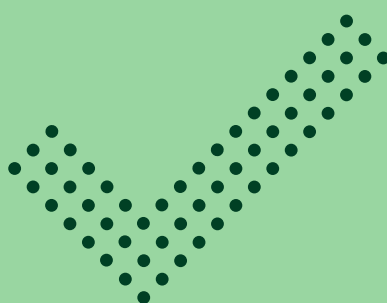
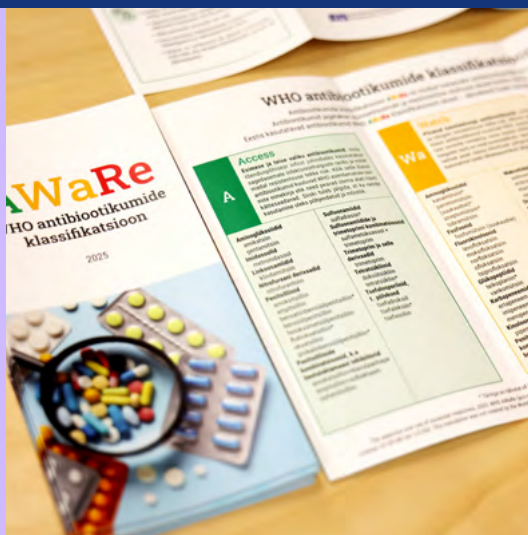
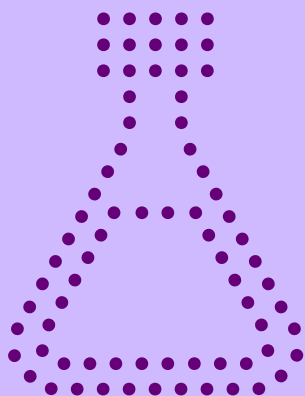




RAVIMIAMET

2025

Y E A R B O O K



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Dear Yearbook Reader!

This yearbook is more than a record of our achievements; it serves as both a mirror, reflecting our current position, and a guidepost, illuminating the path ahead to help us prepare for the future.

Responsibility lies at the heart of the State Agency of Medicines' work: responsibility for people's health, for maintaining trust, and for ensuring the effective operation of the healthcare system. This responsibility must be upheld in a rapidly changing environment where there are few easy decisions. The past year has brought both the anticipated and the completely unforeseen, requiring swift responses and close cooperation within Estonia and internationally.

We began the year with an expanded team and in a new capacity, as the medical devices sector returned to the State Agency of Medicines. This integration is a logical and comprehensive solution, given the overlap in our areas of responsibility and services. The year brought us yet another new responsibility – ensuring the continuity of a vital service and guaranteeing that people retain access to medicines in times of crisis.

While our daily work involves collaboration with businesses, the needs of medicine users remain at the heart of every decision we make. We have strengthened our engagement with young people and the elderly, investing time in direct communication at day centres and schools – a commitment that is demanding but invaluable. Our key messaging focuses on promoting healthier and medicine-waste-free environments, evidence-based information sources, digital access to medicine data, and the responsible use of medicines.

The true strength of the State Agency of Medicines lies in its people, whose expertise, accountability, and willingness to make tough decisions, even amid uncertainty, set us apart. Genuine dedication comes not from obligation, but from within.

I would like to thank my colleagues and partners for their efforts in keeping Estonia's medicines sector trustworthy and effective!

With gratitude,

Katrin Kiisk



2025 in numbers for the State Agency of Medicines

43

EU-wide
reports of supply
shortages of
essential medical
devices

304

supply
shortage
notification

Submitted

416

drug safety
reports

Submitted in
Estonia

487

initial reports of
a medical device
serious incident

Laboratory
analysed

65

medicinal
products used in
Estonia

Our
laboratory
carried out

384

tests

27

new
clinical trial
applications

8

clinical
trial
inspections

11

new applications
for medical
device clinical
investigations/
performance
studies

Added

1493

medical to the
database of
medical devices
and aids

There are

27

pharmaceutical
manufacturers
and over

200

medical device
manufacturers in
Estonia

402

new marketing
authorisations
for human
medicines

49

new
veterinary
marketing
authorisations

250

young people
learned about
the work of the
State Agency of
Medicines

Nearly

300

elderly people
attended
lectures on drug
safety

101

initial
information
requests from
press

34

posts in the
new blog

272

social media
posts

We took part in

14

court cases

22

new employees
joined

7

new general pharmacies and

3

branch pharmacies were
added, while

13

general pharmacies and one
veterinary pharmacy ceased
operations

The State Agency of Medicines is an innovative and valued partner

Ott Laius

The State Agency of Medicines is a member of the pan-European network of medicines regulatory authorities. While each country's medicines agency has its own unique character, they all share a common expectation: that medicines used in their respective countries are manufactured to a high standard, are effective, and are safe. Achieving this requires that each agency's operating principles – their quality system – are firmly established, clearly communicated to all staff, and subject to ongoing improvement.



In order to identify areas for improvement in the quality systems of national medicines agencies, the agencies have agreed on a voluntary assessment scheme known as Benchmarking of Medicines Agencies (BEMA). Last year, we underwent our fifth BEMA assessment. The three-day visit to Estonia involved external auditors who thoroughly reviewed our quality system and discussed any identified shortcomings with us. However, our organisation's preparation for BEMA began long before the visit. More than a year beforehand, we provided a detailed description of the work processes to be examined during the BEMA assessment, explaining exactly what we do and why. During the audit itself, only details not fully explained in our initial submission required further clarification.

Every audit has its share of nerves, but this time we excelled in the BEMA assessment, achieving a score of 4.5 out of 5. This represents a significant improvement on our previous results and was even better than we had anticipated. We are extremely pleased that our diligent efforts have once again received international recognition. Estonian patients can rest assured that the State Agency of Medicines upholds the highest standards.

While BEMA focused on reviewing the State Agency of Medicines and assessing our internal processes, another significant advancement for the people of Estonia last year was the revision of regulations governing the manufacture of novel medicines under the hospital exemption scheme. An exceptional use authorisation may now be granted in cases where a new medicine is not available to Estonian patients, it lacks a marketing authorisation, and where the patient cannot participate in a clinical trial. Although hospital exemptions were already available in Estonia, recent regulatory changes have expanded opportunities for patients to receive treatment through this pathway. The regulations were amended to remove the upper limits on the number of patients and the duration of authorisation. These changes were necessary to keep pace with the times, facilitate the development of innovative medicines for hospital use, and take into account the

expanded opportunities in circumstances where conducting large-scale clinical trials is not possible or practical. We are pleased that these changes will offer Estonian patients an even broader range of treatment options.

In 2025, we re-engaged with the medical devices sector. At the beginning of the year, responsibility for supervising medical devices was transferred to us from the Health Board. Over the course of the year, we have successfully integrated medical devices staff into the rest of the team and harmonised our work processes – a valuable learning experience for everyone involved. Meanwhile, our legal department conducted a thorough review of medical device regulations in Estonia. We have since submitted proposals to the Ministry of Social Affairs regarding areas where further legal clarity could be provided.

In addition to expanding into the medical devices sector, we have also taken on a second important role as the agency responsible for organising the continuity of essential services, specifically an authority providing a vital service. As an authority organising a vital service, our responsibility is to ensure the reliability of the medicine supply chain, with a particular focus on medicine wholesalers and pharmacies. Our initial task was to designate the first group of Estonian pharmacies and wholesalers to whom the obligations of a provider of vital service would apply. Going forward, our responsibilities will naturally expand to include advising and supporting providers of vital services, facilitating training and exercises, and monitoring compliance with the established requirements. After years of discussion, we are pleased to see that crisis resilience in the medicines sector is now being addressed in a more systematic way. Every beginning comes with challenges, but through constructive cooperation with all stakeholders, we are confident that we will achieve our objectives. Ultimately, ensuring the availability of medicines for patients must be guaranteed, even in crisis situations.

Last year was also a busy and productive period across many areas of our work. We would like to extend our sincere thanks to all of our colleagues at the State Agency of Medicines who put their heart and soul into their efforts and remained focused on our overarching goal: ensuring that medicines, biological products, and medical devices for both human and veterinary use in Estonia are of the highest quality, effective, and safe.

Ajajoon tähtsündmustest 2025

January

- The Department of Medical Devices at the Health Board joined the State Agency of Medicines
- The State Agency of Medicines processed transition applications under an accelerated procedure and assisted applicants where necessary, ensuring that all trials were successfully transferred to the new Clinical Trials Regulation

February

- Desynchronisation from the Russian electricity grid. A small-scale crisis exercise conducted by the State Agency of Medicines and its partners was successfully completed
- For the first time, we issued a wholesale distribution authorisation exclusively for the wholesale distribution of active substances
- The Ethics Committee for Clinical Trials began work with a new membership

March

- The State Agency of Medicines underwent its first audit in accordance with the Estonian information security standard

April

- The State Agency of Medicines passed an international quality system audit (BEMA), achieving the highest score in several areas. The average score was 4.5 out of 5
- Siim Suutre presented the changes arising from Regulation 2024/1938 on human-derived materials (SoHO) at the spring seminar of the Estonian Society of Fertility Treatment and Embryology, and Kertu Liin took part in the panel discussion 'Regulations on fertility treatment'

May

- A campaign on pharmaceutical waste, led by the State Agency of Medicines in collaboration with the Ministry of Social Affairs and other partners, was launched

June

- The State Agency of Medicines has a social media account on LinkedIn
- We presented changes relating to hospital discharge to stakeholders at an information session organised by the State Agency of Medicines

- In collaboration with the Institute of Pharmacy at the University of Tartu and the Agricultural and Food Board, we updated the list of medicinal plants on the State Agency of Medicines' website. We removed plants from the list that lack evidence-based therapeutic effects. The Agricultural and Food Board, in turn, updated the list of dangerous plants and those prohibited in food

July

- We issued the first manufacturing authorisation for the production of an active substance for a biological medicinal product
- Janne Sepp and Katrin Kurvits attended an international conference in Uppsala 'European Drug Utilization Research Group Conference 2025'. Janne's paper 'Insights into Methylphenidate Consumption Trends in Estonia between 2005 and 2024' was ranked among the top 12. Katrin gave a presentation on 'Trends in the use of benzodiazepines and benzodiazepine-related drugs in Estonia from 2010–2024'

September

- Led by the medicines agencies of Estonia, Sweden, the Netherlands, and Spain, the pan-European awareness campaign 'Medicines are not sweets!' was launched
- Presentation on the paperless package leaflet project in Estonia, Latvia, and Lithuania at a roundtable organised by EU pharmaceutical companies, professional associations and non-profit organisations Electronic Product Information (ePI) Implementation'

October

- From 1 October 2025, the Ethics Committee operating under the State Agency of Medicines will also assess the ethicality of medical device clinical investigations and performance studies
- A cooperation meeting between the Baltic and Polish medicines agencies took place in Vilnius
- A social media awareness campaign was held by the State Agency of Medicines and the Association of Pharmaceutical Manufacturers on the Register of Medicinal Products, aimed at encouraging people to critically evaluate medicines and health information found online and to use official sources when searching for information
- In collaboration with the Ministry of Social Affairs and the Estonian Academy of Arts, we conducted a pilot project in Pärnu pharmacies, introducing innovative medicine waste collection bins to encourage the sorting of medicine waste
- Allan Reinapae spoke alongside a colleague from the Health Board at the PERH conference, where they outlined the progress made in crisis preparedness within the field of blood used for transfusions

- The CTIS database features an interactive map in Estonian, offering patients and healthcare professionals simple and up-to-date access to information on clinical trials being conducted in the European Union
- The State Agency of Medicines was awarded the 'Sirguja' label as an organisation that values mental health

November

- The State Agency of Medicines has been designated as the authority responsible for ensuring the continuity of supply of medicines as an essential service. We are actively promoting measures to support operational continuity among pharmaceutical wholesalers and pharmacies that provide this critical service
- At an information day organised for pharmacists, we presented the principles of ensuring the security of supply of medicines as a vital service, discussed the dispensing of medicines on the basis of European Union prescriptions, and addressed other topical issues
- Helve Vestman and Katrin Kurvits spoke to 250 senior citizens at Tartu Folk High School's University for the Elderly on the topic of 'Medicines and medication dependency in old age'
- Led by the State Agency of Medicines, and in collaboration with the Health Board, the Estonian Society for Infectious Diseases, and the Estonian Society of Laboratory Medicine, AWaRe information materials were developed. These were distributed to doctors to support their decision-making when prescribing antibiotics
- In collaboration with the Institute of Pharmacy at the University of Tartu, the State Agency of Medicines published Estonia's first analysis of trends in the use of antibiotics in veterinary medicine based on AMEG categories
- Katrin Lambing participated in the assessment of the Mozambican Medicines Agency's quality system as part of the WHO Global Benchmarking Tool collaboration
- Jana Danilovič was elected as Estonia's representative to the European Medicines Quality Advisory Board (Chemical TAB)

December

- Maia Uusküla, Maria Kukk and Aet Viispart visited the Haabersti and Imavere day centres for the elderly in Tallinn to talk about medicine safety and storage
- At a clinical conference at Tartu University Hospital, Triin Suvi gave a presentation on the types of biological materials used in clinical work
- At the pharmaceutical wholesalers' information day, we presented the European Union's pharmaceutical reform and discussed the organisation of supply of medicines as a vital service
- Maia Uusküla took part in a WHO mission to Kyrgyzstan to assess the functioning of the vaccine pharmacovigilance system

A quiet year to focus on awareness-raising

Maia Uusküla

The Department of Post-Authorisation Safety collects, evaluates, and forwards drug safety information to international organisations (European Medicines Agency and World Health Organisation), assesses the effectiveness of risk minimisation measures and rational drug use, and informs healthcare professionals and medicine users about the risks associated with medicines.



Assessment of adverse reaction reports

The purpose of collecting and assessing information on potential adverse reactions to medicines, including vaccines, during their marketing is to detect rapidly possible new adverse reactions, changes in the frequency or severity of known adverse reactions, and medication errors.

In 2025, 416 reports were submitted to the State Agency of Medicines, of which:

49 reports

concerned potential adverse events and the ineffectiveness of vaccines

367 reports

concerned potential adverse reactions and the lack of efficacy of medicines

47 reports

described potential adverse events following immunisation (shingles and pneumococcal vaccines)

2 reports

indicated that the vaccine was ineffective

351 reports

described potential adverse reactions

16 reports

described the lack of efficacy of the medicine (contraceptives)

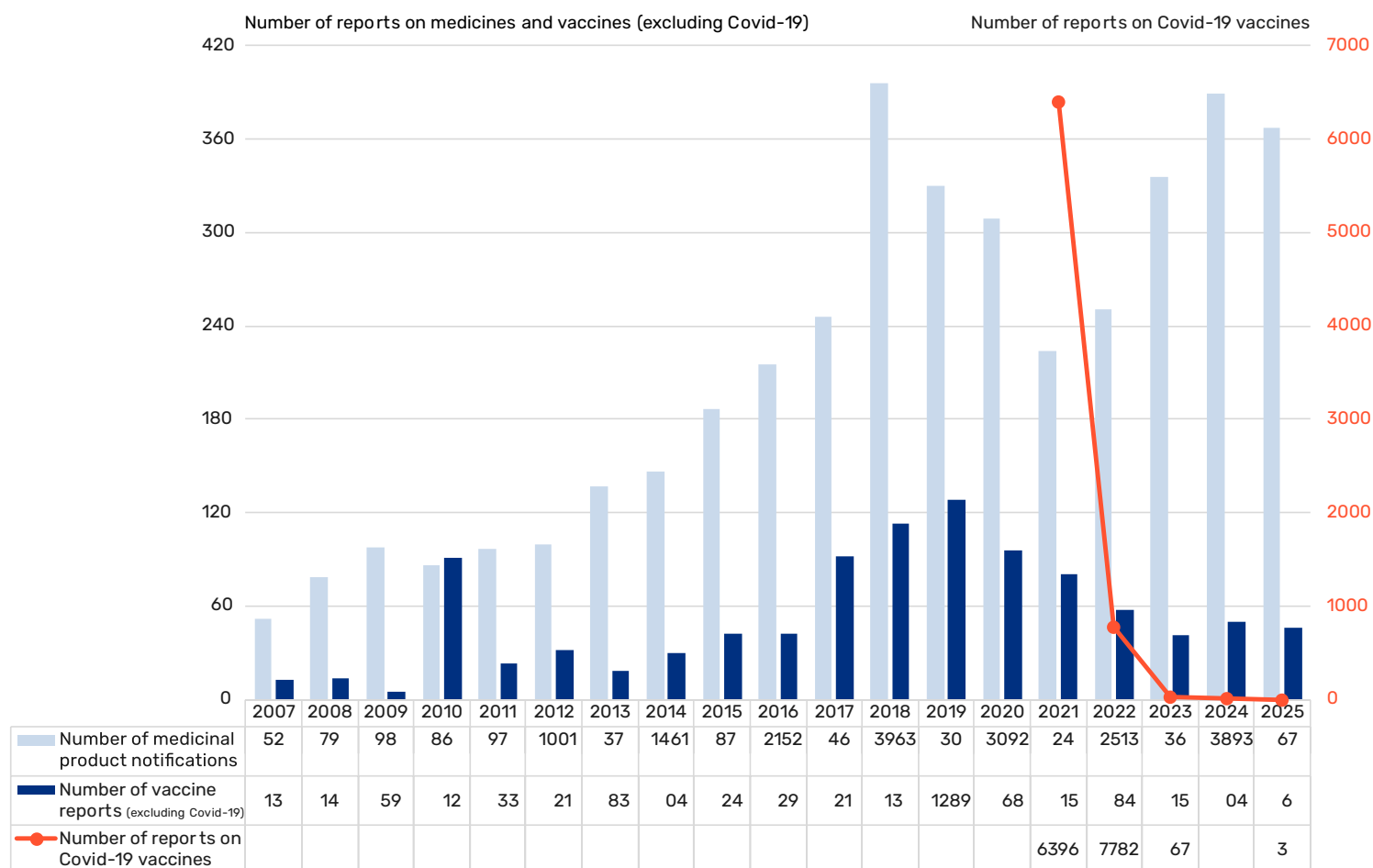


Figure 1. Number of vaccine adverse reaction reports 2007–2025. The number of Covid-19 vaccine reports is shown on a separate scale in the figure (line chart (red), 2021–2025).

Vaccines

A total of 47 adverse event reports following immunisations were received, with the highest number (10) related to the tick-borne encephalitis vaccine. The 6-in-1 vaccine (diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type B infection, hepatitis B) and the influenza vaccine each accounted for seven reports.

Twelve reports described serious adverse events following immunisation.

According to the assessment of the State Agency of Medicines, a probable causal relationship between the vaccine and the event was found in one case (World Health Organisation (WHO) class A1, compatible – known adverse reaction): a measles-like rash following administration of the trivalent measles, mumps, and rubella vaccine.

In two cases, the State Agency of Medicines assessed the reaction as being related to immunisation anxiety (WHO class A4); in three cases, the link was uncertain (possible new adverse reaction) (WHO class B1): multiform erythema following administration of the quadrivalent diphtheria, tetanus, pertussis, and polio vaccine; central retinal vein occlusion (including papilledema and optic neuritis) following administration of the influenza vaccine; paralysis of the third cranial nerve (oculomotor) following administration of the tick-borne encephalitis vaccine and the two-component diphtheria and tetanus vaccine.

Medicines

A total of 362 reports regarding possible adverse reactions were received, with 142 describing serious reactions. Possible adverse reactions not currently considered causally related to the medicine were described in 48 reports (112 previously unknown serious adverse reactions). The highest number of reports concerned anti-tumour agents (56), medicines that lower blood glucose levels (excluding insulins; 50), and immunosuppressants (47).

The total number of reports received was slightly lower than in 2024.

Assessment of vaccine injury claims

In 2025, the Health Insurance Fund submitted **six applications** to the State Agency of Medicines to assess the causal link between vaccination and the injury (in two applications, the cause of the vaccine injury was the COVID-19 vaccine, and in four applications, other vaccines – the flu vaccine, HPV vaccine, and 2 cases related to the tuberculosis vaccine). In 2025, the State Agency of Medicines assessed six applications regarding the probable existence or absence of a causal link; **in four** cases, the Agency concluded that a causal relationship between the vaccine and the reported injury was **probable (positive assessment)**.

- For two applications, the State Agency of Medicines a probable causal link with immunisation was established (WHO class A1, compatible – known adverse reaction):
 - Tuberculosis vaccine – BCG-induced lymphadenitis.
- For 2 applications, the State Agency of Medicines assessed the causal link as probable (WHO class B1, unspecified – possible new adverse reaction):
 - HPV vaccine – reactive arthritis;
 - Influenza vaccine – central retinal vein occlusion (including papilledema, and optic neuritis).

Studies on the effectiveness of risk-minimisation measures and rational drug use

We assessed the use of mycophenolate in women of childbearing potential in terms of the effectiveness of risk-minimisation measures. Mycophenolate is teratogenic, with the incidence of congenital malformations estimated to be up to 27%. It must not be used in women of childbearing potential who are not using highly effective contraception. The study results indicate that there is room for improvement in the prescribing of the medicine to women of childbearing potential.

Between 2011 and 2023, a total of 294 women of childbearing potential used mycophenolate in Estonia:

- 63% used the drug to prevent graft rejection; 37% for rheumatological autoimmune diseases (i.e. one-third were off-label use);

- only 30% used effective contraception concurrently;
- there were six pregnancies during the treatment period, three of which were intra-uterine and attributed to the drug

We also assessed outpatient use of medicines with addictive potential. Between 2019 and 2024, the use of benzodiazepines and benzodiazepine-like medicines among the population decreased from 103 to 88 users per 1,000 inhabitants. In contrast, the use of opioids (from 56 to 70 users per 1,000 population), gabapentinoids (from 26 to 38 users per 1,000 inhabitants) and amphetamine-type stimulants (from 2 to 10 users per 1,000 inhabitants) increased. The rise in usage is largely attributed to better disease diagnosis and increased treatment availability, though the data also indicate some use outside of approved treatment guidelines. The reversal in the decline in the use of benzodiazepine and benzodiazepine-like medicines can be linked to changes in prescribing restrictions in 2023. In 2024, compared with the period preceding the changes to the restrictions (2019–2022), there were on average 2.5 fewer users per 1,000 inhabitants each month (–9%).

As part of an international collaboration, we conducted a comparative study on the use of benzodiazepine and benzodiazepine-like medicines in the Baltic states. Compared to Latvia and Lithuania, Estonia had the lowest prevalence of use population, but the highest intensity per user, suggesting longer treatment durations or the use of higher doses among Estonians.

Awareness-raising on adverse reactions, medication errors and addictive medicines

We provided drug safety education to medical and pharmacy students and visited schools to talk about the topic. Under the guidance of colleagues from our department, a pharmacy student's research project was successfully defended.

We spoke to doctors at Tallinn Children's Hospital about medication errors and risk-reduction measures; addressed the use of potentially inappropriate medicines in the elderly with geriatricians and general practitioners, and talked about medication errors with hospital pharmacists.

We delivered lectures on medicines and their adverse reactions, medication errors, medication dependency, and the specific needs of older people regarding medicines at the University of the Third Age, the Haabersti and Imavere activity centres, and at a patient safety conference.

We spoke about antibiotic resistance at the LABRIS information day.

At the European Drug Utilization Group Conference 2025, we presented a paper on the use of methylphenidate, benzodiazepines, and benzodiazepine-like medicines in Estonia. This presentation was ranked among the top 12.

An overview of compensation for vaccine-related injuries was published in the journal *Eesti Arst*, in collaboration with the Health Insurance Fund.

Since 2025, patient-focused materials highlighting serious medicine-related risks have been available on the Health Portal.

Last autumn, the 'State Agency of Medicines Statistical Yearbook 2025' was published.

Adverse events of veterinary medicines

**In 2025, 31 reports were submitted regarding possible adverse reactions observed in animals.
The majority of reports concerned pets:**



The reports were categorised as follows:

- 26 reports concerning drug safety issues;
- 4 reports concerning drug efficacy issues;
- 1 report describing both safety and efficacy issues.

Fewer reports were submitted than in 2024, but, as in previous years, most concerned adverse reactions arising from the use of antiparasitic agents and vaccines.

We also provided third-year veterinary students with instruction on the topic of medicinal product safety.

The new AWaRe and AMEG antibiotic information materials support healthcare professionals in making evidence-based treatment decisions in both human and veterinary medicine



Marju Sammul, Janne Sepp

In addition to analysing pharmaceutical and pharmacy statistics, antimicrobial resistance (AMR) and the related One Health concept have been key focus areas for the Bureau of Drug Statistics over the past few years. We have actively contributed to Estonia's cross-sectoral AMR Steering Group, the AMR Human Health Working Group and the Veterinary Medicine Working Group. The national objectives are outlined in the document 'Estonian Strategy for the Control of Antimicrobial Resistance 2025–2030'¹

An important part of tackling antimicrobial resistance is avoiding the misuse and overuse of antibiotics and analysing data across sectors and countries. For many years, we have represented Estonia in international collaboration networks (ESAC-Net, GLASS, ESUAvet, and WOA) that focus on analysing antimicrobial use and conducting cross-country comparative studies. Antimicrobial resistance (AMR) has emerged alongside the introduction and use of new antimicrobial agents and has become an increasingly serious global challenge. The prudent and responsible use of antibiotics is therefore essential. In both human and veterinary medicine, antibiotics are classified into different categories based on their resistance risk and clinical importance, helping healthcare and veterinary professionals make appropriate treatment decisions.

AWaRe classification for antibiotics used in human medicine

To support appropriate antibiotic use, antibiotics used in human medicine are classified into three categories based on a traffic-light approach: Access, Watch, and Reserve (the AWaRe classification):

Access

– this group includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while also showing lower resistance potential than antibiotics in the other groups. Selected Access group antibiotics are recommended as essential first or second choice empiric treatment options for infectious syndromes and are listed as individual medicines on the Model Lists of Essential Medicines to improve access and promote appropriate use.

¹ https://www.sm.ee/sites/default/files/documents/2024-11/Eesti%20AMR%20ohjamise%20strateegia_28.11.pdf

Watch

- this group includes antibiotic classes that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine¹ and/or antibiotics that are at relatively high risk of selection of bacterial resistance.

Reserve

- this group includes antibiotics and antibiotic classes that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms. Reserve group antibiotics should be treated as “last resort” options.

The European Centre for Disease Prevention and Control (ECDC) has set a target for European countries that at least 65% of antibiotic use should consist of antibiotics in the Access category, while the World Health Organization (WHO) has established a more ambitious global target of 70%. Currently, Access-category antibiotics account for an average of 60% of antibiotic use across Europe and 64% in Estonia (Figure 2).

In many countries, Watch-category antibiotics are still used excessively, and reducing their use is considered one of the key measures for slowing the spread of antimicrobial resistance (AMR). This remains an area requiring continued attention and further development.

To support the achievement of these objectives in Estonia, in 2025, under the leadership of the State Agency of Medicines and in cooperation with the Health Board, the Estonian Society of Infectious Diseases, and the Estonian Society of Laboratory Medicine, we developed AWaRe information materials. These materials are available in the new AMR information section on the State Agency of Medicines' website, which serves as a central repository for antimicrobial resistance-related resources.



AMEG classification of Antibiotics for Use in Animals

To promote the responsible use of antibiotics in animals, the European Medicines Agency's expert group has developed the AMEG classification system for veterinary antibiotics:

Category A, or 'Avoid'	– antibiotics that should be avoided in the treatment of animals. These antibiotics are not registered as veterinary medicines and their use in the treatment of food-producing animals is prohibited.
Category B, or 'Restrict'	– antibiotics of critical importance in human medicine, the use of which in animals must be restricted. The use of antibiotics in this category must be based on antibiotic susceptibility testing.
Category C, or 'Caution'	– antibiotics for which alternatives exist among those used in human medicine. These are used when first-choice medicines are not clinically effective.
Category D, or 'Prudent use'	– first-line antibiotics that are narrow-spectrum and have a good safety profile. These should always be preferred where possible.

The classification of antibiotics into different categories is based on the potential public health consequences of increasing antimicrobial resistance when antibiotics are administered to animals, while also taking into account the need for antibiotic use in veterinary medicine. This is particularly important for antibiotics that are used in both human and veterinary medicine and that serve as last-resort treatment options for critical infections in humans. In cooperation with the Ministry of Regional Affairs and Agriculture, we have emphasized to veterinarians the importance of adhering to the AMEG categories when prescribing and using antibiotics in animal treatment. In Estonia, the proportion of D-category antibiotics, also known as the Green category, has remained between 64% and 68% over the past five years (Figure 2).

The updated 2025 AMEG information material is available on the website of the State Agency of Medicines.

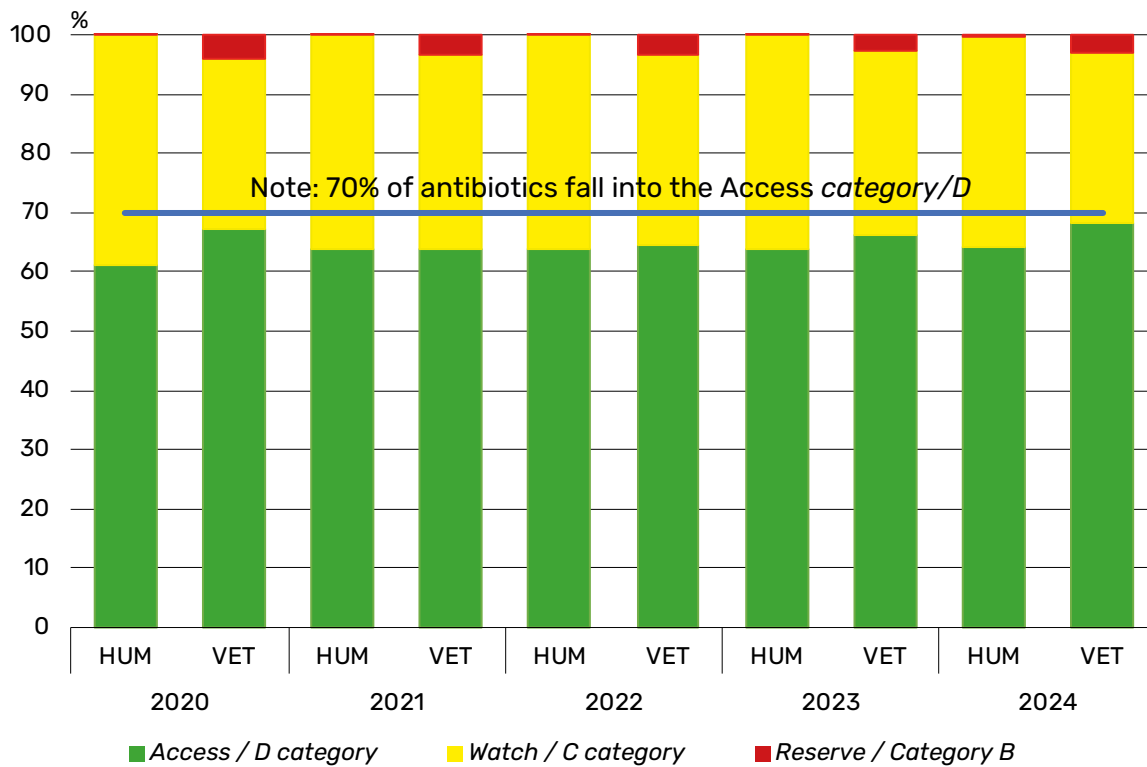


Figure 2. Use of human (HUM) and veterinary (VET) antibiotics in Estonia
Based on the AWaRe and AMEG classifications, 2020–2024.

Loomadel kasutatavate antibiootikumide liigitus vastutustundlikuks kasutamiseks

A-kategooria – „Vältida”
ELis ei ole veterinaarravimite müügiluba, neid ei tohi kasutada toiduloomadel

B-kategooria – „Piirata”
kriitilise tähtsusega humaanmeditsiinis (kinoloonid, 3. ja 4. põlvkonna tsefalosporiinid, polümüksiinid)

C-kategooria – „Ettevaatlik”
mõne veterinaarse näidustuse korral puuduvad alternatiivid D-kategoorias

D-kategooria – „Mõistlik”
esimese valiku antibiootikumid

4

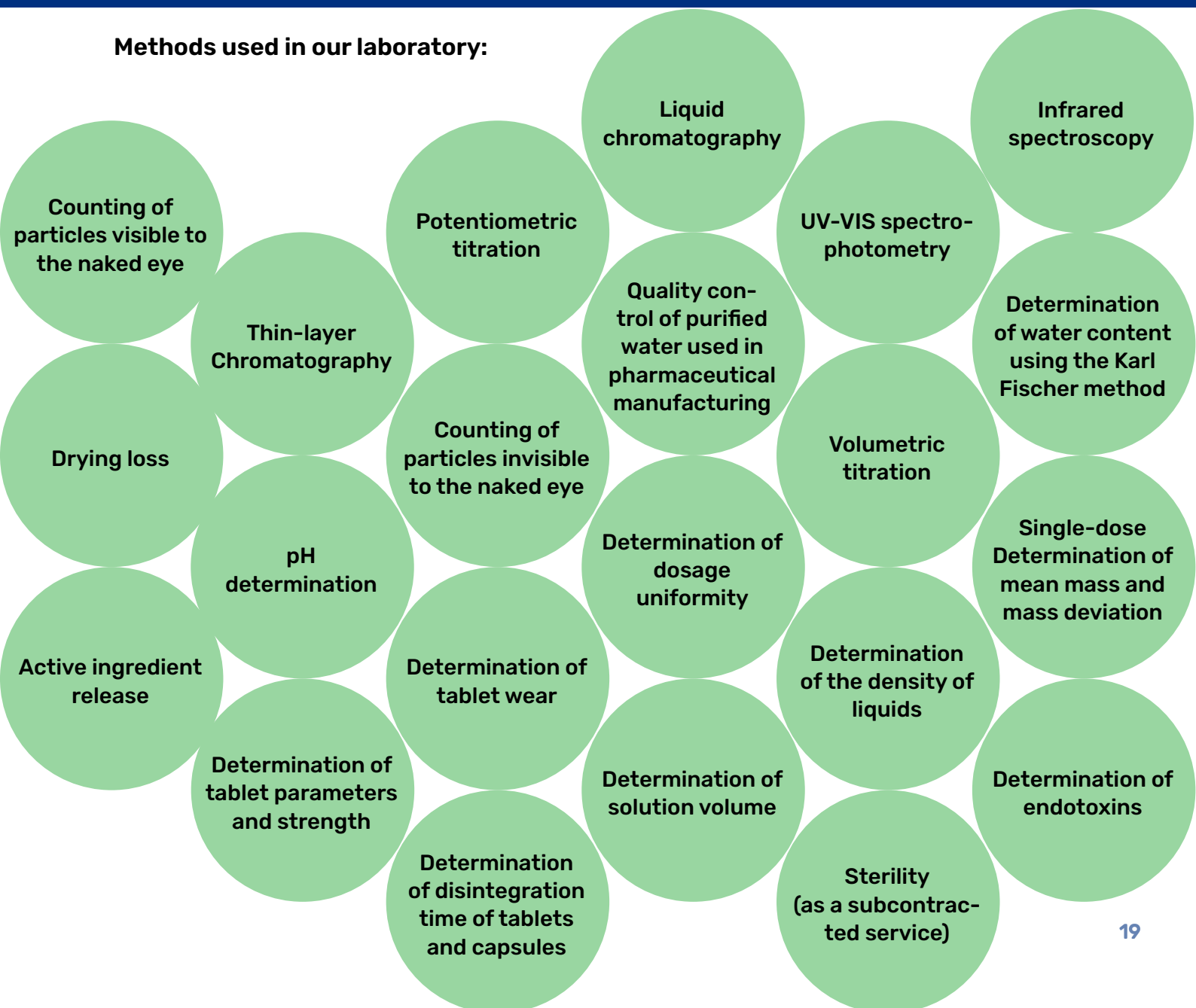
Our laboratory – safeguarding the quality and reliability of medicines

Aune Ahman



Laboratory testing of medicines is a vital part of the State Agency of Medicines' regulatory oversight. Our laboratory's primary role is to verify that medicines used in Estonia meet quality standards, supplementing the quality control performed by manufacturers on each production batch. Using 22 chemical and pharmaceutical methods, our laboratory is able to perform quality control on a variety of dosage forms and paramet

Methods used in our laboratory:



In 2025, our laboratory analysed **65 medicines used in Estonia**. We also contributed to the development of two reference standards and conducted nine analyses for the laboratory of the State Medicines Control Agency of Lithuania.

We also participated in **five international proficiency testing studies**, which assess laboratory competence by analysing identical samples across different laboratories and statistically comparing the results.

In total, we carried out **384 tests** across 81 assays, using an average of 6–7 different methods to assess the quality of each medicinal product.

The laboratory identified six medicines of non-compliant quality. These included discrepancies in the volume, quantitative content of the active substance, dosage and mass uniformity, tablet splitting (halving and quartering), and one instance where a medicinal plaster did not adhere to the skin. In cooperation with the State Agency of Medicines, the following actions were taken:

- the marketing of one medicinal product was suspended, and the marketing authorisation holder recalled it from pharmacies and wholesalers as instructed by the State Agency of Medicines;
- one medicinal product was found to be non-compliant, but did not pose a risk to the life and health of patients, so its marketing was allowed to continue;
- decisions are still pending for four medicinal products.

Our laboratory has been accredited by the Estonian Accreditation Centre as a testing laboratory for medicinal product analysis.



Clinical trials in Estonia in 2025

Keiu Lember

2025 marked the end of the transition period for clinical trials. This means that, from the end of January last year, all clinical trials conducted in the European Union must comply with the Clinical Trials Regulation and be registered in the Clinical Trials Information System (CTIS). The World Health Organisation (WHO) has designated CTIS as the primary registry for the International Clinical Trials Registry Platform (ICTRP), which unites clinical trial registries worldwide.



During the transition period, our focus on awareness-raising ensured a smooth and timely process. We supported academic researchers in the preparing and submitting transition applications and updated the European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) to maintain data accuracy.

Activities of the Ethics Committee

A new Ethics Committee, selected through an open competition, began its work in February of last year. The committee brought added expertise and diversity to its operations, now including not only doctors but also a patient representative and a data protection lawyer.

Committee members completed the necessary training for their roles. We reviewed work processes, shared workspaces, and began holding monthly meetings with the Ethics Committee to discuss emerging issues and improve assessment processes. Regular tripartite meetings between the State Agency of Medicines, the Ethics Committee, and the Association of Pharmaceutical Manufacturers also continued.

Medical device studies

With the supervision of medical devices transferred to the State Agency of Medicines from 1 January 2025, we proposed legislative amendments for the agency's Ethics Committee to also assess the ethical aspects of medical device clinical trials. From 1 October, medical device trials will officially fall under the remit of the State Agency of Medicines' Ethics Committee. Consolidating the assessment processes within a single agency and committee will make the application process clearer for trial organisers and reduce application assessment times.

Ensuring the quality of clinical trial supervision and the processing of trial applications

In 2025, the European Commission assessed the implementation of Good Clinical Practice (GCP) requirements in clinical trial inspections across all European Union Member States, using a self-assessment questionnaire. We submitted the required data to the European Commission and demonstrated that both Estonian national legislation and the State Agency of Medicines' procedures enable effective and independent supervision. All inspections are properly documented and accessible in the CTIS database.

In the spring, we participated in our fifth Benchmarking of European Medicines Agencies (BEMA) assessment. The clinical trials domain achieved the maximum score of 5.0 and was recognised for best practices, particularly in supporting academic sponsors and in the Ethics Committee's systematic training and guidance programme. This result marks a significant improvement over the 2018 assessment (4.5 points), and exceeded the 2025 average score for the European Medicines Agencies network.

Guidelines on Good Clinical Practice updated

It is important for trial investigators to be aware that the updated guidelines on Good Clinical Practice (ICH GCP E6 (R3)) came into force on 23 July 2025.

While the primary objectives of clinical trials remain unchanged – ensuring participant safety and well-being, as well as the reliability and integrity of trial data – the updated guidelines place greater emphasis on risk-based approaches and the use of new technologies.

CTIS has become more user-friendly for both doctors and patients

- As a new feature, an interactive map has been available in the CTIS database since March. Since the end of October, the map and detailed search functionality have been accessible in all official EU languages, including Estonian.
- Clinical trials can now be searched by geographical region and medical condition. Advanced search filters allow users to narrow results by age group, trial phase, investigational medicinal product, and other criteria. Search results display contact information for each trial, allowing interested parties to contact sponsors directly.

Clinical trial applications

In 2025, we received just 27 initial applications for clinical trials. Estonia acted as the Reference Member State (RMS) on five occasions during the joint assessment procedure. No applications for academic trials (i.e. those initiated by doctors), were submitted in 2025.

Most applications (24) were for Phase 3 trials, which involve large patient groups and aim to collect comprehensive data on the efficacy and safety of a medicinal products – often compared to medicines already in use.

Only two applications were submitted for Phase 2 trials, marking a significant decrease compared to 2024. One application was submitted for a Phase 1 (early-stage) trial, and none were submitted for Phase 4 (post-marketing) studies in 2025.

The leading clinical specialties were oncology (8 applications), neurology (5 applications), and infectious diseases (4 applications).

European cooperation and global competitiveness

In recent years, a decline in the number of clinical trial applications has been observed across Europe. Increased competition with the United States and China has prompted efforts to boost the number of clinical trials conducted in Europe. At the end of last year, HMA, CTCTG and MedEthics EU launched the FAST-EU project, which aims to simplify and accelerate the assessment procedure of multinational clinical trials within the EU.

Clinical trial inspections

Last year, we conducted eight clinical trial inspections, five of which took place at trial sites in Estonia. Additionally, as part of the centralised marketing authorisation procedure led by the European Medicines Agency, we participated in three international inspections (two at trial sites and one at a sponsor's site). The international trial site inspections took place in India and Bulgaria, while the sponsor inspection took place in India. The purpose was to assess compliance with regulatory requirements and provide the Committee for Medicinal Products for Human Use with insight into the quality and reliability of the data collected. An Estonian inspector participated in the inspections alongside colleagues from Austria and Bulgaria.

Marketing authorisations for medicinal products

Aet Viispert



The purpose of a marketing authorisation is to ensure that patients, healthcare professionals, and veterinarians only use medicines that have been proven safe, high-quality, and effective, with the benefits outweighing the potential risks. During a medicine's development, the pharmaceutical company submits extensive data for review. Our experts then conduct a thorough and independent scientific assessment of this information. When assessing a marketing authorisation application, we consider the Estonian-language Summary of Product Characteristics (SPC) for doctors or veterinarians, as well as the Package Information Leaflet (PIL) and labelling intended for the user of the medicinal product. If the assessment is positive, we issue a marketing authorisation number for the medicinal product, and enter its key details, together with the product information, into the medicinal products register.

At the State Agency of Medicines the Marketing Authorisation Department evaluates and manages applications for medicinal products throughout their entire life cycle – from development to the end of its marketing. The manufacture and control of medicinal products must keep pace with scientific and technical advances. Companies may change manufacturing process, raw material supply chains, or control strategies, and new safety information may arise during use, necessitating updates to the summary of product characteristics and the package leaflet. Our experts assess data for applications involving the variation, renewal, transfer, and revocation of marketing authorisations, as well as applications for secondary marketing authorisations for human medicines. They also review applications related to parallel trade in veterinary medicinal products and the variation or revocation of these authorisations.

There are several procedures for obtaining a marketing authorisation for a medicinal product, including **the national procedure**, **the Mutual Recognition Procedure** (MRP), and **the Decentralised Procedure** (DCP). Both the MRP and DCP involve submitting applications to several EU Member States at the same time. One country acts as the Reference Member State (RMS), and prepares a scientific assessment of the medicinal product, while the other countries participate as Concerned Member States (CMS), primarily reviewing the RMS's evaluation.

For **parallel import authorisation** applications, we verify whether a medicinal product with an authorisation for marketing originating from another EU Member State – via an alternative supply chain – is identical by its clinical effect as the medicinal product already being placed directly on the market by the marketing authorisation holder.

In 2025, the State Agency of Medicines granted marketing authorisations for a total of **402 new medicinal products for human use**. Issued:



- 130 new marketing authorisations following the national procedure, including 120 parallel import authorisations;
- 47 marketing authorisations that have undergone the MRP;
- 203 marketing authorisations that had undergone the DCP procedure, in which Estonia participated as RMS;
- 22 marketing authorisations were granted for medicinal products where the State Agency of Medicines participated in the DCP procedure as RMS.

In terms of numbers, the largest number of new entries in the Register of Medicinal Products were anti-thrombotic medicines, followed by medicines for hypertension acting on the renin-angiotensin system of the cardiovascular system, and medicines used to treat diabetes.

The centralised procedure is coordinated by the European Medicines Agency and results in a marketing authorisation granted by the European Commission, which is valid throughout the European Economic Area. These marketing authorisation applications are assessed by the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency. The assessment is led and the scientific evaluation prepared by Member States (experts from national medicines agencies) designated as the lead assessor (rapporteur) and co-rapporteur.

In 2025, Estonia participated as co-rapporteur or rapporteur in five centralised marketing authorisation procedures for medicines for human use.

In 2025, the European Commission granted marketing authorisation for two medicines used to treat multiple myeloma, a form of bone cancer, with the Estonian State Agency of Medicines involved in their evaluation. The CHMP also issued a positive opinion on a medicine used to treat prostate cancer, which was evaluated by our experts.

In 2025, the State Agency of Medicines granted marketing authorisation for **49 veterinary medicines**. Issued:



- 1 new marketing authorisation following the national procedure;
- 8 marketing authorisations that have undergone the MRP or subsequent recognition procedure;
- 40 marketing authorisations that had undergone the DCP, in which Estonia participated as Reference Member State.

The largest number of newly authorised veterinary medicinal products added were those with antiparasitic, anti-inflammatory, antirheumatic and antiepileptic effects.

Based on safety data submitted with the marketing authorisation application, a medicinal product is classified as an over-the-counter or prescription-only medicine. New data collected during the use of a medicine may result in a change to its classification. The type of prescription status category may also vary depending on the pack size. In 2025, we decided to reclassify two medicines used in human healthcare: vaginal tablets containing 10 mg of dequalinium (6 tablets per pack) for bacterial vaginosis will now be available over the counter, and tablets containing 20 mg of bilastine (10 tablets per pack) for allergic rhinitis and urticaria will also be available without a prescription.

To ensure that manufacturing processes, controls, and product information remain current with scientific and technical developments, the marketing authorisation holder submits a marketing authorisation variation application with supporting data for assessment.

In 2025, it became mandatory to assess variations concerning medicinal products with the same content but authorised in different Member States through a worksharing procedure, whereby one Member State would provide the substantive assessment. While we played a leading role in fewer than 10 such amendments in previous years, by 2025 this figure had risen to over 50, significantly reducing duplication of work in the assessment process.

The responsible use of veterinary medicines plays a vital role in safeguarding the health of both animals and humans

Epp Ülevaino

In veterinary medicine, the focus continues to be on the availability of veterinary medicines and promoting the appropriate use of antimicrobials and antiparasitic agents to address antimicrobial resistance (AMR).



We have compiled AMR information on the agency's website to give veterinarians easy access to essential resources. We are also preparing a summary of restrictions on the use of antimicrobial medicines under the so-called 'cascade' approach, and can provide concise summaries of relevant regulatory texts to make veterinarians' work easier.

Availability of veterinary medicines

By the end of 2025, the Estonian Register of Medicinal Products contained 1,593 authorised veterinary medicines, of which 745 were marketed in Estonia. The corresponding figures for the previous year were 1,532 and 743, respectively. Despite a slight increase in authorised products, overall availability has not improved significantly.

If a suitable veterinary medicine or an authorised human medicine is unavailable, veterinarians may, with permission from the State Agency of Medicines, use an unauthorised human medicine to treat animals. Since most applications are not patient-specific, a single positive decision on our part allows vets to treat multiple patients.

Last year, the State Agency of Medicines gave permission for the use of an unlicensed medicinal product intended for human use on 158 occasions, including applications for the use of 45 different active substances. By way of comparison, in 2024 the Agency gave permission on 99 occasions, indicating a significant increase in the number of applications over the course of the year. This is due to an increased awareness among vets of various newer treatment approaches, as well as a greater awareness of the possibility of submitting an application.

The sharp increase in the number of applications highlights the ongoing insufficient availability of both veterinary and authorised medicines for human use to fully meet the treatment needs of animals.

Veterinary

As in the previous year, we contributed to the education of future veterinarians. In collaboration with the Estonian University of Life Sciences, we have spoken to final-year veterinary students about veterinary medicines, their use, and the relevant legislation in both Estonia and the European Union.

We are very pleased to be receiving an increasing amount of important questions from veterinarians, whether concerning issues related to the availability of medicines or the clarification of legislation. It is through cooperation that we can find practical solutions.



Pharmacies

Katrin Kõiv

As of 1 January 2026, a total of 468 general pharmacies were operating in Estonia. This includes 104 branch pharmacies, five online pharmacies, and four providers of personalised dispensing services. Additionally, there were 25 hospital pharmacies and one veterinary pharmacy. While hospital pharmacies supply medicines to hospitals and ambulance services, general pharmacies ensure the availability of medicines to the public and to all businesses and institutions that require them in the course of their activities to provide healthcare services.



Last year, seven general pharmacies and three branch pharmacies were added, whilst 13 general pharmacies and five branch pharmacies ceased operations. One veterinary pharmacy also ceased operations, meaning that only one veterinary pharmacy remains in Estonia and veterinary medicines are now purchased from general pharmacies instead. In most cases, the closure of a pharmacy does not affect the availability of medicines, as there are usually other pharmacies operating in the same settlement, or a closed pharmacy is replaced by another. However, in 2025, the island of Kihnu, the Oru district of Kohtla-Järve, and Raasiku Rural Municipality were left without pharmacy services.

A pharmacy must provide high-quality, safe and effective medicines, together with appropriate and evidence-based advice from a pharmacist. It is also important that the medicines are affordable and accessible to patients. In 2025, we inspected a total of 104 pharmacies, including 98 general pharmacies and their branch pharmacies, as well as six hospital pharmacies.

In our supervision of pharmacies, we are placing an increasing focus on counselling and prevention. We have sent six information bulletins to pharmacists on topics including the dispensing of non-prescription medicines, customer identification, and the dispensing of medicines on the basis of European Union prescriptions in Estonian pharmacies. We also wrote an article for the magazine Apteek TÄNA on the dispensing of medicines based on European Union prescriptions. In November, we organised an information day for pharmacists, where we discussed the use of European Union prescriptions, the provision of medicines as a vital service, planned regulatory changes affecting pharmacies, supply difficulties, the possibilities offered by the Register of Medicinal Products, the verification of medicine authenticity, and the medicine waste collection container pilot project.

For both the State Agency of Medicines and pharmacists, providing medicines as a vital service was a new focus last year. We played an active role in developing the requirements and began the process of selecting the first pharmacies to provide this vital service, a

process which should culminate around the time of this yearbook's publication. This is the first step towards ensuring a more secure supply of medicines during crises. The selected pharmacies have only just begun to increase their resilience to crises, and it is likely that more pharmacies will be needed to provide this vital service in the future.

In collaboration with pharmacies, we organised a public awareness campaign about pharmaceutical waste. Together with the Ministry of Social Affairs, the Estonian Academy of Arts, and pharmacies in Pärnu, we also took part in a pharmaceutical waste collection bin trial. The bin was well-received by both pharmacy customers and pharmacists in Pärnu, who all wanted to keep the prototype in their pharmacies permanently. Meanwhile, the LAETUS project was piloted in pharmacies across Pärnu County, where practical information was gathered on ways to reduce the generation of pharmaceutical waste. As part of this project, pharmacies collaborated with the State Agency of Medicines, the Ministry of Social Affairs, and students from the Estonian Academy of Arts, who, under the guidance of a supervisor, compiled an overview of the impact of medicine handling processes on waste generation.

There continues to be growing interest among general pharmacies in the personalised dispensing of medicines using automated equipment. This service is primarily aimed at care homes and is likely to become a significant trend in the coming years, encouraging wider adoption of the service in pharmacies. As of January, four pharmacies are offering this service, three of which have joined in the last year.

We discussed the preparation of eye medicines, particularly the preparation of atropine sulphate eye drops used in the treatment of myopia in children, with hospital pharmacies. In collaboration with the Institute of Pharmacy at the University of Tartu, one hospital pharmacy conducted a stability study on atropine sulphate eye drops, and we evaluated the results. Based on this data, we authorised the preparation of atropine sulphate eye drops with a shelf life of up to 28 days, instead of the previous one week. This improves the availability and continuity of myopia treatment for children in situations where there are no equivalent commercial medicines available on the market in Estonia.

Moreover, at the initiative of hospital pharmacies and with our advisory support, there has been a growing focus on adopting modern technological solutions in hospital pharmacies. The implementation of innovative solutions for transporting and storing medicines enables more efficient stock management and improved inventory control, as well as increasing handling capacity where necessary. Last year, one hospital pharmacy introduced a hospital-wide vertical warehouse and another a robotic warehouse, both of which support the traceability of medicines and streamline work processes.

Hospital pharmacies are increasingly seeking to centralise activities related to preparing medicines for administration in hospital wards, thereby reducing the risks associated with the handling of medicines.

Manufacturers and suppliers

Liis Prii

Medicine manufacturers

As of 1 January this year, 27 pharmaceutical manufacturers were operating in Estonia across 29 sites. Of these, nine produce medicines, four produce active substances, one produces medical gases, three produce herbal medicines, and one imports medicines from third countries. The remaining nine are involved in labelling and/or packaging medicines. Additionally, one manufacturer of biological active substances – with a dedicated microbiology laboratory for quality control – and one active substance manufacturer opened an additional site. Several manufacturing sites expanded or updated their production conditions, and changes occurred among qualified persons responsible for production. In January 2025, one excipient manufacturer ceased operations. We are pleased to note that, for several years running, a number of manufacturers have continued to expand or modernising their operations in both biological and chemical medicine or active substance production.



To ensure the quality, safety and efficacy of medicines, all Estonian pharmaceutical manufacturers adhere to the Good Manufacturing Practice (GMP) guidelines. Over the course of 19 inspections we checked compliance with GMP requirements at Estonian manufacturing sites and issued 11 GMP certificates to ten of those sites. Six of the inspections were related to the market entry of one new medicinal product manufacturer and two new active substance manufacturers. The remaining five inspections were related to a follow-up at one manufacturing site regarding the rectification of serious non-compliance issues identified last year, as well as ensuring continued compliance of production.

We believe it is important to support companies by helping them identify areas for improvement and prevent non-conformities that could affect the quality of medicines, through the systematic application of good practice. In addition to manufacturers already established in the market, we have advised a manufacturer wishing to establish a new production unit to replace their existing plant, a third-country manufacturer seeking to collaborate with an Estonian manufacturer, a company interested in importing medicines from third countries, and a company wishing to enter the pharmaceutical market – the only one in the Baltic States to use gamma radiation for sterilisation.

Wholesalers

As of 1 January 2026, there were 54 pharmaceutical wholesalers in Estonia. Of these, 35

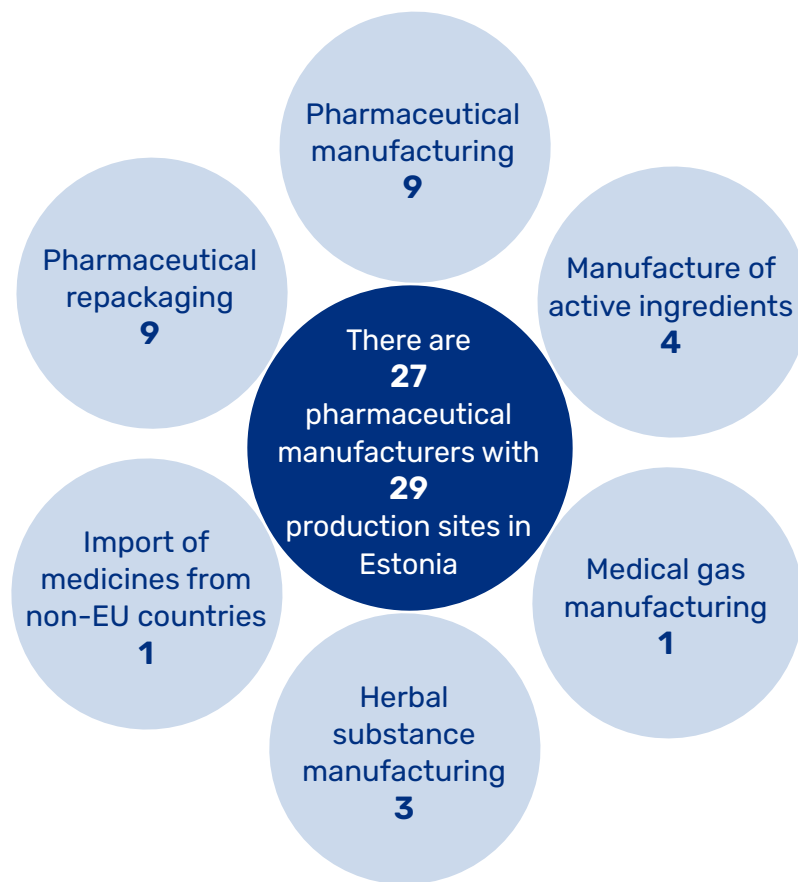
dealt in medicinal products for human use, two in veterinary medicinal products, and 17 in both. Twenty-eight of these held a storage licence. Two new companies with wholesale licences were added in 2025. One of these holds a licence for the manufacture of early-stage medicinal products. Changes to licences were predominantly related to the relocation of wholesale premises, the expansion of business premises, or changes in storage partners. Three wholesalers ceased their medicinal product wholesale activities of their own accord.

All Estonian pharmaceutical wholesalers follow Good Distribution Practice (GDP) guidelines to ensure that medicines reach pharmacies in the same high quality state as when the manufacturers released them onto the market. Over the course of 22 inspections, we checked compliance with GDP requirements, 13 of which covered the entire operations of a wholesale company and nine of which were necessary to verify that previously identified non-compliances had been rectified. We issued a five-year GDP certificate, confirming compliance with good distribution practices, to nine wholesale companies.

Our work focused on wholesale transactions carried out by Estonian companies outside Estonia, where medicines are not imported into Estonia; companies with few transactions for whom the wholesale of medicines is a secondary activity; and the storage conditions for narcotic and psychotropic medicines at wholesalers. We observed that companies for whom the wholesale of medicines is not a core activity require more guidance from the supervisory authority to successfully implement good distribution practices. We hope that the advisory support and, where necessary, repeated supervision offered will make it easier for these companies to systematically comply with good distribution practices in the future.

At the information day organised for wholesalers over the past several years, we have focused on storage requirements for medicines during transport, changes to pharmaceutical regulations at the European level, the supply of medicines as a vital service, and issues related to the import and export of medicines, including supply chain challenges. We are also making preparations to designate two wholesalers as providers of the vital service of medicine supply to strengthen crisis resilience.

We receive reports of quality defects in medicines from manufacturers, suppliers, and pharmacies, as well as from healthcare professionals and patients. We share these reports with colleagues in other European medicines agencies via the Rapid Alert system (RAS) and analyse each case to identify links to safety incidents, the point in the supply chain where the defect occurred, and its causes, so that the same defect can be prevented in the future. In addition, a decision must be made in each case as to whether the medicinal product is safe and effective for use by patients, or whether risk-mitigating measures need to be applied, up to and including the withdrawal of the medicinal product from the market. In 2025, we received 132 reports of quality defects concerning medicines marketed in Estonia, of which 12 cases required the medicine to be withdrawn from the market.



Early notification of supply difficulties is important

Marko Tiisler

The supply of medicines must meet the country's need for them, i.e. demand. Situations in which it is not possible to meet the need of patients for medicines are referred to as supply shortages, and the manufacturer of the medicine must notify the State Agency of Medicines of these. It is also important to notify the State Agency of Medicines of any discontinuations of medicines. Timely notification enables the State Agency of Medicines to act promptly.



Last year, the State Agency of Medicines was notified of supply issues affecting 304 medicines, as well as the discontinuation of 140 medicines. While most of the notifications concerned the availability of medicines for human use, two supply-related issues and four discontinuations of veterinary medicines were also reported. Based on the notifications, supply shortages were most frequently linked to manufacturing problems and unexpected increases in demand, whilst discontinuations of medicines were primarily linked to commercial decisions.

The State Agency of Medicines must be notified of any issues affecting the availability of a medicinal products at least two months in advance, including the expected duration and cause. Timely and thorough information sharing enables solutions to be found in cooperation with other market participants and allows for the planning of alternative supply volumes, including those without a marketing authorisation, which entails a greater commercial risk for both wholesalers and pharmacies. This reduces the impact of supply difficulties on patient care and the healthcare system. While many manufacturers do report supply difficulties and discontinuation of marketing in accordance with the requirements, delays in notifications and insufficient information regarding the causes and duration of supply difficulties are often a cause for concern. The obligation to notify lies with the marketing authorisation holder, but reports are also welcomed from wholesalers, pharmacists, doctors, and other healthcare professionals who encounter supply difficulties with medicines in their daily work.

To assess the criticality of supply difficulties, the State Agency of Medicines primarily monitors the medicinal product's indication, the level of demand for the medicinal product, and whether equivalent alternatives are available or whether the medicinal product can be substituted. The figures below show the number of notifications regarding supply shortages and discontinuation of marketing for human and veterinary medicines, based on the marketing status of alternatives or substitute medicines.

61% (269 medicines) In these cases, at least one alternative with the same active substance strength and pharmaceutical form was available in Estonia when the supply difficulties or discontinuation of marketing were reported	21% (93 medicines) In such cases, other medicines were supplied that could be used as a substitute for the medicine in short supply (e.g. by halving a tablet or taking two at a time, using a single-component preparation instead of a combination preparation, prescribing another active substance with the same indication and mechanism of action, etc.)	18% (82 medicines) In cases where there was no alternative to the medicine at the time that the supply shortage or discontinuation of marketing was reported
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Since last year, the European Union's list of critical medicines has been helpful in assessing criticality. This list includes life-saving medicines for human use, for which the availability of alternatives is limited across Europe. In 2025, we were notified of supply difficulties for 41 medicinal products on the list and 10 discontinuations. We addressed these supply disruptions with the utmost care.

Where it was not possible to meet patients' medication needs with all available medicine packages, active substance strengths and pharmaceutical forms, we implemented the following measures:

- In 38 cases, we granted authorisation for the marketing of a medicinal product in a foreign-language package, either to the marketing authorisation holder who had reported a supply shortage or discontinuation of marketing, or to the marketing authorisation holder of an equivalent medicinal product, in order to ensure sufficient availability of an alternative;
- In 42 cases, due to supply difficulties or the discontinuation of marketing, it was necessary to authorise the marketing of equivalent medicinal products available in other countries as medicinal products without a marketing authorisation;
- In seven cases, to ensure sufficient availability, it was necessary to authorise both the marketing of a medicinal product with a marketing authorisation in foreign-language packaging, as well as the use of a medicinal product without a marketing authorisation;
- In three cases, we imposed export restrictions to alleviate supply difficulties.

One of the most complex cases last year was the disruption to the supply of clobazam, a vital but unlicensed epilepsy medicine, where, due to a change in contractual partners, wholesalers had to quickly find new supply chains and resolve a critical availability issue. The joint efforts of wholesalers, neurologists, pharmacists and the State Agency of Medicines ultimately ensured that treatment could continue.

Supply difficulties

In 2025, patients were most affected by supply disruptions to propranolol and tamoxifen, for which we authorised the use of off-label medicines to alleviate the situation, and by supply difficulties with timolol eye gel, where the solution was to market the medicine in foreign-language packaging. This year's seasonal surge in flu cases has kept us on our toes since November regarding the availability of the influenza medicine oseltamivir. However, thanks to rational prescribing by doctors and the stabilisation of the influenza spread, no supply difficulties have arisen with this medicine.

In addressing supply shortages of veterinary medicines, we would like to thank veterinary medicine wholesalers, who often have the most up-to-date information on medicine availability and who share this promptly with vets. At the same time, we are working with vets and importers to find solutions for medicines where there is a clinical need but the medicines have not yet reached the Estonian market.

It is in everyone's shared interest to ensure that high-quality medicines are available and used appropriately and rationally. By providing advance notice of supply difficulties and collaborating with all relevant parties to find solutions, we can ensure that, in most cases, patient can continue their treatment despite the supply difficulties.



We have contributed to the development of cell therapy and are preparing for changes in legislation of substances of human origin

Triin Suvi



Substances of human origin (SoHO) includes cells, tissues, organs and blood from donors which are used to treat patients. Procurement, processing, storage and issuing of SoHOs to doctors for transplantation requires the relevant activity license issued by the Agency. Currently, 27 such licences have been issued, of which 13 are for procuring and/or handling of cells, tissues and organs, and 14 of which are for handling of blood. In 2025, we issued three new licences for procuring and/or processing of cells, tissues, and organs. Two licences were issued to hospitals that began procuring umbilical cord blood and tissue. Both hospitals send the collected material to a cell bank in another country, where cells derived from umbilical cord blood and tissue are stored. In addition, we issued one licence for the handling of bone.

In Estonia, the following cells and tissues are procured and handled: haematopoietic stem cells; therapeutic cells (T-lymphocytes and peripheral blood mononuclear cells); reproductive cells and embryos; umbilical cord blood and tissue; skeletal tissues; skin, the cornea and amniotic membrane; teeth; and vascular tissue. Organs procured and handled include kidneys, liver, lungs, pancreas, and heart.

Blood centres prepare red cell suspensions, freshly frozen plasma, platelet concentrates and cryoprecipitates from collected donor blood. Any plasma not used for transfusion is sent to a plasma fractionator, which uses it to produce various medicinal products.

All 27 establishments are subject to our supervision and inspection, with 22 inspections conducted last year. Establishments are reporting all serious incidents (including those concerning adverse reactions experienced by patients). This reporting system is known as hemovigilance for blood and biovigilance for cells, tissues, and organs. We analyse all incidents and, where necessary, request additional information or clarification on measures implemented to prevent recurrence, and so on, to ensure patient safety. Last year, we received 93 hemovigilance reports and 16 biovigilance reports. The number of reports was similar to that of previous years. The fact that these cases are reported indicates that establishments are vigilant regarding deviations and adverse events, and understand the importance of case analysis and prevention.

In 2024, the European Union adopted a new regulation on substances of human origin, which will enter into force in August 2027. It will replace the current directives on blood, cells, and tissues. The new regulation will also cover a number of human-derived materials used in healthcare which were previously unregulated or regulated differently across EU Member States, such as breast milk, eye drops made from blood serum, and faecal microbiota preparations. Last year, our experts actively participated in European Commission working groups that are drafting guidelines to facilitate adoption of the regulation, as well as discussing and proposing solutions to issues that have arisen in Member States. Due to the new EU regulation, Estonian legislation must also be reviewed. Work on this began last year under the leadership of the Ministry of Social Affairs.

Advance therapy medicinal products

Advance therapy medicinal products (ATMP) are biological medicinal products that contain viruses, living cells and/or tissues. The cells and tissues in ATMPs have been substantially manipulated or are being used to perform different essential function. These medicines form a small, distinct group for which specific regulations and good manufacturing practices have been established, as they involve unique characteristics and risks that do not allow them to classify under the regulations for cells, tissues, blood or, more broadly, biological medicines. Advanced therapy medicinal products reach patients in the same way as other medicinal products - they need marketing authorisation. All ATMPs marketed have been issued a European Commission marketing authorisation valid in the entire EU.

Unlike other medicines, ATMPs can be prepared without marketing authorisation within the scope of hospital exemption. Hospital exemption means the making and use of a custom-made ATMP in Estonia on non-routine basis for an individual patient in a hospital and under the professional responsibility of a doctor. The exemption allows ATMPs to be prepared, for example, in situations where ATMP with a marketing authorisation is unavailable, or where the development of a completely new novel medicine is desired.

One of last year's objectives was to amend the existing requirements of hospital exemption. Work on this began in 2024, when we collaborated with all stakeholders to ensure that the forthcoming legislative amendment would be substantive and well-founded. The new requirements entered into force in May 2025, bringing about several changes, including enabling more patients to receive treatment under a hospital exemption licence in the future and extending the validity of such licences. It is encouraging to see that the recent amendment has already sparked active interest in starting or extending a hospital exemption. Currently, there is one hospital exemption in Estonia, which we also inspected last year.

Pharmacies 2025

General pharmacies	Pharmacy turnover	€641 million
	Turnover of medicines	€480 million
	Turnover of over-the-counter medicines	€79 million
	Turnover from prescription medicines	€401 million
	Turnover of subsidised medicines	€349 million
Hospital pharmacies	Pharmacy turnover	€178 million
	Turnover of medicines	€137 million



Wholesale of human medicines 2025



Market volume of human medicines: €559 million	Drug groups with the highest turnover:	1,470 active substances Top five active substances:	Total of 34.5 million packs sold
	1. antineoplastic and immunomodulating agents 27% €149 million	1. rosuvastatin	5,054 medicine packs
	2. gastrointestinal and metabolic medicines 15% €85 million	2. ramipril	858 million tablets/capsules
Medicines for human use sold 26 whole-salers	3. nervous system medicines 10% €53 million	3. atorvastatin	72 t cream/gel/ointment
	A total of 52% of total sales of human medicines	4. acetylsalicylic acid +magnesium oxide	650,000 dose of vaccine
		5. 5. omeprazole	



Wholesale of veterinary medicines 2025



Veterinary market volume of medicines €21 million	Medicine groups with the highest	375 active substances Top five active ingredients:	Total: 800,000 packages sold
	1. antiparasitic agents 25% €5.2 million	1. oclacinib (dermatitis treatment)	4.7 million tablets
	2. immunological agents 23% €4.8 million	2. fluralaner (antiparasitic parasite treatment)	0.7 t ointments
Veterinary medicines sold 9 wholesale sellers	3. anti-infectives 16% €3.4 million	3. Circovirus (inactivated viral vaccine for pigs)	13.7 million vaccine doses
	Total 64% of total sales of veterinary medicines	4. milbemycin oxime + afoxolaner (treatment for skin parasites)	18,900 medicated collar
		5. flumethrin + imidacloprid (treatment for skin parasites)	

The Medical Devices Department's first year at the State Agency of Medicines

Piret Põiklik

Since last January, the medical devices sector has once again been under the remit of the State Agency of Medicines. Nine specialists, one inspector and the head of the department moved from the Health Board to the State Agency of Medicines, thereby ensuring the continuity of operations. Alongside our regular duties, we familiarised ourselves with the inner workings of the State Agency of Medicines, introduced our field to new colleagues, and increased our visibility on the Agency's social media.



The market for medical devices is common across the European Union

In Estonia, all medical devices that are sold in other European Union countries may be sold here, as the same rules apply. To ensure the functionality and safety of medical devices, whilst making the most effective use of joint supervisory capabilities, Member States work closely together. Member States can submit requests to one another to inspect the activities of a particular company. In 2025, we received a total of five such requests, essentially complaints, regarding our companies. At the same time, we approached other countries on 18 occasions. In total, 232 requests were exchanged between countries to clarify circumstances or issue warnings about dangerous equipment.

Information is also exchanged in connection with (serious) incidents. Last year, we received 1,334 safety-related reports and, upon analysing these, identified devices also believed to be in use in Estonia (244 in total). We published information about these on the State Agency of Medicines' website and sent it to healthcare providers who had requested direct notification.

In recent years, increasing attention has been paid to the availability of medical devices and their importance during crises. From 2025 onwards, manufacturers will be required to report supply shortages in the supply of medical devices if the lack of availability of a device could have significant consequences for patients or public health. In 2025, Member States received 45 such notifications. As this is a new requirement, it is not yet entirely clear which devices fall under the notification obligation.

One of the most contentious issues regarding medical devices is their legal status, as in many cases a product falls into what might be called a 'grey area'. For example, there is

often uncertainty over whether a product should be classified as a medical device or a medicinal product, or which risk class the device belongs to. The risk class determines the scope of the manufacturer's obligations and how long it takes to place the device on the market. As the market is a single market, consistent treatment of manufacturers and devices is important. To this end, authorities can seek the opinions of all Member States (the so-called Helsinki procedure). A total of 18 such procedures were initiated in Europe last year.

Activities in Estonia

Since moving to the State Agency of Medicines, we have worked with management, the legal department, and the medical devices department to identify which provisions of the Medical Devices Act may require amendment. Proposals for amending the Act have now been finalised. One significant change has already been introduced: from 1 October 2025, the Ethics Committee operating within the State Agency of Medicines will issue opinions on medical device studies.

The Medical Devices Department manages Estonia's national database of medical and assistive devices. Companies use this database to notify the relevant authorities of the placement of devices on the market, their distribution, the cessation of such activities, and any updates to the data. In 2025, 1,493 new medical devices were entered into the database, and the database records covered a total of more than 5,000 changes.

We inspected 10 companies (five manufacturers, four distributors, and one authorised representative); in four cases, this was proactively, and in six cases we acted on a complaint. In addition to inspections, we drew attention to the requirements of the medical devices sector on 16 occasions during our supervisory activities, most frequently in relation to claims made in advertisements for devices.

To ensure that safe and effective devices are available on the Estonian market, we are working in partnership with the Tax and Customs Board. In total, we assessed 362 items (e.g. syringes, tests), of which 168 did not meet requirements, 125 did meet requirements, 66 were not medical devices, and three were used medical devices. All the goods together comprised approximately 240,000 medical devices. At customs, the most common non-compliances relate to device labelling: mandatory elements are missing, or the devices are not suitable for the European Union market.

We are pleased to see that an increasing number of applications and notifications are being submitted for clinical investigations and performance studies involving medical devices. This issue is precisely why the location of our department within the State Agency of Medicines is particularly sensible – many trials involve the simultaneous investigation of a medicinal product and a medical device, or a product that encompasses both. Until now, sponsors of such trials have had to obtain approvals from two agencies and two ethics committees. From 1 October 2025, applications can be submitted to a single agency. Last year, we assessed 11 new study applications, which is significantly more than usual; in 2024, the Health Board granted authorisation for only two studies.

We are creating a new version of the national database

The European Union's database on medical devices (Eudamed) has been under development for years and will, in the future, provide a comprehensive overview of the devices made available on the European Union market. However, the need to collect information on devices in Estonia remains, as only a fraction of the devices listed in Eudamed reach our market. Furthermore, there is no obligation to register custom-made medical devices (e.g. dental prostheses) in Eudamed, many of which are manufactured in Estonia. Therefore, maintaining the national database of medical devices and assistive devices (EMDDB)

remains important. The current version of the database is outdated and difficult to use, which is why we began developing a new MSA together with our partners in 2024. Its launch is scheduled for 1 June 2026.

It has been an eventful year. We said goodbye to our former colleagues and once again got to know the hard-working and helpful team at the State Agency of Medicines. The transition from one agency to another has gone smoothly for us, and we are delighted to see that the vast majority of stakeholders have embraced the new location of the Medical Devices Department. However, the department owes a special debt of gratitude to the Legal Department of the State Agency of Medicines for the great strides it has made in entering the medical devices sector over the past year. It has become an invaluable partner to us, particularly at a time of significant change in sector-specific regulations.



A year of development in 2025 – clearer processes, smarter systems, and a stronger team

Märt Roogna



From the perspective of the State Agency of Medicines' development, 2025 can be characterised as a year of maturing and purposeful progress. The focus was on the bigger picture, rather than on individual technical solutions, and how business processes, information systems and people can work together to ensure that information on medicines is up-to-date, reliable, and accessible to both the public and healthcare professionals.

Data as a strategic asset

Over the course of the year, we carried out a thorough analysis to describe the State Agency of Medicines' existing data processing procedures and define the technological development requirements for creating a more modern statistical solution. The outcome of this work provided a clear understanding of how data flows, where bottlenecks occur, and which solutions would best support informed decision-making. More diverse options for managing and processing pharmaceutical data will ensure that various stakeholders receive information in future that is of even higher quality and greater detail than before. The outcome of the analysis was not merely a document, but a shared understanding of the direction in which to proceed with development.

We compiled up-to-date data dictionaries for several datasets, laying the foundation for the consistent interpretation and use of data. This increases data transparency and reusability, thereby improving quality and reliability. In addition, we began migrating the data dictionaries to the new Accurity data intelligence platform and the public portal 'Data Gateway', to consolidate all descriptions into a more manageable format accessible to a wider user base.

Samtrack – from a local system to an international reference

The development of the Samtrack medicines information system continued to play a significant role in our work last year. In 2025, we proceeded with the second phase of this system's upgrade, creating modules to support business processes related to unauthorised medicines, goods requiring special permits, pharmaceutical statistics, drug safety, and supply chain issues. Samtrack's importance has grown each year – it now serves as a comprehensive platform that integrates various procedures and data flows, supporting the State Agency of Medicines' daily operations as a whole.

During Samtrack's new development phase, we continued to improve the existing system. Over the course of the year, we made several improvements to Samtrack's marketing authorisation module. Database enhancements have made workflows smoother and more user-friendly, providing better support for the work of specialists and thereby ensuring further improvements in data quality. It is often precisely these consistent yet less visible improvements that create long-term value.

The State Agency of Medicines' development work is also taking on an increasingly clear international dimension. Last year, we presented the Samtrack solution to medicines agencies in other European countries on several occasions and shared our experiences integrating it with European Medicines Agency (EMA) information systems. Samtrack has attracted attention beyond Estonia and stands out as a leading example of how a national information system can be flexible, reliable, and forward-looking.

A new gateway for customers: the customer portal

One of our most ambitious projects of the year was the launching of the development of a new customer portal. During 2025, we established the necessary infrastructure for future developments and completed the initial design of the reporting user interface. This is a long-term investment aimed at providing our partners with a convenient, unified, and intuitive channel of communication with the State Agency of Medicines. Development will continue in the coming years.

People and dedication are at the heart of our development

Technology is merely a tool; real change is brought about by people. Over the course of the year, new members joined our development team, bringing fresh energy and additional expertise with them. At the same time, the product portfolio of the systems we manage has grown and become clearer. Alongside technical developments, we have focused on enhancing the skills of our team members to ensure smoother collaboration and more efficient implementation of developments.

Overall, we made balanced progress with the State Agency of Medicines' developments in 2025. More systematic processes, more mature solutions, and a strengthened team have created a solid foundation for further development, helping us to better fulfil the State Agency of Medicines' primary objective of ensuring that information and decisions relating to medicines are reliable, transparent, and up to date.

Communication efforts focused on pharmaceutical waste and drug safety

Carmen Katariina Sikk



In this age of information overload, having science-based information available is simply not enough. It is vital that this information reaches people in a way they can understand and that it supports their everyday choices and decisions. This also forms the basis of the State Agency of Medicines' approach to planning our communication and public information work. Our aim is to be visible in the public debate, both as a responder and a guide, providing science-based information at the right time and in the right place.

Digital information channels as the foundation of communication

Well-functioning digital information channels play a key role in achieving visibility. For this reason, we placed greater emphasis than ever before on the development of the State Agency of Medicines' digital channels and content creation in 2025.

We systematically improved the Agency's website to make the information there easier for the public, healthcare professionals and partners to find and understand. We grouped similar topics together and created new sections as needed.

We also focused on developing the State Agency of Medicines' blog, which has now become an important source of information for both healthcare professionals and patients. On the blog, we cover various topics related to medicines and medical devices, and share tips and recommendations from specialists. Last year, our most popular posts were viewed thousands of times, shared by healthcare professionals, and referenced by media outlets.

In 2025, we deliberately increased the State Agency of Medicines' presence and visibility on social media. In the spring, we joined LinkedIn, a platform that enables us to showcase the Agency's work and activities more effectively in a professional and international context. LinkedIn complements our existing information channels and facilitates collaboration with partners and target groups in Estonia and beyond.

A more strategic approach, the implementation of new ideas and the new visual identity launched in the second half of 2024 clearly contributed to our increased visibility. The State Agency of Medicines' social media following grew steadily throughout the year, and we set several records for reach and engagement. Our posts were viewed more than 3.5 million times, confirming the importance of digital channels.

Awareness-raising is an important part of prevention work

In the public sphere, particularly on social media, information moves faster than ever before, and the battle for people's attention is fought in seconds. Unfortunately, a great deal of misleading information is also circulating, which is why the role of preventive awareness-raising in communication is becoming increasingly important.

Over the course of the year, we carried out several awareness campaigns aimed at raising public awareness of medicine-related issues, with the aim of encouraging people to rely on evidence-based information so they can look after their own health and that of their loved ones.

The first campaign, which took place in May, focused on pharmaceutical waste. It aimed to draw attention to the risks associated with using expired medicines and to the correct disposal of pharmaceutical waste. We mainly shared the campaign materials on social media, and by collaborating with pharmacies, hospitals and GP centres, which distributed them further, our information materials reached an even wider audience. Feedback confirmed that people need practical and clear information on sorting pharmaceutical waste.

The topic of pharmaceutical waste was not limited to this campaign alone. In collaboration with the Ministry of Social Affairs and the Estonian Academy of Arts, we carried out a pilot project in Pärnu, testing innovative pharmaceutical waste containers in pharmacies. We were involved in the project from developing solutions right through to the planning of communication activities, and the results were also very positive.



In September, the pan-European medicine safety campaign 'Medicines are not sweets' took place, was launched in collaboration with the medicines agencies of Estonia, the Netherlands, France, Sweden, and Spain. This cross-border cooperation enabled us to pool our knowledge and experience, resulting in the campaign attracting attention in many European countries.

In October, together with the Association of Pharmaceutical Manufacturers and GPs, we ran the campaign "If you're looking for information about medicines online, always check the Register of Medicinal Products". The campaign aimed to encourage people to critically evaluate information about medicines and health found online and to use official channels as their primary source when searching for such information.

Whilst in 2024 the State Agency of Medicines' awareness-raising work focused primarily on raising young people's awareness of medicines, in 2025 we also paid greater attention to older people. As people age, their use of medicines increases, so awareness of how to use them correctly and safely is particularly important. We gave lectures at the University of the Third Age, which were attended by over 250 people, as well as at the Imavere Day Centre and the Haabersti Activity Centre. The feedback on the lectures was positive, and we will continue giving them in the new year.

Effective communication is achieved through collaboration

We would like to thank the pharmacists, GPs, international colleagues, and other professionals and organisations with whom we planned and carried out communication activities last year. It is precisely through cooperation that we can convey important and reliable messages to a wider audience than ever before.

Promoting the pharmaceutical sector here

Triin Suvi, Liis Prii, Aet Viispert

Local pharmaceutical production plays a vital role in healthcare systems, particularly by facilitating access, and means less dependence on international supplies. Supporting local pharmaceutical development stimulates economic growth by creating jobs in manufacturing, research, and marketing. It also encourages innovation and helps to develop a skilled workforce in the sector.



Supporting the development of the pharmaceutical sector is part of the State Agency of Medicines' mission, and is therefore integral to our day-to-day work. We believe it is important to support Estonian pharmaceutical developers and manufacturers on their journey with our expertise, helping them to become trusted partners beyond Estonia's borders. Navigating regulatory and scientific requirements is challenging, and developers should not have to manage this alone.

Support is needed not only for new initiatives and innovation. For example, academic clinical trials are often hindered by a lack of information needed for day-to-day work, such as suitable drug dosages for children, and so on. We can also assist the Estonian medical community with designing and conducting drug trials.

The first manufacturer of active pharmaceutical ingredients for biological medicines in Estonia

Last year brought a major change to the Estonian pharmaceutical industry. Specifically, the first manufacturer of active pharmaceutical ingredients for biological medicines began operating in Tartu. This process took place in two stages: first, Icosagen Cell Factory (which is responsible for producing the active substances) applied for a licence to manufacture medicines; and second, Icosagen AS's pharmaceutical microbiology laboratory (which is responsible for performing various microbiological tests) applied for a licence. Cooperation with Icosagen began several prior to the licence applications being submitted. Early communication helps identify potential bottlenecks and familiarises the parties with the licence application process. This helps to prevent problems during the licence application process. Icosagen's licence application process went smoothly, and they now have a licence to produce various antibodies that are used as active pharmaceutical ingredients.

New operational active pharmaceutical ingredient manufacturing facility

In 2025, TBD Pharmatech, a manufacturer of active pharmaceutical ingredients, completed a construction of a new production facility that began operating alongside the existing facility. The company has worked closely with the authorities for several years to ensure the gradual commissioning of the new plant. The manufacturing authorisation granted at the end of April was amended at the end of the year to permit the use of the production-ready premises. We have already verified compliance with Good Manufacturing Practice (GMP) requirements, and as a result, the company will shortly receive a GMP certificate confirming compliance for the first commissioned production facilities. This assures our customers that we produce high-quality, safe active ingredients, and that a successful investment has been made in the Estonian economy.

Pharmapark Production, a manufacturer of veterinary medicines that began operating in 2024, commissioned a new production unit for non-sterile sprays and oral solutions last year. This unit has also been granted GMP certification, confirming compliance with good manufacturing practice. Given that Pharmapark Production has begun collaborating with the Estonian veterinary medicine manufacturer Interchemie Werken De Adelaar Eesti AS, we can also expect changes to the operations of both companies in the coming years. We are pleased to note that we have established a good, mutually beneficial form of cooperation with both companies, which we intend to continue.

A supportive regulatory environment

In addition to supporting drug developers on substantive issues, we also play a key role in creating a supportive legal framework. In 2024, we began preparing amendments to the provisions regulating hospital prescriptions, which came into force in May 2025.

A hospital exemption refers to the exceptional preparation and use of novel medicines (such as gene and cell therapy products) for a small number of patients in Estonia. These medicines are used based on an individual prescription from a specialist, who is responsible for their use. Previously, the requirements were very strict: a hospital exemption permit was granted for the treatment of up to 10 patients or for up to two years, whichever condition was met first. The new requirements are significantly more flexible in this regard: there is now no limit on the number of patients who can be treated under the hospital exemption scheme and, once the hospital exemption permit has expired, it can be extended repeatedly. Other changes have also been made, and we organised an information day for stakeholders in June to discuss them. We will certainly see the impact of these changes in the coming years.

Development Strategy, Direction 1: Value-creating medicinal product information

Medicine information – clearer, more accessible, and more user-friendly



Keiu Lember

Medicines information plays a vital role in healthcare decision-making. Our aim is therefore to ensure that reliable, clear, and up-to-date information on medicines is available to patients, healthcare professionals, and other stakeholders. In 2025, our focus in developing medicines information was primarily on user-friendliness, collaboration, and raising public awareness.

We discussed the current situation of clinical trials in Estonia and sought ways to simplify and facilitate their conduct in collaboration with representatives from hospitals, doctors, research institutions and pharmaceutical manufacturers. During the discussions, it was noted that the number of trials has fallen and that few young doctors are interested in participating in them. The State Agency of Medicines has set itself the goal of improving access to information on clinical trials and ensuring faster authorisation processes for trials in the future.

Drug safety also played a key role in our awareness-raising work. Last year, we delivered lectures to doctors and pharmacists, emphasising the importance of reporting adverse reactions and accessing drug information and risk-reduction measures. We also addressed the risks of medication errors and the safe use of medicines across different age groups. We also summarised our experience to date with the vaccine injury compensation system in the journal *Eesti Arst*.

On 1 January 2025, the Medical Devices Department joined the State Agency of Medicines, having previously been part of the Health Board. We involved our new colleagues in strategic activities. Throughout the year, we ran various training sessions for both healthcare and educational institutions, introducing them to the world of medical devices and applicable requirements.

To raise awareness among medicine users, we shared information in both schools and day centres. Discussion groups held specifically for older people and a 'University of the Third Age' lecture attended by 250 older people proved particularly popular, with participants highly valuing the practical advice on the correct use of medicines. Around 250 young people took part in our workshops over the course of the year. We helped both young people and older adults understand how medicines work and how to use them safely.

Next steps in our digital initiatives

Significant progress has been made in the area of digital solutions for medicine information: package leaflets and safety information are now accessible via the Health Portal when a prescription is dispensed. Medicine users can access the electronic package leaflet, which is always up to date and easily accessible. This digital solution aims to encourage people to read the electronic package leaflet, while reducing the need for paper leaflets. This improves access to medicines, particularly for those with foreign-language packaging or which are marketed at the request of a professional association when there are supply difficulties. While risk-reduction materials intended for patients should be provided by a doctor or nurse, or included in the packaging, their additional availability via the Health Portal offers an additional opportunity to mitigate risks. Additional risk-reduction materials are expected to reach doctors' digital workspace during 2026. These materials will ensure the safer use of medicines, raise awareness of significant safety issues associated with medicines, and describe actions to prevent or reduce these risks. The ultimate goal is for both doctors and patients to be able to access the necessary information automatically and without any unnecessary intermediate steps in the future.

The State Agency of Medicines website has been made more user-friendly. Its structure has been improved, its search options enhanced, and its content reorganised. These updates make it easier to find the information you need, and user satisfaction with the website has clearly increased as a result. At the same time, work began on updating the English-language section of the website to make the information more accessible to international users.

A significant development last year was that information on clinical trials became more accessible via the CTIS (Clinical Trials Information System) interactive map, which is managed by the European Medicines Agency. The map enables anyone interested – including patients and doctors – to search for clinical trials by location, disease, or medicine, and find out whether a trial is currently recruiting patients. Since October, the map and detailed search function have been available in all European Union languages, including Estonian. We now direct interested parties straight to the CTIS portal from our website, providing a significantly better opportunity than before to find clinical trials in which to participate or refer a patient to participate, either across Europe or specifically in Estonia. There are diseases and conditions for which clinical trials represent the only or final treatment option.

Development Strategy, Direction 2: An Innovative and Valued Partner

Focus on the development of scientific advice and an advisory role in sharing best practices



Jana Danilovič

One of the directions of the development strategy is to enhance our advisory role. A year ago, the State Agency of Medicines' advisory role was strong. We created a best-practice document that became an appendix to our quality manual, the guiding principles of which are permanently displayed on the walls of our organisation. To ensure that the document was implemented, we introduced the best practice principles to all staff members. In addition, we held a practical workshop on case analysis and exchanged experiences in a discussion group.

Another key area of focus is the development of our scientific advice service. Last year, in the benchmarking of the State Agency of Medicines' quality systems (BEMA), the organisation of our scientific advice service was awarded four out of five points. Our goal this year is to join the European Medicines Agency's Scientific Advice Working Party (SAWP) in order to achieve the maximum score. We are currently participating as observers in the Simultaneous National Scientific Advice (SNSA) working group within the EU Innovation Network. The working group provides advice on both clinical trials and pan-European marketing authorisation procedures. In 2025, the State Agency of Medicines was asked to provide scientific advice on two planned academic clinical trials. Additionally, 30 meetings were held with pharmaceutical manufacturers, during which we provided regulatory/pre-submission advice.

When assessing the need to expand the competence and services of the State Agency of Medicines' laboratory, the development of analytical capabilities for nitrosamines was a key consideration. Currently, no single device is capable of analysing nitrosamines in all active substances, and few methodologies for doing so are available. The development and validation of new methodologies is also very costly. Therefore, we concluded that investing in such a device is not reasonable, and that it is more practical to continue commissioning nitrosamine analyses from external laboratories. Should the number of samples increase significantly or regulatory requirements explicitly necessitate it, the need to acquire such a device should be reassessed.

In our day-to-day work, we monitor stakeholders' needs for updated legislation and identify areas of current legislation that require amendment.

Estonia's interests must also be safeguarded within the legislative process of the European Union. We submitted 38 proposals regarding the European Union's draft legislation on medicinal products, 10 of which were taken into account. These proposals covered technical and substantive issues and reflected the interests of a small country. For example, they allowed for multilingual and electronic package leaflets.

We translated the guidelines for the amending regulation into Estonian to make them clearer and easier for local marketing authorisation holders in Estonia to understand.

Development Strategy, Direction 3 Sustained national capacity to guide and develop the medicines sector

A caring and sustainable State Agency of Medicines: sustainable capacity in the pharmaceutical sector



Reelika Jõgi

The ability to steer and develop the pharmaceutical sector starts with people. In 2025, we at the State Agency of Medicines focused on ensuring that the working environment was motivating and balanced, and that our operations became more environmentally friendly. At the same time, we kept two issues in focus: how to support staff development and ensure that the workload remained reasonable.

The development of our specialists is one of the cornerstones of the organisation's core capability. We want every specialist to have a clear career path and the opportunity to continuously develop their skills. Last year, we created a specialist development chart, updated the training plan, and produced a guide to best practice for mentors. We also revised the cover plan and added a question about cover quality to the annual manager-specialist performance review. These measures allow us to prevent overwork and maintain service quality, even during periods of absence due to holidays or illness.

Well-being is part of capability. In 2025, we were awarded the peaasi.ee mental health value-based organisation label, which helped us analyse our existing activities and plan the next steps to support employees' mental health. We conducted our first job satisfaction pulse survey. This year, we will continue with the pulse survey on a quarterly basis to identify changes early on and prevent concerns from escalating.

Sustainability is becoming an integral part of our day-to-day work. We have continued to measure our greenhouse gas footprint and organise regular lectures and joint events on environmental topics. Our sustainability activities were highly rated in the agency's health survey: 6.2 out of 7. The involvement of two green ambassadors has provided momentum and ideas, and will help us implement new initiatives in 2026.

In 2025, we launched the Medicines Agency's LinkedIn page to maintain connections with our staff, partners, and the public. We also continued to improve the user experience of our website so that important information is easier to find and presented more clearly.

The steps taken in 2025 have laid a strong foundation for the ongoing development of a caring and sustainable Medicines Agency. If we support our people and enable them to grow alongside the organisation, we will continue to provide expert knowledge and be a reliable partner to both citizens and businesses.

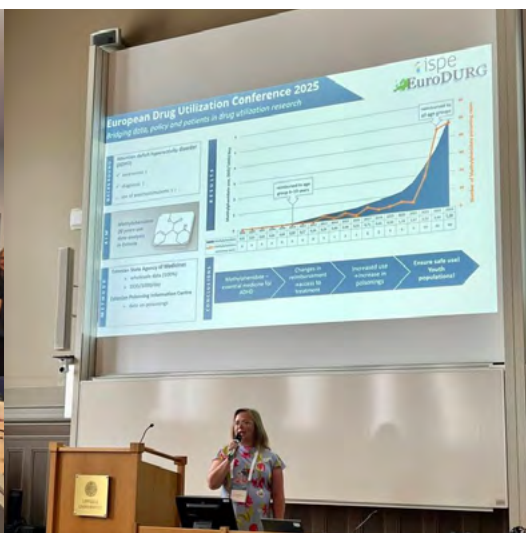
International cooperation

International cooperation at the laboratory

We also engage in international cooperation in the field of medicines quality control. The laboratory is a member of the Network of Official Medicines Control Laboratories (OMCL). The network is coordinated by the European Directorate for the Quality of Medicines and Healthcare (EDQM). This cooperation network ensures the international recognition of analytical results and encompasses the majority of the 59 European Medicines Agency laboratories.

Cooperation in the field of biological products

There have been many changes in the field of Substances of Human Origin (SoHO) in recent years. A new European Union regulation was adopted in 2024, which will come into force in August 2027. To ensure that the regulation is adopted as smoothly as possible, the European Commission has established the SoHO Coordination Board and its six working groups. These working groups are responsible for preparing guidelines for implementing the new regulation and, where necessary, providing support in resolving issues raised by Member States. For example, one working group has been tasked with the responsibility of addressing regulatory issues. All Member States are invited to submit questions regarding the new regulation, and the working group's responses will be published online to ensure consistent interpretation across all Member States.



The working groups also address various issues, such as harmonising Member States' approaches to planning inspections and granting operating licences, and assessing which SoHO preparations are critical from a national perspective on a uniform basis. Member States organise the substantive work and management of the working groups, whilst the European Commission provides technical support and helps organise working group meetings. This working arrangement gives all countries the opportunity to contribute. Four colleagues from the State Agency of Medicines participate in all working groups.

International cooperation in the field of medical devices

In the field of medical devices, we collaborate within the working groups of the Medical Device Coordination Group (MDCG), where the State Agency of Medicines is represented by nine members. Through this cooperation, we gain valuable insights and, in turn, contribute our knowledge and experience to discussions, the drafting of guidelines, and the ongoing process of amending legislation. The working groups play a key role in harmonising practices across Member States. We also participate in the work of the Competent Authorities for Medical Devices (CAMD), a network comprising representatives of the competent authorities for medical devices in the Member States. In addition to these ongoing forms of cooperation, the JAMS 2.0 project (Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Diagnostic Medical Devices) is currently underway, carrying out activities to develop and strengthen market surveillance in the sector. We are participating in an EU-wide campaign to monitor the activities of selected device manufacturers, with the aim of developing tools for conducting similar campaigns in the future.

In 2025, preparations were made for legislative amendments. A study conducted by the European Commission from 2023–2024 on two major sectoral EU regulations, (EU) 2017/745 (the MDR) and (EU) 2017/746 (the IVDR), has been completed. The aim of the study was to assess the impact of these regulations on innovation in the sector and patient safety, and to identify the benefits and challenges. The expectation is that bringing new and urgently needed medical devices to market will be easier and faster, without compromising on safety. The European Commission published its proposals on 16 December 2025. Discussions will continue in 2026. In June of last year, Implementing Regulation (EU) 2025/1234 was also published, expanding the possibility of supplying medical devices exclusively with electronic instruction manuals.

Update of the European list of critical medicines

For two consecutive years, the State Agency of Medicines has participated in the updating of the European Union's list of critical medicines. First published in 2023, the list is updated annually. Specialists in supply shortages from all EU Member States contribute to the update, providing assessments of a medicine's indications and the availability of alternatives in accordance with a standardised methodology. The latest version, published in December 2025, is available on the European Medicines Agency's website.

Cooperation between Nordic pharmacy inspectors

In September 2025, our representatives attended the annual meeting of pharmacy inspectors from the Nordic medicines agencies, which was held in Oslo and hosted by the Norwegian Medicines Agency. This cooperation format was established on the initiative of the Nordic Medicines Agencies, where specialists in the field exchange professional information and experiences and discuss common challenges. Topics discussed at the 2025 meeting included the organisation of European Union prescriptions and cross-border data exchange, the protection of personal data in pharmacies, the verification of medicine authenticity using security features, substitution of medicines in the event of supply difficulties, the verification of data relating to operating licences, and the quality of pharmaceutical advice. The challenges relating to the supervision of pharmacies are similar across the Nordic countries, which underscores the importance of regular cooperation and the exchange of experiences.



Year of Streamlining the Legal Framework

Andrus Varki

The Legal Department's task is to provide the agency's specialists with legal support that helps them make balanced and considered decisions to protect people's health amidst the constant evolution of the pharmaceutical sector.



Last year, we continued to streamline the legal framework governing our areas of supervision, introducing greater flexibility in the process. Life changes faster than the law. Legal rules that take account of general developments help healthcare providers, drug developers, and distributors keep pace with sector developments. Flexibility does not mean arbitrariness. Good legislation is clear enough for everyone to understand the rules, while also be flexible enough to be fair in real life. Flexible legislation takes into account differences between people and situations, supports drug development and the development of the sector more broadly, and increases public trust in the state.

In 2025, changes were made regarding the manufacture of medicines under a hospital exemption, allowing for more flexible extensions and amendments to authorisations. This improves patients' access to treatment. We merged the responsibilities of the Ethics Committee for Medical Device Investigations and Performance Studies and the Ethics Committee for Clinical Trials of Medicinal Products, meaning that trial sponsors no longer need to submit multiple applications.

In 2025, we made the following proposals:

- to extend the right to prescribe medicines to dentists and midwives;
- to allow for exceptions for providers of vital services in emergency situations, in specific cases, and under defined conditions;
- to simplify the requirements for the import and export of goods requiring a special permit (in certain cases, replacing the application for a permit with a notification, and in certain cases, neither is required);
- to allow for the repeated prescription of narcotic medicines (when a prescription is issued multiple times, the next prescription is activated upon the previous one being dispensed), etc.;
- to reduce bureaucracy, so that supervision of healthcare or veterinary services and medicines is carried out by a single authority.

Legal activities

We have also made various proposals to the Ministry to streamline the legal framework by removing outdated provisions. One of the most extensive proposals last year was the proposal to amend the Medical Devices Act.

Unfortunately, the implementation of the legislation has also given rise to various disputes. Last year, we were involved in 14 court cases, 12 of which involved us acting as an expert body, providing assessments on the presence or absence of possible vaccine side effects. Five of the disputes reached a final resolution, with the courts agreeing with our position in four of them. In one case, the Supreme Court found that the legal provision was not in accordance with the Constitution. Proceedings in nine cases are ongoing.

Our international activities were linked to the review of new pharmaceutical regulations in the European Union. We help shape Estonia's positions in the formulation of requirements within the European Union. We also share our knowledge and experience within the European Medicines Agencies' cooperation network and the EMACOLEX working group, which deals with legal and regulatory issues.

In April 2025, the State Agency of Medicines successfully underwent the Benchmarking of European Medicines Agencies (BEMA) assessment. The Legal Department assisted in preparing the section on transparency of decisions. We reviewed whether information required to be made public was also accessible to stakeholders, market participants, and the wider public, as well as addressing data protection issues. The auditors awarded the Agency the maximum score of 5 in this area.



The people at the heart of the State Agency of Medicines

Mari Kompus

As of 2025, the State Agency of Medicines employs 131 people. Our team brings together leading specialists from various fields, including pharmacists, doctors, chemists, veterinarians, cell biologists, genetic engineers, nurses, lawyers, and representatives of many other professions.



Last year, we conducted an employee satisfaction survey. When asked, 'What do you like most about working at the State Agency of Medicines?', employees highlighted the presence of good colleagues and a positive working atmosphere, the importance and diversity of the work, as well as flexibility and mutual trust. Several respondents emphasised the opportunities for self-development and professional growth. It is beneficial to strive towards common goals together.

Last year, the Medical Devices Department rejoined the State Agency of Medicines, having moved to the Health Board in 2010. At the start of our journey towards a unified work culture and shared values, it became important to support our new colleagues and ensure a smooth induction process. Last year, a total of 22 new employees joined us, so the year was filled with learning, mentoring, and adaptation.

Over the course of the year, we took part together in various training sessions focusing on taking responsibility, time management, and coping with work-related stress.

In October, we were awarded the Mental Health Friendly Workplace Label. Safeguarding our employees' mental wellbeing is a priority for us. We offer counselling services, organise training sessions, and actively participate in *peaasi.ee* initiatives. Receiving the label was important recognition of the conscious and systematic work we have done so far.

Around half of the State Agency of Medicines' staff work from home on a daily basis, and hybrid working is also widely practised. At the same time, we consider regular office meetings to be important and value the time spent together outside the workplace. Over the course of the year, we took part in a number of joint activities, including a cycling trip and CrossFit training sessions. September, 'Movement Month' offered staff a variety of memorable experiences, resulting in more than 1.3 million steps being taken.

As every spring, we recognized those who embody the values of the State Agency of Medicines. As in previous years, all employees participated in selecting the recipients of Values Awards. Receiving one of these distinctions is considered a valued recognition within our organization.

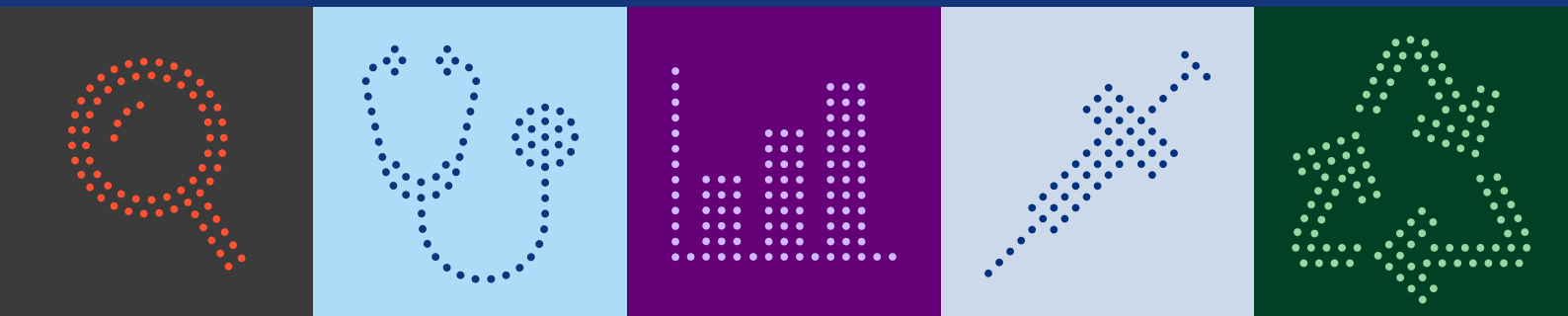
The strength of the State Agency of Medicines lies in its dedicated people, who are not just colleagues – we are one united whole!

Our people



Our people





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