



# 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.

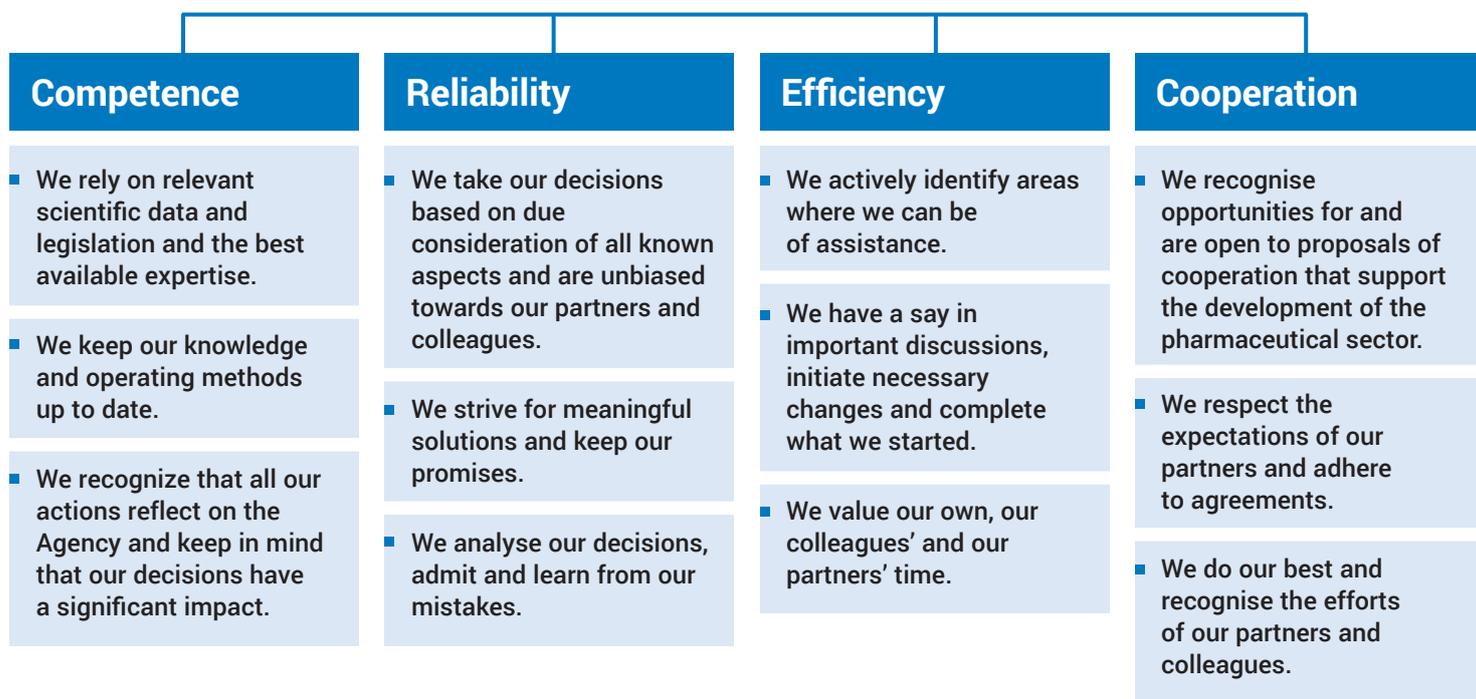
## Mission:

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

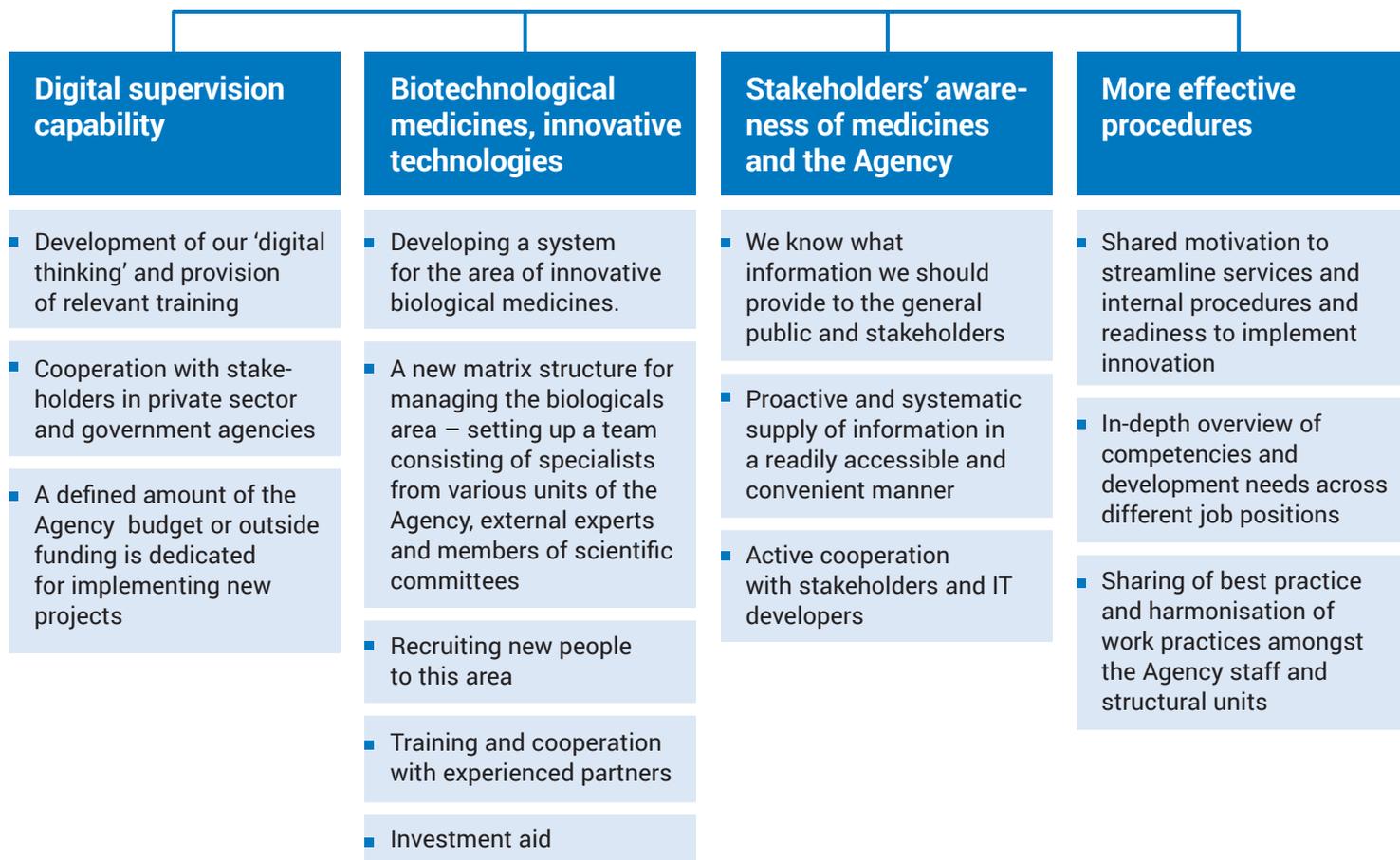
## Agency's values:



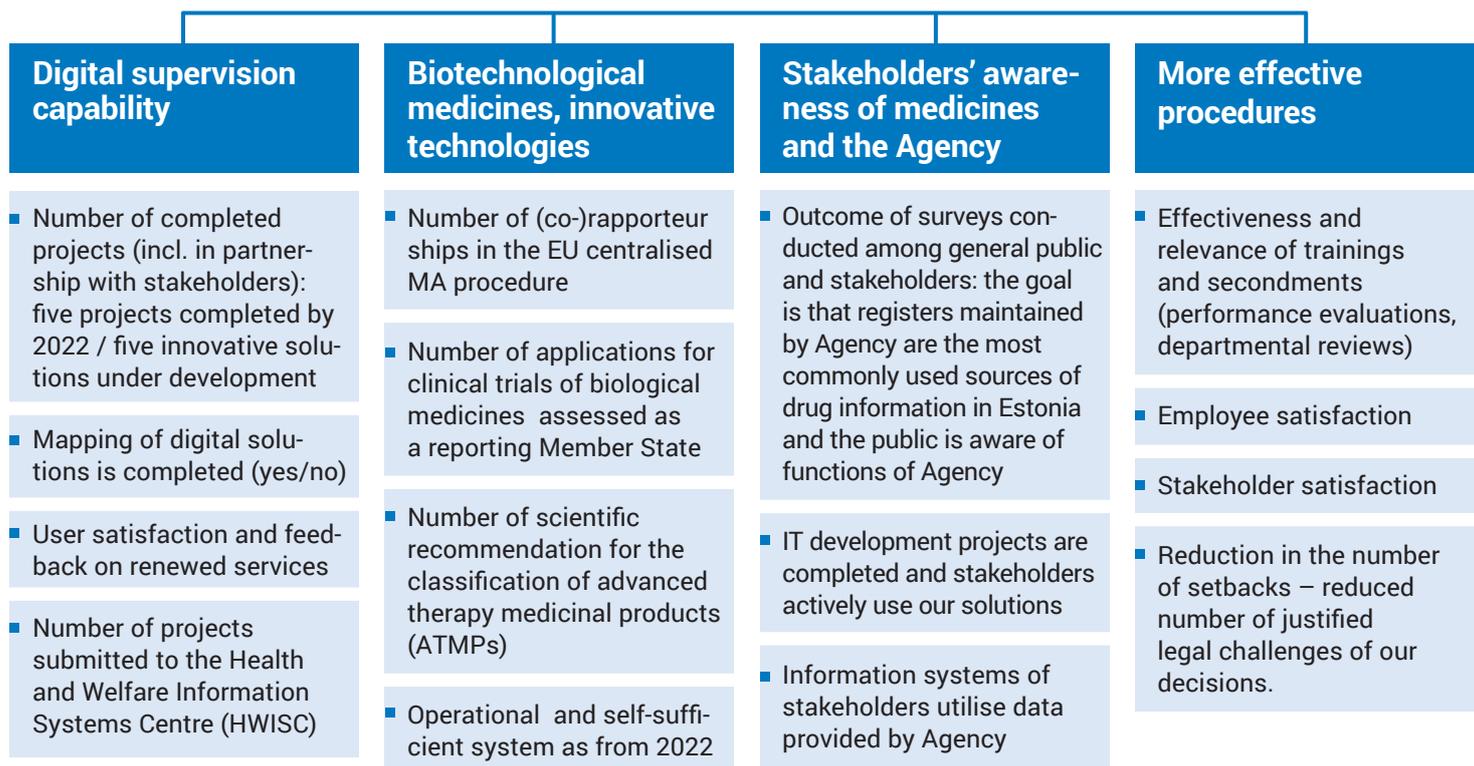
## Priority development areas and goals of the Agency in 2019–2022:



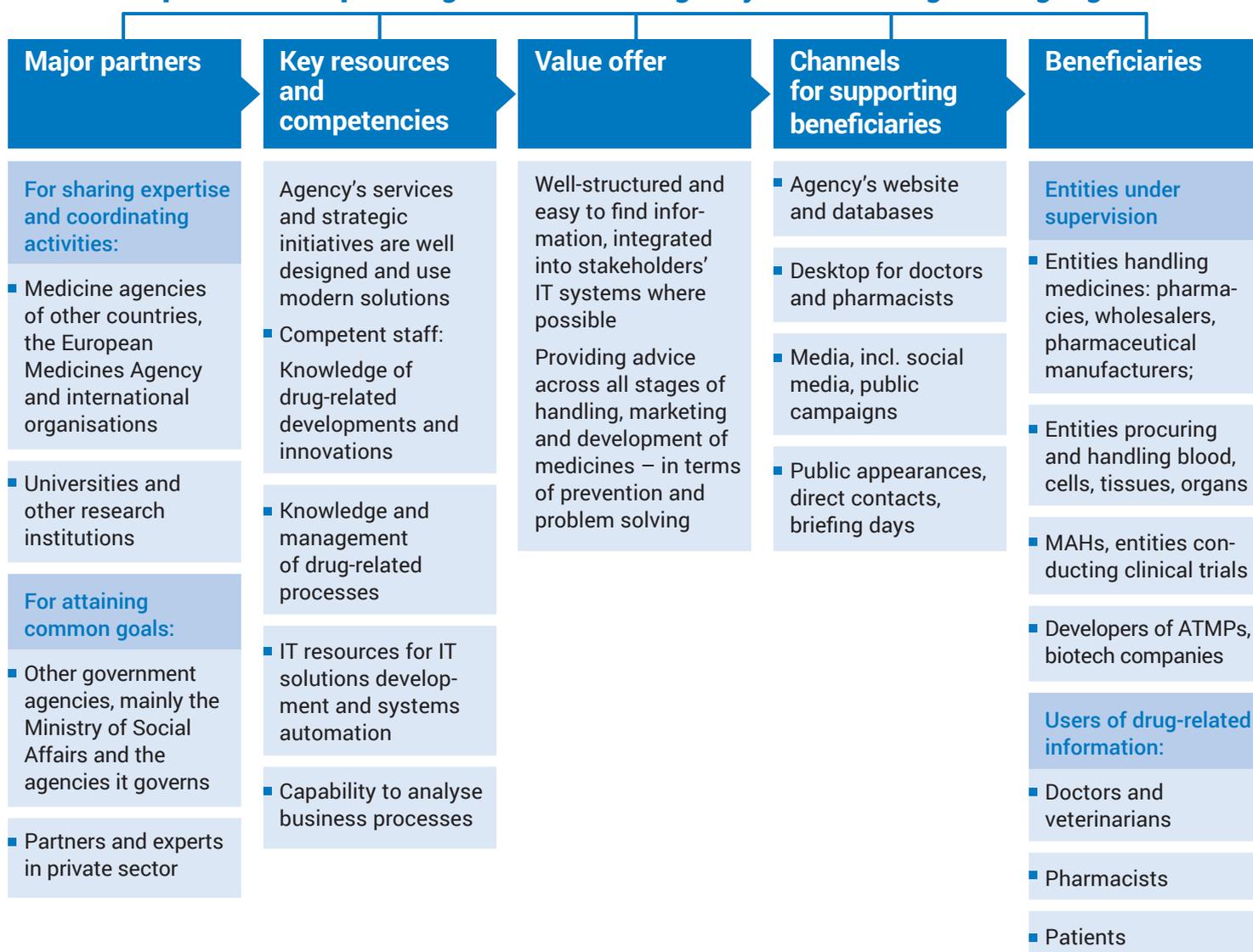
## Essential success factors for attaining our goals:



## The Agency assesses its performance using these key indicators



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



# 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 Agency'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.