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.