HALMED

Agency for Medicinal Products
and Medical Devices of Croatia

DEVELOPMENT STRATEGY

2014 – 2018

ACTIVELY CONTRIBUTE TO THE PROTECTION AND PROMOTION OF PUBLIC HEALTH

HALMED's role is
to actively contribute to the protection and promotion of public health
through the regulation of medicines and medical devices

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FOREWORD

This strategic plan has been developed by HALMED's Directorate and the heads of divisions in order to provide a disciplined approach to the management of our Agency for the 2014-2018 period. The plan sets out the conditions and developments expected over the given period, our strategic goals and defined roadmap to our stakeholders and staff indicating how we will achieve these goals.

1.1 Protecting public health

The Agency for Medicinal Products and Medical Devices (HALMED) is the independent Croatian national competent body that is the regulator of medicines and medical devices. Our role is to actively contribute to the protection and promotion of public health through the regulation of medicines and medical devices in the Republic of Croatia, as well as in the EU.

We do this by

- mobilizing highly-skilled and experienced experts and healthcare professionals in order to achieve the high quality assessment of medicinal products and medical devices, promoting research and development programs, as well as providing clear and useful information to the public and healthcare professionals;
- developing effective and transparent procedures aimed at providing the public with prompt access to medicinal products based on decisions taken in the interests of public health;
- supervising the safe use of medicinal products and medical devices across the entire product lifecycle by monitoring adverse reactions and the quality of medicinal products and medical devices marketed in the Republic of Croatia;
- collaborating with international authorities competent for medicinal products and medical devices on an EU and global level; and
- developing collaboration with all stakeholders including national health regulatory authorities, healthcare professionals, academics and researchers, patient associations, and the research and manufacturing industries, to maximise the availability of medicines and medical devices with a positive benefit/risk profile.

The pharmaceutical sector is a significant contributor to Croatian economic development and is set by Croatian Government as one of the most important strategic sectors that has to play an important role in driving export-led growth in the future. This is why HALMED's strategic orientation is to support this sector through providing regulatory and technical advice in relation to new or expanded facilities and ensuring compliance with all the standards of good practices.

1.2 What has been achieved

During the past three years under the leadership of the Head of HALMED, significant organisational changes have taken place, scientific knowledge has been successfully increased and staff capacities have been improved and well trained in order to prepare the Agency for new challenges in the EU environment:

- The Medicines Authorisation Division was reorganised with the introduction of coordinators in the Regulatory Affairs Department necessary to facilitate MA procedures. Moreover, overall expertise, especially in preclinical and clinical assessment was strengthened and the number of staff has increased significantly.
- The Department for Pharmacovigilance and Rational Pharmacotherapy fully implemented the new EU regulations. The number of staff has increased significantly and a new structure introducing coordinators was established in order to properly meet all regulatory requirements.
- OMCL achieved a high standard of quality control performance that was recognised by the European Directorate for the Quality of Medicines and Health Care that issued attestation in accordance with ISO/IEC 17025.
- The Office for Pharmacopoeia was founded and has been producing updated versions of Croatian Pharmacopoeia in line with Ph. Eur.
- The Office for Quality Management was established in order to integrate the quality system of HALMED and organized it in accordance with the international standards and best practices of the EU regulatory network.
- The IT development programme included a broad scope of improvements. Thus, significant improvements were achieved and specific databases were produced, e.g. the National medicines registry, Quality control registry etc.
- The Inspection of Good Manufacturing Practice and the Pharmacovigilance inspection were established in HALMED based on ISO/IEC 17020.

All these achievements point HALMED towards the new perspectives and challenges of the coming years.

1.3 History

HALMED was established on 1st October 2003 as a legal successor to the Croatian Institute of Medicines Control and the Croatian Institute of Immunobiological Preparations Control, albeit with a considerably broader scope of work.

The Agency was established by the Parliament of the Republic of Croatia. The legal compliance of the Agency is supervised by the Ministry of Health.

1.4 Looking forward

In looking forward to these next five years, we will maintain our mission and vision statements that are completely focused on public health.

We will continue collaboration with other national competent authorities within the EU as well as the European Medicines Agency (EMA). We want to become an important and respectable player within the EU regulatory network in the field of medicine marketing authorisation and GMP/PV inspections, and to continue the development of the pharmacovigilance process in order to contribute to building a safe and effective public health system. We will intensify our efforts in marketing surveillance for medicines, as well as combating illegal and counterfeit medicines through strong cooperation with the national police and custom services.

We will further develop our quality management system to achieve the highest standards as defined in the principles of Benchmarking of the European Medicines Agencies (BEMA), and finalize the building of our integrated IT system that will facilitate the planning, monitoring and performance of all HALMED activities. Furthermore, we will build a strong risk management system that will encompass all the key processes and professional duties of HALMED, bearing in mind the strengthening of our business continuity capabilities, as well as specific risk-based pharmacovigilance and inspection activities.

Our stakeholders are a focus of our interest and communication with them is of crucial importance to HALMED. We will establish new ways of communication and improve those that are already well established. Introducing of the Annual Stakeholders Meeting and redesigning of the web site will be a part of these activities.

HALMED will continue participation in all the initiatives of Republic of Croatia in EU activities that will lead us to a stronger and more efficient legal framework of medicines and medical devices.

In order to achieve all our goals, we will continue building our capacities focusing on strengthening our expertise, scientific knowledge and necessary skills needed in the EU environment.

Zagreb, October 10th 2014

Head of Agency

Viola Macolić Šarinić, M.D., Ph.D.

2. ORGANISATION TENETS

Based on Article 125 of Act on Medicinal Products and Medical Devices ("Official Gazette", No. 121/03.), HALMED was founded and started to operate in 2003.

The activities of the Agency are defined by Article 212 of Medicinal Products Act ("Official Gazette", No. 76/13. and 90/14.).

2.1 Mission

HALMED's mission is to protect and promote public health through the regulation of medicinal products and medical devices.

2.2 Vision

Our vision for HALMED is to become one of the key and recognizable factors of the health system, providing the public of the Republic of Croatia with safe, effective and quality medicinal products and medical devices through professional and regulatory excellence.

2.3 Values

We are competent

We perform our legal tasks in a professional and scientific manner. We pay special attention to personal development with the only aim of achieving an appropriate knowledge level that will enable us to efficiently evaluate issues related to the safety and quality of medicines and medical devices.

We are patient and public health oriented

The patient and their needs are always the focus of our interest, bearing in mind that only high quality work, as well as prompt reactions contributes to public health well-being.

We are a European agency

With our committed work in the European bodies for medicines and medical devices, we actively contribute to the development and strengthening of the regulatory framework, thus ensuring the availability of exclusively those medicines and medical devices with an indispensable quality and safety profile.

We are committed to our tasks

We collaborate closely with the users of our services by insisting on a partner relationship and a professional approach. We do not consider comments from our clients as criticism but rather as a possibility to improve the quality system, which we are permanently building upon.

We are open to new findings

We closely follow the latest achievements in science and technology that contribute to the treatment of all diseases, notably the rare and severe ones. We recognise all new findings that lead to innovative approaches in the development and use of medicines and medical devices.

We are ethical

We perform our committed tasks persistently, maintaining high ethical standards. We know that we are guided by the principles that are oriented towards the protection of the rights of society as a whole, with a special emphasis on the patients who in a given moment should have access to the most beneficial medicines and medical devices.

2.4 *Legal framework*

Before joining the EU, HALMED was involved in the preparation for the transposition of all EU legislative requirements regarding medicines and medical devices into the Croatian Medicinal Products Act and Medical Devices Act. Moreover, HALMED was involved in drafting a number of corresponding ordinances that were approved by that Minister for Health. HALMED's experts will also be involved in the preparation of drafts of the remaining ordinances in cooperation with the responsible personnel of Ministry of Health.

HALMED will continuously follow all changes in the EU legislation in the field of medicines and medical devices and will contribute to the preparation of all the necessary documents for their transposition into the Croatian legal framework.

Pharmacovigilance

Although significant changes have been made in relation to the system for pharmacovigilance (medicine safety monitoring) for human medicines in the EU, there are certain additional Modules to be adopted on the level of the EU:

- Module XI – Public participation in pharmacovigilance.
- Module XII – Continuous pharmacovigilance, ongoing benefit-risk evaluation, regulatory action and planning public communication.
- Module XIV – International cooperation.

Upon the adoption of all Modules into the legal framework, the Pharmacovigilance system will be completed and able to serve as a valuable tool in the protection of Public Health.

Medical devices

Although The Medical Devices Directives have already been subject to revision, which came into force in 2010, additional revision is in progress in the EU Commission. Our experts will closely monitor any information in the field and actively participate in the process.

Counterfeit medicines

Since counterfeit medicines must be treated as a significant threat to public health, it is of crucial importance that the Republic of Croatia signs and ratifies the Medicrime convention and develops all the necessary mechanisms that will be used in combating this crime.

2.5 Role of HALMED

The agency's remit in the field of medicinal products and medical devices is regulated under the Medicinal Products Act ("Official Gazette", No. 76/13. and 90/14.).

Since the establishment of HALMED, the scope of functions that have been conferred on our Agency have changed several times. According to Article 212 of the above mentioned Act, we are responsible for the following service areas:

- granting marketing authorisations for medicinal products and homeopathic medicinal products
- carrying out registration procedures for traditional herbal medicinal products and homeopathic medicinal products
- granting authorisations for the parallel imports of medicinal products
- making expert assessments of the quality, efficacy and safety of medicinal products
- performing laboratory analyses of medical devices
- performing tasks of the official laboratory for quality control for the Republic of Croatia
- performing quality control of medicinal products and homeopathic medicinal products, and issuing certificates of quality control
- analysing and assessing adverse reactions and the safety of subjects in clinical trials
- preparing the Croatian Pharmacopoeia
- issuing the Croatian Pharmacopoeia and other expert publications from its scope of work
- performing pharmacovigilance tasks
- granting manufacturing authorisations to manufacturers and importers of medicinal products and investigational medicinal products
- keeping the register of manufacturers, importers and wholesale distributors of active substances and excipients
- granting authorisations for the wholesale distribution of medicinal products
- granting authorisations for the retail sale of medicinal products in specialized retail sale outlets
- granting authorisations for brokering medicinal products
- giving approval for the entry and importation of medicinal products
- giving approval for the emergency entry and importation of medicinal products
- monitoring adverse reactions and defects in medicinal products
- initiating procedures for the suspension marketing medicinal products and performing product recalls
- monitoring the supply of medicinal products
- monitoring the consumption of medicinal products and promoting their rational use
- proposing measures to the Minister to supervise the consumption of medicinal products
- engaging in waste management activities (for its own needs)
- ensuring education and providing information on medicinal products
- providing expert advice from its scope of activities

- providing expert guidelines from its scope of activities
- proposing the harmonisation of regulations on medicinal products with those of the European Union, as well as with the regulations and guidelines of international institutions
- establishing international cooperation in the field of medicinal products
- carrying out inspections of the production of medicinal products, investigational medicinal products, active substances or excipients and the inspection of pharmacovigilance
- keeping the register of manufacturers of medical devices, the register of medical devices and the register of wholesale distributors of medical devices
- analysing and evaluating adverse events in clinical trials of medical devices
- granting authorisation for the retail sale of medical devices in specialized retail sale outlets - keeping the register of medical devices marketed in the Republic of Croatia
- operating a vigilance system for medical devices, and monitoring the safety of medical devices
- carrying out the procedure for the emergency recall of medical devices
- carrying out the procedure for the classification of medical devices
- issuing certificates for the free sale of medical devices
- ensuring education and providing information on medical devices
- establishing international cooperation in the field of medical devices
- proposing the harmonisation of regulations on medical devices with those of the European Union, as well as with the regulations and guidelines of international institutions
- performing other tasks in the field of medicinal products in line with this Act and the ensuing regulations and in the field of medical devices in accordance with the Medical Devices Act and the ensuing regulations

2.6 Organisational structure

HALMED is governed by a Management Board of five members appointed by the Croatian Government.

Day-to-day management of HALMED is devolved to the Head of the Agency, who is assisted by the Deputy Head of Medicinal Products, Medical Devices and Quality Management and the directors of divisions.

The Head of the Agency has appointed the following Committees:

- Committee for Medicinal Products
- Committee for Medical Devices
- Medicinal Product Safety Committee

  Members of the Committees are experts of the Agency for Medicinal Products and Medical Devices, as well as independent experts (medical doctors, doctors of dental medicine and masters of pharmacy). Members of the Committees provide expert opinions on the quality, efficacy and safety of medicinal products, or the quality or conformity and safety of medical devices.

- Agency's Scientific Council

  The Scientific Council of the Agency is an advisory body to the Head of the Agency.

  Members of the Scientific Council are employees of the Agency for Medicinal Products and Medical Devices appointed by the Head of the Agency at the proposal of the heads of the Agency's organisational units.

Operations of the Agency are conducted through the following organisational units:

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

According to legal requirements, HALMED has an Employees' Council, which is a representative body of employees.

2.7 Qualification structure

HALMED as an employer, has engaged professionals with specific expertise in the field of medicines and medical devices due to its legal obligations.

In total, almost 200 employees or 67% belong among those with a master university degree, 10% with a bachelor university degree and 19% with finished secondary school.

Furthermore, 13 of our employees have a PhD degree, 8 of our employees have a Master of Science degree, 10 of our employees have a medical specialisation diploma and 3 of our employees have a diploma for professional specialisation.

2.8 Financing

HALMED is a self-funded agency that generates its own income through service fees and annual charges for the provision of services approved by the Minister for Health and operates in accordance with the Medicinal Products Act and other regulations to the strictest ethical principles to ensure the highest quality of service combined with value for money.

2.9 Networking and Communication

HALMED is deeply involved in networking activities in the EU and international community. We have established intensive cooperation with the European Commission, the Council of Europe – European Directorate for Quality of Medicines and Health Care, the European Medicines Agency, the World Health Organisation and the Uppsala Monitoring Centre, Heads of Medicines Agencies, as well as with national competent bodies from the EU/EEA. In the future, we plan to broaden our cooperation and to continue our activities as members in boards, working groups and parties bearing in mind that only mutual international efforts will ensure safe, reliable end effective medicines and medical devices in the Republic of Croatia.

We will organise a National Medicines and Medical Devices Forum where all our key stakeholders will be able to provide their input into HALMED's area of work.

Their input will help us in building a stronger and more advanced management system that will be able to answer to all the demands of our stakeholders in a more efficient manner.

HALMED will continue to use a variety of means to provide access to clear, accessible, transparent and readily available information on the regulatory system for healthcare products to all stakeholders, such as healthcare professionals, patients, industry and general public.

We are aware that only the proper selection of communication channels for risks associated information regarding medicines and medical devices ensures that new and emerging information on benefits and risks is brought to the attention of healthcare professionals and to the public in a timely manner.

Thus, we will improve our risk management system and adapt it to the European requirements. Furthermore, the Agency will continue to follow the most recent transparency policy, bearing in mind that the standards of transparency are constantly increasing through time. Additionally, with an aim of continuous improvement in facilitating access to information for specific groups of stakeholders, the Agency's website will be redesigned.

SWOT Analysis

A SWOT Analysis was performed based on an organisational maturity self-assessment questionnaire that was in accordance with the Benchmarking of EU Agencies requirements. The results of the analysis were used for defining the goals and specific objectives of the Strategy.

2.10 Sustainable competitive advantage

Based on our experience, we think that our sustainable competitive advantage is employees that are willing to gain new knowledge and to share their expertise, our employees that are ready to take on all task in the field of the regulatory network for medicines and medical devices, our employees that are devoted to the development and constant improvement of our Agency.

3. STRATEGIC GOALS AND OBJECTIVES

The strategic direction for HALMED over the next five years will be in line with our policy of public health protection, the challenges we identify in the operating environment in Republic of Croatia and the EU, and the strategies of our regulatory partners. It will be oriented to all possible improvements in service delivery based on building a quality and management system that is dedicated to continuous improvement.

Our high-level strategic goals are:

1. *To contribute to the safety and quality of medicines and medical devices through effective risk management and market surveillance.*
2. *To improve provided services within a high quality, risk-based regulatory framework.*
3. *To deliver transparent, pertinent and well-timed communications to patients, the public and healthcare professionals.*
4. *To strengthen capacities as a response to developing regulatory requirements and scientific and technological advances.*
5. *To participate in medicines and medical devices policy and legislation development for the benefit of public health at the national and EU level.*

We have put our stakeholders in the focus of our interest for the first three goals. Thus, to achieve goal one, we have to ensure that both healthcare professionals and the public have access to medicines and medical devices that will be safe and effective for use and of appropriate quality.

Goal two is dedicated to improving all our processes and activities through the allocation of the necessary resources, which have to be proportionate to the expected applications in the future, and to HALMED's aim, as a new member in the EU regulatory framework, to be actively involved in EU procedures as much as possible.

For HALMED, being a public institution, well-timed and adequately formatted information on medicines and medical devices dedicated to health professionals, patients and consumers is of major importance. Thus, goal three addresses transparent and pertinent information delivery on specific benefit/risk issues and other topics of public interest in the domain of HALMED services.

In order to realise the goals mentioned above, as well as goal four that is closely linked to them, we have to allocate all the necessary resources and ensure a proper level of investment in our staff, IT technologies and equipment.

As we presume that certain legislative changes will happen during the course of this strategic plan, the fifth goal will be directed to our active participation in the creation of new legislation, both national and international, for the better protection of patients and consumers.

All these high-level goals represent solid ground for establishing and improving the processes and activities of HALMED over the next five years. In the following sections, we will set out the strategic objectives for each of the goals connected to the identified issues.

3.1 Goal #1

To contribute to the safety and quality of medicines and medical devices through effective risk management and market surveillance

3.1.1 Objective #1.1

To ensure the continued and high quality monitoring of adverse reactions/events concerning medicinal products and medical devices in the territory of the Republic of Croatia.

Strategy for the objective

This objective is supported by two core vigilance processes, pharmacovigilance and vigilance of medical devices, which ensure that medicines and medical devices on the market in Croatia are regularly and actively monitored due to possible adverse reactions/events and the consequent impact assessment on health issues.

Action steps

- Develop a training programme to support the increase in patient and healthcare professionals reporting adverse reactions for medicines and adverse events for medical devices by enhancing public awareness on the importance of reporting.
- Support scientific efforts in the field of pharmacovigilance and rational pharmacotherapy with the inclusion of information on pharmacogenomics.
- Collaborate with other competent authorities in the EU involved in signal detection activities.
- Collaborate with healthcare professional bodies, patient associations and academia in education training programmes.
- Collaborate with national and international health institutions in the development of a mutual interoperable system and the sharing of relevant information of common importance.
- Develop new tools such as a database for pharmacoepidemiology and an on-line application dedicated to healthcare professionals for medicine adverse reaction reporting.

Prerequisites

- Sufficient and well educated and trained staff.
- Allocation of financial resources.
- Adequate IT tools.
- Preparedness and willingness for collaboration on the part of national and international institutions and bodies, as well as healthcare professionals and patient associations.

Responsibility

The Head of the Department for Pharmacovigilance and Rational Pharmacotherapy, as well as the Head of the Department for Medical Devices will be responsible for the implementation of Objective 1.1.

Evaluation of indicators

- Increased levels of adverse reaction reports, including serious adverse reaction reports with higher quality information received from patients and healthcare professionals.
- Increased levels of adverse reaction assessments connected to pharmacogenomics issues.
- An increased number of signal detection cases that are assessed according to the EMA's active ingredients list for signal management work-sharing.
- HALMED has developed strong links with other national and regional institutions and patient associations involved in patient safety and works closely with them to maximise patient safety.
- A database for epidemiological data is used in benefit-risk assessments and ongoing therapeutic risk management.
- With the help of an on-line tool, adverse reaction reporting by healthcare professionals is increased and report quality is improved.
- HALMED is recognised as a relevant and useful source of information on safe medicines by healthcare professionals and patients.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.1.2 Objective #1.2

To improve managing the risks of medicinal product use

Strategy for the objective

This objective is supported by the core pharmacovigilance process, which ensures that medicines on the market in Croatia have a positive benefit-risk ratio and that those products with risks higher than the estimated benefits are removed from the market.

Action steps

- Develop a training programme for healthcare professionals on how to actively manage the risks for medicinal product use.
- To adapt risk minimisation measures to national specificities.

Prerequisites

- Sufficient staff for training performance.
- Preparedness and willingness for collaboration on the part of national healthcare professionals.

Responsibility

The Head of the Department for Pharmacovigilance and Rational Pharmacotherapy will be responsible for the implementation of Objective 1.2.

Evaluation of indicators

- High awareness of risk minimisation measures among healthcare professionals.
- Healthcare professionals recognise training materials and follow the given instructions.
- New medicines are intensively monitored by the Medicinal Products' Safety Committee to evaluate the effectiveness of the implemented national risk minimisation measures.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.1.3 Objective #1.3

To ensure the continuous monitoring of medicine consumption and their rational use

Strategy for the objective

This objective is supported by the pharmacoeconomic process designated for medicinal product consumption monitoring and the pharmacovigilance process designated for their rational utilisation by healthcare professionals and patients.

Action steps

- Develop a training programme for healthcare professionals on how to rationally use medicinal products based on data on consumption collected on a national level.
- Support scientific efforts in the field of pharmacovigilance and rational pharmacotherapy.
- Collaborate with healthcare professional bodies, patient associations and academia in education training programmes.
- Develop a new database for medicine consumption monitoring.

Prerequisites

- Sufficient and well trained staff for training performance.
- Allocation of financial resources.
- Adequate IT tools.
- Preparedness and willingness for collaboration on the part of national healthcare professionals and patient associations.

Responsibility

The Head of the Division for the Safe Use of Medicinal Products and Medical Devices and the Head of the Department for Pharmacovigilance and Rational Pharmacotherapy, as well as being responsible for the implementation of Objective 1.3.

Evaluation of indicators

- Adequate response from physicians that prescribe medicines to patients in line with HALMED recommendations.
- A new database verified and developed

Time

All the actions regarding this objective will start in the year 2014, except for development of the new database for medicine consumption monitoring that will start in 2018.

All the actions regarding this objective are supposed to be finished by the end of 2018.

3.1.4 Objective #1.4

Market surveillance

Strategy for the objective

This objective is supported by two core processes, quality control of medicinal products and licensing, GMP and PV inspection. Both processes have the common purpose of ensuring high quality legal medicines on Croatian market that are produced according the GMP standards of Croatia.

Action steps

- Continue to develop a stable risk-based system for medicine quality control based on annual programs.
- Continue to actively participate in the OMCL network to promote work-sharing principles and maximise surveillance data.
- Collaborate with the Ministry of Health, the Croatian Public Health Institute and regional public health institutes, the Croatian police and Customs, as well as the competent EU authorities and the WHO in market protection activities against illegal or counterfeit medicinal products and borderline products.

- Develop a training program for healthcare professionals, wholesalers and retailers, patients and consumers designated for the explanation of risks posed by illegal and counterfeited products, underlining the dangers of purchasing from illegal resources.
- Continue to improve the expertise required for the quality control of medicines with a special emphasis on counterfeiting.

Prerequisites

- Sufficient and well educated and trained staff with equipped laboratory facilities dedicated to specific needs in the quality control of counterfeit and borderline products.
- Allocation of financial resources.
- Access to adequate IT databases.
- Preparedness and willingness for collaboration on the part of national and international institutions and bodies, as well healthcare professionals and patient associations.

Responsibility

The Head of OMCL and the Head of the Department for Licensing, GMP and PV Inspection will be responsible for the implementation of Objective 1.4.

Evaluation of indicators

- There is stable risk-based system of medicine quality control that allows the regular performance of legal duties; medicines are controlled in accordance with approved annual plans.
- Information is regularly exchanged among national and international institutions and bodies and necessary activities regarding protection of Croatian market are undertaken.
- There is a high level of understanding by the public of the risks posed by counterfeit/falsified medical products, as well as illegal products.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.1.5 Objective #1.5

Collaboration with key stakeholders on the *reduction of unauthorised medicinal products in legal supply chain*

Strategy for the objective

This objective is supported by key processes for the distribution of medicinal products and marketing authorisations. In cooperation with potential marketing authorisation holders with an interest in obtaining marketing authorisations for unauthorised medicinal products imported under the legislative exception, supervision of these medicines would be improved.

Action steps

- Review the extent of the importation of medicinal products under the legislative exemption provided for medical doctors who prescribe unauthorised medicines for patients under their direct responsibility, and work with key stakeholders to provide authorised alternatives for high-volume or high-risk products.

Prerequisites

- IT database with relevant data.
- Analysis of data linked to high-volume or high-risk unauthorised products.
- The preparedness of potential marketing authorisation holders to apply for marketing authorisation.

Responsibility

The Head of the Department for the Distribution of Medicines and Pharmacoeconomics will be responsible for the implementation of Objective 1.5.

Evaluation of indicators

- Decrease of high-risk or high-volume exempt medicinal products in the supply chain.
- Improved understanding among relevant healthcare professionals about the legislative requirements regarding the supply of exempt medicinal products and a preference for using authorised products.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.1.6 Objective #1.6

The establishment of a Pharmacopoeia committee

Strategy for the objective

This objective is supported by the Office for Pharmacopoeia within the OMCL Division. Experts of HALMED will include national experts in pharmacopoeial activities that will contribute to the further development of Croatian pharmacopoeia. Through the establishment of HALMED's new committee, the members will foster the implementation of pharmacopoeial requirements in pharmacies and industry. According to the current Pharmacies' law, the Croatian Pharmacopoeia is mandatory literature in public and hospital pharmacies. There are 1153 public pharmacies and about 60 hospital pharmacies registered in the Croatian Pharmacy Chamber. It is expected that they will all have at least one pharmacopoeia per pharmacy. As one licence allows access from two personal computers, theoretically one licence can be used in two pharmacies. This makes about 600-700 licences sold to pharmacies. Other potential users are wholesalers, industry, representatives and academies, all together about 100 addresses.

Action steps

- Establish a Committee for Pharmacopoeia.
- Strengthening cooperation with the Pharmaceutical chamber, industry and pharmacies on pharmacopoeial issues.
- The issue of new chapters and monographs of Pharmacopoeia.
- Training healthcare professionals on Pharmacopoeia usage.

Prerequisites

- The preparedness of stakeholders for cooperation on Croatian Pharmacopoeia.

Responsibility

The Head of the OMCL Division will be responsible for the implementation of Objective 1.6.

Evaluation of indicators

- The Committee for Pharmacopoeia is established and collaboration on pharmacopoeial activities has resulted in the preparation of new chapters and monographs on Pharmacopoeia.
- Awareness of the importance of Pharmacopoeia among stakeholders is higher.
- The number (%) of Pharmacopoeia subscribers is higher in comparison to previous years.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.2 Goal #2

To improve the provided services within a high quality, risk-based regulatory framework

3.2.1 Objective #2.1

Contribute to the assessment of the quality, efficacy and safety of medicines on an EU level

Strategy for the objective

This objective is supported by two key processes – the marketing authorisation process and the pharmacovigilance process – based on the knowledge and expertise of HALMED's staff. The permanent education of staff and active cooperation with other EU and international competent bodies engaged in this field will lead to building the necessary know-how, and consequently the implementation of this objective.

Action steps

- Actively participate in the assessment of medicines on the EU level.
- To establish broader collaboration with national experts in the field, especially for specific areas of expertise.

Prerequisites

- Sufficient and well educated and trained staff.
- Adequate IT tools and databases.
- Well established intra-organisational cooperation between HALMED assessors, HALMED committees and involved external experts.

Responsibility

The Head of the Marketing Authorisation Division, the Head of the Department for Regulatory Affairs, the Head of the Department for Quality, Safety and Efficacy Assessment, and Head of the Department for Pharmacovigilance and Rational Pharmacotherapy will be responsible for the implementation of Objective 2.1.

Evaluation of indicators

- Increased levels of EU applications in which HALMED is rapporteur/co-rapporteur or RMS.
- HALMED continuously delivers its comments to the rapporteur/co-rapporteur or RMS in relation to quality, safety and efficacy assessment.
- HALMED has a broad and stable base of external experts who are involved in the assessment process when necessary.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.2.2 Objective #2.2

Establishment of new processes in the area of medicine safety

Strategy for the objective

This objective is supported by three key processes: the inspection process, the marketing authorisation process and the pharmacovigilance process based on the interaction, knowledge and expertise of HALMED's staff. Intra-HALMED cooperation that will include training and participation of staff from both departments in strengthening GMP and PV inspection will create HALMED's ability to perform GMP and PV inspections on the global market.

Action steps

- The Marketing Authorisation Division and the Department for Pharmacovigilance and Rational Pharmacotherapy permanently support the Department for Licensing, GMP and PV Inspection with their expertise in activities related to the performance of both GMP and PV inspections.
- The Department for Licensing, GMP and PV Inspection in collaboration with Office for Quality Management will make all the necessary preparations for establishing a quality system based on ISO/IEC 17020.
- The Department for Licensing, GMP and PV apply for the international verification of the established quality system.

Prerequisites

- Sufficient well educated and trained staff.
- Adequate IT tools and databases.
- Well established intra-organisational cooperation between the assessors and inspectors of HALMED.

Responsibility

The Head of the Marketing Authorisation Division, the Head of the Department of Regulatory Affairs, the Head of the Department for Quality, Safety and Efficacy Assessment, Head of the Department for Pharmacovigilance and Rational Pharmacotherapy, and the Head of the Department for Licensing, GMP and PV Inspection will be responsible for the implementation of Objective 2.2.

Evaluation of indicators

- Increased levels of EU applications whereby HALMED is the inspection body.
- HALMED is verified by international organisations/bodies responsible for the verification of the performance of inspection activities.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.2.3 Objective #2.3

Meet agreed timelines for all procedures

Strategy for the objective

This objective is supported by all key and non-key processes of HALMED that have to be organized in a way to be capable to deliver well-timed services in accordance with pre-set national and EU timelines.

Action steps

- Put in place organization that will be able to cope with national and EU procedures timelines.
- Continuously review key processes, and non-key processes with influence to key processes timelines to optimize them and eliminate any unnecessary steps or delays.
- Regularly track and monitor timeline compliance.
- Regularly monitor ratio of number of received and solved applications.
- Review allocation of staff over time.
- Strengthen HALMED staff's ability to continuously improve their own working skills.

Prerequisites

- All HALMEDs processes are mapped.
- Adequate staff allocation possibilities.
- Adequate IT tools and databases.

Responsibility

The heads of all HALMED divisions will be responsible for the implementation of Objective 2.4.

Evaluation of indicators

- 95% of procedures are completed within EU or nationally set timelines.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.3 Goal #3

To deliver transparent, pertinent and well-timed communications to patients, public and healthcare professionals

3.3.1 Objective #3.1

Prompt public oriented communication on safety, efficacy and quality issues

Strategy for the objective

This objective is supported by all three core HALMED divisions: OMCL, Marketing Authorisation Division and the Division for the Safe use of Medicinal Products and Medical Devices in close cooperation with the Public Relations Office. Continuous and prompt cooperation between the units has to be ensured.

Action steps

- The regular and well-timed delivery of public oriented information on safety, efficacy and quality issues.
- Regular communication with relevant stakeholder in relation to shortages on the market.
- The intensive collection of information on safety, efficacy and quality issues on the national and international level archived by broadening cooperation with relevant competent institutions/bodies, marketing authorisations, academia, healthcare professionals and patent associations.
- Stakeholder survey on HALMED's web site on adequacy and communication policy; use feedback from the stakeholders to improve our methods of communications
- Involve patient associations in developing communication tools and content.

Prerequisites

- Adequate IT tools and databases.
- Well-established cooperation within and outside HALMED in relation to communication on safety, efficacy and quality issues that includes HALMED experts and committees, as well external experts involved in safety, efficacy and quality issues.
- The communication effectiveness survey is performed.

Responsibility

The Head of the Marketing Authorisation Division, The Head of the OMCL and the Head of Safe Use of Medicinal Products and Medical Devices, together with PR will be responsible for the implementation of Objective 3.1.

Evaluation of indicators

- Stakeholders are well informed on safety, efficacy and quality issues, as well as on medicine shortages.
- There is a high-level of awareness among the public of the risks posed by counterfeits.
- Communication tools and materials are effective and information is relevant, clear and in line with the regulatory and safety guidance meaning that the language and information content is adjusted to targeted audience needs.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.3.2 Objective #3.2

Strengthening HALMED's Transparency

Strategy for the objective

The entire organisation has to perform the necessary actions that will, together with a well-established transparency policy, lead to more transparent information on all the activities of HALMED, both scientific and legal ones.

Action steps

- Publish minutes, CV's and declarations of interest for members of HALMED's committees.
- Publish all relevant approved education material dedicated to healthcare professionals and patients.
- Review the current provision of information to all stakeholders with a special emphasis on healthcare professionals and the public against the legal requirements and best practice models in EU agencies for medicines, and create an action plan for improving transparency.
- Ensure that all communication channels are customised to the needs of patients and healthcare professionals.
- Stakeholder survey on HALMED's web site transparency.

Prerequisites

- The adoption of a Transparency policy.

Responsibility

The Head of the Agency together with the heads of all divisions and PR will be responsible for the implementation of Objective 3.2.

Evaluation of indicators

- HALMED is recognised by patients, healthcare professionals and the general public as a transparent agency.
- Minutes, CV's and declarations of interest for members of the HALMED's committees are on the web site of HALMED, all data is frequently updated.

Time

- All the actions regarding this objective will start in year 2014 and are supposed to be finished by the end of 2016.

3.3.3 Objective #3.3

Patient associations, healthcare professional organisations and public engagement strengthening in the activities of HALMED

Strategy for the objective

The Public Relations Office will develop suitable communication tools that will enable patient associations, healthcare professional organisations and the public to be more deeply involved in the activities of HALMED in relation to safety, efficacy and quality issues of medicinal products and medical devices.

Action steps

- Review patient and public engagement models of other regulatory and state agencies and implement a plan for the more profound involvement of patients in regulatory activities of HALMED.
- Improve collaboration with patient associations and healthcare professional organisations.
- Strengthen the possibilities of public involvement through new media.

Prerequisites

- Well-established cooperation with national patient associations and other national organisations with a specific interest in medicinal products and medical devices.

Responsibility

PR will be responsible for the implementation of Objective 3.3.

Evaluation of indicators

- Public and patient representatives are engaged in the activities of HALMED and their knowledge, experience and views are taken into account in decisions and communications.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.3.4 Objective #3.4

Ensure the public and stakeholder perception of HALMED as an effective, independent and reliable regulatory agency

Strategy for the objective

Public Relations Office will work on the promotion of HALMED regarding the perception of our Agency as an effective institution for the regulation of medicines and medical devices that is independent in its decisions and a reliable source of information for patients and patients associations.

Action steps

- Participate in national and regional, health, online and specialist media in topics related to safety, efficacy and quality issues concerning medicinal products and medical devices.
- Deliver information on relevant activities to key influential health commentators or key public opinion makers.

Prerequisites

- Well trained and sufficient staff in the Public Relations Office capable of prompt actions.

Responsibility

- PR will be responsible for the implementation of Objective 3.4.

Evaluation of indicators

- HALMED is recognised as the regulatory authority responsible for ensuring public health in respect of safety, efficacy and quality issues concerning medicinal products and medical devices.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.4 Goal #4

To strengthen capacities as a response to developing regulatory requirements and scientific/technological advances

3.4.1 Objective #4.1

Further development of the quality management system

Strategy for the objective

This objective is supported by the BEMA system that is designed for the continuous improvement of all aspects and processes within medicine agencies. BEMA requirements are to be integrated completely into all areas of HALMED's business processes, the achieved results are to be measured and evaluated, and new plans for improvements are to be done. All the managerial staff of HALMED as a leading force, in close cooperation with the Office for Quality Management will continuously work on the further development of quality system.

Action steps

- Finalisation of the Integrated quality system that will, besides the exiting standards, fully include the following norms HRN EN ISO 9004; HRN EN ISO 19011; HRN EN ISO 27001; HRN EN ISO 31000; OHSAS 18001.
- Strengthening crisis management and business continuity management.
- Strengthening project management.
- Strengthening risk management.

Prerequisites

- Allocation of financial resources.
- Staff training.
- Well established intra-organisational cooperation between responsible employees for IT, quality management, project management and the heads of divisions/departments.

Responsibility

The Deputy Head of HALMED and the heads of divisions/departments will be responsible for the implementation of Objective 4.1.

Evaluation of indicators

- An integrated quality system is operational and in accordance with the selected international norms.
- The HALMED Risk management registry exists, risk minimisation actions are implemented and monitored, potential risk is re-assessed.

- Crisis management and business continuity management is implemented and checked, either in real case situation or planed simulation.
- Project methodology exists, projects are planned, monitored, and improvement actions for future projects are defined.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.4.2 Objective #4.2

Further development of the Information Management System

Strategy for the objective

This objective is supported by all HALMED divisions with a special emphasis on the IT Department, which has a leading role in all IT projects. Close cooperation between all the units of Agency on IT projects will help finalize an integrative IT system as a strong supportive tool for HALMED's processes and activities.

Action steps

- Develop an IT strategy for the 2014-2018 period.
- Perform design work for IT projects according to the IT Strategy.
- Monitor the development of projects and verify them.
- Monitor the intra-operability of developed IT tools.
- Finalisation of an Integrated IT system on the level of HALMED.

Prerequisites

- Allocation of financial resources.
- Allocation of adequate IT human resources.
- Allocation of expert resources within HALMED units for IT projects.
- Well-established cooperation within HALMED in relation to the realization of IT projects.

Responsibility

The Heads of divisions together with the Head of the IT Department will be responsible for the implementation of Objective 4.2.

Evaluation of indicators

- The developed IT tools are reliable and fit for use.
- The integrated IT system is operational in all units of HALMED.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.4.3 Objective #4.3

Improve expertise across the Agency and use the gained knowledge for academic purposes

Strategy for the objective

The directorate of HALMED is determined to support intensive education and training in all units of the Agency, including all our employees. We are aware that only well-educated and trained staff can be able to give reliable and professional service to our stakeholders. In-house and external education will be organised frequently as a response. HALMED is determined to further develop the collaboration with academia in the field of regulatory activities relating to medicines and medical devices.

Action steps

- Strengthen the awareness among all employees in the Agency about the importance of continuous education and training.
- Strictly monitor the implementation of annual education plans and assess the effectiveness of the education performed.
- Permanently re-assess competence needs and make the necessary adjustments of education plans.
- Careful and selective recruitment of new staff.
- Negotiation and defining agreements with selected academic institutions, which are closely connected to the health issues and activities of HALMED, for providing the lectures for students in the field of regulatory activities related to medicines and medical devices.
- Developing academic activities.

Prerequisites

- Allocation of financial resources.

Responsibility

The heads of the divisions and the Deputy Head of Medicinal Products, Medical Devices and Quality Management will be responsible for the implementation of Objective 4.3.

Evaluation of indicators

- The staff is ready to respond to the requirements of stakeholders.
- Applications are processed in a timely manner with high quality performance.
- HALMED is included in academic research and lecturing

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.4.4 Objective #4.4

Ensure balance between income and costs

Strategy for the objective

HALMED will regularly review its financial situations regarding income and cost based on the fee structure that is being approved by the Minister of Health in order to be ready to inform its Management Board and Minister about the sustainability of the financial system.

Action steps

- Perform a permanent cost income ratio.
- Play an active role at the EU level when debating about fees for services related to medicinal products and medical devices.

Prerequisites

- Adequate tools for monitoring the cost income ratio.
- Timely evaluation of all cost needs.

Responsibility

The Deputy Head of Medicinal Products, Medical Devices and Quality Management, the Head of the Division for Legal, Financial, IT and General Affairs, as well as the Head of the Department for Financial, Legal and General Affairs will be responsible for the implementation of Objective 4.4.

Evaluation of indicators

- The fee model ensures adequate incomes that are in line with the planned costs of the Agency.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.4.5 Objective #4.5

Construction of a new office building

Strategy for the objective

HALMED has already ensured a financial fund for the construction of a new office building at the site Ksaverska cesta 4 near the existing main building. With the permission of HALMED's Management Board and the pre-approval of Croatian Government, all the necessary construction plans will be developed following the completion of the public procurement procedure.

Action steps

- Completion of the public procurement procedure for the selection of an architect studio responsible for project developments.
- Project developments.
- Completion of the public procurement procedure for the selection of the CE company.
- Construction of new building in accordance with the developed projects.
- Furnishing the building.
- Validation (attestation) of all the parameters required by Croatian laws.

Prerequisites

- Political support from the HALMED management Board and the Ministry of Health.
- Pre-approval of the Croatian Government.
- Financial fund ensured.

Responsibility

The Head of HALMED is responsible for ensuring the financial fund and for the approval of main project. The Head of the Legal, Financial, IT and General Affairs Division will be responsible for legal procedures including public procurement procedures. The facility manager will be responsible for supervision of all the construction steps.

Evaluation of indicators

- Public procurement procedure for the selection of an architect studio responsible for project developments is completed.
- Projects are developed and approved.
- Public procurement procedure for the selection of a construction company is completed.
- Construction of the new building in accordance with the developed projects is finished.
- Furnishing the building is completed.
- Validation (attestation) of all the parameters required by Croatian laws is performed.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.5 Goal #5

To participate in medicines and medical devices policy and legislation development for the benefit of public health at the national and EU level

3.5.1 Objective #5.1

Influence the strategic direction of new legislation and regulation, as well as strategic discussions at the EU and international level.

Strategy for the objective

This objective is supported by the wide knowledge and expertise of HALMED in contribution to the development of national and EU legislation, and in the implementation of new and amended legislation in the field of medicines and medical devices.

Action steps

- Contribute to discussions regarding legislation being proposed or progressed through the EU Council, working parties and the European Parliament.
- Represent HALMED in EMA's Management board, working groups and committees of the EC, EMA EDQM and WHO contributing to policy proposals and discussions on regulatory system effectiveness improvements.
- Active and constructive participation in the process of drafting guidelines, official forms and other documents conducted by the EMA, EDQM, EC or WHO.
- Active collaboration with the Ministry of Health in national legislation development.

Prerequisites

- Legal expertise, experience and knowledge on the part of HALMED's staff.
- Well-established collaboration with experts for legal affairs of the ministry of Health, as well as the EMA.
- HALMED's representatives are included in EC, EMA, EDQM and WHO boards, working groups or committees.

Responsibility

The Head of the Agency and the heads of the divisions will be responsible for the implementation of Objective 5.1.

Evaluation of indicators

- HALMED fully participates in the development of new legislation and regulation, and its opinion is taken into account.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

3.5.2 Objective #5.2

Influence IT developments within the EU regulation network.

Strategy for the objective

This objective is supported by the preparedness of HALMED to participate in the development of common IT tools within the EU regulatory network.

Action steps

- Participate actively in the EMA Telematics Committee and the relevant EU working parties.
- Implement IT solutions in HALMED.

Prerequisites

- Experienced IT staff.
- Well-established cooperation with EMA's IT.

Responsibility

The Head of the IT Department will be responsible for the implementation of Objective 5.2.

Evaluation of indicators

- HALMED's contribution to integrated IT development across the EU is recognised.

Time

- All the actions regarding this objective will start in the year 2014 and are supposed to be finished by the end of 2018.

4. IMPLEMENTATION AND MONITORING

This strategic plan defines the direction for HALMED over the next five years from 2014 to 2108, including our service delivery, as well as supporting functions. The expected achievement of the set objectives depends on the adequacy of the resources available in HALMED, on the ability of our Agency to respond to governmental and public demands, and the requirements of national and EU legislation.

The plan defines the framework for the development of annual business plans based on our strategic goals identified in this plan and the performance standards to be achieved by 2018.

The annual business plans define the specific tasks to be implemented for each strategic objective, the timeframes involved and the responsibilities within HALMED for their implementation. The annual plans are developed down to levels of the departments, allowing each employee to see how their work contributes to the achievement of the organisation's goals and objectives.

We will monitor our accomplishments against the strategic plan through our business planning and reporting system. We will report progress against the plan to the Board of HALMED and to Ministry of Health in our annual reports.

GLOSSARY

EDQM (*European Directorate for the Quality of Medicines & HealthCare*)

A European organisation involved in the harmonisation and co-ordination of the standardisation, regulation and quality control of medicines, blood transfusion, organ transplantation, pharmaceuticals and pharmaceutical care.

EMA (*European Medicines Agency*)

An agency of the European Union with its headquarters in London. Its main responsibility is the protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use. The IMB is represented on the scientific committees that conduct the main scientific work of the EMA.

GMP (*Good Manufacturing practice*)

A set of internationally recognised requirements or standards that ensure products are consistently produced and controlled to the appropriate quality for their intended use.

OMCL (*Official Medicines Control Laboratories*)

The Official Medicines Control Laboratories support the regulatory authorities and the national inspection services in controlling the quality of medicinal products on the market through independent retesting based on legal requirements.

PV (*Pharmacovigilance*)

The system consisting of activities related to identification, evaluation, understanding, prevention and response in the event of adverse reactions to medicinal products and which takes in account current scientific knowledge relating to harmful effects of the medicinal products use.

Rapporteur(*ships*)

A person who is responsible for a regulatory activity such as assessing an application for marketing authorisation in a centralised procedure or drafting a guideline or legal instrument. A rapporteurship is the activity the rapporteur carries out.

RMS (*Reference Member State*)

The EU country that takes the lead in assessing applications for marketing authorisation on behalf of other countries.

Telematics

EU Telematics are a set of systems and databases that provide information on medicines to the general public and support the post-authorisation monitoring of medicines in the EU.

WHO (*World Health Organization*)

WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

COLOPHON

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