REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

2019–2022 Development Strategy of the State Agency of Medicines

The STATE AGENCY OF MEDICINES (AGENCY) is a government agency that:

- advises citizens on issues related to medicines;
- verifies the efficacy, quality and safety of medicines and issues marketing authorisations (MAs) for such products;
- verifies the permissibility of clinical trials;
- issues authorisations for handling medicines and supervises compliance with regulations;
- collects and analyses information on the use and side effects of medicines;
- monitors the legal movement of medicines, narcotic and psychotropic substances and their precursors across the Estonian border;
- monitors the procurement and handling of blood, cells, tissues and organs;
- monitors compliance with advertising rules for medicines and the effectiveness of pharmacovigilance mechanisms of marketing authorisation holders (MAHs);
- represents Estonia at the committees and other bodies of the European Medicines Agency and the European Pharmacopoeia, and in the working groups of the European medicines regulatory network.

The Agency employs approximately 90 people most of whom are pharmacists and medical doctors. Others include chemists, veterinarians, nurses, lawyers, etc.

Most of the funding for the Agency comes from supervisory revenue (70–80%) and the remainder from the state budget.

The Agency Development Strategy is a strategic document covering a four-year period which sets out the agency's development areas and goals as well as the activities to achieve the said goals. The Development Strategy is implemented by means of annual work plans.

Mission:

The mission of the Agency is to protect human and animal health, promoting the rational use of medicines and supporting development of the pharmaceutical sector.

Vision 2023:

The Agency is a competent and effective agency providing medicines related information and support in an appropriate and convenient manner

Agency's values:

Competence

- We rely on relevant scientific data and legislation and the best available expertise.
- We keep our knowledge and operating methods up to date.
- We recognize that all our actions reflect on the Agency and keep in mind that our decisions have a significant impact.

Reliability

- We take our decisions based on due consideration of all known aspects and are unbiased towards our partners and colleagues.
- We strive for meaningful solutions and keep our promises.
- We analyse our decisions, admit and learn from our mistakes.

Efficiency

- We actively identify areas where we can be of assistance.
- We have a say in important discussions, initiate necessary changes and complete what we started.
- We value our own, our colleagues' and our partners' time.

Cooperation

- We recognise opportunities for and are open to proposals of cooperation that support the development of the pharmaceutical sector.
- We respect the expectations of our partners and adhere to agreements.
- We do our best and recognise the efforts of our partners and colleagues.

Priority development areas and goals of the Agency in 2019–2022:

Digital supervision capability

By 2022, we have at least five innovative digital services and a plan for further development.

Biotechnological medicines, innovative technologies

We have undertaken to assess three MA applications for biotechnological medicines and review applications for clinical trials using the common EU-wide procedure.
We have developed expertise to give scientific advice on biological, biotechnological, and innovative drugs as well as novel health technologies.

Stakeholders' awareness of medicines and the Agency

We have become the main centre of drug information for the general public and stakeholders, and by 2022 we provide information in a more user friendly manner.

More effective procedures

We only collect and process information that can be used for the benefit of public health. We only engage in activities that are essential and contribute to the protection of public health. We know which regulations should be worded more clearly and which should provide a wider margin for discretion. Our workload is distributed more evenly and staff members have time available for self-development.

Essential success factors for attaining our goals:

Digital supervision capability

- Development of our 'digital thinking' and provision of relevant training
- Cooperation with stakeholders in private sector and government agencies
- A defined amount of the Agency budget or outside funding is dedicated for implementing new projects

Biotechnological medicines, innovative technologies

- Developing a system for the area of innovative biological medicines.
- A new matrix structure for managing the biologicals area – setting up a team consisting of specialists from various units of the Agency, external experts and members of scientific committees
- Recruiting new people to this area
- Training and cooperation with experienced partners
- Investment aid

Stakeholders' awareness of medicines and the Agency

- We know what information we should provide to the general public and stakeholders
- Proactive and systematic supply of information in a readily accessible and convenient manner
- Active cooperation with stakeholders and IT developers

More effective procedures

- Shared motivation to streamline services and internal procedures and readiness to implement innovation
- In-depth overview of competencies and development needs across different job positions
- Sharing of best practice and harmonisation of work practices amongst the Agency staff and structural units

The Agency assesses its performance using these key indicators

Digital supervision capability

- Number of completed projects (incl. in partnership with stakeholders): five projects completed by 2022 / five innovative solutions under development
- Mapping of digital solutions is completed (yes/no)
- User satisfaction and feedback on renewed services
- Number of projects submitted to the Health and Welfare Information Systems Centre (HWISC)

Biotechnological medicines, innovative technologies

- Number of (co-)rapporteur ships in the EU centralised MA procedure
- Number of applications for clinical trials of biological medicines assessed as a reporting Member State
- Number of scientific recommendation for the classification of advanced therapy medicinal products (ATMPs)
- Operational and self-sufficient system as from 2022

Stakeholders' awareness of medicines and the Agency

- Outcome of surveys conducted among general public and stakeholders: the goal is that registers maintained by Agency are the most commonly used sources of drug information in Estonia and the public is aware of functions of Agency
- IT development projects are completed and stakeholders actively use our solutions
- Information systems of stakeholders utilise data provided by Agency

More effective procedures

- Effectiveness and relevance of trainings and secondments (performance evaluations, departmental reviews)
- Employee satisfaction
- Stakeholder satisfaction
- Reduction in the number of setbacks – reduced number of justified legal challenges of our decisions.

Components of operating model of the Agency for attaining strategic goals:

Major partners

For sharing expertise and coordinating activities:

- Medicine agencies of other countries, the European Medicines Agency and international organisations
- Universities and other research institutions

For attaining common goals:

- Other government agencies, mainly the Ministry of Social Affairs and the agencies it governs
- Partners and experts in private sector

Key resources and competencies

Agency's services and strategic initiatives are well designed and use modern solutions

- Competent staff:

Knowledge of drug-related developments and innovations

- Knowledge and management of drug-related processes
- IT resources for IT solutions development and systems automation
- Capability to analyse business processes

Value offer

Well-structured and easy to find information, integrated into stakeholders' IT systems where possible

Providing advice across all stages of handling, marketing and development of medicines – in terms of prevention and problem solving

Channels for supporting beneficiaries

- Agency's website and databases
- Desktop for doctors and pharmacists
- Media, incl. social media, public campaigns
- Public appearances, direct contacts, briefing days

Beneficiaries

Entities under supervision

- Entities handling medicines: pharmacies, wholesalers, pharmaceutical manufacturers;
- Entities procuring and handling blood, cells, tissues, organs
- MAHs, entities conducting clinical trials
- Developers of ATMPs, biotech companies

Users of drug-related information:

- Doctors and veterinarians
- Pharmacists
- Patients

Agency's operational programme

Digital supervision capability

2019: determine the scope of digital supervision

- In H1 2019, carry out provisional mapping with service descriptions (see development area "More effective work flows"), and analyse current databases – what kind of information to collect and how: what is missing or excessive, what could be collected easier.
- In 2019, find external cooperation partners – contacts, examples of existing practices of others, examples of what can be done together and what the Agency, public sector partners, the EU and the private sector are doing or planning. Analyse the legal framework (what we can do, where are legislative changes needed) and the readiness of partners. Analysis of current systems.
- Ensure that developments essential for the Agency remain topical at the HWISC and the Ministry of Social Affairs

2020: identification of priorities, cooperation with stakeholders, analysis of legislative drafting

- Conduct business analysis to develop innovate IT services.
- Outsource developments from the HWISC.

2021: launch pilot projects.

- Carry out procurement procedures.
- Draft proposals for legislative amendments if necessary.

2022: the first five effective solutions; detailed plan for further action is finalised.

Biotechnological drugs, innovative technologies

2019: setting of priorities, recruitment.

- At the beginning of 2019, determine the types of biological medicines and innovative technologies for which we intend to develop our expertise, map the new competencies required, incl. set up a database of experts and inform members of the EMA's scientific committees.
- At the beginning of 2019, find experienced partners and start with recruitment.
- At the beginning of 2019, start with in-house training.
- In Q2 2019, enter into agreements with partners and start with training.
- In Q4 2019, start with peer reviews of assessment reports on MA applications for biological medicines.

2020: continued training.

- In H2, participate in the MA application procedure for at least one biological medicine either as a co-reviewer or member of an international team.
- Build our competence in the course of reviewing applications for clinical trials related to biological medicines.

2021–2022: continue with co-reviews of MA applications for biological medicines.

- At least two independent reviews of MA applications for biological medicines or applications for clinical trials.

Stakeholders' awareness of medicines and the Agency

- At the end of 2018, the management formulates expectations to the position of communication specialist based on the Agency's communication needs.

2019: new rules and procedures for managing communication.

- In Q1 2019, recruit a communication specialist.
- In Q2 2019, develop a communication plan (incl. expectations related to the Agency), revise the communication policy In Q3 2019, conduct a baseline study on medicinal products among citizens, broken down by individual services offered by the Agency.

2020: IT developments.

- Develop registers to ensure that the necessary information is available on healthcare professionals' desktop – influence the decision-makers.
- By the start of 2020, the new Register of Medicinal Products is complete.
- By the end of 2020, the Ministry of Social Affairs, the HWISC and the Health Insurance Fund engage in smooth cooperation as regards the development of professional software used by doctors.

2020–2021: analyse the stakeholders' expectations to drug-related information and initiate developments accordingly. Start of proactive and intensive communication aimed at target groups.

- Renew forms of presentation of drug-related information.
- Renew channels for communicating drug-related information and advice to citizens.

2021: measure the effectiveness of communication, analyse the results of customer surveys, plan further action.

More effective procedures

2019: More effective procedures

- Revise all 90 services offered by the Agency (their legal basis, necessity, incl. whether all the data collected is actually needed, alternative data collection/automation methods, rationality of processes, availability and use of support services, etc.).
- Conduct an employee satisfaction survey putting greater focus on the wording of questions so that information obtained would have practical value.
- Formulate principles for human resources development (availability of alternatives to traditional training, or additional possibilities, for example).

2020: review the five general procedures of the Agency – simplify and retain only the necessary elements, avoid duplication.

- In Q1 2020, adjust the Agecny's structure as necessary.
- In Q2 2020, adopt the renewed list of services.
- Employee satisfaction and human resources development: analysis as to what can be done in-house to promote development, whether and how should general meetings be held in the future, how should in-house training be organised.
- Analysis of the Agency's working environment, modern office premises (incl. in Tallinn)

2021: reorganisation of services.

2022: draft proposals for legislative amendments based on the evaluation of services.