State Agency
of Medicines
Republic of Latvia

State Agency of Medicines

ANNUAL REPORT 2025

Contents

Abbreviations

Agency	State Agency of Medicines
ATMP	Advanced Therapy Medicinal Product
BKUS	Children's Clinical University Hospital
CAP	Centralised authorisation procedure
CHMP	Committee for Medicinal Products for Human Use
CDC	Centre for Disease Prevention and Control
CM	Cabinet of Ministers
CTIS	Clinical trials information system
DCP	Decentralised authorisation procedure
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
FVS	Food and Veterinary Service
GMP	Good Manufacturing Practice
HI	Health Inspectorate
HMA	Heads of Medicines Agencies
ICT	Information and communications technology
ISO	International Organization for Standardization
IT	Information technology
LATMED	Electronic database of the Registers of Medical Devices
LFB	Pharmacists Society of Latvia
MAH	Marketing authorisation holder
MH	Ministry of Health
MRP	Mutual recognition procedure
NHS	National Health Service
OMCL	Official Medicines Control Laboratory
PRAC	EMA Pharmacovigilance Risk Assessment Committee
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PSKUS	Pauls Stradins Clinical University Hospital
SAMIS	State Agency of Medicines information system
SBDC	State Blood Donor centre
SoHO	Substances of human origin
SOP	Standard operating procedure
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

Forewords

Indra Dreika,
Director of State Agency of Medicines

The year 2025 has come to an end. It was a colourful and eventful year at the State Agency of Medicines

There are things that we managed to plan and accomplish exceptionally well, and I would like to begin with those.

We were a reliable cooperation partner for the Ministry of Health, the pharmaceutical sector, and society as a whole in planning the medicines pricing reform, monitoring the impact of policy decisions, as well as informing the public and explaining the changes. Throughout the year, we analysed and monitored changes in medicine prices, but considered the actual availability of medicines to the population to be the most important aspect, regarding any potential changes in their availability as the greatest risk. We gained valuable experience, as well as new tools and instruments. An indirect effect of the medicines pricing reform is increased transparency of the pharmaceutical distribution market, which, from the middle of 2026, will enable monitoring of medicine availability in pharmacy chain stock.

We were also successful in planning our budget. In 2025, the European Medicines Agency introduced changes to its fee schedule, and Latvia also began applying a revised schedule of fees. The Agency's fee schedule was redesigned, taking into account the risks and needs of the sector, while also being aligned with the objective of promoting the authorisation of new medicines and, most importantly, their availability in Latvia. We are moving towards a model in which a greater share of revenue is generated from services required by the sector rather than from annual fees.

We abolished the annual pharmacovigilance fee, reduced the authorisation fee,

and, in the future, discounts will be applied to promote the availability of medicines. Fees for participants in the pharmaceutical distribution market remained unchanged, as they had already been affected by the medicines pricing reform. Additional challenges arose from the centralisation of accounting services within the Shared Service Centre of the public administration. I mention this to emphasise the financial risks with which we entered 2025. Nevertheless, both careful planning and budgetary control throughout the year enabled us to cover all necessary expenditure, invest in development, and strengthen our confidence that the chosen direction for our budget planning is the right one.

In 2025, we successfully addressed cybersecurity challenges, actively contributed to the development of new European legislation, worked on the establishment of the list of critical medicines, and strengthened cooperation with Latvian and European partners, patient organisations, the pharmaceutical sector, and society. We openly explained complex issues, built mutual trust, and demonstrated that clear communication is just as important as professional decision-making. Most importantly, throughout all these activities, we believed that we could do even better.

The completion of the reconstruction of the archive building became a particularly symbolic event. In May 2025, both the archives and our colleagues returned to renovated, modern, and comfortable premises that will serve the Agency for many years to come.

In 2025, there were also things we did for the first time.

One of the most significant events was the Patient Organisations Forum, which strengthened dialogue with the public and patient representatives. We expanded our international cooperation by establishing new contacts and launching new projects. Cooperation agreements were signed with institutions in Ukraine and Uzbekistan. We actively contributed to the development of the regulatory framework for substances of human origin (SoHO), working closely with all relevant stakeholders in Latvia. We also began exploring the opportunities offered by artificial intelligence in our day-to-day work. Together, we participated in the Riga Marathon. And we started paying greater attention to our own well-being – to how we feel in our daily work and what each of us can do to work in a healthier, more sustainable and more fulfilling way.

Of course, there were also areas in which we continued to work consistently and professionally, carrying out the functions that society and the State expect from us. Like the entire public sector, we sought opportunities to reduce bureaucratic requirements, shorten processes and discontinue activities that no longer create added value. This work will continue in the years ahead.

Looking back honestly at the Agency's performance over the past year, I must acknowledge that not everything was accomplished as well as we had hoped. There are areas where we would have liked to see faster progress.

We still need to strengthen our ability to focus on results and the achievement of our objectives, rather than solely on performing functions. We need to enhance cooperation among colleagues, organisational units, in-

stitutions and partners. We must continue improving resource planning and balancing workloads. Greater attention should be paid to the timely identification and assessment of risks. We also seek faster development of the State Agency of Medicines' information systems and more effective use of digital solutions. We have not yet succeeded in identifying and implementing a convenient, commonly used tool for work planning and monitoring, whether a digital platform or another fully functional system.

However, these are precisely the areas that define our future development objectives. In 2026, we will continue to launch new initiatives, implement digitalisation projects and expand international cooperation. It will also be a special year in the history of our organisation – in October 2026, the State Agency of Medicines will celebrate its 30th anniversary. Therefore, we already know what we will be doing for the first time – this will be the first time the Agency celebrates such a milestone. Over the past thirty years, the Agency has become an important part of the Latvian and European medicines regulatory system, and this anniversary year will provide an opportunity not only to reflect on what has been achieved, but also to clearly define our future development goals.

I would like to thank every employee of the Agency, every cooperation partner and every professional in the sector for their contribution to our shared work.

See you in the anniversary year of the State Agency of Medicines!

About the Agency

The State Agency of Medicines is a State institution under the supervision of the Minister of Health, the activities of which are regulated by the Law on Public Agencies, the Law on the structure of State administration, the Law on Pharmacy, Cabinet Regulation No 537 of 31 July 2012 on the Statute of the State Agency of Medicines and other regulatory enactments. The Agency was established on 9 October 1996. As of 16 February 2023, the Director of the Agency is Indra Dreika.

THE AIM OF THE AGENCY'S

activities is to implement high-quality and justified services in the assessment of places of procurement and use of medicinal products used in health care, human blood, tissues, cells and organs, as well as pharmaceutical activities in accordance with the interests of the state and society in the health care sector.

MISSION OF THE AGENCY

The Agency works in the public interest to ensure that citizens have access to safe and effective medicines, medical devices and biological materials of human origin.

VISION

Agency – a professional public administration institution focused on development and high quality of services, which is respected by the public, customers, national and international collaboration partners.

FUNCTIONS

- evaluate and authorization of medicines
- establish and update the Register of Medicinal Products
- carry out an assessment of the quality of the medicinal product
- perform pharmacovigilance of medicinal products
- performs vigilance of medical devices
- issue authorisations for the conduct of clinical investigations of medicinal products and medical devices;
- assess compliance with the requirements of good clinical practice, good manufacturing practice and good distribution practice;
- issue authorisations for the import, export, transit, distribution and use of medicinal products;
- compile and provide information on the consumption of medicinal products;
- licenses pharmaceutical activities
- assess the cost-effectiveness of medicinal products and medical devices;
- approve medical technologies used in medical treatment
- and other functions

In 2025, the Agency operated as a public agency, and its financing was mainly ensured through revenue generated from fee-based services.

Agency Activities in the Reporting Year

Marketing authorisation of medicines

Dace Peiseniece,
Head of Medicines Marketing Authorisation Department

In 2025, the Medicines Marketing Authorisation Department continued to ensure a high-quality, evidence based and public health-oriented medicines authorisation process in Latvia. Efforts were focused on ensuring that safe, effective and high-quality medicinal products become available on the Latvian market.
In 2025, a stable workload intensity was maintained, successfully managing both national and European-level authorisation procedures, while also actively participating in international expert groups. The Medicines Marketing Authorisation Department continued its close cooperation with the Pharmacovigilance Unit (ensuring a unified approach to medicines safety monitoring), the Medicines Examination Laboratory (ensuring quality control of medicines and compliance with established standards), and the Initial Assessment and Procedure Coordination Unit (ensuring the availability of the necessary documentation for assessment and monitoring compliance with procedural timelines). This cooperation ensured a unified, coordinated and transparent medicines authorisation process.
The Medicines Marketing Authorisation Department actively participated in the working groups and scientific committees of the European Medicines Agency, as well as in

mutual recognition and decentralised procedures, ensuring the contribution of Latvian experts to the common European medicines evaluation process and to regulatory cooperation networks promoting the exchange of knowledge and implementation of best practices. This involvement strengthens Latvia's reputation as a reliable and professional partner within the European medicines regulatory system.

Despite these achievements, 2025 was also marked by a significant challenge – insufficient human resources and limited capacity, which affected work planning and workload management. This factor required particular attention to process prioritisation and efficiency improvement.

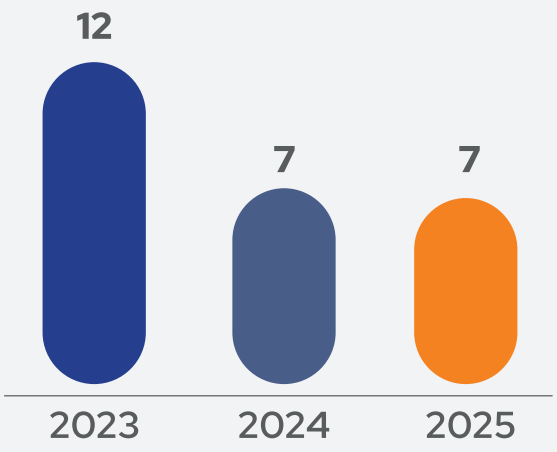
Last year, Latvia, acting as the Reference Member State (RMS), carried out 40 marketing authorisation and renewal procedures for medicines within the Decentralised Procedure (DCP) and Mutual Recognition Procedure (MRP).

At the same time, Latvia participated as a Concerned Member State (CMS) in 416 MRP and DCP marketing authorisation and renewal procedures for medicines.

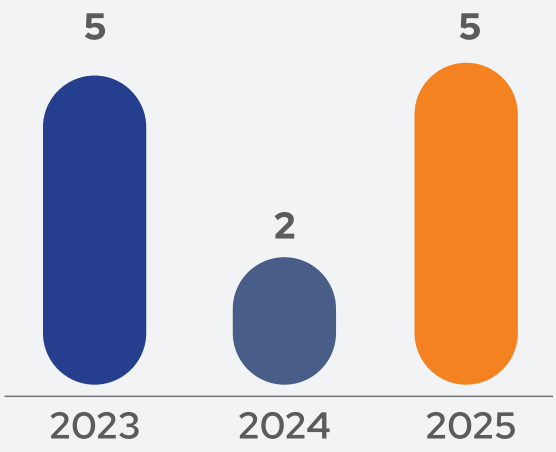
In 2025, compared with the previous year, the number of variations to medicines marketing authorisation documentation remained similar to 2024; however, the number of evaluated variations for which Latvia acted as the RMS increased. There was also a significant increase in the number of variations evaluated within Latvian worksharing (WS) procedures: 24 variation procedures in 2025, compared with 7 in 2024, 6 in 2023, and 4 in 2022.

The rapid increase in the number of WS variation procedures is related to the amended Variations Regulation No. 1234/2008, which entered into force on 1 January 2025 and stipulates that Type IB and Type II variations must be submitted through the worksharing procedure.

Marketing authorisations via national procedure with positive outcome



Medicinal product renewals via national procedure



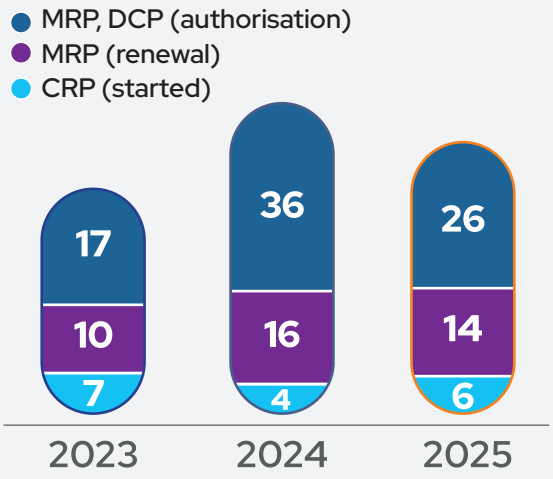
In accordance with the above-mentioned Regulation, which now allows medicines authorised via national procedure to be included in Type IA super-grouping procedures, five Type IA super-grouping variation procedures were assessed in 2025. No such procedures had been conducted during previous periods.

In 2025, the Agency's experts assessed five applications and issued opinions regarding product compliance with the definition of a medicine. Last year, responses were also provided to enquiries from residents and Latvian institutions regarding various issues related to medicines marketing authorisation and safety, as well as other matters.

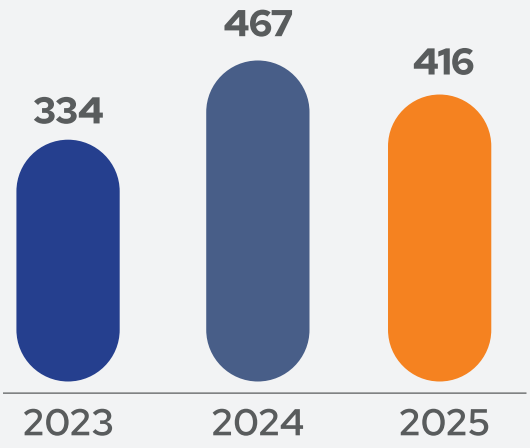
Experts of the Agency's Medicines Marketing Authorisation Department informed sector representatives about current developments in medicines authorisation both during the Agency's informational seminars – Client Days – and through in-person meetings with representatives of manufacturers.

In 2025, the Agency issued 247 Free Sale Certificates and Product Certificates, thereby promoting the export of medicines authorised in Latvia to countries outside the

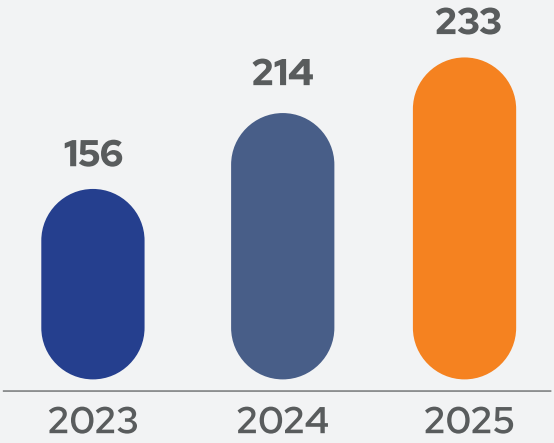
Marketing authorisations and renewals (Latvia as a Reference Member State)



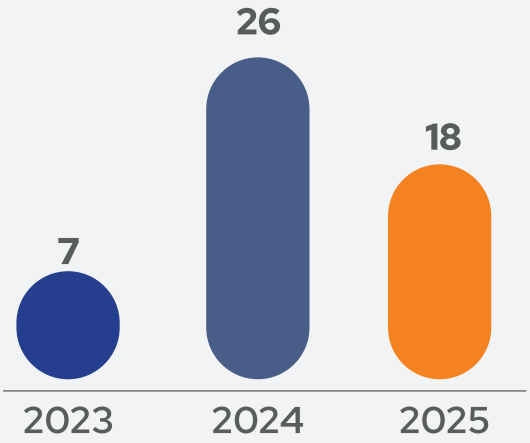
Marketing authorisations and renewals (Latvia as a Concerned Member State) with positive outcome



Type IA/IB variations (Latvia as a Reference Member State) with a positive outcome



Type II variations (Latvia as a Reference Member State) with a positive outcome



European Union. These certificates confirm that companies manufacture medicines in compliance with Good Manufacturing Practice, in accordance with strict and harmonised quality standards and requirements.

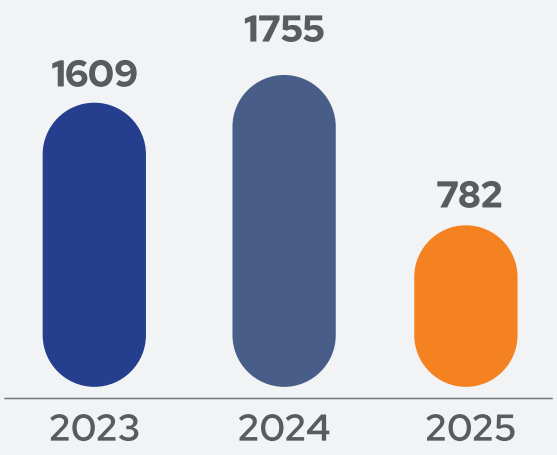
As in previous years, the Agency's experts remained highly active in international cooperation within the European medicines regulatory network. Agency experts carried out scientific evaluation in five centralised marketing authorisation procedures (CRP) initiated already in 2024, as well as in several variation procedures concerning centrally authorised medicines.

Experts of the Medicines Marketing Authorisation Department and external experts actively participated in the activities of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products, the Committee on Herbal Medicinal Products, the Paediatric Committee, and other committees. Experts of the Agency's Medicines Marketing Authorisation Department also regularly participated in EDQM working sessions as external experts. Through participation in the EMA Scientific Advice Working Party, the Agency's medicines marketing authorisation experts, in cooperation with external experts, provided scientific advice on 19 aspects related to medicines development, research and marketing authorisation.

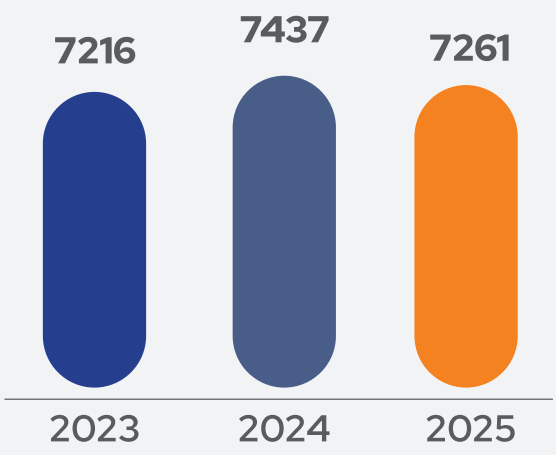
AT THE END OF THE REPORTING PERIOD, THE AGENCY:

- carried out a scientific evaluation of more than 7769 applications for marketing authorisation, renewal and variations to marketing authorisation documentation of medicines by reviewing data and evidence included in medicines marketing authorisation documentation that confirm quality, safety and efficacy of medicines. Reviews included also administrative information, as well as chemical, pharmaceutical, preclinical and clinical sections of the documentation and pharmacovigilance documents;
- out of all the applications evaluated, the Agency has taken a positive decision on authorisations and renewals of 468 medicinal products;
- evaluated 6913 applications for variations to marketing authorisation documentation of medicines with a positive outcome.

Variations via national procedure



Total number of variations to marketing authorisation documentation



Distribution of medicinal products

Katrīna Lukša,
Head of the Department of Information on Distribution of Medicinal Products

In 2025, one of the main tasks of the Department of Information on Distribution of Medicinal Products continued to be ensuring the availability of medicinal products and addressing related issues – including the issuance of permits, application of exemptions, as well as ensuring communication and cooperation with all stakeholders involved. Amendments to regulatory enactments were introduced in order to facilitate medicinal product distribution processes and to prevent medicinal products from being exported from Latvia in certain cases, thereby primarily ensuring the needs of Latvian patients. Significant work also continued regarding changes to the principles of medicinal product pricing.

Efforts to ensure the availability of medicinal products were carried out both at national level – through communication with marketing authorisation holders, wholesalers, pharmacies, healthcare institutions, patients, medical associations and other stakeholders – and at international level, including participation in various working groups, development of the European list of critical medicines, involvement in the European Single Point of Contact network, and cooperation with EDQM. Each situation related to medicinal product availability was assessed individually in order to identify the most appropriate and effective solution, ensuring primarily that Latvian patients received the medicinal products they required.

To facilitate and accelerate access to medicinal products in cases where medicinal products not authorised in

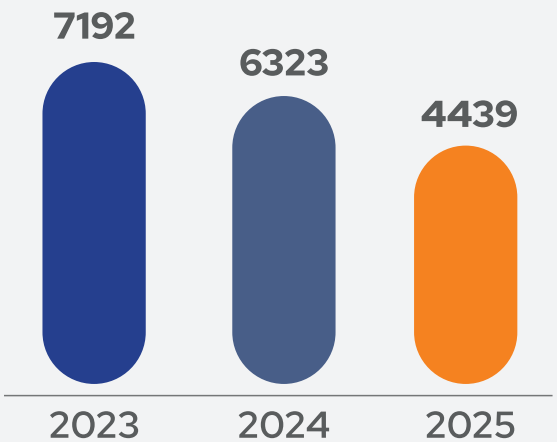
Latvia but authorised in another country, or centrally authorised medicinal products for which the marketing authorisation holder has not initiated placement on the Latvian market, amendments were introduced to Cabinet Regulation No. 416 of 26 June 2007 'Procedures for the Distribution and Quality Control of Medicinal Products'. In certain cases, an individual authorisation is no longer required; instead, a notification to the Agency is sufficient (the amendments entered into force in the second half of the year). This enables patients to receive medicinal products more quickly and reduces the administrative burden for both operators and the Agency.

Within the framework of these amendments, the list of medicinal products subject to stricter control has also been expanded (including assessment of reimbursement lists) in cases where operators intend to distribute medicinal products intended for Latvian patients to another EU/EEA Member State or export them. Such activities are allowed only with the Agency's permit, once it has been established that the needs of Latvian patients are ensured as a priority. During the previous year, regular review and updating of this medicinal product list was ensured, operators were informed about changes to the list, and applications for distribution/export of medicinal products were assessed.

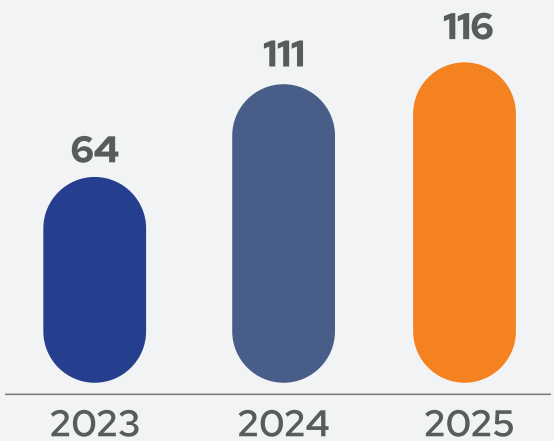
In response to a request from a medical association, the information available in the Latvian Register of Medicinal Products was expanded by adding information on issued permits for the distribution of unauthorised medicinal products with a validity period of one year. These permits are also based on close cooperation with professional medical associations and wholesalers. The published information allows easy identification of medicinal products for which permits have already been issued (meaning that neither an individual permit nor a notification is required) and indicates which wholesalers can provide the medicinal products as quickly as possible.

Taking into account changes to the medicinal product pricing model, which from 1 January 2025 establishes a fixed mark-up

Permits for distribution of unauthorised medicines



Number of permits for parallel import

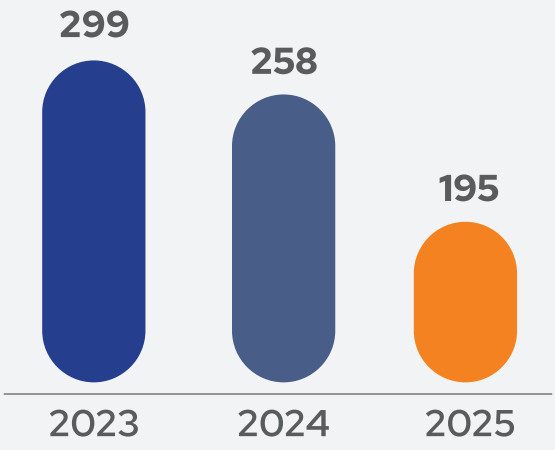


for prescription medicinal product packages both for wholesalers and pharmacies and stipulates that the declared medicinal product price may not exceed the price in Lithuania and Estonia, the Department actively communicated with clients and the sector, including regarding temporarily reduced medicinal product prices. Explanations and information were provided on medicinal product price changes and the maximum permissible pharmacy prices applicable at a given time to the public, patients, journalists, MH and other institutions. The display of the new prescription medicinal product prices in the Latvian Register of Medicinal Products from 1 January 2025 was ensured. Changes were introduced into SAMIS, and price declaration forms were adapted for reporting temporarily reduced prices. Data were regularly compiled and analysed for MH, including within the framework of working groups.

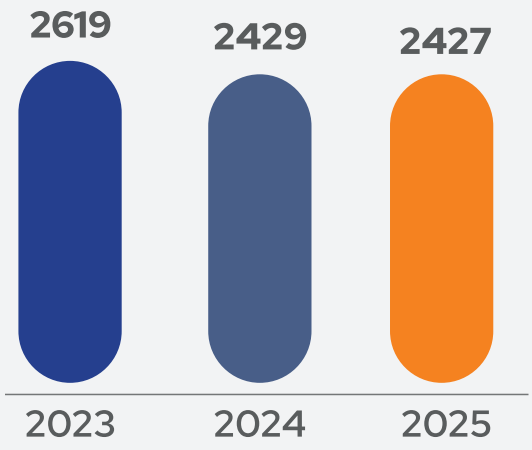
Last year, the Department continued reviewing and improving internal documentation, thereby updating and optimising processes, and continued work on amendments to regulatory enactments by providing proposals for improving legal provisions (Law on the Legal Circulation of Narcotic and Psychotropic Substances and Medicines and Precursors, Procedures for the Distribution and Quality Control of Medicinal Products, etc.). In the Data Analytics Unit, the audit 'MH Audit 5/2025 Circulation of Human Medicinal Products' was initiated, and the Department also successfully completed the recertification audit.

Last year, continuing the previously initiated transition from paper-based document circulation to electronic format and facilitating information exchange with competent authorities of other countries, information was compiled and the necessary activities were carried out to enable the introduction, from 1 January 2026, of electronic issuance of individual import/export permits for controlled narcotic drugs, psychotropic substances and precursors in Latvia. This will facilitate and accelerate the issuance and circulation of permits with clients, customs authorities and competent authorities of other countries. At the same time, the per-

Number of variations to permits for parallel import



Permits for import/export of narcotic drugs, psychotropic medicines/substances and precursors



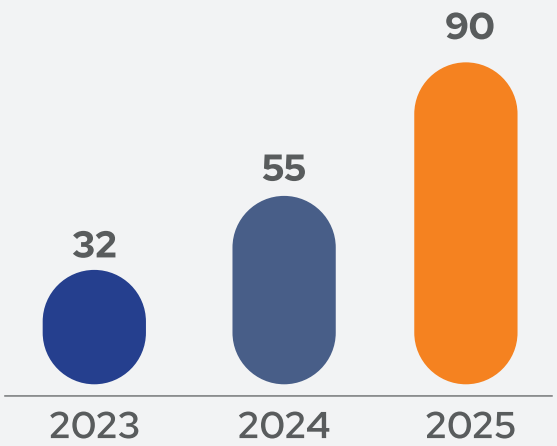
mit format was reviewed and improved. It is planned that this will allow the current permit issuance timelines to be maintained – in 2025, individual import/export permits were issued within an average of 1.7 days, thereby minimising delays in medicinal product deliveries caused by obtaining the necessary permits from the Agency.

During the previous year, statistical data were regularly compiled and published on a monthly, quarterly and annual basis. The published data provide information on turnover, medicinal product price changes and exported medicinal products, including medicinal products included in the reimbursement system. Support was also provided to the Department of Marketing Authorisation of Medicinal Products, the Clinical Trials Unit and the Pharmacovigilance Unit in evaluating pre- and post-clinical trial methodologies and statistical methods, validating their results, and assessing data and data quality. Various analyses and reports related to medicinal products, their consumption, availability and prices were prepared both for the Agency's internal needs and in support of MH. Calculations and analyses of antibiotic consumption were also carried out, data were prepared for ECDC, information was provided to Latvian specialists (infectologists, the Centre for Disease Prevention and Control), and a publication was prepared for the Agency's website.

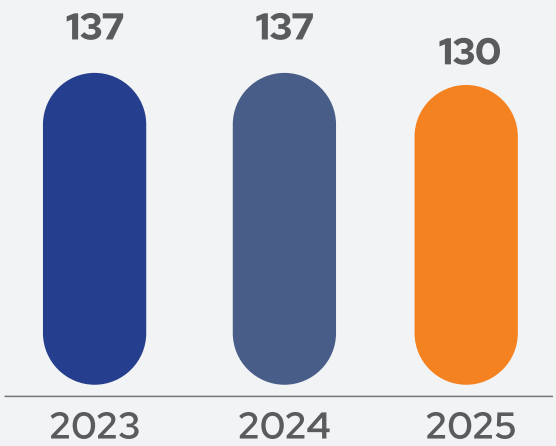
The Department actively participates in the Agency's Client Days, informing the sector and patients about updates, regulatory requirements, amendments thereto and other current issues. Through participation in Client Days and seminars, information was provided on medicinal product prices, amendments to regulatory enactments and requirements concerning the distribution of unauthorised and centrally authorised medicinal products, supply of medicinal products to another EU/EEA Member State or export thereof, and the availability and distribution of medicinal products in packaging intended for another country's market.

Taking into account the changes in the procedure for obtaining permits for unauthorised medicinal products, the number of permits issued in 2025 decreased by 30%

Permits for import of samples of medicines



Permits for supply of medicines to export other EU member states or export of medicines



compared with the previous year (a total of 4,439 permits issued). The objective of ensuring the assessment of urgent applications within the same working day was maintained. During the year, 261 permit for the distribution of unauthorised medicinal products with a validity period of one year were issued, either based on opinions provided by medical associations or because the medicinal products were included in the hospital medicinal product list or reimbursement list.

Applications were received and permits issued for parallel imported medicinal products (including amendments and provision of information to other countries regarding parallel imported medicinal products originating from Latvia), medicinal products for compassionate use, medicinal product samples, import and export of narcotic and psychotropic medicinal products and substances, import and export of precursors, registration cards and licences for precursor operators, use of plants, substances and medicinal products included in Lists I, II and III of narcotic drugs, psychotropic substances and precursors controlled in Latvia for medical and veterinary scientific research, determination of physical and chemical properties or training purposes, procurement of medicinal products for operational needs, supply of medicinal products to other EU Member States or export thereof, as well as preparation of other outgoing correspondence and responses to information requests.

The number of applications and notifications regarding packaging intended for another country's market increased significantly – compared with 2024, the number increased by 28%, reaching a total of 548 notifications and applications. This regulatory exemption allows the availability of medicinal products for Latvian patients to be ensured in cases where medicinal products intended for the Latvian market could not be manufactured, supplied or repackaged. As a result, Latvian residents also have access to medicinal products with low demand, small patient populations, interrupted manufacturing or other limiting factors.

Clinical trials of medicinal products

Jana Migliniece,
Head of the Clinical Trials Unit

At the beginning of 2025, the transition of clinical trials to the new EU Clinical Trials Information System (CTIS) was completed. The Clinical Trials Unit assumed the role of Reporting Member State (RMS) for three new multinational clinical trials of medicinal products and two mono-national clinical trials. Clinical trials of medicinal products were assessed in cooperation with the Ethics Committee of the Development Society of Pauls Stradiņš Clinical University Hospital and competent authorities of other EU Member States. Last year, the Agency participated in the clinical trials expert working groups established by EC and HMA, contributing to the harmonisation of clinical trial authorisation across Europe, as well as in the EMA Good Clinical Practice Inspectors Working Group to harmonise inspection procedures.

In 2025, the Agency issued 44 authorisations for conduct of clinical trials of medicinal products in Latvia and authorised the transition* of two ongoing academic clinical trials to the new EMA CTIS database.

Last year, Good Clinical Practice (GCP) compliance inspections were carried out at four clinical trial sites in Latvia and three sites outside Latvia, including one inspection initiated by EMA. Information on these inspections was submitted to EMA CTIS database. In the assessment of clinical trial conduct, the requirements of the ICH GCP E6 (R3) guideline, which entered into force on 23 July 2025, began to be applied.

During the reporting year, eight initial reports and 32 follow-up reports were

* Transitional clinical trials are trials that have been approved in accordance with the requirements of the Clinical Trials Directive 2001/20/ EC and whose sponsor has decided to modify documentation as stipulated by the requirements of the EU Regulation 536/2014 by submitting it in CTIS.

received concerning serious unexpected adverse reactions identified at Latvian clinical trial sites that were potentially related to investigational medicinal products.

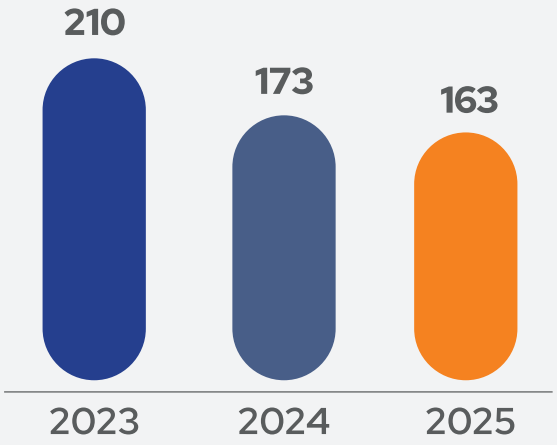
In total, the Agency received and assessed 114 annual safety reports prepared by sponsors concerning clinical trials of medicinal products conducted in Latvia.

To promote coordinated safety assessment of investigational medicinal products among EU Member States, the EU4Health-supported SAFE-CT project was continued, within the framework of which Latvia provided safety monitoring for 16 investigational medicinal products.

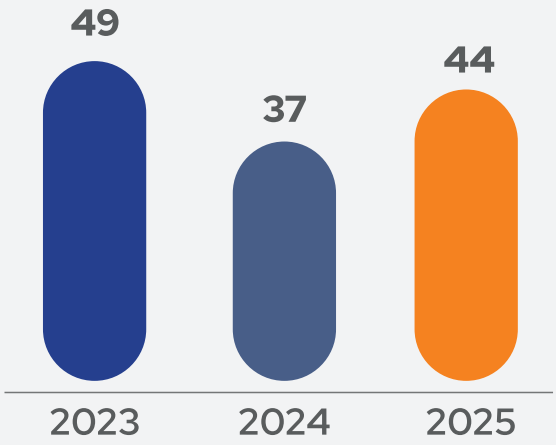
Clinical trials conducted in Latvia in 2025 were sponsored by a total of 76 foreign pharmaceutical companies and three non-commercial sponsors (Prinses Máxima Centrum voor Kinderoncologie B.V., the Netherlands; Tartu University Hospital, Estonia; and Riga Stradiņš University, Latvia).

Experts of the Clinical Trials Unit participated in the Riga Stradiņš University Doctoral School with presentations on regulatory aspects of clinical trials, the EMA CTIS database and safety reporting requirements. The public was informed about the new interactive clinical trial map.

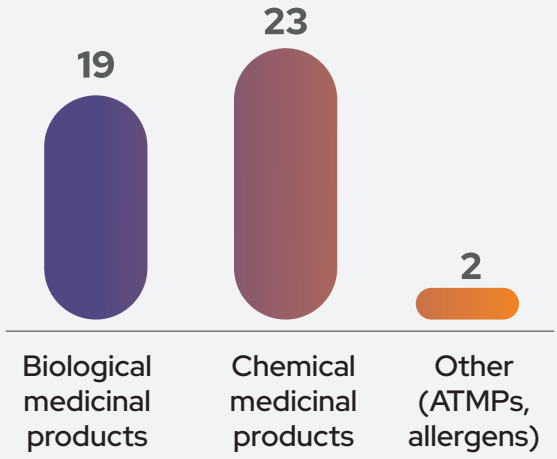
Total number of clinical trials conducted in Latvia



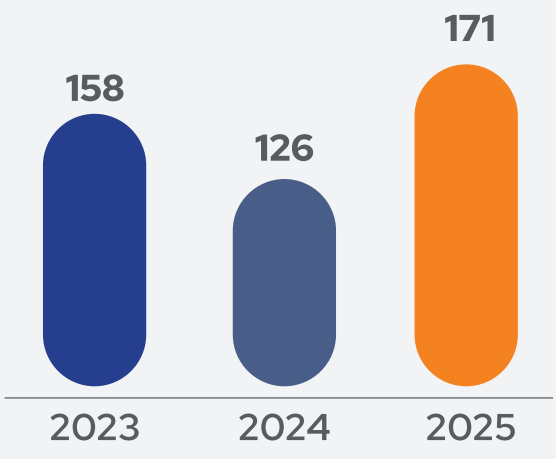
Newly Authorised Clinical Trials of Medicinal Products



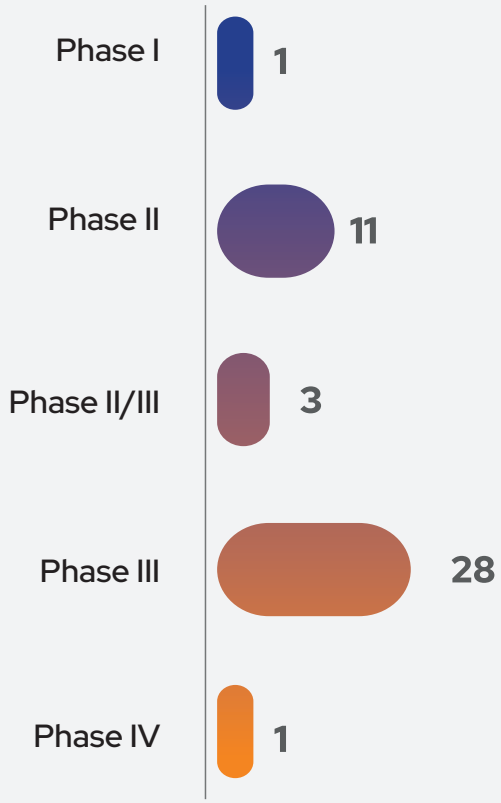
Distribution of investigational medicinal products' clinical trials authorised in 2025



Amendments to clinical trials



Number of clinical trials authorised in 2025, according to trial phase



Number of clinical trials authorised in 2025, according to medical specialty

Medical sector	Number of allowed clinical trials
Cardiology	7
Neurology	6
Gastroenterology	5
Dermatology	4
Oncology	4
Endocrinology	3
Ophthalmology	3
Pulmonology	3
Cardiovascular surgery	2
Psychiatry	2
Rheumatology	2
Haematology	1
Nephrology	1
Neurology / Paediatrics	1

Clinical trial sites where clinical trials of medicinal products were allowed in 2025

Clinical trial site	Number of clinical trials
Pauls Stradiņš Clinical University Hospital	28
Riga East Clinical University Hospital	13
Health Centre 4	12
Daugavpils Regional Hospital	9
Liepāja Regional Hospital	8
Riga 1st Hospital	7
M & M Centre	5
J. Ķīsis Ltd.	4
Semigallia Ltd.	4
Sigulda Hospital	4
Health and Aesthetics Ltd.	4
Association of Health Centres	4
Children's Clinical University Hospital	3
Professor Skride Heart Clinic	3
Dr. Aija Šmite Dermatology and Venereology Practice	3
North Kurzeme Regional Hospital	3
Orto Clinic	3
Adoria Ltd.	2
Linda Ķeruže Psychiatry Centre	2
Riga 2nd Hospital	2
Hospital of Traumatology and Orthopaedics	2
Vidzeme Hospital	2
Ģintermuiža Hospital	2
Association of Health Centres	2
APS Health and Social Care Clinic	2
Other clinical trial sites (12 in total)	1 clinical trial at each site
Total number of clinical trial sites	38

Pharmacovigilance and risk minimisation

Ilze Viņķele,

Head of the Pharmacovigilance Unit

In 2025, the guiding principle of the Pharmacovigilance Unit remained unchanged – to ensure that medicinal products available in Latvia are safe and are also used safely. The work of the Unit's experts covered several areas. We actively informed the public and healthcare professionals about current and latest information regarding medicinal product safety. We participated in public information campaigns on the responsible use of medicinal products, including currently highly topical semaglutide-containing products. We cooperated with professional organisations of physicians and pharmacists and provided consultations to marketing authorisation holders on pharmacovigilance matters, implementing the principle 'consult first'.

Experts of the Pharmacovigilance Unit also actively participate within the scope of their competence in the work of the EMA, representing Latvia's interests in the PRAC, as well as participating in an international pharmacovigilance inspection in France.

In 2025, 436 reports of adverse drug reactions to medicinal products were received, including reports concerning vaccine adverse drug reactions. The information received in the reports was assessed, appropriately prepared and submitted to the EU common reporting system EudraVigilance. Out of all reports, 194 were assessed as significant reports providing valuable information on medicinal product safety during the post-authorisation period.

Compared with the previous year, healthcare professionals sub-

mitted more reports last year (313 reports), while patients were less active reporters (123 reports, compared with 216 patient reports in 2024).

Almost all adverse drug reaction reports were received electronically through the Agency's Adverse Drug Reaction Reporting Information System, which is continuously improved and upgraded to ensure convenient daily use and efficient extraction of statistical data.

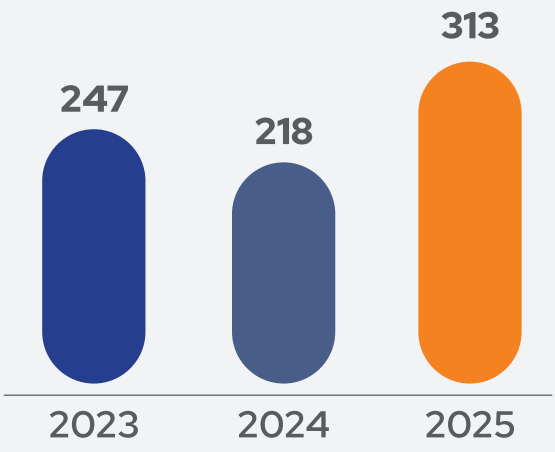
Pharmacovigilance experts also addressed physicians during an event organised by family physicians and at a meeting of the Board of the Latvian Medical Association (LMA), as well as chief nurses of leading hospitals. The objective of the Agency's representatives was to promote reporting activity among healthcare professionals regarding observed adverse drug reactions to medicinal products and to encourage physicians to understand the importance of risk minimisation measures within patient treatment processes. Possibilities for more effective cooperation promoting safe use of medicinal products in Latvia were discussed with members of the LMA Board.

It can be stated that pharmacovigilance experts also made a significant contribution in the field of public information regarding both adverse drug reaction reporting and other medicinal product safety-related matters. They provided interviews to the media, participated in online discussions on issues relevant to society, for example semaglutide use and potential risks, and prepared publications for healthcare-related press editions.

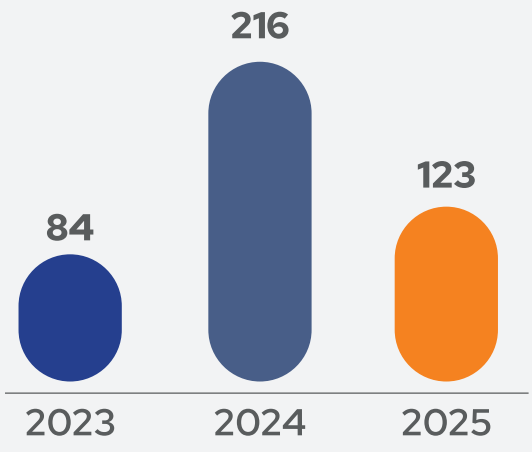
Within EU single assessment procedures (PSUSA), the Agency's pharmacovigilance experts assess periodic safety update reports for active substances for which the EMA has assigned responsibility to Latvia as the Reference Member State. In 2025, pharmacovigilance experts carried out 16 single assessment procedures.

In 2025, in accordance with the EMA worksharing procedure, the Agency's experts monitored 29 active substances for signal detection, i.e. performed regular safety surveillance of these substances in Europe and analysed adverse drug reaction reports received from European countries in con-

Reports of Adverse Drug Reactions to Medicinal Products. Cases reported by healthcare professionals



Reports of Adverse Drug Reactions to Medicinal Products. Cases reported by patients



nection with the use of these medicinal products in order to determine whether new information indicating a safety signal could be identified.

Last year, Risk Management Plans were also assessed and assessment reports prepared within 71 national marketing authorisation procedure (including mutual recognition and decentralised procedures). In addition, pharmacovigilance experts actively participated in the performance of EMA delegated tasks as lead rapporteurs of PRAC. Within centralised marketing authorisation/variation procedures, six Risk Management Plans and two Post-Authorisation Safety Study (PASS) protocols were assessed.

In 2025, a total of 96 additional risk minimisation materials intended for physicians and patients and developed for the purpose of minimising risks associated with specific medicinal products were approved by the Agency. Consequently, physicians received 14 "Direct Healthcare Professional Communications" containing important and up-to-date medicinal product safety information, as well as educational materials for both physicians and patients providing information on the prevention or minimisation of risks associated with prescribed medicinal products.

Healthcare professionals regularly received monthly updates on current issues following meetings of PRAC, in which the Latvian representative participated and presented the assessments prepared by pharmacovigilance experts. Physician associations and medical specialists in Latvia were regularly informed about PRAC decisions related to medicinal product safety and recommendations for risk minimisation.

Exchange of information on pharmacovigilance matters with EMA and medicines agencies of European countries was also carried out, including responses to 14 Non-Urgent Information (NUI) request documents submitted by EU Member States.

Compensation for damage from adverse reactions to Covid-19 vaccines

In 2025, the Agency received six compensation claims concerning severe or moderately severe damage to health or life caused by adverse drug reactions to COVID-19 vaccines. This represents 38 fewer applications than in 2024. The decrease in the number of received applications indicates a diminishing impact of the pandemic, a possible decline in vaccination volumes and increased public confidence.

The compensation programme for moderately severe and severe damage to health caused by adverse drug reactions to COVID-19 vaccines in Latvia was established in May 2022. Since the establishment of the programme, the Agency has received 270 compensation claims. Overall, causal relationships between adverse drug reactions to vaccines and moderately severe or severe damage to patients' health have been established in 13 cases.

The total amount of compensation paid has reached EUR 364,580. Of this amount, in two cases the maximum amount established by regulatory enactments – EUR 142,290 – was paid; in five cases EUR 10,000 was paid; and in six cases EUR 5,000 was paid.

Compensation may be requested within two years from the date on which the damage was discovered, but no later than three years from the date of vaccination.

To apply for compensation, a compensation claim must be submitted to the Agency together with medical documentation confirming the damage caused to health or life, as well as a physician's opinion regarding a possible causal relationship between the adverse drug reaction to the COVID-19 vaccine and the damage caused to the patient's health or life.

Received applications are assessed within a period ranging from six months to one year.

Medicinal product quality control

Guntars Kaspars,
Head of the Medicines Examination Laboratory

In 2025, a surveillance visit by the Latvian National Accreditation Bureau (LATAK) took place, during which the accreditation of the Agency's Medicines Examination Laboratory (hereinafter – the Laboratory) was maintained for compliance with the requirements of the LVS EN ISO/IEC 17025:2017 standard in the following areas: physical and physico-chemical testing of medicinal products, active pharmaceutical ingredients and excipients (fixed and flexible scope), as well as physical testing of purified water (fixed scope).

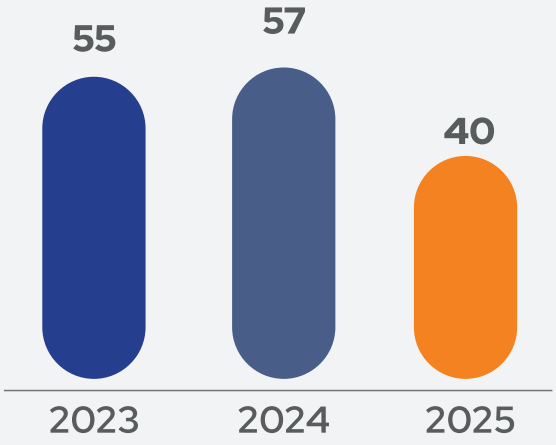
In 2025, the Agency underwent ISO 9001 recertification. The Laboratory actively participated in the audit process and responded to auditors' questions within the scope of its competence.

Successfully completed audits constitute important confirmation of the quality of the Agency's professional activities. Confirmation of certification compliance ensures that clients can have confidence in our work – healthcare professionals, cooperation partners in Latvia and abroad, and the residents of Latvia can rely on the quality of the Agency's work.

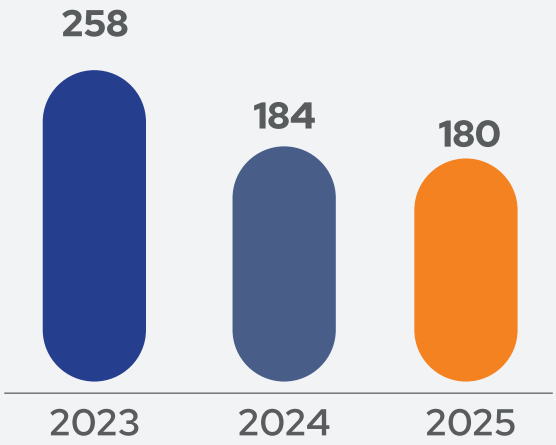
Laboratory specialists successfully participated in professional proficiency testing programmes organised by the EDQM and the Royal Dutch Pharmacists Association.

In addition, three EDQM reference standard qualifications that had not previously been performed by the Medicines Examination Laboratory were carried out, and the EDQM recognised this contribution from the Latvian OMCL.

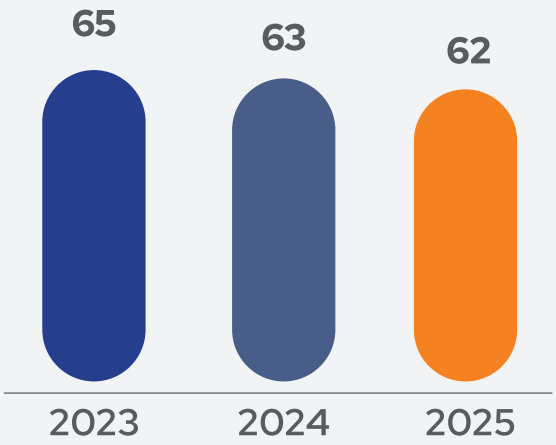
Tested Samples of Medicinal Products



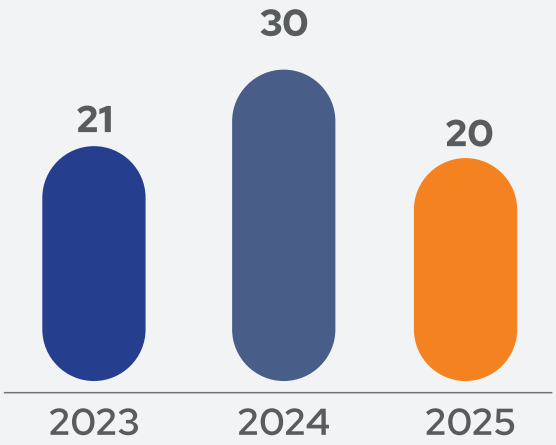
Standardised Solutions, Indicators and Reagents Prepared Upon Request of Pharmacies



Tested Samples of Purified Water Produced in Pharmacies



Expert Assessments Performed at the Request of the Medicines Authorisation Department for Registration Documentation Submitted for Medicinal Products, Including Evaluation of Analytical Methods and Validation of Active Substances and/or Finished Products



Biological products unit

Ilze Pučkure,
Head of the Biological Products Unit

In 2025, the newly established Biological Products Unit commenced the implementation of new functions in the field of substances of human origin (SoHO) and Advanced Therapy Medicinal Products under Hospital Exemption (ATMP HE), ensuring preparations for the implementation of the SoHO Regulation in Latvia and developing proposals for the use of ATMP HE therapies in healthcare.

The activities of the Unit were organised with a focus on strengthening international cooperation in order to facilitate the transfer of best practices at national level and reinforce the representation of Latvia's interests within the EU, promoting the development of high-quality, safe and patient-centred healthcare in accordance with the strategic directions of the State Agency of Medicines.

Preparations for the Implementation of the SoHO Regulation in Latvia

On 27 May 2024, the Council of the European Union adopted a new Regulation on standards of quality and safety for substances of human origin (SoHO).

The Regulation will enter into force on 7 August 2027. Until then, guidelines, implementing acts and good practice requirements are being developed at EU level, while Member States are preparing national processes and regulatory enactments for the application of the Regulation.

The new Regulation introduces harmonised and modern standards across the EU in order to:

- ensure higher levels of patient and donor safety;
- improve traceability – from

donor to recipient;
- facilitate faster and safer availability of biological materials;
- strengthen cooperation between countries during crisis situations.

Patient Experience: Safety You Can Trust

When a patient requires a blood transfusion, stem cell therapy or donor tissues, the most important factor is confidence that the biological material used in treatment complies with established quality and safety criteria. This process is ensured by healthcare professionals and a modern digitally supported supervisory system.

Implementation of the SoHO Regulation introduces a unified approach to the circulation of biological materials throughout the entire lifecycle – from donor to recipient. The Regulation establishes common principles for quality, safety and traceability, as well as harmonised supervisory processes across all Member States.

What Does the SoHO Regulation Mean for Patients in Latvia?

- Harmonised quality and safety standards for the use of substances of human origin in healthcare;
- Traceable circulation – clearly defined processes for documenting the procurement and use of biological materials of human origin;
- Harmonised EU supervisory principles – common rules for information exchange and assessment of safety-related issues.

In 2025, the newly established Biological Products Unit (BPU) ensured coordinated preparations for the implementation in Latvia of Regulation (EU) 2024/1938 of the European Parliament and of the Council on standards of quality and safety for substances of human origin (SoHO).

- During the reporting year, the BPU promoted the development of the national regulatory framework by ensuring the Agency's representation in MH SoHO Working Group and by providing proposals for the improvement of regulatory enactments. An analysis of the Regulation's impact on the Agency's functions was carried out, proposals were prepared regarding the allocation of roles among competent authorities, the delegation model for functions and the implementation sequence, and the need to amend several laws and Cabinet regulations was identified.
- At the same time, the Unit developed an initial approach to the registration, authorisation and supervision processes for SoHO entities and prepared informative materials regarding the objectives and scope of the Regulation and related data management requirements, including the functionality of the European SoHO Platform.
- These measures strengthened the BPU's competence in the SoHO field and promoted closer cooperation among the institutions involved, thereby establishing a clear basis for the practical implementation of the Regulation requirements.

For patients, this means greater confidence that biological materials of human origin used in treatment are traceable, comply with established requirements and are used

within a controlled system. This promotes transparent circulation and strengthens public confidence in healthcare.

Transfer of Vigilance Functions

In addition to preparing proposals for the national regulatory framework, from 1 September 2025 the BPU assumed responsibility from the Compliance Assessment Unit for receiving and assessing biovigilance reports and annual reports, thereby ensuring systematic analysis of serious adverse reactions and adverse events.

During the reporting period, notifications received through EC Rapid Alerts system and information submitted by healthcare institutions were assessed, and proposals were prepared for improving reporting processes and strengthening cooperation with healthcare institutions.

International Cooperation

In 2025, the Biological Products Unit significantly expanded international cooperation by ensuring Latvia's participation in EC and Nordic cooperation formats related to the preparation of the SoHO regulatory framework. Active involvement in EU-level structures promoted harmonised interpretation of the Regulation, timely exchange of information and transfer of best practices to national level.

- BPU experts participated in the work of the EC SoHO Coordination Board (SCB) and Regulatory Committee, as well as in five thematic working groups and nine subgroups aimed at developing harmonised EU guidelines, procedures and documents in the SoHO field. Joint principles were developed for the registration and authorisation of SoHO entities, identification of critical biological materials and structures, traceability requirements and vigilance processes. Comments on draft guidelines, proposals regarding data protection and reporting principles, and contributions to the development of the functionality of the SoHO Platform were also provided.
- Registration of SoHO entities and authorisation of SoHO centres (Registration WG): guidelines for the registration/authorisation of non-hospital SoHO entities were developed.
- Supply WG: an algorithm for identifying critical SoHO products and critical SoHO entities (centres) was developed.
- Regulatory WG: more than 25 responses were prepared to questions submitted by EC; since December 2025, Latvia has chaired the "Essential Functions" subgroup.
- SoHO Product Assessment and Authorisation (SPA WG): comments were provided on the draft PPD document intended for the development of the SPA module of the SoHO Platform.
- Vigilance WG: proposals concerning adverse reaction reporting (SAR/E), donor data protection and traceability requirements were refined.
- Participation in the Nordic Council of Ministers SoHO Expert Working Group promoted a regional approach to implementation of the Regulation, exchange of experience regarding the application of EDQM and ECDC guidelines and transfer of best practices.

- During the reporting year, Unit experts participated in discussions regarding application of the Regulation and clarification of terminology and prepared responses to EC requests concerning national processes, information systems and compliance with EDQM standards.
- Unit experts also responded to EC surveys regarding national IT systems, criteria for identifying critical SoHO materials, vigilance requirements and compliance of nationally prepared SoHO products with EDQM standards, while also contributing to clarification of terminology used in the SoHO Regulation.
- In 2025, the international visibility of the State Agency of Medicines and representation of Latvia's interests were purposefully strengthened through active participation in EC SoHO Coordination Board, the European Commission SoHO Regulatory Committee and the Nordic Council of Ministers SoHO Expert Working Group. This involvement ensured timely formulation of Latvia's position and strengthened the Agency's reputation as an active and competent partner within the EU SoHO regulatory network.

Development of the ATMP Hospital Exemption Regulatory Framework in Latvia

In 2025, the Biological Products Unit coordinated the harmonisation of the regulatory framework for Advanced Therapy Medicinal Products under Hospital Exemption (ATMP HE), providing methodological support to MH, healthcare institutions and Ethics Committees.

Unit experts participated in interinstitutional meetings, prepared proposals for draft regulatory texts and developed informative materials regarding practical implementation of the framework, traceability requirements, the competence of qualified persons and pharmacovigilance.

These activities promoted a common understanding of the application of ATMP Hospital Exemption in Latvia and established the basis for implementation of the framework following approval of the regulatory act.

What Will the Introduction of the ATMP HE Regulatory Framework Mean for Patients in Latvia?

- the possibility to receive individually tailored therapy where no authorised treatment options are available;
- use of therapy under defined supervision arrangements, including informed consent and follow-up requirements;
- traceability and safety monitoring throughout the therapy use process.

Strengthening the Capacity of the Biological Products Unit and Knowledge Transfer

In 2025, the BPU recruited the Head of Unit and two experts and ensured targeted training for all Unit employees in the fields of SoHO and ATMP HE regulation.

The Unit organised informative events for healthcare institutions and sector partners, explaining the requirements and practical aspects of the new regulatory framework.

Challenges in 2025

The main challenges during the reporting year were related to preparations for implementation of the SoHO Regulation in Latvia, delays in the approval timelines of regulatory enactments and simultaneous involvement in ensuring Latvia's participation in several EC and Nordic cooperation formats related to preparation of the SoHO framework.

Additional workload was also created by the transfer of vigilance functions and the need to develop appropriate IT solutions for data processing.

Despite these challenges, the BPU ensured fulfilment of the planned tasks and timely preparation of processes and competences required for implementation of the new functions.

Planned Development in 2026

In 2026, further development of processes is planned, focusing on practical implementation of the SoHO Regulation and the regulatory framework for Advanced Therapy Medicinal Products under Hospital Exemption (ATMP HE).

Planned activities include:

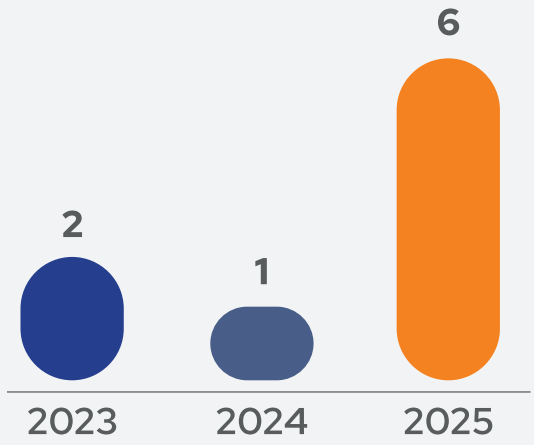
- improving Agency processes, SOPs and operational procedures for implementation of the SoHO Regulation;
- participating in the development of EU implementing acts (donor compensation, traceability, Single European Code, datasets);
- developing registration processes for SoHO entities and authorisation processes for SoHO centres using the EU SoHO Platform;
- developing SoHO product assessment, registration and authorisation processes using the EU SoHO Platform;
- improving vigilance processes (SAR/E, Rapid Alerts, clinical outcome monitoring);
- strengthening the competences of BPU staff and digitalising data collection and analysis;
- increasing process efficiency, data quality and satisfaction of internal and external stakeholders.

Medical device monitoring, clinical trials and vigilance

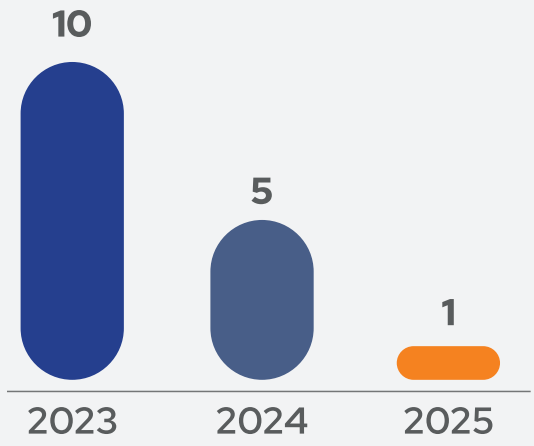
Andis Viļums,
Head of the Medical Devices Division

In 2025, an important decision was adopted in Europe regarding the mandatory use of the first four electronic systems of the European Database on Medical Devices (EUDAMED) from 28 May 2026. This decision effectively establishes a One-Stop Shop for the registration of medical devices, systems and procedure packs, and certificates throughout the EU. It will significantly reduce the administrative burden on economic operators, increase transparency within the sector and improve traceability of devices, as well as strengthen market monitoring, thereby ensuring patient safety and protection of public health.

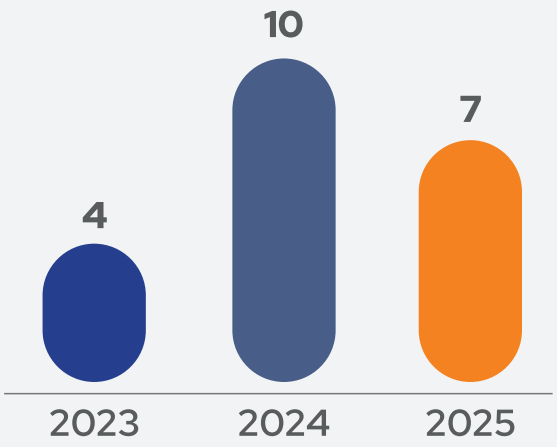
Latvian Medical Device Manufacturers and Their Devices: Information Assessed and Included in the LATMED Medical Devices Database



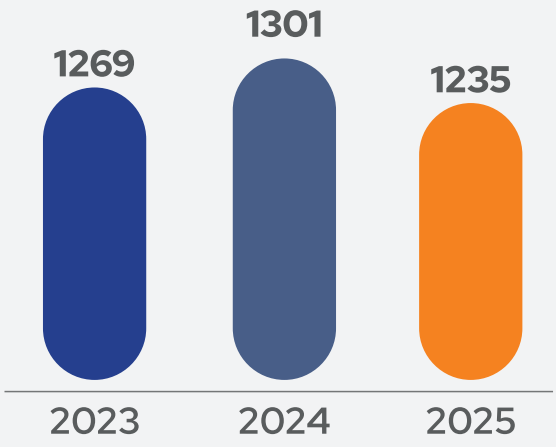
Authorised Representatives in the EU of Third-Country Medical Device Manufacturers Registered in Latvia: Information Assessed and Included in the LATMED Medical Devices Database



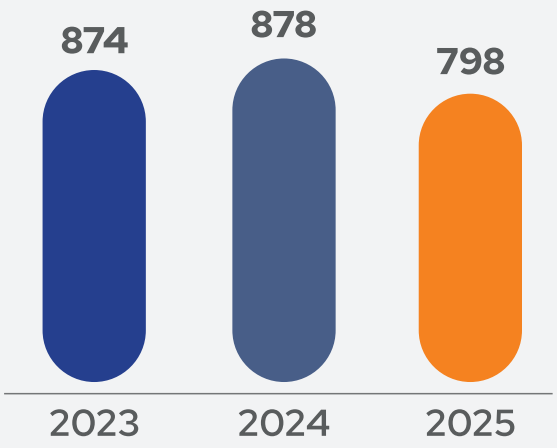
Clinical Trials of Medical Devices (Authorisations Issued)[1]



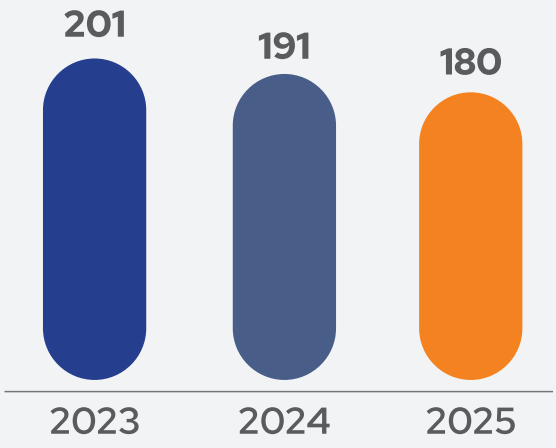
Medical Device Vigilance[2] Reports (Total Number of Reports Received by the Agency)



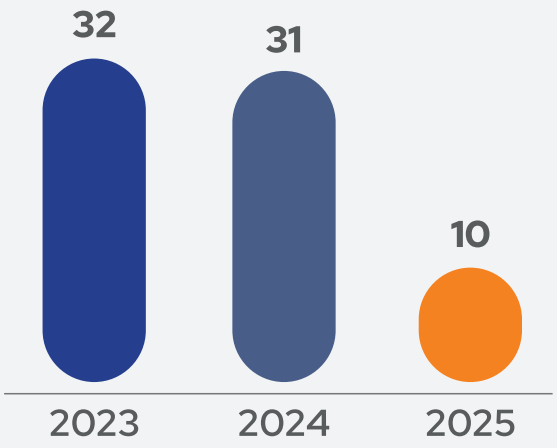
Initial Medical Device Vigilance[2] Reports (Number of Initial Reports Received by the Agency)



Initial Vigilance[2] Reports Concerning Medical Devices Located in Latvia and Implementation of Safety Monitoring Measures



Issued Free Sale Certificates for Medical Devices



[1] Authorisations for conducting clinical trials of medical devices and authorisations for substantial modifications to ongoing clinical trials.

[2] The medical device vigilance system is a unified EU reporting system concerning incidents involving medical devices, corrective actions undertaken by manufacturers or competent authorities, and the assessment of reports and information. The objectives of the vigilance system are: 1) to prevent recurrence of incidents; 2) to protect patients through a medical device user incident reporting system operating across all EU Member States; 3) to ensure that Member States are able to simultaneously identify non-compliant medical devices placed on the market and in use.

Health technology assessment

Antra Fogele,
Head of the Health Technology Assessment Division

On 12 January 2025, the Joint Clinical Assessment established under Regulation (EU) 2021/2282 of the European Parliament and of the Council on Health Technology Assessment (HTA) commenced for new medicinal products intended for the treatment of cancer, as well as for advanced therapy medicinal products. In March, the first application meeting the criteria for the authorisation of a new medicinal product was received by the EMA, for which a parallel clinical assessment within the health technology assessment framework will also take place.

Within the Joint Clinical Assessment process, each Member State is responsible for formulating nationally relevant questions regarding the target patient population for the new medicinal product, the comparative therapy used and the relevant outcomes by completing the so-called PICO (population, intervention, comparator, outcome) survey. This information is essential to enable the marketing authorisation holder, following authorisation of the medicinal product by EMA and completion of the joint clinical assessment report, to approach each Member State with pharmacoeconomic calculations prepared as comprehensively and appropriately as possible.

Based on these calculations, decisions are taken at national level regarding the cost-effectiveness of medicinal products and the possibility of reimbursement from public funds.

Of the 13 Joint Clinical Assessment procedures for new medicinal products initiated during 2025, three concerned advanced therapy medicinal products and seven concerned medicinal products intended for the treatment of rare diseases.

To formulate a set of questions precisely tailored to the Latvian healthcare system, the Agency cooperates with professional medical associations in the relevant fields.

Following consolidation of the PICO surveys submitted by Member States, it was concluded that there is substantial diversity at national level both regarding currently available or comparative therapies in each country and regarding the regulation of clinically relevant outcomes. In each individual case, assessors and co-assessors invest significant effort in the consolidation process to minimise these differences in wording while preserving the substance – the needs of the Member States.

Based on these consolidated questions, the marketing authorisation holder prepares documentation containing clinical evidence demonstrating the comparative effectiveness of the medicinal product.

Opinion on clinical and cost-effectiveness of new nonproprietary names or new combinations of medicines

Alongside the implementation of the European Joint Clinical Assessment procedure, equally important work is carried out in preparing opinions on the clinical and cost-effectiveness of medicinal products.

In 2025, the Agency received 41 application and prepared 50 opinions.
Opinions provided according to diagnostic groups (according to the International Classification of Diseases (ICD-10))

- Neoplasms – 31 opinions (62%)
- Endocrine, nutritional and metabolic diseases – 6 opinions (12%)
- Diseases of the nervous system – 3 opinions
- Diseases of the skin and subcutaneous tissue – 3 opinions
- Diseases of the circulatory system – 2 opinions
- Diseases of the musculoskeletal system and connective tissue – 2 opinions
- Diseases of the digestive system – 1 opinion
- Diseases of the genitourinary system – 1 opinion

Of all opinions issued in 2025, 17 applications (34%) concerned treatment of rare diseases. For comparison, in 2024 the Agency prepared 47 opinions, including 21 (45%) concerning treatment of rare diseases.

As the Agency's opinion constitutes a necessary step towards the possibility of reimbursement of new medicinal products from the state budget, according to information available on the website of NHS, during the year 16 applications concerning medicinal products for which the Agency had issued an opinion were submitted for inclusion in the reimbursement system for medicinal product acquisition costs.

Since 2021, the Agency has developed questionnaires enabling professional medical associations to express their views regarding the role of new medicinal products in the treatment process for a specific disease, expected benefits and unmet medical needs, as well as to indicate important information regarding currently available and used comparative therapies in Latvia.

Following meetings in autumn 2024 with the Latvian Association of Oncologists-Chemotherapists and the Latvian As-

sociation of Haematologists, the questionnaires were redesigned to be shorter and more targeted, thereby facilitating completion by specialists.

In 2025, questionnaires regarding 44 new international non-proprietary names or new diagnoses/patient groups were sent to professional medical associations. Responses from specialists were received in 25 cases. The information provided in these questionnaires is incorporated into the prepared opinions on the clinical and cost-effectiveness of medicinal products.

Approval, supplementation and cancellation of medical technologies and updating of the database of medical technologies used in treatment

In 2025, the Agency received 17 applications for approval, supplementation or cancellation of medical technologies (MT). A total of 16 decisions were prepared (see table), including two decisions adopted within 30 days.

For comparison, in 2024 the Agency received 20 applications for approval, supplementation and cancellation of new medical technologies and prepared 19 decisions regarding approval of medical technologies.

Using the possibilities provided by regulatory enactments, opinions from the Latvian Medical Association and the Union of Professional Healthcare Organisations of Latvia were requested regarding two medical technologies submitted for approval. In two cases, taking into account the complexity of the administrative proceedings, it was necessary to extend the decision-making deadline to one year.

Thanks to the successful cooperation initiated in 2024 with the Riga Stradiņš University Institute of Stomatology and the Latvian Orthodontists Association, the subsection "Orthodontic Technologies" within Section "10. Dentistry Medical Services" was supplemented with five new medical technologies.

At the same time, restructuring and updating of the orthodontic medical technologies list and its content has commenced. Taking into account the rapid development of the field, increasing public demand and the fact that the existing list had not been updated since 2003, this initiative is re-

Name of MT group	Approved MT	Supplemented MT	Cancelled MT	Rejected
Anaesthesiology, resuscitation, transfusiology and intensive care medical services		2		
Dentistry medical services	5		3	
Psychiatry and psychotherapy medical services		1		
Physical medicine and rehabilitation medical services				
Complementary medicine medical services				1

garded as a significant and positive step towards ensuring quality and compliance.

In 2025, the Agency also approached other professional organisations related to dentistry, inviting them to review the medical technologies already approved and included in the Database of Medical Technologies Used in Treatment, update them where necessary and consider approval of new medical technologies. A new direction of cooperation has also emerged in the field of endodontics.

Preparation and submission of applications to the Agency fall within the competence and discretion of healthcare institutions and professional medical associations.

In 2025, the Agency also approached the Latvian Association of Narcologists and several associations and healthcare institutions related to aesthetics and dermatology, inviting them to review technologies already approved and included in the Database of Medical Technologies Used in Treatment that are related to their respective fields.

In 2025, the Medical Technologies Assessment Commission, whose purpose is to assess whether documentation submitted to the Agency regarding approval, supplementation and cancellation of medical technologies complies with the requirements established by regulatory enactments and to provide an opinion to the Director of the Agency, held seven meetings.

In addition to Agency specialists, representatives from NHS and HI also participated in the Commission.

Licensing of pharmaceutical activities

Signe Čudare,
Head of the Pharmaceutical Activity Licensing Division

The Agency's constant objective has always been to provide clients with the necessary services as quickly and efficiently as possible, while offering consultations and support in the preparation of documentation.

In our daily work, we provide services to operators engaged in pharmaceutical activities: we issue and renew special permits (licences) for the establishment and operation of community and closed-type pharmacies, medicinal product wholesalers, medicinal product manufacturing and import companies, as well as manufacturers of active pharmaceutical ingredients. We also issue registration certificates to active substance manufacturers, importers and distributors and issue Good Manufacturing Practice and Good Distribution Practice certificates using the EMA EudraGMDP information system.

In 2025, we commenced a new task – issuing permits for the use of human blood, tissues, cells and organs in healthcare institutions and higher education institutions implementing medical study programmes – which now falls within the competence of the Pharmaceutical Activities Licensing Unit (transferred from the Compliance Assessment Unit). Last year, work was carried out on updating (renewing) five permits for the use of tissues, cells and organs.

In 2025, the Agency carried out activities related to updating and renewal of data concerning licensed pharmaceutical activity operators and legal addresses, aligning address data with the State Address Register and the data specified in the information system of the Register of Enterprises.

Current data are available on the Agency's website in the Register of Pharmaceutical Activity Companies and the Pharmacy Map, where information may also be obtained regarding community pharmacies that deliver medicinal products to residents' homes if patients are unable to visit the pharmacy themselves.

The register also contains information on sole community pharmacies and their branches located within a specific administrative territory that are the only pharmacies supplying medicinal products to residents in the respective region. This service has become particularly useful both for residents and the Agency's clients.

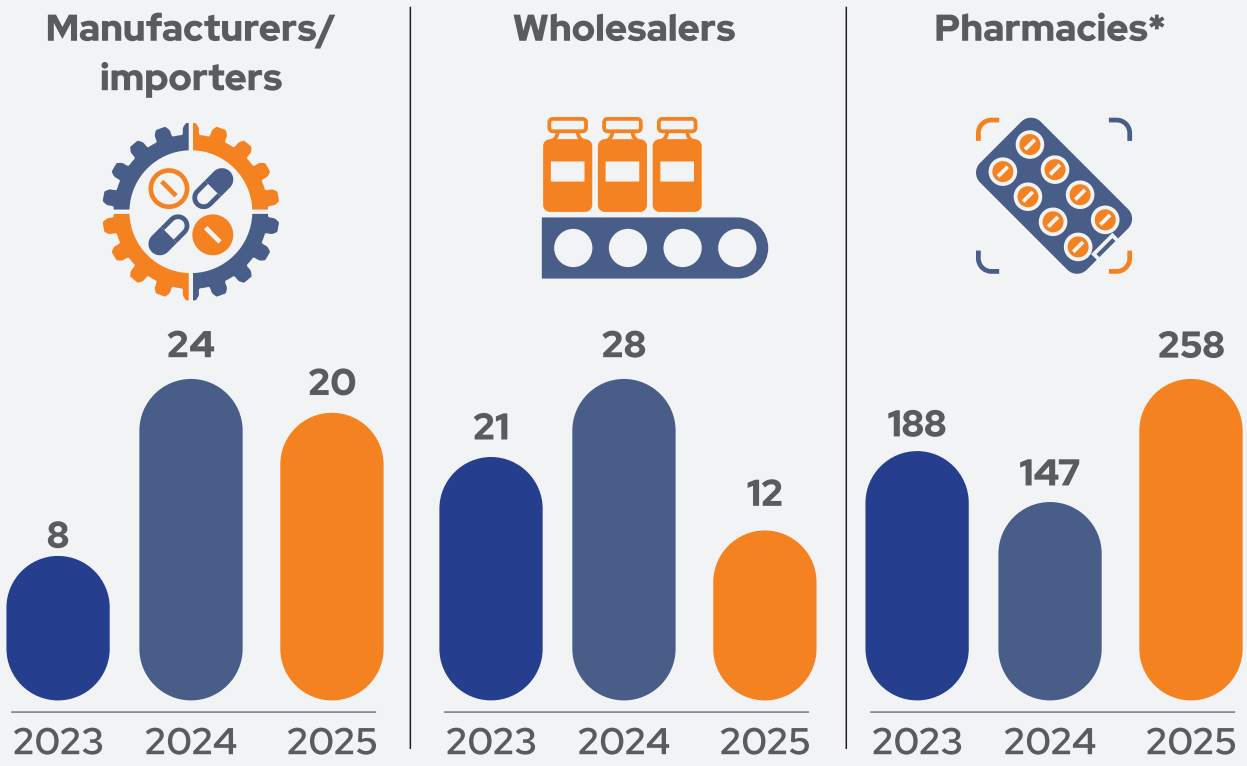
At the end of the year, an option became available to submit information on temporary suspension of pharmacy operations by completing an online form regarding current pharmacy operation information, without submitting a separate application.

In 2025, the Agency renewed or issued licences to 295 pharmaceutical activity companies (including one new community pharmacy):

- 258 community pharmacies (including one newly established community pharmacy),
- 1 closed-type pharmacy,
- 12 medicinal product wholesalers,
- 20 medicinal product manufacturing or import companies,
- 4 active pharmaceutical ingredient manufacturers.

In 2025, the Agency also issued 12 registra-

Amendments to Pharmaceutical Activity Licences



* Excluding pharmacy branches

tion certificates to active substance manufacturers, importers and distributors.

Comparison of data for 2025 and 2024 indicates that the number of pharmaceutical activity companies has remained stable, demonstrating that the pharmaceutical market in Latvia remains stable.

In 2025, the Agency revoked special permits (licences) for the operation of four community pharmacies, as these pharmacies had ceased operations. This suggests that establishing new pharmacies in less populated areas is not popular and may not be economically viable (only one new community pharmacy was established in 2025), despite greater state support provided to pharmacies in less populated areas through higher pharmacist service fees.

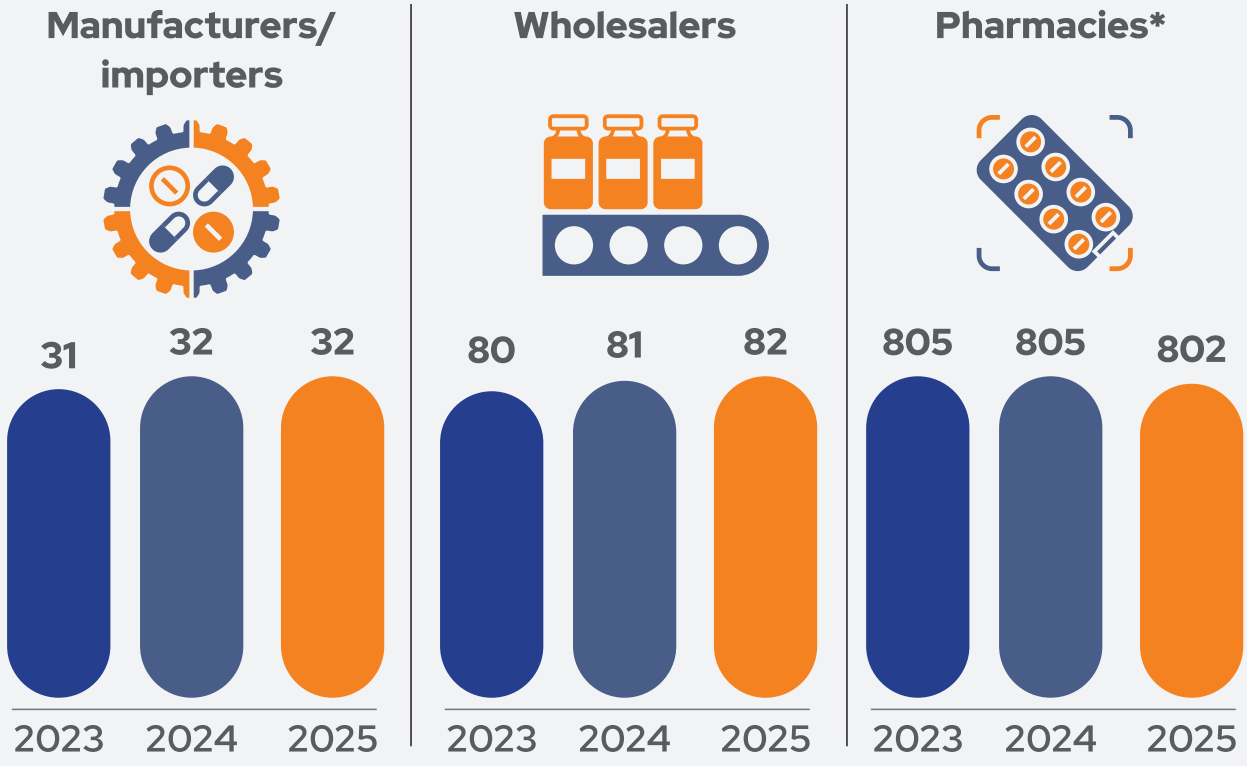
In 2025, new pharmaceutical activity locations (addresses) of community pharmacies (pharmacy branches) were assessed in 27 cases where licence holders planned to change the operating locations of pharmacies or pharmacy branches.

Last year, 19 meetings of the Agency's Pharmaceutical Activity Licensing Commission (hereinafter – the Commission) were held. During these meetings, issues related to the issuance, renewal and suspension of pharmaceutical activity licences and special operating conditions were reviewed and recommendation-type decisions were adopted in accordance with the procedures established by the Commission's regulations.

Faster licence renewal processes and service provision to operators are ensured by the Commission's regulations regarding cases that may be reviewed without convening a Commission meeting.

In 2025, work continued on optimising the

Total Number of Licensed Pharmaceutical Activity Companies in Latvia



2025 – 64 pharmacy branches, 2024 – 63 pharmacy branches, 2023 – 70 pharmacy branches, 2022 – 72 branches

Data valid as of 31 December 2025.

content of issued documents (e.g. decisions), making them easier to understand and reducing administrative and bureaucratic burden.

Unit specialists also actively participated in drafting regulatory enactments and amendments thereto, including cooperation with MH in developing a new draft regulation "Regulations on Licensing of Pharmaceutical Activities", participating in preparation of amendment proposals to the Law on the Legal Circulation of Narcotic and Psychotropic Substances and Medicines and Precursors, as well as other regulatory enactments related to pharmaceutical activity licensing.

This included amendments to Cabinet Regulation No. 416 of 26 June 2007 "Procedures for the Distribution and Quality Control of Medicinal Products" (entered into force on 11 July 2025), amendments to Cabinet Regulation No. 288 of 23 March 2010 "Pharmacy Operation Regulations", and others.

Required comments and proposals were provided, wording of legal provisions was coordinated within the Agency, and participation in meetings and public consultations organised by MH regarding draft legal acts was ensured.

Last year, amendments to the Law on the Legal Circulation of Narcotic and Psychotropic Substances and Medicines and Precursors were adopted, introducing changes to the activities of veterinary medicinal product wholesalers that had received special permits (licences) from the Agency for the manufacture, import and wholesale distribution of veterinary narcotic and psychotropic medicinal products (in accordance with Cabinet Regulation No. 35 of 11 January 2011 "Procedures for Issuing, Suspending, Renewing and Revoking Special Permits (Licences) for Veterinary Pharmaceutical Activities").

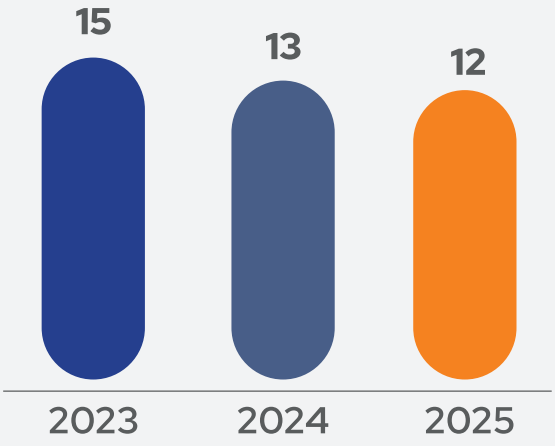
The Agency carried out all necessary activities to ensure that, from 1 December 2025 onwards, these clients would receive services from the Food and Veterinary Service, thereby ensuring continuity of functions.

We would like to thank every Agency client for the cooperation and understanding shown thus far in ensuring lawful service provision.

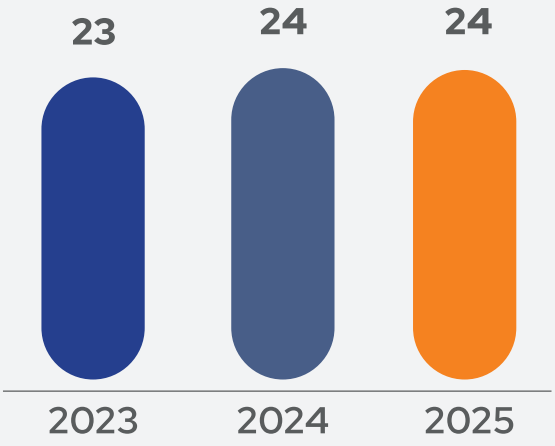
"Coming together is a beginning, staying together is progress, and working together is success."

- Henry Ford

Registration of Active Substance Manufacturers, Importers and Distributors (API) (including new registrations and renewals)



Total Number of Registered APIs in Latvia



Data valid as of 31 December 2025.

Compliance evaluation of pharmaceutical activity companies, healthcare and higher education institutions

Iveta Vilcāne,
Head of the Compliance Assessment Division

Preparedness for future challenges begins today – in 2025, active preparations were initiated for implementation of the SoHO Regulation, ensuring that its application can commence within the established timeline of 7 August 2027. The implementation of the SoHO Regulation will significantly change the framework for the use of substances of human origin by establishing broader involvement of healthcare institutions using such materials in humans, with the aim of making therapies involving substances of human origin safer and more effective, by assessing not only preparation of these materials, but also the respective products and their application.

In cooperation with the Department of Biological Products, the best possible approaches and solutions are being sought for more efficient organisation of processes required for implementation of the Regulation within the Agency. The Compliance Assessment Department and the Department of Biological Products jointly represent Latvia in the SoHO Coordination Board and participate in its working groups established in 2025.

In the field of inspections, a long-awaited opportunity arose to enhance competencies through training seminars specifically designed for inspectors in the areas of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP). These seminars were

prepared and partially funded through the European Health Programme "EU for Health" Joint Action JA11 grant. The aim of the project was to strengthen the competencies and capacities of Member State inspectorates and ensure sustainability and capacity building of the Joint Audit Programme (JAP), which in the future will also cover GDP inspection functions. Employees from several other Agency structural units also participated in training activities financed by the project.

The functions of the Compliance Assessment Department include assessment of compliance of medicinal product manufacturers, contract laboratories, medicinal product wholesalers and manufacturers, importers and distributors of active substances in relation to the issuance or re-registration of special permits (licences) for pharmaceutical activities (excluding pharmacies) and registration certificates for manufacturers, importers and distributors of active substances, as well as supervision of compliance of these operators.

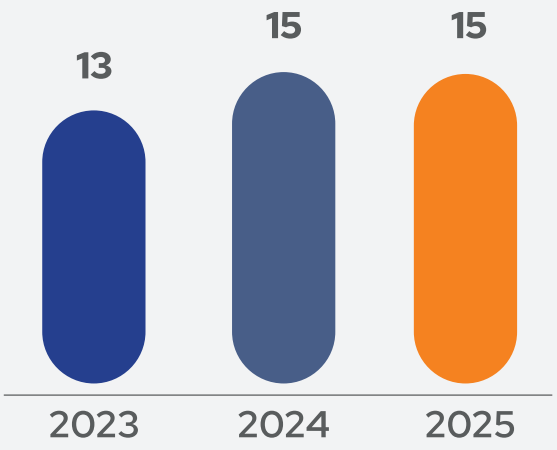
Department experts participated in a meeting of the Industrial Pharmacists Section of the Latvian Pharmacists Society, presenting principles for oversight of outsourced service providers.

In 2025, the Agency carried out 15 on-site Good Manufacturing Practice inspections of medicinal product (13) and active substance (2) manufacturing companies, including one inspection at a manufacturing company in China, as well as 11 document reviews related to re-registration of special permits (licences) for manufacture or import of medicinal products. Overall, manufacturing of 10 active substances was inspected during active substance manufacturing inspections. Within the framework of the JA11 Joint Action project, inspectors from other competent authorities were also provided with opportunities to improve their knowledge and skills by observing inspections conducted by Agency experts at Latvian pharmaceutical companies. Cooperation with the Food and Veterinary Service regarding inspector training and qualification continued, and training of an expert from the Lithuanian Veterinary Agency was carried out. Within the project, the Agency received additional funding that could be used for training of Department experts.

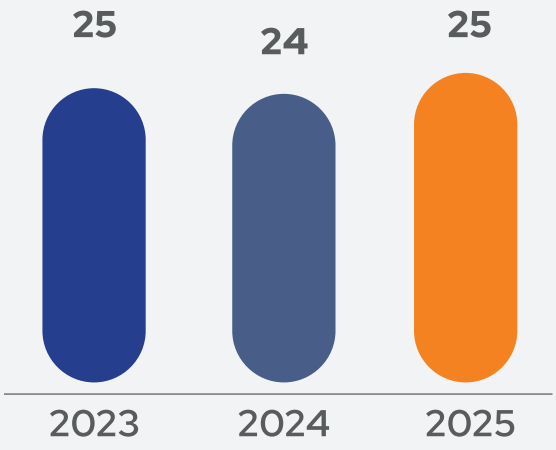
The Agency also carried out 25 Good Distribution Practice inspections of medicinal product wholesalers, six of which were related to issuance or re-registration of special permits (licences) for wholesale distribution of medicinal products.

Based on inspection results, the Department

Good Manufacturing Practice inspections



Good Distribution Practice inspections



prepares draft Good Manufacturing Practice and Good Distribution Practice certificates within the EudraGMDP database, while providing ongoing support to the Pharmaceutical Activity Licensing Department regarding issuance of these certificates.

Implementation of certificate generation exclusively within the EudraGMDP database, from which companies receive printouts, has reduced the Agency's administrative burden, including reduction of inquiries from foreign regulatory authorities regarding minor information discrepancies between database entries and Agency-issued documents.

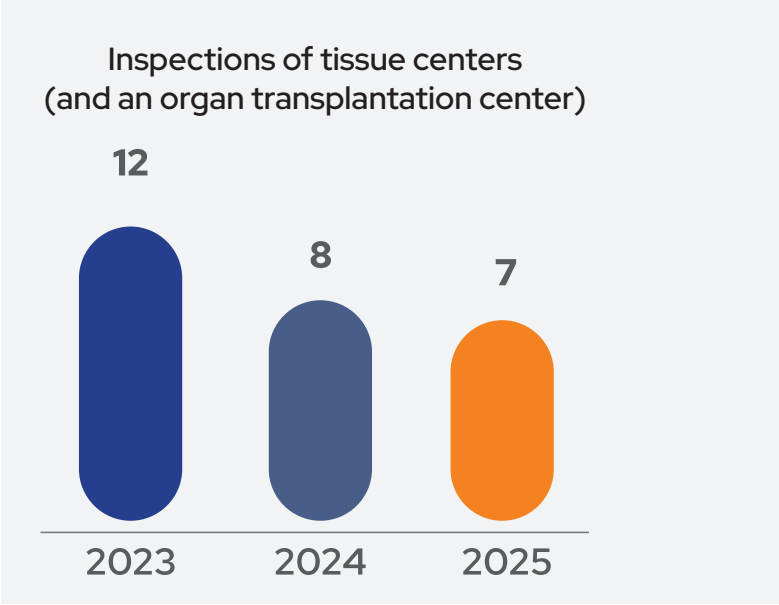
The Department is also responsible for assessment of compliance regarding the use of human blood, tissues, cells and organs in healthcare institutions and universities implementing medical study programmes, in relation to issuance of permits for these activities, which since December 2024 has been carried out by the Pharmaceutical Activity Licensing Department.

The Department performs regular compliance supervision of permit holders authorised by the Licensing Department and until 31 August 2025 was also responsible for biovigilance oversight. In 2025, 15 supervisory inspections of healthcare institutions (tissue centres, blood cabinets, etc.) were conducted. One inspection was carried out in cooperation with the Health Inspectorate. The Department also ensured six document reviews and/or support activities related to assessment of compliance of operational changes in cases where on-site inspections were not required. These involved analysis and evaluation of documentation submitted by institutions against regulatory requirements in relation to issuance of new permits following operational changes (4 cases), change of responsible person and related register amendments (1 case), cancellation of issued permits at the request of the client and removal from the register (1 case).

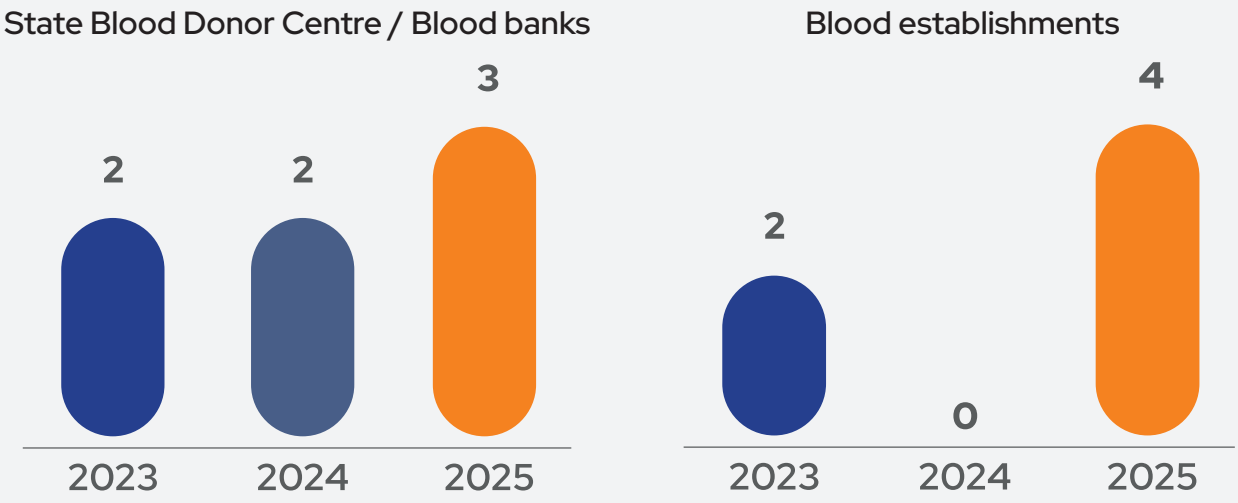
In 2025, no inspections were planned or conducted at the human organ transplantation centre or universities implementing medical study programmes. However, the Agency cooperated with healthcare institutions and NHS to ensure kidney transplantation for children in Latvia in the most efficient manner possible.

Within a short period and successfully, the biovigilance function was transferred to the Department of Biological Products, including training activities, explanation of related processes and documentation (including registers), and implementation of modifications to the online reporting system. The Head of the Department of Biological Products was introduced to Agency SoHO processes and outputs of previous EU Health Programme Joint Action projects related to registration of SoHO products and biovigilance (Notify; SoHO V&S).

In 2025, specialists of the Pharmaceutical Compliance Assessment Department prepared annual reports for EC on serious adverse reactions and serious adverse events in the fields of blood, tissues and cells. Until 31 August, the Department also ensured communication with healthcare institutions re-



Compliance inspections of human blood banks and blood establishments.



garding urgent notifications received online on serious adverse reactions and events, as well as notifications received through EC Rapid Alert Systems in the fields of tissues and cells (RATC) and blood (RAB).

Provision of the biovigilance function was transferred to the Department of Biological Products from 1 September.

The Agency ensured representation in the EMA Working Group of GMP and GDP Inspectors (including expert groups on GDP and revision of GMP guidelines), Pharmaceutical Inspection Co-operation Scheme (PIC/S) activities and working group meetings organised within Joint Action projects (JA11).

The Agency also participated in working groups organised by the European Commission Directorate-General for Health and Food Safety (DG SANTE) in the field of organ transplantation; the SoHO Coordination Board (SCB); three SCB working groups (Regulatory Issues, Vigilance and Traceability, and Inspection); the Nordic Council of Ministers SoHO working group.

For several years, the Agency has also been involved in international cooperation regarding oversight of blood and blood components, tissues and cells, participating in expert working groups of competent authorities established by DG SANTE in the fields of organ donation and transplantation, as well as in the SoHO Coordination Board and its working groups, which commenced operation in 2025 and assumed functions previously performed by DG SANTE expert groups (CASoHO) in the areas of tissues and cells and blood and blood components.

Department specialists also ensured communication with the State Blood Donor Centre and specialists of the Latvian Transplantation Centre regarding submission of vigilance data within EC pilot projects, and with the Latvian Society of Human Reproduction regarding submission of data for a survey on gamete donors. Department experts also prepared responses to several surveys related to the SoHO Regulation.

During the reporting period, work on implementation of the SoHO Regulation in Latvia continued. During routine supervisory inspections, institutions were informed about the requirements of the SoHO Regulation, forthcoming changes related thereto, and opportunities for SoHO professionals to participate in training activities organised by the EDQM.

Information and communication technology management

In 2025, work continued on the development and improvement of information systems and ICT solutions, as well as enhancement of their availability and management. During the year, 1,393 IT support tasks of varying complexity and resource intensity were implemented, including 22 ICT change requests, contributing to increased operational efficiency and providing substantial support to economic operators, the public and Agency employees.

Several significant improvements were implemented on the Agency's website:

- introduction of a local web analytics tool replacing Google Analytics. In the Agency website's section "Medicinal Products Register", Google Analytics was replaced with a fully local website traffic statistics tool in order to avoid complications related to cookie consent notifications and user privacy;
- implementation of cookie consent functionality on dati.zva.gov.lv, enabling users to allow or refuse collection of website traffic statistics;
- updates to the list "Annual Authorisations for Distribution of Unregistered Medicinal Products" on dati.zva.gov.lv;
- updates to the list "Medicinal Products Approved for Distribution in Packaging Intended for Another National Market", enabling searches also by medicinal product batch number;
- NZIP: additional columns "INN" and "ATC code" in exported data, and an additional column "number of medicinal product stock units" in the list of proposed medicinal product analogues;
- RegslotDB: addition of two indicators – medicinal product replacement and cancellation;
- NZIP – the notification system for distribution of unauthorised and centrally authorised medicinal products – enabling receipt and processing of notifications from wholesalers regarding commencement of distribution activities, in connection with amendments to Cabinet Regulation No. 416;

- development of a medicinal product registration documentation variation management tool for handling variations submitted to SAMIS for expert assessment;
- development of a "slot" system for assessment of medicinal product registration documentation for marketing authorisation holders, enabling appointment booking for documentation assessment through the website and operation of a separate system for processing received information;
- publication of the long-list authorisations for unauthorised medicinal products on the website;
- integration of the NHS KZS-L list into the SAMIS database classifier structure. The current KZS-L list is required for compilation of the unauthorised medicinal products list and other purposes within SAMIS;
- Pharmaceutical Activity Companies Register: information on temporarily closed pharmacies obtained from SAMIS.

In 2025, measures were implemented to reduce risks related to IT security, including introduction of new security monitoring solutions and implementation of a computer management tool. Guidelines for the use of artificial intelligence within the Agency were developed. A compliance security audit was carried out and an audit opinion was received.

The following were introduced:

- Cybersecurity and Information Security Policy;
- ICT Information Systems Catalogue;
- Cyber Incident Log;
- updated Risk Register.

Several system and infrastructure improvement activities were also implemented:

- SAMIS servers ensuring operation of the Agency Information System were upgraded;
- Power BI reporting servers were upgraded to a new software release;
- LAN and Wi-Fi network infrastructure was installed, including equipment for data transmission networks, IP telephony and Wi-Fi functionality in the archive building;
- modifications were introduced in SAMIS to collect information regarding sole pharmacies or pharmacy branches and transfer this information to the national e-Health portal in a previously agreed data structure together with other pharmaceutical activity data;
- a total of 39 tasks related to development and maintenance of SAMIS were implemented;
- SAMIS was supplemented to collect information regarding temporarily closed pharmacies and information on the working hours of responsible pharmacy officials and pharmacy opening hours;
- publication of marketing authorisations within the Medicinal Products Register for the respective medicinal products.

Last year, maintenance of the ICT infrastructure used by MH and its subordinate institutions continued, and support was provided to ICT specialists within these institutions.

In 2025, cooperation in electronic information exchange with various European institutions and competent authorities of other countries also continued through the use of common ICT solutions, including:

- the European clinical trials database EudraCT;

- secure email system EudraMail;
- data exchange system Eudralink;
- pharmacovigilance system EudraVigilance;
- data analysis system EVDAS;
- European Database on Medical Devices (EUDAMED);
- CTS solution for mutual recognition procedures;
- Common European Submission Portal (CESP);
- Common Repository for documentation related to centralised marketing authorisation procedures;
- PSUR Repository for Periodic Safety Update Reports.

A new generation version of the medicinal product documentation assessment system – EURSnext – was also introduced.

Priorities for 2026

1. Continued work on standardisation of the EU IDMP project data structure required for EU cross-border data interoperability.
2. Migration of server infrastructure to the national Data Centre.
3. Introduction of a Security Operations Centre (SOC) service.
4. FDU PharmSys: development of web-based forms for submission of information and systems for processing submitted information, including future forms such as notification of working hours and others.
5. Development of a model for collection of medicinal product information to be provided by pharmacies to the Department of Medicinal Product Distribution Information.

Regulatory implementation and amendments

The decisions adopted by the Agency are balanced, lawful and compliant with the requirements of regulatory enactments. In 2025, only 7 out of 6,698 decisions adopted by the Agency were challenged before MH. In 2025, MH revoked two of the Agency's decisions adopted in 2025 that had been challenged.

In 2025, in cooperation with MH, the Agency participated in the drafting of several regulatory enactments that were reviewed and adopted during the year, including the following significant amendments:

- On 11 July 2025, Cabinet Regulation No. 426 of 8 July 2025 "Amendments to Cabinet Regulation No. 416 of 26 June 2007 'Procedures for the Distribution and Quality Control of Medicinal Products'" entered into force. The amendments established:
  - that pharmacies are permitted to distribute non-prescription medicinal products using online platforms, including platforms such as "Wolt". The amendments stipulate that, in such cases, the pharmacy manager is responsible for ensuring the quality of the delivery service provided and supervision of all stages of delivery – order acceptance, consultation on medicinal products, packaging of ordered medicinal products, labelling and attachment of labels to packages, dispatch of shipments and transfer to the courier delivering the medicines;
  - that, in order to improve public awareness, information on medicinal product stocks and prices at individual pharmacies must be made public. According to the amendments, pharmacy owners whose combined pharmacy turnover has exceeded 5% of the total pharmacy turnover in Latvia in at least one year during the previous five-year period are required to publish on their websites information easily accessible to the public regarding medicinal products available at each pharmacy and their prices;
  - the introduction of a notification procedure and determination of cases in which operators are not required to obtain authorisation for distribution of unauthorised medicinal products;
  - that, in order to improve the availability of medicinal products, amendments to the Cabinet Regulation provide that the Agency monitors availability and may restrict export of all reimbursable medicinal products (except medicinal products included in List M), as well as

medicinal products identified by the Agency as associated with public health protection risks, where unavailability of medicinal products has been identified.

- On 24 December 2025, amendments to Cabinet Regulation No. 461 of 15 August 2023 "Medical Devices Regulation" and Cabinet Regulation No. 582 of 10 October 2023 "In Vitro Diagnostic Medical Devices Regulation" entered into force, significantly changing requirements for distributors. According to the amendments, registration in the LATMED database is mandatory only for distributors who:
  - make medical devices available to healthcare institutions;
  - make them available to healthcare professionals;
  - supply devices to other distributors.

These amendments introduce a new balanced payment model for costs related to vigilance of medical devices and in vitro diagnostic medical devices (IVDs).

Medical devices may be distributed in Latvia only by operators registered in the LATMED database. This requirement applies both to medical devices and in vitro diagnostic medical devices.

In 2025, amendments to more than 21 regulatory enactments were reviewed, and proposals and opinions were prepared and submitted both to MH and to other public administration institutions.

International cooperation

The Agency is a member of the European medicines agencies network, and the implementation of the Agency's functions and tasks is closely linked to participation in the common European medicines regulatory network through cooperation among EMA, EC and more than 47 regulatory authorities in the pharmaceutical sector across the EEA.

This cooperation network provides access to a broad range of experts, enabling the Agency to ensure the best possible scientific expertise within the EU medicines regulatory environment. National experts, including specialists from the Agency, participate in the work of the EMA as members of working parties, scientific advisory groups and scientific committees.

In 2025, Agency employees were involved in cooperation with EMA scientific committees, working groups of the EC and the Council of Europe, EDQM, and working groups established by the HMA network, among others.

EMA Committees in Which the Agency Participates

- Committee for Medicinal Products for Human Use (CHMP)
- Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- Committee for Advanced Therapies (CAT)
- Committee for Orphan Medicinal Products (COMP)
- Committee on Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)

Overall, the Agency participates in more than 30 international working groups, including EMA working parties dedicated to specific regulatory aspects.

For example, Agency representatives participate in:

- the EMA CHMP Biologics Working Party,
- the EMA Medicines Shortages and Safety Steering Group (MSSG),
- the Medical Devices Shortages and Safety Steering Group (MDSSG),
- the EMA Quality Review of Documents Working Group,
- the Pharmacovigilance Inspectors Working Group,
- the Good Clinical Practice Inspectors Working Group,
- the Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Inspectors Working Group,
- the European Medicines Regulatory Network international cooperation platform,
- and other international expert groups.

Last year, the management of the State

Agency of Medicines also participated in the EMA management group.

In 2025, the Agency also ensured participation in the Working Group of Experts on Drug Precursors, as well as participation in the 62nd session of the United Nations Office on Drugs and Crime (UNODC) Commission on Narcotic Drugs.

For several years, the Agency has also been involved in international cooperation regarding supervision of medical devices and blood and blood components, tissues and cells by participating in working groups established by the Directorate-General for Health and Food Safety of the European Commission, including the Competent Authorities Working Group on Organ Donation and Transplantation, the Competent Authorities Working Group on Tissues and Cells, the Competent Authorities Working Group on Blood and Blood Components.

The Agency is the competent authority in Latvia for issuing authorisations for clinical investigations of medical devices and for conducting vigilance activities. Responsible Agency specialists regularly attend meetings of representatives of European national competent authorities for medical devices.

The Agency also has a binding cooperation agreement with the medicines agencies of Estonia and Lithuania, promoting closer cooperation among the Baltic medicines agencies in regulatory matters. Last year, a joint working meeting of the medicines agencies of the Baltic States and Poland was also held.

In order to fully participate in common European procedures, which constitute additional responsibility and obligations for the Agency, qualified human resources and adequate financial resources are undeniably necessary.

More detailed information regarding the results of international cooperation activities can be found in the respective sections of this report covering the Agency's achievements in specific areas.

Communication

In 2025, the Agency's external communication was also carried out in accordance with the institution's medium-term operational strategy and the Communication Strategy for 2024–2026, providing evidence-based, independent information in the public interest to residents, specialists and the pharmaceutical sector.

In 2025, the Agency significantly exceeded planned indicators across all communication areas, ensuring broad, timely and high-quality information exchange.

Publications and media

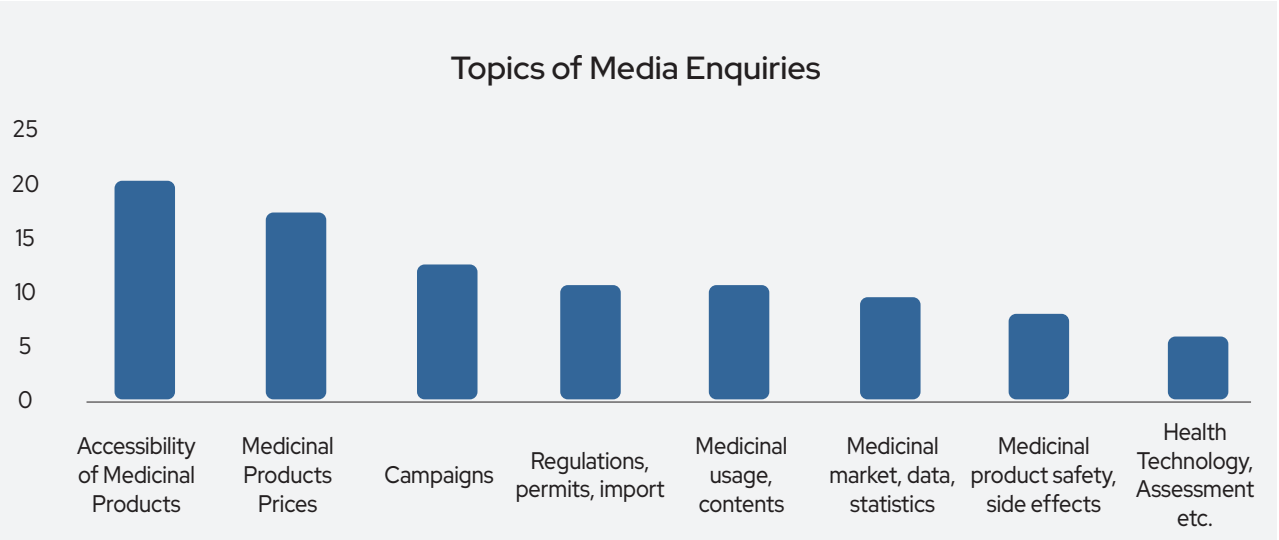
in 2025, the Agency prepared 20 press releases, ensuring 100% coverage in national media. The Agency received 91 media enquiries.

Agency specialists regularly participated in discussions and broadcasts, explaining issues of public relevance concerning the safety and use of medicinal products.

Information on the Agency's website

in 2025, 92 news items were published on the Agency's website, and information in website sections was updated approximately 600 times, demonstrating that informing patients, society, healthcare professionals and the pharmaceutical industry was a significant priority.

The Agency provides objective, reliable and up-to-date information on medicinal products and medical devices on its website, as well as information on the Agency's services and institutional activities.



Social media

in 2025, the Agency created 303 social media posts, published 25 videos and 6 infographics, and delivered 5 informative presentations. Social media served as an important channel for informing the public about medicinal product safety, adverse drug reaction reporting, availability of medicinal products and other current topics.

The Agency's informative materials and videos on social media reached a total of 212,665 views.

Campaigns

1. Campaign "Medicines Are Not Sweets"

The aim of the campaign was to promote public awareness of the correct and responsible use of over-the-counter medicines. The campaign emphasised that over-the-counter medicines must also be used in accordance with the information provided in the package leaflet and the instructions of a doctor or pharmacist.

This campaign took place simultaneously in EEA countries and was organised by European medicines agencies.

In Latvia, the Agency carried out communication on social media, an outdoor advertising campaign at public transport stops, prepared an advertising video, and Agency experts explained medicine-use-related topics in the media, including in the programme "Science or Nonsense", along with other activities.

2. Medicines Safety Week (#MedSafetyWeek)

In November 2025, the Agency participated in the international campaign "Medicines Safety Week", involving more than 130 organisations worldwide. During the campaign, patients and healthcare professionals were encouraged to report suspected adverse reactions to medicines.

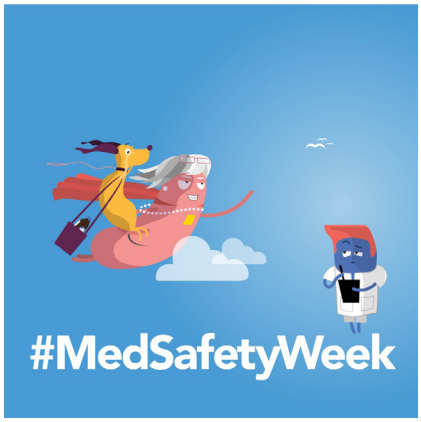
Overall, through informative activities on social media, the Agency reached more than 133,000 users.

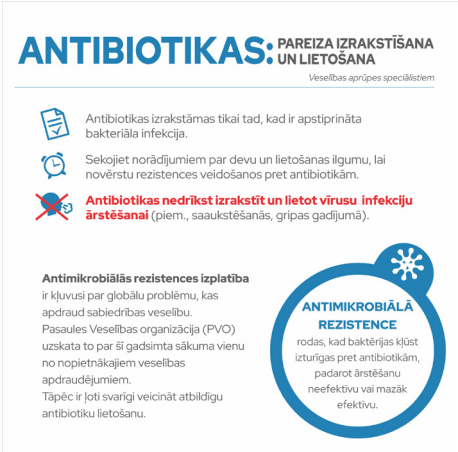
3. European Campaign "Health, Not Hype" and Agency Discussion on the Safe Use of GLP-1 Medicines

In cooperation with external experts, the Agency organised a public discussion on the safe use of GLP-1 medicines.

The aim of the discussion was to promote public understanding and provide science-based information on the use of these medicines.

On social media, the discussion content



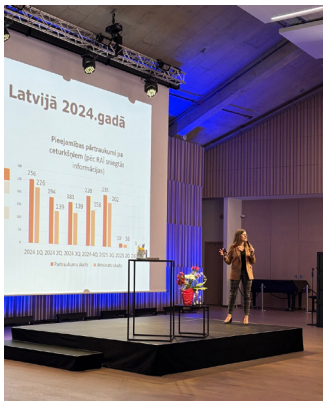


reached more than 21,000 views. The discussion was streamed live and also published in podcast format.

4. **World Antimicrobial Awareness Week**
   In support of World Antimicrobial Awareness Week activities, the Agency provided information on the correct and prudent use of antibiotics in order to draw attention to bacterial resistance to antibiotics.
5. **Information Campaign on Availability of Medicines "It Takes a Team"**
   The Agency participated in joint activities of the European medicines regulatory network, informing the public that cooperation between healthcare professionals, pharmacists, medicines users, pharmaceutical companies and public authorities plays an essential role in ensuring the availability of medicines.
6. **Campaign "Do Not Believe Fairy Tales! Believe in Science! Get Vaccinated!"**
   The Agency participated in the campaign organised by the Children's Clinical University Hospital and the National Immunisation Council by preparing informative articles on vaccines and their adverse reactions, as well as carrying out social media activities to promote reporting of adverse reactions.

Patient organisations forum "Availability of medicines, awareness and involvement"

Last year, the Agency organised the Patient Organisations Forum "Availability of Medicines, Awareness and Involvement". The forum focused on dialogue with patient organisations on current issues related to ensuring availability of medicines and



strengthening patient involvement in healthcare system processes.

The forum brought together representatives of various patient organisations. During the event, the Agency presented current developments in the field of medicines availability and discussed future cooperation opportunities with the patient community.

The programme included presentations and discussions on habits related to the use of over-the-counter medicines, solutions in cases of medicines supply disruptions, and innovative initiatives such as the introduction of electronic package leaflets and availability of the clinical trials map.

The forum provided a platform for representatives of patient organisations to express their views, share experience and make proposals for future cooperation and improved patient awareness, thereby strengthening patient participation in decision-making and communication on the availability and safety of medicines.

Informing healthcare professionals and pharmacists

Last year, three issues of the Agency's informative publication for doctors, pharmacists and other healthcare professionals, "Cito!", were published, providing important information on the safety of medicinal products and medical devices.

The main purpose of the publication is to introduce healthcare professionals in Latvia to the latest scientifically based information and recommendations on the safe use of medicines.

Last year, the number of "Cito!" recipients increased, reaching 717 readers.

Cooperation and information for the sector

In 2025, the Agency strengthened cooperation with the sector and improved information provision to the pharmaceutical industry regarding changes in the regulatory framework.

Client seminars were organised, during which regulatory requirements were explained, practical application recommendations were provided, client questions were answered and sector challenges were discussed.

Last year, the Agency's cooperation with regulators in the EEA and beyond was also promoted.

An interactive client feedback tool was introduced – surveys using a QR code after seminars – in order to improve service quality and cooperation.

Strengthening trust in the Agency

In 2025, informative and educational activities were implemented to strengthen trust among the public, healthcare professionals and the pharmaceutical industry.

Particular attention was paid to cooperation with future sector professionals, promoting understanding of the Agency's work and career opportunities.

In 2025, the Agency participated in "Ēnu diena" and organised several meetings during which presentations were delivered to students.

Targeted cooperation with professional organisations was also continued, strengthening the Agency's reputation as a reliable and science-based regulator.

Last year, the annual public report on the institution's activities and achievements in 2024 was prepared in Latvian and English.

International cooperation

The activities of the Agency's Public Relations Unit in two international working groups should be highlighted – the HMA Working Group of Communication Professionals (WGCP) and the European Medicines Regulatory Network international cooperation platform.

This cooperation ensured proactive communication of information provided by the EMA to Latvian society, delivering important information on centrally authorised medicines in the EU, their approval and safety, adverse reactions and other aspects.

Research

- Last year, the Public Relations Unit conducted a **public opinion survey** in cooperation with the research centre KANTAR on adverse reaction reporting, use of medicines and preferred communication channels.
- **A client and cooperation partner survey** was conducted to assess the Agency's work and services, with the aim of using the results to improve client service, information provision, cooperation with clients and the quality of services provided by the Agency.
- The purpose of the **employee survey** was to identify employees' views on work organisation, involvement in processes, cooperation and other important aspects.
- **Ad hoc surveys** were also conducted last year to ensure that the Agency's communication activities are data-driven.

Internal communication

In order to embed the Agency's values and develop organisational culture, five internal events for Agency employees were organised last year.

In 2025, the Agency provided up-to-date information to employees through the internal information platform – the intranet "Agency Pulse".

More information on communication activities carried out last year is available in the section of this public report on the work completed during the reporting year.

Integrated management system and audits

In order to implement the principles defined in the Agency's Quality Policy and achieve the established objectives, maintenance and continuous improvement of the quality management system continued in 2025, ensuring certification in accordance with the requirements of ISO 9001:2015 "Quality Management Systems", ISO/IEC 27001:2022 "Information Security, Cybersecurity and Privacy Protection – Information Security Management Systems", and ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories", as well as international guidelines and recommendations.

During the reporting period, the audit "Audit of Human Resource Management Functions and Improvement of Human Resource Processes", initiated by MH in 2024, and the audit "ICT Security Management", initiated in 2025, were completed. Both audits concluded without observations. The audit "Circulation of Human Medicinal Products", initiated in 2025, continued.

In addition to external audits, nine internal audits were conducted within the Agency, focusing on the effectiveness of internal processes, management of pharmaceutical activities and information security management.

The integrated management system facilitated coordination and management of the Agency's activities in order to comply with customer and regulatory requirements and continuously improve organisational effectiveness. One of the outcomes was that 93% of respondents in the client survey provided a positive assessment of the quality of services delivered by the Agency.

Following changes to the Agency's organisational structure, approval of a new strategy and consideration of future challenges, a decision was taken to review the concept of quality indicators, with particular emphasis placed on process optimisation.

In order to reduce the administrative burden on clients, the Agency continued work on process optimisation. During 2025, five processes were successfully optimised, thereby exceeding the strategic objective of optimising at least two processes to reduce administrative burden for clients.

Guidelines for the use of artificial intelligence were developed and implemented within the Agency. These measures represent a purposeful response to current global developments and rapid technological progress, while demonstrating the Agency's commitment to actively using new technologies to improve work efficiency and quality.

Particular attention within the guidelines was devoted to data security, information protection and responsible use of artificial intelligence tools in daily operations.

Special attention was also devoted to Agency security – despite the complex geopolitical situation, the Agency successfully ensured 98% availability of information systems during working days throughout the year.

It is particularly important to highlight that:

- the Agency was recertified for a further three years in accordance with ISO 9001:2015 "Quality Management Systems" and ISO/IEC 27001:2022 "Information Security, Cybersecurity and Privacy Protection – Information Security Management Systems";
- the State Agency "Latvian National Accreditation Bureau" accredited the Agency's laboratory, recognising its compliance with the requirements of LVS EN ISO/IEC 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories" and confirming its competence to perform testing activities.

Planned Activities for the Next Period

- In 2026, active work will continue on implementation of International Organization for Standardization (ISO) standards for Identification of Medicinal Products (IDMP).
- Together with other EU, EEA and several EU candidate countries, activities will be carried out within the framework of the Joint Action "EU4H-2026-JA-SANTE-IBA-03 – Direct grants to Member States' authorities to support the implementation of a common standard for medical product identification and AI capabilities across Member States" in order to coordinate implementation of the ISO IDMP standard across the network.
- In 2026, the Agency's Medicines Examination Laboratory will once again undergo an audit within the framework of Mutual Joint Audits (MJA) organised by the EDQM.
- Provision of new services and participation in the national public service environment improvement plan through enhancement of service management processes.

Energy efficiency at the Agency

In 2025, reconstruction of the Agency's archive building was completed, significantly improving energy efficiency and reducing energy consumption for heating across an area of 940 m².

The Agency's building heating system operates using autonomous gas heating equipment. In order to reduce dependence on natural gas and energy resources, development of a project was initiated in 2025 to integrate renewable energy technologies (air-to-water heat pumps) into the existing building heating system.

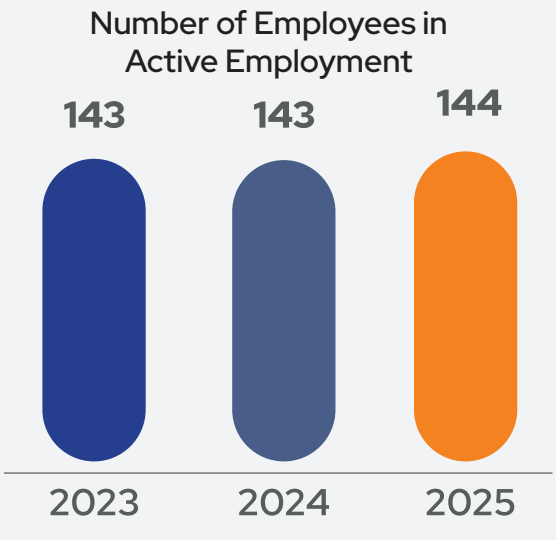
Continuity of the Agency's operations in the event of electricity supply interruptions is ensured by a diesel generator.

The Agency continuously ensures efficient use of resources under its management by implementing sorting of paper, glass, metal and PET waste, as well as collection and recycling of obsolete electrical and computer equipment.

In addition, only energy-efficient lighting solutions are used for building illumination.

Personnel management and training

At the end of 2025, a total of 151 employees were in employment or civil service relationships with the Agency. Staff turnover amounted to 7% (the proportion of employees whose employment relationships were terminated in relation to the average number of employees in active employment). The overall education level of Agency employees remained high – 140 employees, or 93%, held higher education qualifications, including 6 employees with doctoral degrees.



In order to ensure the Agency's sustainable development, particular attention was devoted to mentoring programmes, development of staff competencies and targeted enhancement of required knowledge.

Of the 17 new colleagues who commenced work at the Agency in 2025, 15 received mentor support, while mentors were assigned to 30 employees for professional development purposes.

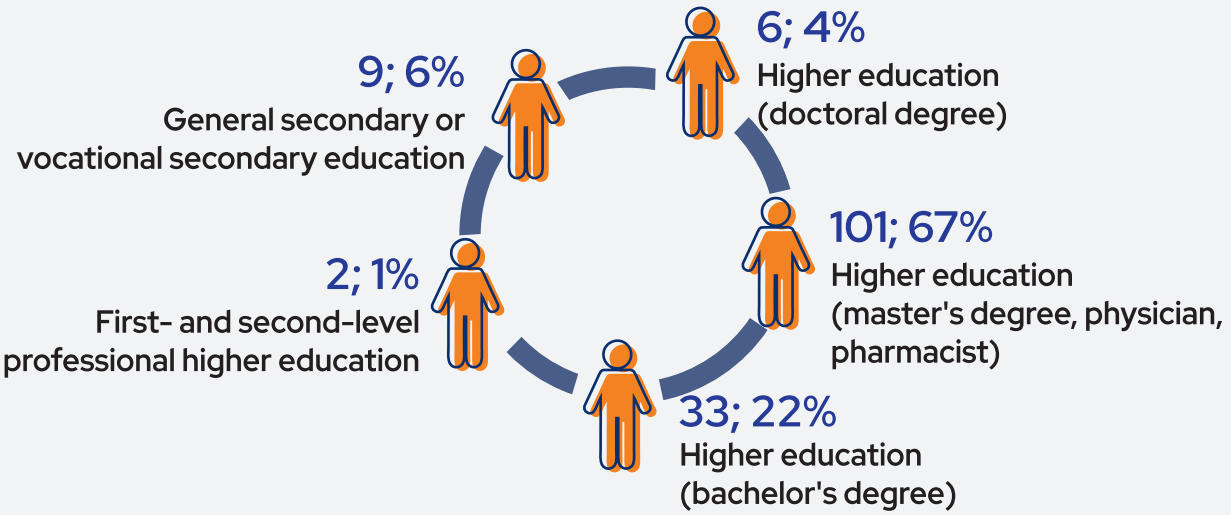
As part of talent management activities, 8 employees (6%) were promoted to higher-level positions.

During the reporting year, all employees received training on risk management, personal data protection, occupational safety, IT security, design thinking and artificial intelligence. Heads of structural units received both theoretical and practical training on risk management, receiving and providing feedback, and media training.

In 2025, Agency's employees participated in 257 international events (including 205 business trips), ensuring both professional competence development and expert representation in

committees, working groups and various expert subgroups established by the EMA, European Commission, Council of Europe, EDQM and the Nordic Council of Ministers.

Distribution of Employees by Education Level



Results of the 2025 Employee Survey

88 %	of employees are satisfied with working at the Agency;
87 %	of employees are satisfied with the handling of human resource management matters and the availability of relevant information (leave and absence applications, business trip arrangements, consultations and support in resolving various HR-related matters);
92 %	of employees are satisfied with the support provided for resolving administrative matters and are satisfied with the working environment, which was assessed as safe and comfortable;
88 %	of employees are satisfied with the technical equipment and IT support provided.

Appendix 1

FUNDING AND ITS UTILISATION

Agency Budget Funding and Its Utilisation

Classification code	Budget item	Annual plan (including amendments)	Budget execution during the reporting period	Previous reporting period
I.	**REVENUE**	6,943,149	7,762,703	7,442,535
3	Fee-based services and other own-source revenue	5,044,313	5,564,608	5,522,266
21.4.0.0.	Other revenue from fee-based services and other own-source revenue of institutions not classified under group 21.3.0.0.	5,044,313	5,564,608	5,502,381
4	Foreign financial assistance	1,824,395	2,123,654	1,835,753
21.1.0.0.	Institutional revenue from foreign financial assistance	1,824,395	2,123,654	1,835,753
5	Transfers	74,441	74,441	84,516
17.4.0.0.	Transfers received by partially state-funded derived public persons and non-budget-financed institutions from other partially state-funded derived public persons and non-budget-financed institutions	0	0	1,125
18.3.0.0.	Transfers received by partially state-funded derived public persons and non-budget-financed institutions // Transfers received from the state budget	74,441	74,441	83,391
II.	**TOTAL EXPENDITURE**	7,954,264	7,749,844	7,841,007
1000	Remuneration	5,926,076	5,914,685	5,856,779
1100	Salaries	4,567,992	4,546,687	4,517,374
1200	Employer mandatory state social insurance contributions, benefits and compensations	1,358,084	1,367,998	1,339,405
2000	Goods and services	1,466,011	1,270,280	1,172,602
1.3.	Subsidies, grants and social benefits	0	0	15,000
6000	Social payments and compensations	0	0	15,000
1.5.	Transfers within one budget category and maintenance expenditure transfers between budget categories // Maintenance expenditure transfers	117,518	123,888	21,102
7810	Maintenance expenditure transfers from partially state-funded derived public persons and non-budget-financed institutions to the state budget	117,518	123,888	21,102
2.1.	Capital formation	444,659	440,991	775,524
5000	Capital formation	444,659	440,991	775,524
5100	Intangible investments	0	0	67,566
5200	Fixed assets	444,659	440,991	707,958
III.	**SURPLUS (+) / DEFICIT (–) (I – II)**	–1,011,115	12,859	–398,472
IV.	**Financing**	1,011,115	–12,859	398,472

Appendix 2

INDEPENDENT AUDITOR'S REPORT

SIA A. Kursīte's Audit Firm
Raiņa Street 13-2
Madona, LV-4800, Latvia
Tel/Fax: +371 6483813
E-mail: anita.kursite@inbox.lv

Independent Auditor's Report

Madona

The date of this document is the date of its electronic signature.

No. 09-03./2026

To the State Agency of Medicines

Our Opinion on the Financial Statements

Opinion

We have audited the financial statements included in the accompanying annual report of the State Agency of Medicines (hereinafter referred to as the "Agency").

The accompanying financial statements comprise:

- the Statement of Financial Position (Balance Sheet) as at 31 December 2025;
- the Statement of Financial Performance for the year ended 31 December 2025;
- the Statement of Changes in Equity for the year ended 31 December 2025;
- the Cash Flow Statement for the year ended 31 December 2025;
- information on budget execution for the year ended 31 December 2025;
- the Notes to the Financial Statements, including explanations of financial statement items, a description of accounting policies, and a description of the principles applied in preparing the annual report.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the State Agency of Medicines as at 31 December 2025, and its financial performance and cash flows for the year then ended, in accordance with Cabinet of Ministers Regulation No. 400 of 1 July 2025, "Procedure for the Preparation of Annual Reports."

Basis for Opinion

We conducted our audit in accordance with the Audit Services Law and the International Standards of Supreme Audit Institutions (ISSAI) recognized in Latvia.

Our responsibilities under those standards are further described in the section "Auditor's Responsibilities for the Audit of the Financial Statements."

We are independent of the Agency in accordance with the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants and the independence requirements contained in the Audit Services Law applicable to our audit of the financial statements. We have also complied with the other ethical requirements and objectivity principles established by the Audit Services Law and the International Code of Ethics for Professional Accountants.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other Matter

The financial statements for the year ended 31 December 2024 were audited by another auditor who issued an unmodified opinion on 20 February 2025.

Other Information

Management is responsible for the other information. The other information comprises:

- the Management Report included in the annual report.

The other information does not include the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information, and we do not express any form of assurance conclusion thereon, except as described in the section "Other Reporting Responsibilities under Latvian Legislation."

In connection with our audit of the financial statements, our responsibility is to read the other information and consider whether it is materially inconsistent with the financial statements or with the knowledge obtained during the audit, or otherwise appears to be materially misstated.

Based on the work performed and our understanding of the Agency and its operating environment obtained during the audit, we have not identified any material misstatements in the other information.

Other Reporting Responsibilities under Latvian Legislation

In accordance with the Audit Services Law, we are also required to assess whether the Management Report has been prepared in accordance with Cabinet of Ministers Regulation No. 400 of 1 July 2025, "Procedure for the Preparation of Annual Reports."

Based solely on the procedures performed within the scope of our audit, in our opinion:

- the information provided in the Management Report for the reporting year for which the financial statements have been prepared is consistent with the financial statements.

Responsibilities of Management and Those Charged with Governance

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Cabinet of Ministers Regulation No. 400 of 1 July 2025 and for such internal control as management determines is necessary to enable the preparation of financial statements free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Agency's ability to continue as a going concern and, where appropriate, disclosing matters related to going concern and applying the going concern basis of accounting unless the Agency is planned to be merged with another institution or divided.

Those charged with governance are responsible for overseeing the Agency's financial reporting process.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion.

Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISSAI will always detect a material misstatement when it exists.

Misstatements may arise from fraud or error and are considered material if they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISSAI, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- identify and assess the risks of material misstatement due to fraud or error;
- design and perform audit procedures responsive to those risks;
- obtain an understanding of internal control relevant to the audit;
- evaluate the appropriateness of accounting policies used;
- evaluate the reasonableness of accounting estimates and related disclosures;
- conclude on the appropriateness of management's use of the going concern basis of accounting;
- evaluate the overall presentation, structure, and content of the financial statements;
- direct, supervise, and review the audit work performed and remain solely responsible for the audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including significant deficiencies in internal control identified during the audit.

SIA "A. Kursīte's Audit Firm"
(Company License No. 20)
Anita Kursīte
Member of the Board

Responsible Certified Auditor:
Ilze Lipska
Certificate No. 213

THIS DOCUMENT HAS BEEN ELECTRONICALLY SIGNED WITH
A SECURE ELECTRONIC SIGNATURE AND CONTAINS A TIME STAMP