or the role of assessor in a multinational team in which the other member state is a rapporteur or co-rapporteur
- At least two commenced centralised procedures in the role of peer-reviewer

2020

- At least three commenced centralised procedures in the role of rapporteur/co-rapporteur or the role of assessor in a multinational team in which the other member state is a rapporteur or co-rapporteur
- At least two commenced centralised procedures in the role of peer-reviewer

2021

- At least three commenced centralised procedures in the role of rapporteur/co-rapporteur or the role of assessor in a multinational team in which the other member state is a rapporteur or co-rapporteur
- At least two commenced centralised procedures in the role of peer-reviewer

1.2. Active participation in simultaneous approval of medicinal products in a number of states in the decentralised procedure and mutually recognition procedure

Strategy for the goal:
Ensure the role of HALMED as a recognisable and desirable regulatory body in the role of a reference member state (RMS) in a decentralised procedure (DCP) in the mutual recognition procedure (MRP)
Action steps:

- Informing interest groups of HALMED's previous experience in the role of RMS
- Active participation by HALMED in the role of concerned member state (CMS) in a DCP and MRP
- Strengthening the capacity of HALMED's assessors with specific knowledge
- Performing activities in assuming part of the duties of the United Kingdom Medicines Agency (after the United Kingdom has exited the EU, so called Brexit)

Prerequisites:

- Successful implementation of goal 8.1
- Advantages of HALMED as a RMS

Responsibility:

- Head of the Medicines Authorisation Division

Key performance indicator:

- Number of DCP/MRP procedures in the role of RMS

Unit: number of commenced DCP/MRP procedures
Time of realisation:
2019

- At least 14 commenced DCP/RMP procedures in the role of RMS

2020

- At least 14 commenced DCP/RMP procedures in the role of RMS

2021

- At least 14 commenced DCP/RMP procedures in the role of RMS

1.3. Active participation in providing scientific advice in European procedures

Strategy for the goal:
Build HALMED's capacity and capability to provide scientific advice in European procedures. Continual education and training of assessors for scientific advising, as well as other assessors at the Agency, are to result in acquiring of and training for the necessary knowledge as well as consequently more active participation by HALMED in centralised procedures for granting approvals.

Action steps:

- Education of assessors for the purpose of obtaining specific knowledge from particular assessment areas
- Employing additional assessors possessing the appropriate knowledge and experience
- Establishing cooperation with external experts from certain scientific and expert areas for more active involvement in providing scientific advice

Prerequisites:

- Successful implementation of goal 8.1
- Proper quality regulatory, IT and administrative support to assessors in providing scientific advice

Responsibility:

- Head of the Scientific Advice Office

Key performance indicator:

- Number of scientific advices

Unit: number of scientific advices

Time for realisation:

2019

- At least two commenced European scientific advices monthly in the role of independent coordinator or as part of a multinational team in terms of SAWP

2020

- At least two commenced European scientific advices monthly in the role of independent coordinator or as part of a multinational team in terms of SAWP
- At least four commenced European scientific advices annually in the role of peer-reviewer
- Assessors are ready to apply and provide scientific advice from various areas of medicinal product development and complexity level of applications

2021

- At least two European scientific advices monthly in the role of independent coordinator or as part of a multinational team in terms of SAWP
- At least four commenced European scientific advices annually in the role of peer-reviewer
- Establishing the ability to provide national scientific advice

2. Safe administering of medicinal products and protection of public health

2.1. Managing risks in administering medicinal products

Strategy for the goal:

Pharmacovigilant activities to ensure continual monitoring of possible risks to health (adverse reactions and adverse incidents) relating to the administering of medicinal products.

Action steps:

- Development of information systems for electronically reporting possible adverse reactions, detection of signals and exchanging other data of interest for the purpose of risk management in the administering of medicinal products
- Encouraging better quality reporting of possible adverse reactions through exchanges in scoring reporting by scientific professionals
- Education of scientific professionals for risk management of medicinal products through education modules in the OPeN system for letters to healthcare professionals (i.e., direct healthcare professional communication) and educational materials
- Collecting information on the safety of medicinal products through cooperation with other institutions and organisations such as the Croatian Health Insurance Fund, Croatian Institute for Public Health, Institute for Medical Research and Occupational Health and the Agency for Quality and Accreditation in Healthcare and Social Welfare
- Transparent informing of safety in administering medicinal products through development of HALMED's periodic bulletin from the area of pharmacovigilance
- Establishing new processes in the area of monitoring the safety of medicinal products

Prerequisites:

- Successful implementation of goal 8.1 and 8.2
- Willingness for cooperation of national institutions and bodies, scientific professionals and patient associations

Responsibility:

- Department for Pharmacovigilance and Rational Pharmacotherapy
- Head of the Division for Safe Use of Medicinal Products and Medical Devices

Key performance indicator:

- Greater number of reporting of possible adverse reactions from patients and healthcare professionals with better quality information
- A greater number of cases of identifying safety signals
- Use of HALMED's database and other pharmacovigilant tools for the purpose of assessing the benefits and risks of medicinal products and continual risk management in administering medicinal products
- Healthcare professionals with the aid of online tools are educated on direct healthcare professional communication and educational materials approved by HALMED and accordingly collect points for maintaining approval for autonomous work (licence)

Unit: YES/NO

Time for realisation:

2019

- Building the educational module in the OPeN system
- Increase in the frequency of reporting possible adverse reactions by 20% compared to 2018

2020

- Increase in the frequency of reporting possible adverse reactions by 20% compared to 2019
- 20% of healthcare professionals attend and actively partake in education via the OPeN system

2021

- Presumptions achieved for establishing the pharmacoepidemiology database

- Exchanged information with most hospital information systems in the Republic of Croatia
- 50% of all healthcare professionals in the Republic of Croatia attend and actively partake in education via the OPeN system

2.2. Active participation in European procedures in the field of pharmacovigilant activities for the approval of medicinal products and for medicinal products in use

Strategy for the goal:
Upon implementation of particular goal 1.1, more actively involved in granting approval for medicinal products through the centralised procedure in the role of rapporteur before the Pharmacovigilance Risk Assessment Committee (PRAC), and as the Lead Member State (LMS) in the Periodic Safety Update Reports Single Assessment (PSUSA) for medicinal products which are administered, before the EMAs.

Action steps:
- Regularly applying (tendering) in the role of rapporteur / co-rapporteur from PRAC in the approval of medicinal products through centralised procedures
- Actively and professional commenting on PRAC assessments in centralised and MRP/DCP procedures for approval of medicinal products
- Regularly applying for participation in European projects in the area of pharmacovigilant activities
- Implementing activities for undertaking a certain number of PSUSAs from the UK Medicines Agency (after the United Kingdom has exited the EU, so called Brexit)
- Applying for the role of rapporteur / co-rapporteur from PRAC in arbitration procedures

Prerequisites:
- Successful implementation of goal 8.1

Responsibility:
- Department for Pharmacovigilance and Rational Pharmacotherapy

Key performance indicator:
- Number of centralised procedures in the role of rapporteur / co-rapporteur from PRAC

Unit: number of commenced PRAC procedures
- Number of expert commentaries in the centralised and DCP/MRP procedures

Unit: number of forwarded expert commentaries
- Number of assessed PSUSAs

Unit: number of received PSUSAs for assessment
- Number of arbitration procedures (independent or as part of a multinational team)

Unit: number of arbitration procedures in the role of rapporteur/co-rapporteur

Time for realisation:
2019
- At least one centralised procedure in the role of PRAC rapporteur
- At least 15 PSUSA procedures
- At least one arbitration procedure in the role of rapporteur/co-rapporteur

2020
- At least two centralised procedures in the role of PRAC rapporteur

- At least 20 PSUSA procedures
- At least one arbitration procedure in the role of rapporteur/co-rapporteur

2021

- At least two centralised procedures in the role of PRAC rapporteur
- At least 25 PSUSA procedures
- At least one arbitration procedure in the role of rapporteur/co-rapporteur

2.3. Active role in challenges to the protection of public health

Strategy for the goal:

The risk management system for administering medicinal products is ready for encountering and reactions to challenges in public healthcare in the context of safe administering of medicinal products, with special emphasis on issues such as antimicrobial resistance and vaccination aversion.

Action steps:

- In terms of its powers, improve the policy for developing vaccines
- In terms of its powers, assist in increasing vaccination coverage
- Encourage adapting vaccination schedules across the EU in terms of activity against vaccination aversion
- Support research into new vaccines and developing vaccine information systems
- Support the policy of preventing antimicrobial resistance

Prerequisites:

- Successful implementation of goal 8.1 and 8.2
- Readiness for cooperation by national institutions and bodies, healthcare professionals and patient associations

Responsibility:

- Head of the Division for Safe Use of Medicinal Products and Medical Devices
- Department for Pharmacovigilance and Rational Pharmacotherapy

Key performance indicator:

- More frequent participation of pharmacovigilant experts in public debates on the safety of administering vaccinations
- Healthcare professionals and the interest public inform themselves with the help of HALMED's online tool on the latest safety information for the safe administering if vaccines and antibiotics
- Participation in the work of the Vaccination Advisory Council
- Participation in national and international initiatives covering issues involving antimicrobial resistance

Unit: YES/NO

Time for realisation:

2019

- Building the educational module in the OPeN system
- Participation by HALMED in a public campaign on issues relating to antimicrobial resistance and/or vaccination aversion
- Vaccination program adopted in cooperation with HALMED's professionals

- Action plan to prevent antimicrobial resistance adopted in cooperation with HALMED's experts

2020

- Increase in the number of interested citizens visiting and actively undergoing education through the OPeN system on safe administering of vaccinations and antibiotics
- Participation by HALMED in a public campaign on issues relating to antimicrobial resistance and/or vaccination aversion
- Vaccination program adopted in cooperation with HALMED's professionals
- Action plan to prevent antimicrobial resistance adopted in cooperation with HALMED's experts

2021

- Increase in the number of interested citizens visiting and actively undergoing education through the OPeN system on safe administering of vaccinations and antibiotics
- Participation by HALMED in a public campaign on issues relating to antimicrobial resistance and/or vaccination aversion
- Vaccination program adopted in cooperation with HALMED's professionals
- Action plan to prevent antimicrobial resistance adopted in cooperation with HALMED's experts

3. Strengthening the regulatory framework for medical devices

3.1. Ensuring prompt and appropriate implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

Strategy for the goal:

With the aim of advancing the protection of public health and safety of patients, Regulation (EU) 2017/745 and Regulation (EU) 2017/746 have been published which establish a stronger legislative framework for regulating the field of medical devices in the European Union. The new legislation is directed to improving the quality, safety and reliability of medical devices, increase transparency of information for users, as well as improve the monitoring of safe use and supervision of the medical devices market. In the time leading to the official commencement of applying the respective regulations, i.e., prior to 26 May 2020, HALMED will undertake the necessary activities for the purpose of implementing the regulations in the Republic of Croatia.

Action steps:

- Draft the proposed legislative act on implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- Conduct an analysis of the discrepancies in processes stemming from the Regulations in relation to HALMED's existing processes
- Conduct an analysis of the discrepancies which stem from new national regulations on medical devices in relation to HALMED's existing processes

- Define new and revise existing processes based on the analysis results of the discrepancies along with an analysis of the necessary resources for implementing the processes
- Educate experts from the Department for Medical Devices on new regulations and processes for medical devices
- Define the communication plan as well as inform and educate the public, including all interested parties of the changes

Prerequisites:

- Successful implementation of goal 8.1 and 8.2
- Clearly define the system along with stipulated responsibilities and the role of all interested parties
- Willingness of all national, international and other organisations, healthcare employees, manufacturers of medical devices and other interested parties to establish cooperation

Responsibility:

- Division for Safe Use of Medicinal Products and Medical Devices
- Department for Medical Devices
- Spokesperson

Key performance indicator:

- Drafted the proposed legislative act on implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- Drafted proposed bylaws regulating the following areas:
  - Limiting the places and manner of delivering medical devices – advising users and issuing them on medical prescriptions
  - Registration of manufacturers of medical devices and conditions for performing the business of distributing medical devices
- Conducted an analysis of discrepancies in processes stemming from the respective Regulations with respect to HALMED's existing processes, as well as an analysis of discrepancies in processes stemming from new national regulations on medical devices with respect to HALMED's existing processes
- Defined new and revised existing processes based on analysis results of discrepancies, conducted analysis of necessary resources for implementing processes and educated experts from the Department for Medical Devices
- Defined a communication plan and the public and other interested parties were informed and education on changes

Unit: percentage (%), YES/NO, number of educational courses

Time for realisation:

2018

- Draft the proposed legislative act on implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
- Conduct an analysis of the discrepancies in processes stemming from the Regulations in relation to HALMED's existing processes
- Implementation of external education of each expert in the Department for Medical Devices in the area of new regulations on medical devices
- Define the educational program for manufacturers, authorised representatives, distributers, healthcare workers and other stakeholders in the system

2019

- Draft of the proposed bylaws which regulate limiting the places and manner of delivering medical devices – advising users and issuing medicinal products with a medical prescription
- Draft of the proposed bylaws which regulate registration of distributers of medical devices and conditions for performing the business of distributing medical devices
- Conduct an analysis of the discrepancies in processes stemming from the national regulations on medical devices with respect to HALMED's existing processes
- Define 60% of new and revise 60% of existing processes based on analysis results of discrepancies
- Draft of the communication plan
- Implementation of external education of each expert in the Department for Medical Devices in the area of new regulations on medical devices
- Hold four courses for the purpose of educating manufacturers, authorised representatives and distributers of medical devices as well as healthcare employees and other stakeholders in the system

2020

- Publish new regulations on medical devices which are applicable at the national level
- Define 100% new and revise 60% of existing processes based on analysis results of discrepancies
- The public and all interested parties are to be informed of new changes
- Implementation of external education of each expert in the Department for Medical Devices in the area of new regulations on medical devices
- Hold four courses for the purpose of education manufacturers, authorised representatives and distributers of medical devices as well as healthcare employees and other stakeholders in the system

2021

- Resolve 100% of received applications from users based on Regulation 2017/745/EU and Regulation 2017/746/EU
- Implementation of external education of each expert in the Department for Medical Devices in the area of new regulations on medical devices
- Hold four courses for the purpose of education manufacturers, authorised representatives and distributers of medical devices as well as healthcare employees and other stakeholders in the system

3.2. Strengthening the system of monitoring adverse incidents relating to the use of medical devices

Strategy for the goal:

Basic purpose of the vigilance system for medical devices is to improve the protection of health and safety of patients, users and other persons using various mechanisms to reduce the number of repeated adverse incidents related to medical devices. This includes evaluation of adverse incidents and related risks, safety corrective actions and informing users, patients and other interested parties. The aim is to support activities of the Division for Safe Use of Medicinal Products and Medical Devices and Department for Medical Devices.

Action steps:

- Ensure transparency of the vigilance system by publishing all received safety notices on HALMED's website
- Expand cooperation in the area of vigilance to other organisations, especially the relevant chambers and healthcare institutions
- Conduct an expert assessment of all adverse incidents which occurred in Croatia and safety corrective actions which are performed in Croatia depending on the assessed risk which includes an assessment of the manufacturer's investigation of the adverse incident and suitability of safety corrective actions based on clearly defined criteria
- Undertake targeted activities for the purpose of informing the public and interested stakeholders of the vigilance system for medical devices

Prerequisites:

- Successful implementation of goal 8.1 and 8.2
- Clearly defined and detailed procedures
- Willingness of all national, international and other organisations, healthcare employees, manufacturers of medical devices and other interested parties to establish cooperation

Responsibility:

- Division for Safe Use of Medicinal Products and Medical Devices
- Department for Medical Devices
- Spokesperson

Key performance indicator:

- Increase in the number and quality of received reports of adverse incidents and safety corrective actions relating to medical devices
- Received safety notices for medical devices are published on HALMED's website
- Relevant chambers and healthcare institutions recognise the vigilance system for medical devices
- Assessment of the registering and reports on adverse incidents as well as reports on safety corrective actions depending on the assessed risk
- Implemented activities for the purpose of informing the public and interested stakeholders of the vigilance system for medical devices

Unit: percentage (%), YES/NO

Time for realisation:

2018

- Ten percent increase in the number of received reports on adverse incidents and safety corrective actions compared to the previous year
- Five percent increase in the share of reports on adverse incidents received from healthcare institutions compared to the previous year
- 100% of all received safety notices on medical devices is published on HALMED's website
- 100% of all received reports on adverse incidents and reports on safety corrective actions is assessed depending on the estimated risk

2019

- 10% increase in the number of received reports on adverse incidents and safety corrective actions compared to the previous year

- 5% increase in the share of reports on adverse incidents received from healthcare institutions compared to the previous year
- 100% of all received safety notices on medical devices is published on HALMED's website
- 100% of all received reports on adverse incidents and reports on safety corrective actions is assessed depending on the estimated risk

2020

- 10% increase in the number of received reports on adverse incidents and safety corrective actions compared to the previous year
- 5% increase in the share of reports on adverse incidents received from healthcare institutions compared to the previous year
- 100% of all received safety notices on medical devices is published on HALMED's website
- 100% of all received reports on adverse incidents and reports on safety corrective actions is assessed depending on the estimated risk
- Undertake targeted activities for the purpose of informing the public and interested stakeholders of the vigilance system for medical devices

2021

- 15% increase in the number of received reports on adverse incidents and safety corrective actions compared to the previous year
- 15% increase in the share of reports on adverse incidents received from healthcare institutions compared to the previous year
- 100% of all received safety notices on medical devices is published on HALMED's website
- 100% of all received reports on adverse incidents and reports on safety corrective actions is assessed depending on the estimated risk

4. Strengthening supervision of the market

4.1. Monitoring the quality and safety of administering medicinal products on sale in Croatia

Strategy for the goal:
Maintain and improve a stable supervision system based on risk estimation and the conducting of sampling based on the approved sampling plan.
Strengthening cooperation with the Customs Administration at the Ministry of Finance, State Attorney's Office and Ministry of the Interior in the area of illegal medicinal products and counterfeiting.
Action steps:

- Education of Inspectorate employees and strengthening specific knowledge for particular areas of work
- Employing and educating new inspectors with the appropriate knowledge and previous relevant experience
- Strengthening cooperation with other national agencies and regulatory bodies in the EU and world for the purpose of education and exchanging experience

- Continual implementation of inspections/re-inspections of manufacturers in Croatia and outside the EU, wholesale, mediation and specialised retail stores in accordance with stipulated European standards for the purpose of ensuring quality and safety in administering medicinal products that have received marketing authorisation
- Continual implementation of inspections/re-inspections of the pharmacovigilant system for holders of marketing authorisations in accordance with European standards for the purpose of verifying compliance with stipulated requirements and guidelines, as well as continual improvement in undertaking corrective and preventive measures for eliminating insufficiencies, with the aim of ensuring safe and effective medicinal products accessible to patients
- Continue to develop a stable quality control system for medicinal products with marketing authorisation based on estimated risks and in line with annual testing programs
- Continue to actively participate in the European network of official laboratories for the purpose of promoting the principle of sharing work and knowledge, as well as optimally increasing data on supervision of medicinal products on the market, especially annual supervision of the quality of medicinal products approved through the centralised procedure

Prerequisites:

- Successful implementation of goal 8.1
- quality regulatory, IT and administrative support to inspectors

Responsibility:

- Head of the Inspectorate
- Official Medicines Control Laboratory Division (OMCL Division)
- Heads of divisions to which employees have been allocated and who are authorised for sampling medicinal products with marketing authorisation

Key performance indicator:

- Implementation of supervision in accordance with the annual inspection program
- Prompt implementation of urgent inspections
- Implementation of the planned number of laboratory quality controls for medicinal products based on a risk assessment

Unit: YES/NO

Time:

In each year of the 2018-2020 Strategic Plan, the plan is to have one-hundred-percent execution of inspections based on the annual program, at the request of parties and requirements for urgent inspections as well as the planned number of laboratory quality controls.

4.2. Active contribution to application of European regulatory GMP standards in the EU and third countries

Strategy for the goal:

Conduct inspections/re-inspections based on the approved annual inspection plan and in line with the risk analysis and at the request of parties as well as participation in inspections

outside of Croatia under coordination of PIC/S, WHO, CAPs (GMP inspections for medicinal products approved via the centralised procedure) and EDQM

Action steps:

- Educate Inspectorate employees and strengthen specific knowledge for particular areas of work
- Employment and education of new inspections with the appropriate knowledge and experience
- Strengthening cooperation with other national agencies and regulatory bodies in the EU and world for the purpose of education and exchanging experience
- Active international cooperation in the work of EMA, PIC/S, EDQM, MRA (FDA, Health Canada) WHO and other organisations with the aim of exchanging experience and contributing to the development of regulatory standards for medicinal products and medical trials
- Ensuring accessing to issued GMP certificates and manufacturing authorisations in the EudraGMDP database within the stipulated deadline for the purpose of exchanging information between national and international institutions

Prerequisites:

- Successful implementation of goal 8.1
- Sufficient number of inspectors with the appropriate knowledge and experience
- Quality regulatory, IT and administrative support to inspectors

Responsibility:

- Head of the Inspectorate

Key performance indicator:

- Increase in the number of inspections outside of Croatia

Unit: YES/NO

Time:

2018: increase the number of inspections outside of Croatia by 5%
2019: increase the number of inspections outside of Croatia by 20%
2020: increase the number of inspections outside of Croatia by 30%
2021: increase the number of inspections outside of Croatia by 50%

4.3. Undertaking activities for the purpose of increasing availability of medicinal products on the market

Strategy for the goal:

Strengthen HALMED's role in ensuring accessibility of medicinal products and effective management of depleted reserves while improving already developed tools for monitoring the status of medicinal products with marketing authorisation, applying available regulatory mechanisms for entry/import of necessary but unapproved medicinal products in Croatia or however for marketing authorisation of medicinal products and adhering to European initiatives in increasing accessibility of approved medicinal products.

Action steps:

- Continually undertake the monitoring of depleted reserves and termination of the supply of medicinal products, maintain up-to-date and accurate records on HALMED's website

- Raise awareness in holders of marketing authorisation of the prompt obligation to report of depleted reserves and terminated supplies of medicinal products
- Encourage manufacturers, holders of marketing authorisations and stakeholders in the distribution chain for proactive management of depleted reserves with the aim of avoiding such situations
- Cooperate with other relevant bodies and relevant organisations in the EU in the area of increasing availability of newly approved medicinal products and ensuring continual supply of medicinal products
- In cooperation with holders of authorisations, establish a system for notifying healthcare professionals of expected unavailability of essential medicinal products, in accordance with the requirement for good pharmacovigilance practices (GPV)
- Organise workshops for holders of authorisations, manufacturers of medicinal products and other interested parties based on depleted reserves and availability of medicinal products
- Issuing consent for the entry/import of appropriate medicinal products which do not have marketing authorisation in the Republic of Croatia in case of medically justified needs or however with the aim of bridging depleted reserves
- Issuing of exceptions for labelling in the Croatian language of an approved medicinal product with the aim of providing marketing authorisation necessary for required medicinal products in foreign packaging
- Strengthening HALMED's role in establishing communication between holders of authorisations without a local representative in Croatia and wholesale with the aim of improving the procedure for marketing in Croatia of medicinal products approved through the centralised procedure
- When required, include EMA in the issue of unavailability of particularly medicinal products in Croatia approved via the centralised procedure
- Education of wholesale and hospitals of the possibility of parallel marketing of medicinal products

Prerequisites:

- Successful implementation of goals 8.1 and 8.2
- Willingness of wholesale, holders of authorisations, healthcare professionals and other interested parties to cooperate

Responsibility:

- Division for Safe Use of Medicinal Products and Medical Devices

Key performance indicator:

- Continual increase in the number of medicinal products receiving marketing authorisation through the centralised procedure in Croatia by 2% compared to the previous year
- Continual decrease in the share of depleted medicinal products by 0.3% compared to the previous year

Unit:

- Percentage (%) of what has been executed

Time:

In each year of the 2018-2020 Strategic Plan, the plan is to have one-hundred-percent execution of inspections based on the annual program.

5. Optimising regulatory processes

5.1. Optimising internal processes

Strategy for the goal:
Analysis of HALMED's internal processes and consequential introduction of changes which will relieve employees and processes in terms of administration and lead to an increase in HALMED's work effectiveness.

Action steps:

- Chose internal processes for which an optimisation process should be implemented
- Analyse the existing state of selected internal processes and identify administrative burdens
- Propose and select changes in internal processes and assess risks associated with changes
- Implement changes in international processes which will relieve employees and processes of administrative burdens
- Assess the success of implemented changes

Prerequisites:

- Suitable IT support

Responsibility:

- All heads of HALMED's organisational units

Key performance indicator:

- Reduce administrative burdens on employees and processes

Unit: YES/NO

Time:

2019

- Implementation of action steps necessary for achieving this goal

2020

- Changes which employees and processes are relieved of administrative burden are introduced in selected standard operational procedures
- Drafting, circulation and archiving of documents within HALMED are digitalised to the greatest possible extent
- Internal communication and communication with parties is digitalised, and reduced in paper form to the least legally permitted level

2021

- Increase effectiveness of employees in undertaking jobs from HALMED's core business and significantly relieve administrative burdens

5.2. Reducing administrative burdens on users of services

Strategy for the goal:
In terms of the national reform program, administrative burdens should be reduced for business entities, users of HALMED's services, by proposing and implementing measures for relief based on undertaken analyses of the costs of administrative obligations faced by

business entities in implementing regulations from the area of medicinal products and medical devices in Croatia.

Action steps:

- Education of HALMED's employees for conducting analyses of costs stemming from administrative obligations by applying a standardised methodology (standard cost model or SCM)
- Conducting analyses of costs stemming from administrative obligations using the SCM methodology
- Proposing administrative relief in the scope dependent on results of conducted analyses which can be implemented internally without changing regulations
- Proposing administrative relief in the scope dependent on results of conducted analyses which require changes to regulations in order to be implemented internally
- Adapting internal processes for implementing adopted measures for administrative relief

Prerequisites:

- Include am adequate number of HALMED's employees for implementation of the SCM analysis within a set deadline in terms of implementing the program for comprehensive reform of the business climate in Croatia as initiated by the Government
- Adopting appropriate changes to regulations
- Appropriate IT support for relief measures related to digital solutions

Responsibility:

- Heads of HALMED's organisational units

Key performance indicator:

- Administrative relief for users of HALMED's services to be reduce by a proportion (%) as defined on the basis of conducted analysis using the SCM methodology

Unit: YES/NO

Time:

2018

- Conducted analysis of costs for administrative obligations using the SCM methodology
- Proposed measures for administrative relief through recommended changes to regulations for achieving relief as defined on the basis of cost analysis using the SCM methodology

2019

- Adoption and implementation of new/amended regulations allowing a decrease in administrative burdens for users of HALMED's services
- Initiating of the process for adapting internal processes which are an administrative relief for users of HALMED's services
- Development of IT support for relief measures related to digital solutions

2020

- Administrative burden for users of HALMED's services is reduced by a proportion defined on the basis of cost analysis stemming from administrative obligations and using the SCM methodology
- Implementation of adapted internal processes providing administrative relief to users of HALMED's services
- Use of IT support for relief measures relating to digital solutions

2021

- Implementation of additional adapted internal processes providing administrative relief to users of HALMED's services
- Additional development of IT support for relief measures related to digital solutions

6. Strengthening international cooperation

6.1. Implementation of programs originating from common HMA and EMA Strategies for the 2016-2020 period

Strategy for the goal:
As part of the regulatory network of European agencies, HALMED monitors and implements programs and goals prescribed in the HMA and EMA Strategy for the 2016-2020 period, as well as in the common strategy which includes activities of the entire network of national agencies and reflects the need for a common approach to numerous challengers and opportunities faced by members of the network.
Action steps:

- Active participation in determining the direction and development of EU legislation through active participation and formulation of guidelines, policies, opinions and views
- Active cooperation with other member states (members of the network) and EMA

Prerequisites:

- Heads of HALMED's organisation units, each in their part which relates to their processes

Key performance indicator:

- Contribution by HALMED through representatives in the EU Council, EC and other bodies
- Implementation of changes as agreed at the European level in Croatia
- Cooperation with other relevant bodies for medicinal products in the EU

Unit: YES/NO
Time:
2019: proportion of participation by HALMED's representatives at meetings is 85%
2020: proportion of participation by HALMED's representatives at meetings is 88%
2021: proportion of participation by HALMED's representatives at meetings is 91%

6.2. Positioning HALMED as a globally recognisable competent regulatory body

Strategy for the goal:
Creating a global perception of HALMED as a relevant body in procedures before and after the granting of marketing authorisation for medicinal products, pharmacovigilance, vigilance of medical devices and positioning it as a professionally recognised institution which provides proper quality and affordable services.
Action steps:

- Proactive participation in working groups and bodies of the EU and EC

- Successfully realization of previously obtained projects with the aim of getting recommendations for future projects
- Maintaining existing accreditation and certificates
- Continuing and strengthening cooperation and professional assistance to regulatory agencies in the region
- Establishment of international cooperation in the area of medicinal products and integration with the EU vigilance system
- Participation at conferences in the role of speaker, panellist and participant, as well as representing the pharmaceutical industry in the role of partner with suitable competencies
- Maintaining existing and concluding new cooperation agreements with other regulatory agencies

Responsibility:

- Heads of organisational units, each in proportion relating to their processes
- Advisor for European activities

Key performance indicator:

- Recognisability of HALMED as an instrument for networking, exchanging information and transferring the know-how of its experts
- Increasing the number of contracted analyses for other regulatory agencies
- Cooperation in the area of medicinal products and integration with the EU vigilance system
- Concluded cooperation agreements and memorandums of understanding

Unit: YES/NO

Time:

2019

- Maintaining existing cooperation agreements and memorandums of understanding
- Establishing cooperation in the area of medicinal products

2020

- Increasing the value of concluded cooperation agreements by 5%
- Increasing specific knowledge of HALMED's employees based on memorandums of understanding as a precondition for increasing the value of resolved cases
- Strengthening cooperation in the areas of medicinal products

2021

- Increasing the value of concluded cooperation agreements by 10%
- Transferring specific know-how from HALMED's employees to colleagues from other agencies
- Active participation in the EU vigilance system for medicinal products

6.3. Preparing for Presidency of the Council of the European Union in the first half of 2020

Strategy for the goal:

On 1 January 2020, Croatia will assume the six-month presidency of the Council of the EU, assisting in ensuring continuity of work by the EU in the Council. Priority of the EU's work in the Council is determined by a common program of a three-member group comprising three member states, known as the "trio". The Croatian Presidency will be part of the trio

along with the presidency of Romania and Finland in the period from January 2019 to 30 June 2020. The trio determines long-term goals and devises a common program in which topic and main issues are identified which will be addressed by the Council over an 18-month period. Based on the mentioned program, each state from the respective trio devises its own detailed six-month program.

Action steps:

- Determining the work program
- Determining meetings and agendas for the meetings which will be held during Croatia's Presidency as organised by HALMED
- Developing the Croatian Presidency website for activities in the area of medicinal products and medical devices
- Cooperation with representatives of the Romanian and Finnish regulatory body in the area of medicinal products and medical devices

Responsibility:

- Head of organisation units, each in part relating to their processes
- Advisor for European activities
- Spokesperson

Key performance indicator:

- Determined work program
- Determined meetings and agendas for the meetings
- Designed website
- Effective cooperation with Romanian and Finnish regulatory bodies in the area of medicinal products and medical devices
- Drafting of final reports and handing over activities to Germany as the Presidency which follows after Croatia

Unit: YES/NO

Time:

2018

- Determine the work program – draft list of meetings and agendas

2019

- Design of a functional website for the Croatian Presidency for activities in the area of medicinal products and medical devices
- Determine the list of meetings and agendas as well as drafted materials for the respective meetings
- Active cooperation with Romania and Finland in terms of the "trio"
- Completed preparatory meetings for assuming the Presidency of the Council of the EU

2020

- Conducting meetings and subsequent activities as organised by HALMED which are included in the Croatian Presidency of the Council of the EU
- Prompt reporting relating to meetings and associated activities via the official website of the Croatian Presidency for activities in the area of medicinal products and medical devices as well as other channels
- Drafting of final reports and cooperation with the German Presidency

2021

- Active participation in the work of the Portuguese and Slovenian Presidency

7. Development of a communication strategy

7.1. Strengthening transparency of work as a public body

Strategy for the goal:
HALMED will act in accordance with the obligations of public bodies and requirements for transparency prescribed by legislation in the area of medicinal products and medical devices. Continued strengthening of transparency in work will increase the level of trust in HALMED's work and its decisions, as well as in the entire regulatory system for medicinal products and medical devices, and will contribute to strengthening national recognition of HALMED as an important factor in the protection of public health.

Action steps:

- Publishing and updating all relevant information, documents and other materials from HALMED's scope of work and its website
- Promptly replying to requests for access to information from HALMED's scope of work
- Publishing and updating instructions for users of HALMED's services on the manner of lodging applications to HALMED and in exercising their rights on HALMED's website
- Submission of relevant documentation from HALMED's scope of work for the Central Catalogue of Official Documents Belonging to the Republic of Croatia

Prerequisites:

- Familiarity with requirements for transparency prescribed by current laws and bylaws

Responsibility:

- Spokesperson
- Heads of organisational units

Key performance indicator:

- Relevant information, documents and other materials from HALMED's scope of work are published on its website and regularly updated
- All received requests for access to information from HALMED's scope of work are promptly resolved
- Instructions to users of HALMED's services on the manner of lodging requests to HALMED and exercising their rights are published on HALMED's website and regularly updated
- All relevant documents from HALMED's scope of work are regularly submitted to the Central Catalogue of Official Documents Belonging to the Republic of Croatia

Unit: number/frequency

Time:
2019

- Continued publishing and updating of all relevant information, documents and other materials from HALMED's scope of work
- Resolving 100% of received requests for access to information
- Continued publishing and updating of instructions to users of HALMED's services on the manner of lodging applications to HALMED and exercising their rights

- All the respective documents from HALMED's scope of work drafted or published in 2019 are submitted to the Central Catalogue of Official Documents Belonging to the Republic of Croatia

2020

- Continued publishing and updating of all relevant information, documents and other materials from HALMED's scope of work
- Resolving 100% of received requests for access to information
- Continued publishing and updating of instructions to users of HALMED's services on the manner of lodging applications to HALMED and exercising their rights
- All the respective documents from HALMED's scope of work drafted or published in 2020 are submitted to the Central Catalogue of Official Documents Belonging to the Republic of Croatia

2021

- Continued publishing and updating of all relevant information, documents and other materials from HALMED's scope of work
- Resolving 100% of received requests for access to information
- Continued publishing and updating of instructions to users of HALMED's services on the manner of lodging applications to HALMED and exercising their rights
- All the respective documents from HALMED's scope of work drafted or published in 2019 are submitted to the Central Catalogue of Official Documents Belonging to the Republic of Croatia

7.2. Strengthening HALMED's national recognisability as an important factor in the protection of public health

Strategy for the goal:

Achieving this particular goal will lead to an increase in the level of trust in HALMED's work and the regulatory system for medicinal products and medical devices. Equally so, it will contribute to facilitating communication between HALMED and interest groups as well as facilitating cooperation with other factors in protecting public health and facilitate finding adequate expert staff necessary for HALMED's work. In terms of this goal, social media will be used in HALMED's communication channels. Achieving this particular goal 7.2 will also contribute and achieve the closely related particular goal 7.1.

Action steps:

- Promptly providing information from the scope of work to interested parties via the website and other accessible communication channels
- Continued cooperation with media representatives (by responding to enquiries, sending out press releases, media conferences and briefings, releasing statements, guest appearances on television and radio shows and through other routes of cooperation)
- Strengthening cooperation with other bodies and stakeholders in the healthcare system
- Organising educational courses and/or gatherings for HALMED's interest groups
- Collecting and analysing comments and other feedback received from HALMED's interest groups

- Improving and adapting channels and methods of communication based on feedback received from HALMED's interest groups
- Preparation and implementation of social media activities intended for positioning HALMED on selected platforms
- Regular communication with HALMED's interest groups on selected social media platforms
- Continued development and extension to profiles/channels as well as monitoring and analysing implementation and effectiveness of social media activities
- Investing the history of control and supervision of the market for medicinal products in Croatia and a history of HALMED as an institution

Prerequisites:

- Employees at HALMED contribute to building a positive picture of HALMED
- Educated employees familiar with the rules and practices in content management on social media profiles/channels
- Funds necessary for implementation of promotional activities on selected social media

Responsibility:

- Spokesperson
- Heads of organisational units

Key performance indicator:

- Increase in the number of new notices on HALMED's website
- Activities and operations of HALMED are followed in the media positively
- Increase in the number of healthcare activities implemented in cooperation with other bodies and stakeholders in the healthcare system
- Educational courses and/or gatherings for HALMED's interest groups are regularly reflected in good attendance figures
- Received comments and other feedback from HALMED's interest groups are positive
- Adequacy of HALMED's communication channels and methods are rated positively by interest groups
- Communication with interest groups on social media is regularly conducted
- Continued development and expansion of the social media profiles/channels
- Regular reports on the effectiveness of social media activities are drafted

Unit: number/frequency

Time:

2019

- 100 notices are published on HALMED's website
- 100% of received enquiries from media representatives in the area of HALMED's scope of work are resolved
- At least 3 healthcare activities are carried out in cooperation with other bodies and stakeholders in the healthcare system
- 3 educational courses and/or gatherings for HALMED's interest groups are well attended
- An annual survey on satisfaction by users of HALMED's services is conducted
- At least 900 enquiries from interest groups have been replied to in writing and/or by telephone

2020

- 110 notices are published on HALMED's website

- 100% of received enquiries from media representatives in the area of HALMED's scope of work are resolved
- At least four healthcare activities are carried out in cooperation with other bodies and stakeholders in the healthcare system
- Four educational courses and/or gatherings for HALMED's interest groups are well attended
- An annual survey on satisfaction by users of HALMED's services is conducted
- At least 1000 enquiries from interest groups have been replied to in writing and/or by telephone
- HALMED is included in selected social media
- The history of control and supervision of the market for medicinal products in Croatia as well as the history of HALMED as an institution is investigated

2021

- 120 notices are published on HALMED's website
- 100% of received enquiries from media representatives in the area of HALMED's scope of work are resolved
- At least five healthcare activities are carried out in cooperation with other bodies and stakeholders in the healthcare system
- Five educational courses and/or gatherings for HALMED's interest groups are well attended
- An annual survey on satisfaction by users of HALMED's services is conducted
- At least 1100 enquiries from interest groups have been replied to in writing and/or by telephone
- Regular communication by HALMED is conducted via selected social media platforms

8. Development of internal resources

8.1. Human resources management

Strategy for the goal:
Strengthen capacities and capabilities of employees so that they can overcome complex scientific and regulatory requirements in HALMED's scope of work in Croatia and the EU. Continued implementation of various forms of scientific and professional ongoing training and new employment will ensure that HALMED has an additional number of experts at its disposal necessary for the proper undertaking of all previous and new job. The introduction of a system for assessing competencies and monitoring work outcomes will enable the monitoring of the quality of work and effectiveness of employees in achieving work tasks based on clearly defined goals.

Action steps:

- Introduction of a system for assessing competencies and monitoring work outcomes
- Education of employees for the purpose of strengthening specific knowledge for particular areas
- Employment and education of new employees
- Adaptation of the systemisation of working positions in line with changes in business processes, as required

Responsibility:

- Head of the Office of the Agency Head
- Heads of HALMED's organisational units

Key performance indicator:

- Introduction of a system for assessing competencies and work outcomes
- Employees are trained for executive specific tasks from the scope of work
- Employing an adequate number of executors in accordance with work requirements
- Systemisation of working positions and descriptions of jobs in line with business processes

Unit: YES/NO

Time for realisation:

2019

- Conducting an assessment of competencies and annual discussions with employees as well as setting work and development goals for each employee
- Conducting professional and scientific training of employees
- Employees fulfil available and new working positions
- Systematisation of working positions conformed with the requirements business processes

2020

- Conducting a repeated assessment of competencies and annual discussions with employees as well as setting work and development goals for each employee
- Conducting professional and scientific training of employees
- Employees fulfil available and new working positions
- Systematisation of working positions conformed with the requirements business processes

2021

- Assessment of competencies, annual discussions with employees and setting of new goals for employees is conducted routinely within defined time intervals
- Conducting professional and scientific training of employees
- Employees fulfil available and new working positions
- Systematisation of working positions conformed with the requirements business processes

8.2. Improving telemetric systems

Strategy for the goal:

Continued development of related and effective telematic systems and expanding them with high quality and economic solutions which ensure optimal working conditions and interoperability towards external systems. The systems need to be developed in accordance with valid strategies and laws of the Republic of Croatia, directives of the European Union and applying work standards and good practices in the IT profession and in sharing information.

Telematic systems should be the source for improving HALMED's business processes, especially in collecting and processing data. Authentic, up to date and networked data is the basis for effective and proper under of all of HALMED's activities and a prerequisite for

proper exchange on information with other systems. Therefore the focus of developing telematic systems should continue to be the establishment of a good quality database modelled in line with valid standards and rules for protection and security, as well as continued participation in joint projects initiated by the EMA, EC and/or relevant national bodies within the EU, and in projects relating to HALMED's activities which are initiated in Croatia.

Action steps:

- Continued collection of requests from users for development of existing systems or establishment of new systems, stemming from changes in business processes, introduction of new business processes or for the purpose of achieving compliance with legislative changes
- Development of systems based on received requests from users and/or for the purpose of achieving compliance and linking to other telematic systems in Croatia and the EU, while adhering to current established rules:
  - Process application to be linked to the Digital Archival Information System as the central location for the archiving of all electronic documentation related to HALMED's business operations
  - Process application to be mutually linked to services in order to automate all steps in business processes
  - Linking systems ensures that functionality is not duplicated, and that data are maintained only in one place (common codebook, central database)
  - Systems are to be developed based on new technologies, in accordance with good practices, giving dominance to internet technologies
  - Exchanging information within HALMED without paper documentation and working with electronic documentation as the preferred form of documentation
  - Systems are to be integrated with systems for creating and verifying advanced electronic signatures and electronic stamps
  - Develop systems in compliance with valid EU norms and standards established at the level of HALMED, EMA and other international bodies relevant for medicinal products and medical devices, especially with standards established through the SPOR project (substance, product, organisation and referential data)
  - Continued optimisation of already developed systems and processes
- Participation in achieving joint projects in the European network
- Educating users on new functionalities and changes in all of HALMED's systems and participation in joint educational programs within the network
- Continually renewing and expanding equipment necessary for the operation of the telematic system and ensuring the necessary number of licences
- Continually monitoring the development of telematic systems within the domain of the EMA and other international bodies relevant for medicinal products and medical devices, as well as actively participating in the work of groups and working bodies of EMAs for telematic issues and other relevant working groups within the EU

Prerequisites:

- Granting of funds
- Adequate number of experienced and education IT personnel

- Granting of professional resources within HALMED's units and establishing cooperation with all organisational units (process owners) in defining, realisation, testing, validation and implementation of expanded systems
- Contractual relationship with qualified contractors

Responsibility:

- Head of the IT Department
- Heads of organisational units who are owners of process supported by the systems

Key performance indicator:

- Collected user enquiries
- Writing up 18 specifications for establishing new or expansion of existing systems
- Establishment of two new and expansion of 16 existing systems
- Renewal equipment in data centres based on criteria: age of equipment less than four years old; renewal of equipment of users based on criteria: age of equipment less than five years old and the criteria: age of equipment less than three years old for specific user equipment; increasing availability of processes power and working memory by 70%, increasing disk capacity by 200%
- Establishing IT infrastructure to meet HALMED's business needs
- The development of systems within the EU and Croatia are continually monitored, and employees regularly and actively participate in the work of relevant bodies and working groups in the EU and Croatia

Unit: YES/NO

Time:

2019

- Establishment of one new system
- Expansion of five existing systems
- Issuing of specifications necessary for development and expansion
- Renewal of equipment in data centres by 10%
- Renewal of user equipment based on the criteria: age of equipment less than five years old and the criteria: age of equipment less than three years old for specific user equipment – 30%
- Increasing available processor power and working memory by 20%
- Increasing disk capacity by 30%

2020

- Expansion of five existing systems
- Issuing of specifications necessary for development and expansion
- Renewal of equipment in data centres by 10%
- Renewal of user equipment based on the criteria: age of equipment less than five years old and the criteria: age of equipment less than three years old for specific user equipment – 20%
- Increasing available processor power and working memory by 50%
- Increasing disk capacity by 20%

2021

- Establishment of one new system
- Expansion of five existing systems
- Renewal of equipment in data centres by 20%

- Renewal of user equipment based on the criteria: age of equipment less than five years old and the criteria: age of equipment less than three years old for specific user equipment – 20%
- Increasing disk capacity by 30%

8.3. Drafting the information management strategy

Strategy for the goal:
Analyse the area and analyse the initial state by applying the maturity model for different segments in the interdisciplinary area of information management. Thereafter, analyse and define the needs and requirements by applying the literature research model (literature, standards, specifications) and survey method. Finally, draft the Information Management Strategy, adopt it and present it to the public.
Action steps:

- Research the literature Information Governance (IG) for the interdisciplinary area, related standards and appropriate models of maturity for key segments which enter the IG area
- Procurement of standards
- Identification of key requirements from the standards
- Drafting a collection of texts and specifications
- Drafting surveys and other methods for collecting data to be analysed
- Analysis of the state of information management at HALMED
- Assessment of the maturity of information management at HALMED
- Identification of needs
- Analysis of conformance of organisational units in relation to information management
- Identification of key concepts in the area of management of data, content, records (records management), security and privacy of information, risks, following by ICT, long-term storage of materials (archiving) and business intelligence, as well as ensuring a readiness for court proceedings and additional harmonisation with legislation
- Drafting of the proposed strategy
- Drafting of the final strategy
- Adoption of the strategy
- Presenting the strategy

Prerequisites:

- Appropriate support from the board and IT Department
- Inclusion of all of HALMED's organisational units

Responsibility:

- Document, Records and Project Management Department

Key performance indicator:

- Strategy in managing information from the institution is drafted in line with modern methods of IG for the interdisciplinary area and adopted
- The strategy is presented to the public

Unit: YES/NO

Time:
2019

- Procurement of and research into literature
- Procurement of standards
- Drafting of a collection of texts and specifications
- Analysis of key requirements from standards, literature and specifications
- Drafting of surveys and instruments for analysis
- Selection of methodology for assessing maturity

2020

- Analysis of the current state
- Assessment of maturity of information management at HALMED
- Identification of needs
- Drafting of requirements which are incorporated into the draft of the Information Management Strategy and devising the draft

2021

- Drafting the final Information Management Strategy
- Adoption of the Strategy
- Planning IG projects
- Presenting the Strategy to the public

8.4. Sustainable self-financing

Strategy for the goal:
Strengthen the financial, staff and other necessary capacities at HALMED for the purpose of successfully overcoming future business challenges on the market which may jeopardise financial stability. The aim of forecasting sustainable self-financing through particular goal 8.4 of the Strategic Plan is to adapt HALMED's business operations to new market conditions in order that it continue to finance itself from its own sources and provide healthcare services and fulfil national obligations of the relevant regulatory body for medicinal products and medical devices, while not burdening the state budget.
Action steps:

- Monitoring, reporting and harmonising the necessary business data with the aim of making timely and quality business decisions
- Maintaining an optimal ratio of operating expenditure and revenue
- Actively participating in nominated EU activities
- Actively participating in providing recommendations and passing laws and bylaws which are consequently related to HALMED's revenue and legal status
- Decisions on the need to invest in construction or buying additional commercial premises, with the aim of resolving the issue of inadequate commercial premises and eliminating leasing costs

Prerequisites:

- Tools for monitoring the execution of operating revenue and expenditure as well as balancing them

- Employing and allocating additional funds for professional ongoing training of HALMED's independent experts (assessors and inspectors) with the aim of creating new revenue
- Achieving the planned number of EU procedures and audits
- Branding HALMED through stronger cooperation with the pharmaceutical industry in Croatia and outside of national borders
- Continual application of the Financial Management Control system (FMC)

Responsibility:

- The Agency Head, assistants to the Agency Head and heads of HALMED's organisational units

Key performance indicator:

- Achieving the forecasted revenue and managing expenditure to levels forecasted by particular years (Table 2)
- Balancing operating revenue and operating expenditure by years

Unit:

- percentage (%) completed

Time:

2019

- Achieve increase in revenue from European activities by 22% compared to 2018 (see Table 2)
- Achieve revenue from national activities at the planned level (see Table 2)
- Managing operating costs with possible increases of up to a max. of 2% compared to 2018 (see Table 2)

2020

- Achieve increase in revenue from European activities by 18% compared to the previous 2019 (see Table 2)
- Achieve revenue from national activities at the planned level (see Table 2)
- Managing operating costs with possible increases of up to a max. of 2% compared to the previous 2019 (see Table 2)

2021

- Achieve increase in revenue from European activities by 37% compared to the previous 2020 (see Table 2)
- Achieved revenue from national activities up to a min. level of 96% of that planned for 2020, due to changes in regulations in the area of medicinal products which will lead to a reduction in revenue from national activities (see Table 2)
- Managing operating costs with possible increases of up to a max. of 2% compared to the previous 2020 (see Table 2)

4. IMPLEMENTATION AND MONITORING

This Strategic Plan for the period covering the next three years was drafted under the assumption that external influences, primarily national legislation, will remain unchanged within its essential determinants. In the event of a risk appearing due to changes in the national legislation or changes in EU legislation or prioritised goals change due to public healthcare risks, the goals of this Strategic Plan will be promptly revised.

Execution of the set general and particular strategic goals will be monitored through a business planning and reporting system. The annual report on execution of the business plan also contains a report on execution of strategic goals and is to be presented to HALMED's Administration Board, Croatian Ministry of Health and the wider public by publishing it on HALMED's website.