State Agency
of Medicines
Republic of Latvia

State Agency of Medicines

ANNUAL REPORT

2024

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ABBREVIATIONS

Agency	State Agency of Medicines
ATMP	Advanced Therapy Medicinal Product
CAP	Centralised authorisation procedure
CHMP	Committee for Medicinal Products for Human Use
CDC	Centre for Disease Prevention and Control
CM	Cabinet of Ministers
CITS	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
MAH	Marketing authorisation holder
MH	Ministry of Health
MRP	Mutual recognition procedure
NHS	National Health Service
NP	National procedure
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
SEMS	State Emergency Medical Service
SoHO	Substances of human origin
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

FOREWORD

Indra Dreika,
Director of the State Agency of Medicines

Dear colleagues, collaboration partners, and the people of Latvia,

The year 2024 has been a year of growth, transformation, and purposeful development for the State Agency of Medicines. Over the past year, the Agency has not only successfully fulfilled its main functions but has also bravely strengthened its position as a reliable, professional, and internationally recognized regulator in the healthcare sector.

Our goal is clear and unchanging – to ensure that citizens have access to safe, effective and high-quality medicines and medical devices, as well as to make decisions based on science, evidence and the interests of human health. We have achieved this goal in 2024 by operating not only at the national level, but also by actively representing Latvia in the working groups and committees of the European Medicines Agency and other international institutions.

The Agency has been focused on development – by introducing processes that promote digitalization, data management, quality management in accordance with ISO standards and efficient use of resources. We have taken significant steps towards improving the client experience by creating a Client Portal and simplifying the procedure for issuing permits. In turn, our Agency's communication in 2024 was assessed as having the highest level of maturity in public administration.

It is particularly gratifying that in 2024, the level of public involvement in the safety monitoring of medicines has increased significantly. The Agency's public information campaign has contributed to an increase in the number of reports on adverse drug reactions by more than 30%, making this pro-

cess more understandable, convenient and accessible to the public.

In 2024, we significantly strengthened cooperation with clients, recognizing that mutual trust is important for joint initiatives and the improvement of regulatory requirements and solutions. We organized more client days and meetings with industry representatives, where we not only provided answers to current issues, but also listened to client's needs and suggestions. These events not only contributed to the development of joint projects, but also strengthened us as a cooperative and professional partner.

At the same time, the past year has also reminded us of areas where improvements are still needed – both in the development of the client portal and in the availability of information on medical device vigilance. These are issues that we will address in 2025.

We also received special recognition at the international level – in October 2024, the Agency successfully participated in the Joint Audit Program (JAP) audit, which assessed our good manufacturing practice monitoring and cooperation with the Health Inspectorate. The audit confirmed the compliance of our systems with international standards and provided recommendations for further improvement.

Looking to the future, the Agency is aware of its role not only as an implementer, but also as a partner, innovator and supporter of the pharmaceutical industry, society and policymakers.

Our vision for 2025 is to become a competence center for pharmaceutical development, an organization that inspires and offers convenient self-service tools to clients, strengthens cooperation with clients and helps local manufacturers grow.

The work of the Agency would not be possible without our employees – highly qualified, motivated professionals, whose knowledge, responsibility and ability to act every day form a solid foundation for our common goal. Therefore, one of our priorities is and will remain the creation of a modern work environment and development for employees, **so that the Agency will continue to be an institution where the best in the industry want to work.** We are aware that each of us – with our work, actions and ideas – contributes to the creation of a healthier society.

The pages of this report reflect not only numbers and facts **– they tell of high professionalism, cooperation and confidence that every decision made, every permit, every authorised medicine and consultation provided brings us closer to a healthier society.**

I would like to thank every employee of the Agency, our partners and clients in Latvia and abroad, as well as all those who collaborated, trusted and supported us in 2024. With confidence and professionalism, we will continue to strengthen public health and its interests in 2025.

With respect and gratitude,
Indra Dreika
Director 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.

FEATURES

- 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 2024, the Agency operated as a public agency and its funding was mainly provided by revenue for fee-based services. On 18 December 2024, new Cabinet Regulation No 895 on the price list for paid services provided by the State Agency of Medicines was adopted, which entered into force on 1 January 2025.

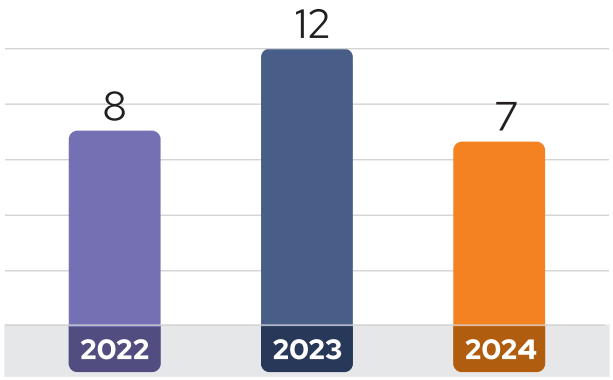
MARKETING AUTHORISATION OF MEDICINES

Inese Birzule,
Deputy Head of Medicines Marketing Authorisation Department

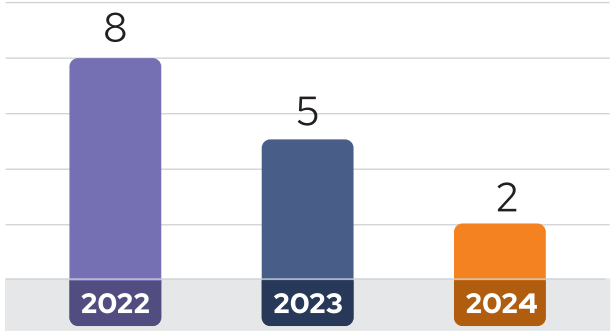
'The principal duty of the Medicines Marketing Authorisation Department is to ensure the scientific evaluation of the marketing authorisation dossiers of medicinal products submitted by the pharmaceutical companies. A positive decision regarding the marketing authorisation of a medicinal product means that the medicinal product has been manufactured in compliance with the requirements, possesses proven efficacy and a positive risk-benefit ratio, and has an adequate safety monitoring plan. Therefore, the personnel of the Medicines Marketing Authorisation Department, in close cooperation with the colleagues from the Primary Expertise and Procedure Coordination Division, the Medicines Safety Division and the Medicines Expertise Laboratory,

make a significant contribution to the availability of high-quality, efficient and safe medicinal products to the population of Latvia.

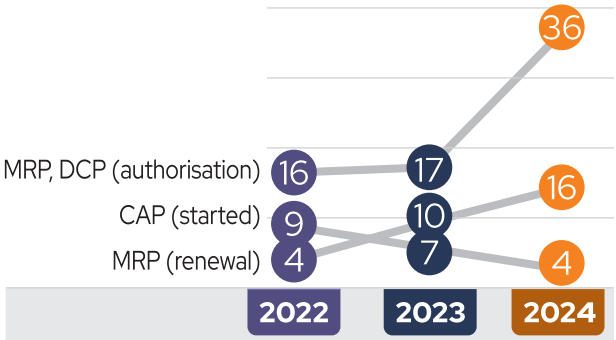
In their scientific evaluation work last year, the Agency's experts also actively took the lead in various international registration procedures and purposefully developed their competencies in order to be able to ensure a consistently high quality of evaluation of registration dossiers also for innovative medicines and complex registration procedures."



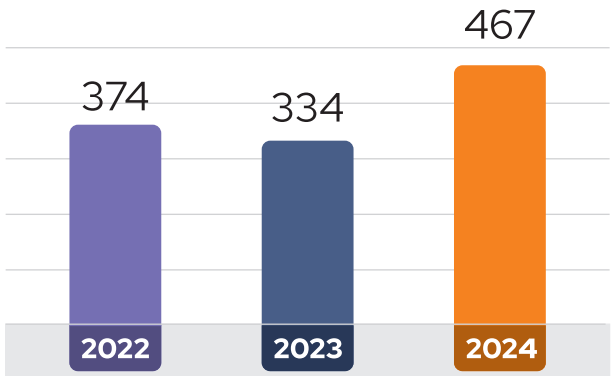
Marketing authorisations via national procedure with positive outcome



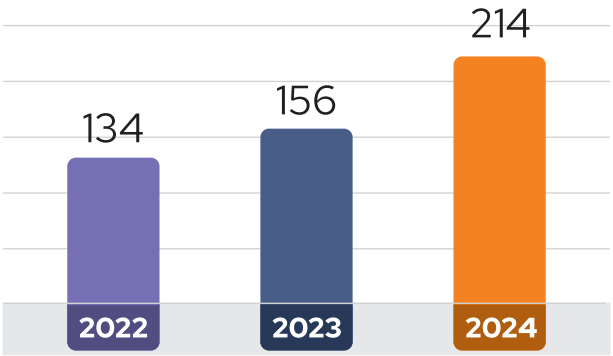
Medicinal product renewals via national procedure



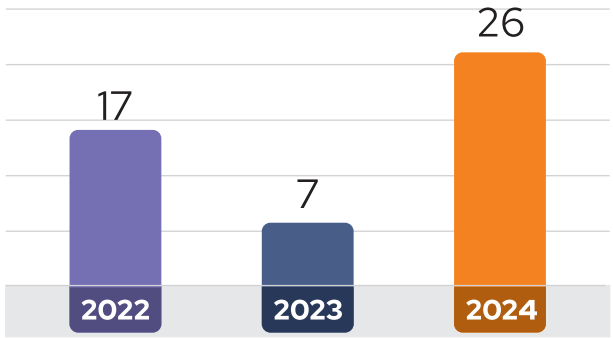
Marketing authorisations and renewals (Latvia as a Reference Member State)



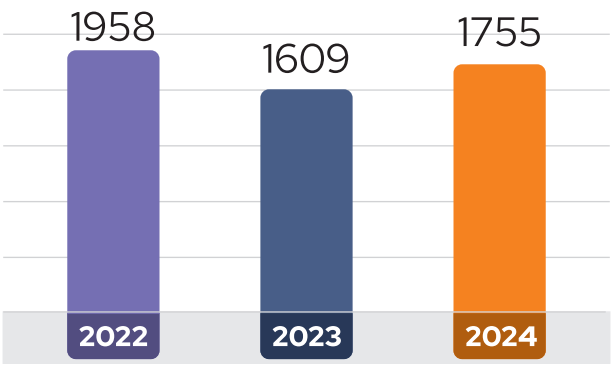
Marketing authorisations and renewals (Latvia as a Concerned Member State) with positive outcome



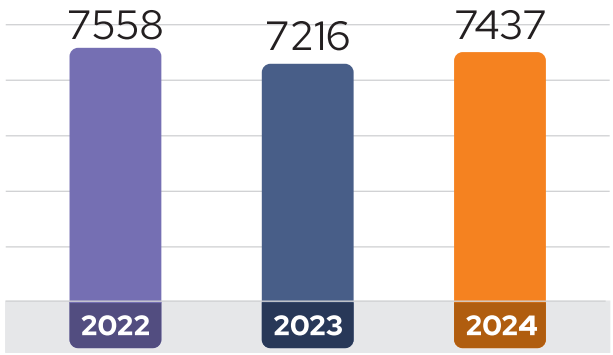
Type IA/IB variations (Latvia as a Reference Member State) with a positive outcome



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



Variations via national procedure



Total number of variations to marketing authorisation documentation

Last year, Latvia ensured marketing authorisation and renewal of 52 medicinal products via decentralised procedures (DCP) and mutual recognition procedures (MRP) as a Reference Member State.

Latvia also participated in 467 MRP and DCP marketing authorisation and renewal procedures as a Concerned Member State.

In 2024, compared to the previous year, the number of variations to the marketing authorisation documentation is almost the same as in 2023, but there has been an increase in the number of pending variations for which we are the RMS, the reference country (almost 50%), for both type I and type II variations. The number of changes to be examined in the Latvian worksharing (WS) procedures has also increased: 4 changes in 2024; in 2023, 3 changes; 2 WS change in 2022.

In 2024, the Agency experts evaluated 4 applications and issued their opinion on product compliance with the definition of medicines. Last year, answers were also provided to questions from citizens and Latvian authorities on various issues related to the authorisation and safety of medicines, as well as other issues.

The experts of the Agency's Marketing Registration Department have informed the industry representatives about the latest developments in the authorisation of medicinal products both within the framework of the Agency's information seminars - Client Days, and during face-to-face meetings with representatives of manufacturers.

Last year, the Agency also issued 318 Certificates of Free Sale and Certificates of Pharmaceutical Products, thus, promoting export of medicinal products authorised in Latvia to countries outside of EU. These certificates verify that companies manufacture medicines in compliance with Good Manufacturing Practice – according to strict and common quality standards and requirements.

Last year, as in previous years, the Agency's experts were active in international cooperation within the European Network of Medicines Agencies. The Agency's experts carried out scientific evaluation for 7 centralised marketing authorisation procedures (CAP), which were started in 2023, as well as for variations of CAP authorised medicines.

Latvia is also represented in the EMA Paediatric Committee. The Agency's delegated representative to the EMA's Paediatric Committee chairs the Neonatal Task Force and acts as rapporteur for the revision of the Guideline on Newborn Medicinal Products.

Experts from the Medicines Marketing Authorisation Department together with external experts actively participated in the work of the Committee for Advanced Therapies (CAT), Committee for Orphan Medicinal Products, Committee on Herbal Medicinal Products and other committees. Experts regularly participated in the work sessions of EDQM as external experts.

By participating in the EMA Scientific consultation working group, Agency's marketing authorisation experts in collaboration with outsourced experts have provided scientific consultations regarding 25 aspects of medicinal product development, research and authorisation.

By the end of the period of review, the Agency had:

- carried out a scientific evaluation of more than 8 023 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 528 medicinal products;
- evaluated 7161 applications for variations to marketing authorisation documentation of medicines with a positive outcome.

MEDICINAL PRODUCT DISTRIBUTION

Katrīna Lukša,
Head of the Medicines Distribution Information Department

"In 2024, the Department for Information on the Distribution of Medicinal Products (further - the Department) had an integral part of its day-to-day work in ensuring access to medicinal products for Latvian patients and solving related issues – both solving acute issues and improving and optimising the basic processes (including making amendments to regulatory enactments) in order to ensure, as far as possible, a more stable and rapid availability of safe and high-quality medicinal products (both the availability of authorized medicinal products, the issuing of distribution permits and the harmonization of exceptional or relief cases)."

Taking into account that availability of medicines is affected by processes both nationally and on a larger scale (in Europe and around the world), cooperation has taken place not only with Latvian stakeholders (marketing authorizations holders, wholesalers, pharmacies, doctors associations and hospitals, other public institutions, etc.), but also with European institutions and their working groups (e.g. EMA, incl. developing Union list of critical medicines, the EU single point of contact, EDQM) to use all the mechanisms that are possible and most relevant to each situation.

In order to facilitate the distribution process of certain medicinal products and to speed up the availability of medicinal products to patients, the Department has prepared and made proposals for amendments to Cabinet Regulation No 416 of 26 June 2007 "On the procedure for the distribution and quality control of medicinal products" – after the amendments have been made, the distribution of certain unauthorized and centrally registered medicinal products will be facilitated by imposing an obligation on economic operators to provide a notification instead of obtaining each distribution authorisation issued by the Agency. This will allow patients to receive medicines more quickly and will make it easier for merchants and the Agency to work.

As part of the amendments, it is also planned to expand the list of medicines subject to stricter control when merchants wish to export or transfer medicines intended for Latvian patients to another EU/EEA country – this will only be allowed with the Agency's permission, (once it has been confirmed that the needs of Latvian patients are primarily ensured).

During the previous year, regular maintenance and updating of the abovementioned list of medicinal products, information of merchants and assessment of applications for the export of medicinal products.

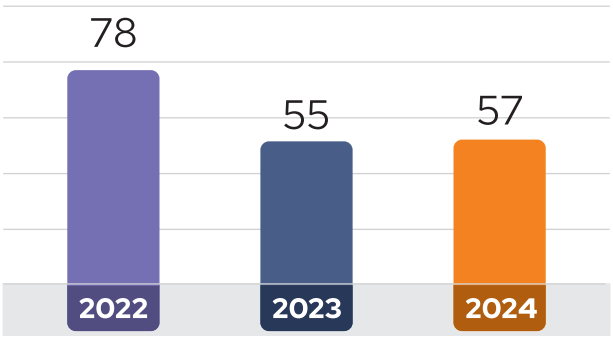
In response to patients' needs, last year amendments were made "To the Law on the Procedures for the Coming into Force and Application of Criminal Law", ensuring that the active substance of medicinal products, which had previously been on the list of prohibited substances but was necessary for Latvian patients to ensure therapy, is now available to doctors for prescription, pharmaceutical companies for distribution and patients for receipt in pharmacies or institutions.

Last year, amendments to the Pharmacy Law, the Law on the Legal Circulation of Narcotic and Psychotropic Substances and Medicinal Products, as well as Precursors, the Rules for the Production and Storage of Prescription Forms, as well as the Rules for Prescription and Storage and other Regulations have also been actively worked on, as well as internal documents of the Agency have been improved, including on the basis of the recommendations of the internal audit.

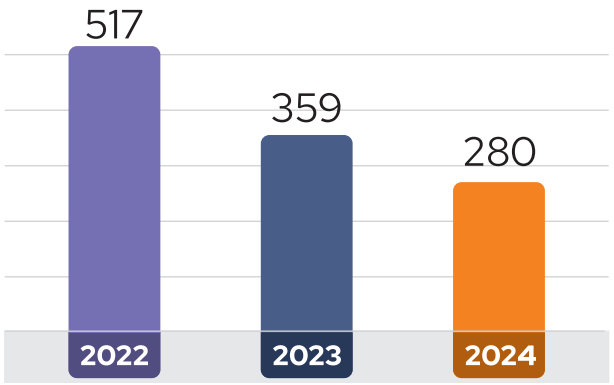
On a daily basis, it is also monitored which medicinal products are planned to be excluded from the Latvian Register of Medicinal Products, so that, in cases where they were needed by Latvian patients, the parties involved could be approached and Latvian patients could continue to be provided with uninterrupted access to the medicinal products they need (for example, as parallel-imported medicinal products). On the other hand, in the case of widespread use of unauthorized medicinal products, close cooperation exists with professional associations of doctors and wholesalers in order to facilitate the granting of annual distribution authorisations allowing the distribution of medicinal products without one-time permit, thereby speeding up the availability of medicinal products.

The exchange of information with the competent authorities of other countries regarding narcotic drugs, psychotropic substances and precursors to be controlled in Latvia has been electronicised and facilitated. Expertise of applications and documents attached to them in order to receive one-time import/export permit last year has been ensured on average within 1.2 days, which minimizes delays in the supply of medicinal products due to the receipt of the necessary permits from the Agency.

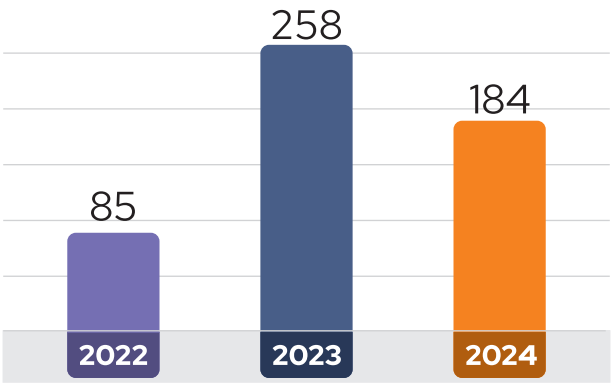
The Ministry of Health has been strongly involved last year in the implementation of the new medicinal products pricing model (which determines fixed pricing additions to the packaging of medicinal products in both wholesalers and pharmacies and stipulates that the declared price of medicinal products may not be higher than in Lithuania and Estonia) – both by providing data at the Agency's disposal, by performing calculations, by communicating with the Ministry of Health and the industry, and by ensuring that the prices of new prescription medicinal products are reflected in the Latvian Register of Medicinal Products as



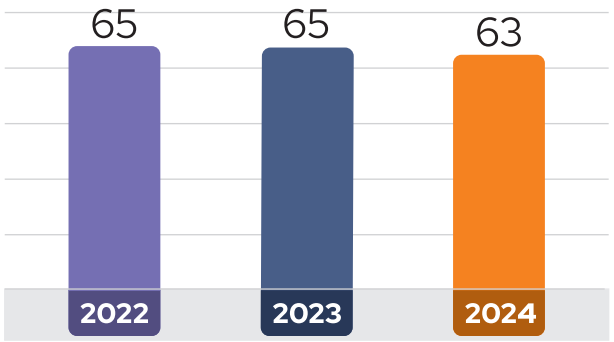
Permits for distribution of unauthorized medicines



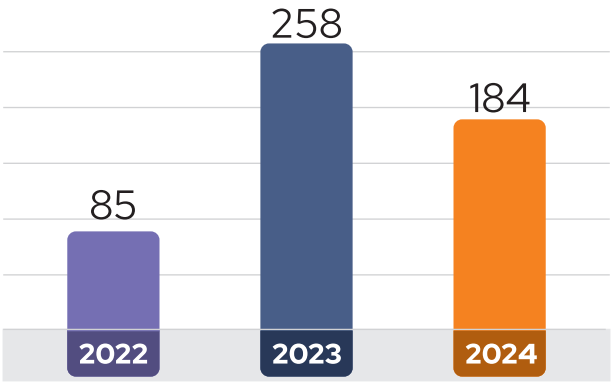
Number of permits for parallel import



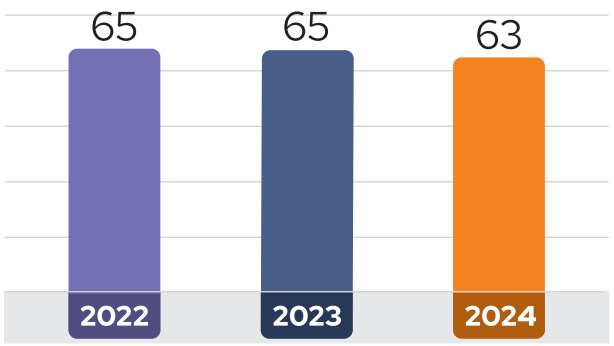
Number of variations to permits for parallel import



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



Permits for import of samples of medicines



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

of 1 January 2025. Last December, a customer day was held at the Agency, during which the Department informed about the changes related to the introduction of this new pricing model, informed about the changes in the documents to be submitted and answered customers' questions. The related tasks will continue actively in the coming year to assess the effectiveness of the pricing model and whether and what improvements may be needed.

Work continued in 2024 on the EU List of Critical Medicines, which contains medicines that are critical due to their indications and the existence of alternatives. The list is developed in cooperation with all EU member states, incl. Latvia. The first version of the list was published in December 2023. An updated and expanded second version of the list was published in December 2024.

The Department ensures that statistical data are published on both turnover and price changes of medicinal products, as well as information on medicinal products exported from Latvia (including medicinal products that are included in the reimbursement system). Data are compiled on a monthly, quarterly and annual basis. Last year, support was also provided to the Medicines Marketing Authorization Department, Clinical Trials Division, etc., assessing research methods and validating their results, evaluating data and their quality, carrying out data analysis, as well as preparing publications.

In order to ensure timely access to medicines for Latvian patients, the smooth assessment of applications and issuing of permits for the import, export and distribution of medicines, as well as active communication with the parties involved, remained an important objective. In 2024, 8 068 permits for the import, export, transit and distribution of medicinal products were issued. As well as coordinated and processed 427 notifications and applications for the distribution of medicinal products in packaging intended for the market of another country.

In 2024, the total number of unauthorized medicines distribution permits has decreased by 12% compared to 2023, while the number of annual permits issued to merchants based on the list of stationary medicines or opinions provided by doctors' associations on the need for medicines for Latvian patients has increased. The issued annual authorisations facilitate faster access to medicinal products for patients, as well as reduce the administrative burden for merchants and the Agency.

Urgent applications for the distribution of unauthorized medicinal products are examined within 1 working day, while the annual permits for the import/export of narcotic drugs, psychotropic medicinal products/substances and precursors were issued within 1.2 days on average, thus ensuring the possibility for patients to receive the necessary medicinal products in a timely manner.

CLINICAL TRIALS WITH MEDICINES

Jana Migliniece,
Head of the Clinical Trials Division

"In 2024, the Clinical Trials Division continued to work in the EudraCT database in parallel with the work in the in the unified European Clinical Trials Information System (CTIS), taking on the role of reporting Member State for 6 transitional clinical trials, 3 new multinational clinical trials and 2 mononational non-commercial clinical trials. Clinical trials were reviewed in collaboration with the Ethics Committee of the Development Society of PSKUS and other EU competent authorities. Last year, the Agency took part in the Clinical Trials Expert Working Groups set up by*

the EC and the HMA, contributing to the harmonisation of EU clinical trial authorisation and in the EMA's Good Clinical Practice Inspectors Working Group to harmonise inspection procedures."

In 2023, the Agency issued 37 authorisations for conduct of clinical trials of medicinal products in Latvia and authorised the migration of 56 ongoing clinical trials* to the new EMA CTIS database. The Agency repeatedly informed the sponsors of the ongoing clinical trials about the need for transition.

Last year, a total of 7 GCP compliance inspections were carried out in Latvian and non-Latvian clinical trial centres, including 3 inspections initiated by EMA.

During the reporting year, the European Clinical Trials database EudraCT regularly provides information on the completion of clinical trials on medicinal products, as well as EudraCT and CITS on Good Clinical Practice inspections. Regular provision of this data is necessary for maintaining and updating the European Clinical Trials Register.

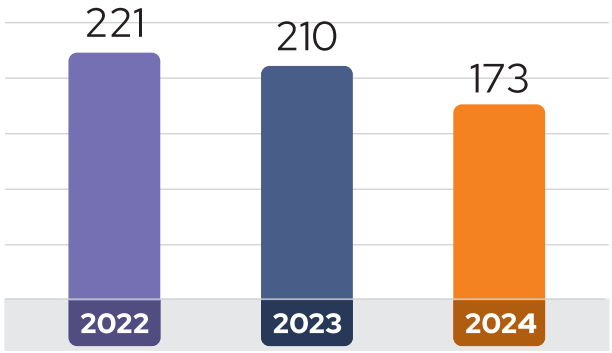
*Transitional clinical trials are trials that have been approved in accordance with the requirements of the Clinical Trials Directive 2001/20/EC and whose sponsor has decided to modify documentation as stipulated by the requirements of the EU Regulation 536/2014 by submitting it in CTIS.

During the reporting year, 28 reports were received on serious unexpected adverse reactions potentially related to investigational medicinal products detected in Latvian clinical trial centres.

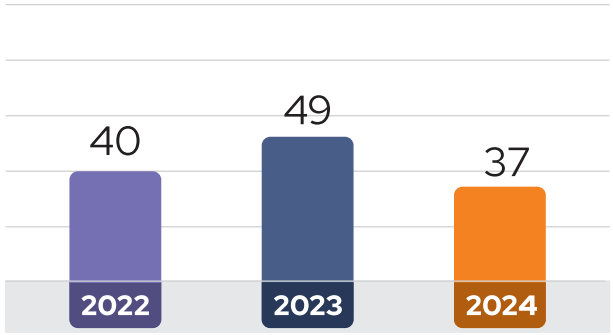
In total, 129 annual safety reports prepared by sponsors were received and reviewed by the Agency, covering clinical trials of medicinal products in Latvia.

In order to facilitate a coordinated safety assessment of investigational medicinal products among EU Member States, the SAFE-CT project supported by EU4Health was continued, where Latvia ensured safety oversight of 15 investigational medicinal products.

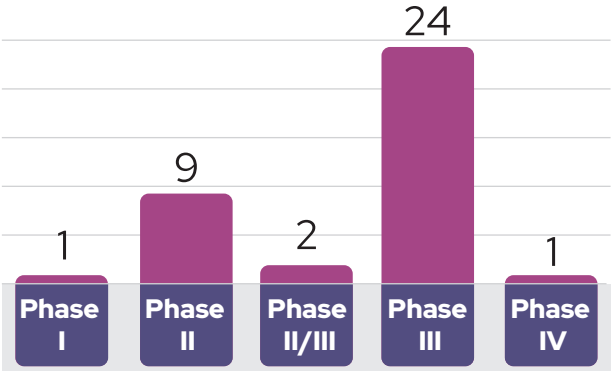
In total, 78 foreign pharmaceutical companies and 3 non-commercial sponsors have sponsored clinical trials taking place in Latvia in 2024 (Prinses Maxima Centrum voor Kinderoncologie B.V., the Netherlands, Tartu University Hospital, Estonia and Riga Stradins University, Latvia).



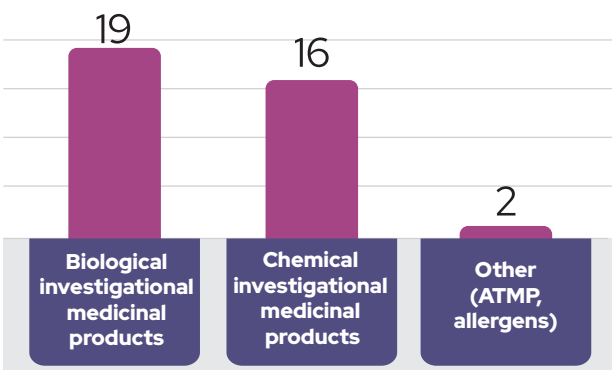
Total number of clinical trials conducted in Latvia



Authorisations for clinical trials



Number of clinical trials authorised in 2024, according to trial phase



Distribution of investigational medicinal products' clinical trials authorised in 2024

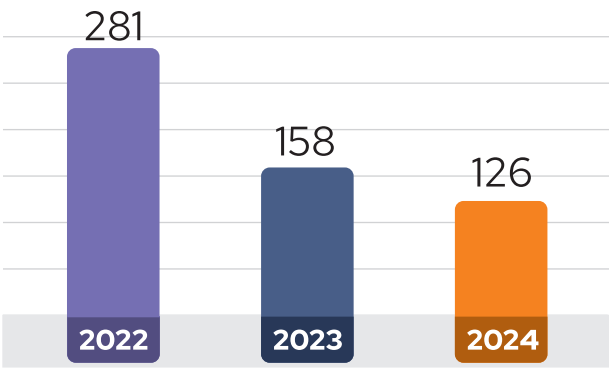
Clinical Trials Division experts participated in the conference of the Latvian Clinical Research Association "Clinical research in Latvia today and future challenges" and the Precision Medicine Network (PMNET) forum with presentations.

Medical sector	Number of allowed clinical trials
Gastroenterology	7
Neurology	5
Cardiology	4
Pulmonology/allergology	
Oncology	3
Urology/nephrology	3
Endocrinology	3
Ophthalmology	2
Pediatrics	2
Dermatology	2
Rheumatology	
Traumatology/ Orthopedics/ surgery	1

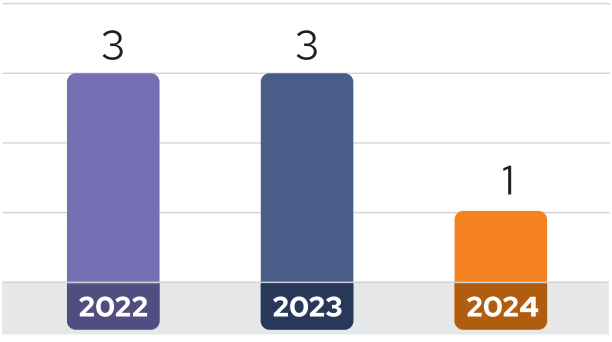
Number of clinical trials authorised in 2024, according to medical specialty

Trial site	Number of trials
VSIA Pauls Stradins Clinical University Hospital	27
SIA "Liepaja Regional Hospital"	10
SIA "Daugavpils Regional Hospital"	8
Riga East Clinical University Hospital	7
Vidzeme Hospital Ltd.	5
Health Centre 4 Ltd.	4
SIA "The Association of Balvi and Gulbene Hospitals"	3
SIA Riga 1st Hospital	3
SIA "GK Neiroklīnika"	3
SIA LOR Klīnika	2
Medical company "Centre for the Investigation and Treatment of Allergic Diseases"	2
LLC "Consilium Medicum"	2
SIA J. Ķīsis	2
SIA "Rūta Eglīte family doctor's practice"	2
VSIA Children's Clinical University Hospital	2
SIA Digestive Diseases Centre "GASTRO"	2
Other clinical trial sites (26 in total)	**1 each center**
Total number of clinical trial sites for medicinal products	**110**

Trial sites of medicinal product clinical trials authorised in



Authorisations for amendments to clinical trial in 2024

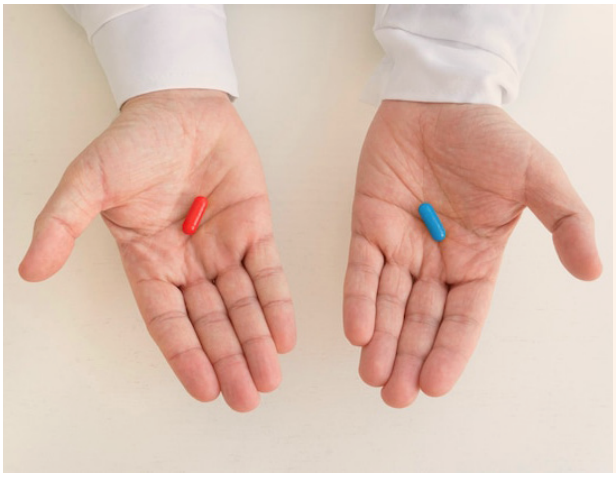


Authorisations for non-interventional studies in 2024

MONITORING OF ADVERSE DRUG REACTIONS AND RISK MINIMISATION

Ilze Viņķele,
Head of the Medicines Safety Division

"2024's pride in pharmaco-vigilance is our expert-cherished and successful public awareness campaign on adverse drug reaction reports. A clear message, an attractive form of presentation, a more convenient reporting option resulted in a significant increase in the number of adverse drug reaction reports, for which we are grateful to citizens and medical practitioners. Cooperation is the key to monitoring the safety of medicines. This is why we are continuously improving and making it easier for stakeholders to exchange information – in 2024, we have created a transparent and easy-to-use list of risk-reduction measures for medicines."



In 2024, 434 adverse drug reaction reports were received, including reports of vaccine side effects. The information received in the reports has been evaluated, properly prepared and sent to the EU common reporting system EudraVigilance. Last year, there has been a significant increase in the number of reports received from citizens, i.e. 216 reports, which can be explained by the Agency's extensive campaign to inform citizens about adverse drug reactions and the importance of reporting, as well as the development of a new possibility to report about adverse drug reactions via smartphones by scanning the QR code. In 2024, the total number of adverse drug reaction reports received increased by 31.12% compared to 2023.

Adverse drug reaction reports

Almost all adverse drug reaction reports have been received in electronic format in the Agency's Adverse Reaction Report Information System (BZIS), which is regularly improved and enhanced to make it easy to use in daily work and to collect statistical data. At the request of colleagues of the Bulgarian Agency, pharmacovigilance experts and an IT representative conducted an online seminar for Bulgarian representatives, demonstrating and explaining the functioning and possibilities of BZIS.

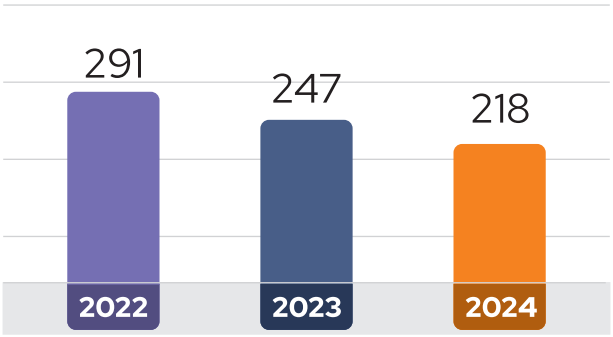
Pharmacovigilance experts have also reached out to doctors at events organised by the Agency and associations, inviting them to become more actively involved in monitoring the safety of medicines by reporting adverse drug reactions, to go through the materials themselves with prescribing risk minimisation measures and other relevant information available on the Agency's website.

In order to facilitate the availability of information on risk minimisation measures for medicines for doctors, marketing authorisation holders and experts, in 2024, experts from the division, in cooperation with an IT specialist, have established a new list of risk minimisation measures, which is now available in the Latvian Medicinal Products Register published by the Agency. The data in the list have been updated and are regularly updated.

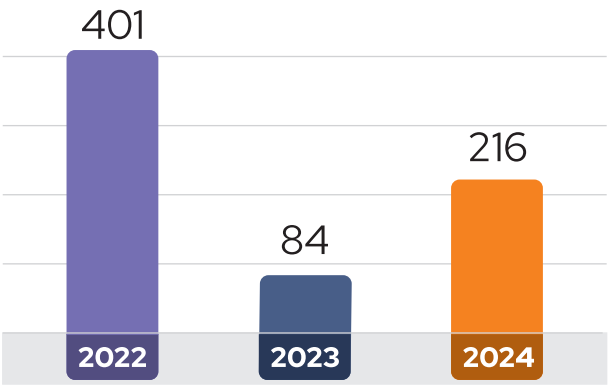
It can be said that pharmacovigilance experts have made an important contribution to informing the public and healthcare professionals on both adverse drug reaction reporting and other issues related to the safety of medicines, provided interviews to the media, participated in a number of events, as well as in the preparation of the electronic news edition 'Cito!'.

In 2024, pharmacovigilance experts also presented the results and conclusions of a study carried out in the previous year at the Agency on the effectiveness of the "Direct healthcare professional communication" (DHPC) letter. The results of the study and the proposals based on the conclusions were shared with the Agency's colleagues, representatives of doctors' associations and participants at a joint meeting of the Baltic Medicines Agencies, as well as with colleagues from all EU Member States at an informal PRAC and CHMP meeting organised under the Hungarian Presidency.

In the 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 reference country. In 2024, 18 single assessment procedures were carried out by pharmacovigilance experts.



Adverse drug reaction reports. Healthcare professionals reports



Adverse drug reaction reports. Patients reports

In 2024, under the EMA's worksharing procedure, the Agency's experts monitored 29 active substances for signal detection, i.e. regular monitoring of their safety information, and concluded one in-depth signal evaluation procedure at European level, where Latvia played a leading expert role.

Last year, the assessment of risk management plans and the preparation of assessment reports were also carried out in 58 national authorization procedures (including 40 mutual recognition and decentralised procedures), as well as comments were provided to Member States on 18 work-sharing procedures. In addition, pharmacovigilance experts have been actively involved in tasks delegated to EMA: as rapporteur-general for the Pharmacovigilance Risk Assessment Committee (PRAC), 8 procedures for the assessment of marketing authorisations/changes and 3 post-authorisation safety studies (PASS), and an assessment of safety concerns was carried out in 2 procedures in collaboration with clinical experts in a working group of the Committee for Medicinal Products for Human Use (CHMP).

In 2024, a total of 87 additional risk minimisation materials for doctors and patients have been approved at the Agency and developed to mitigate the risk of specific medicines. As a result, doctors have received 20 DHPC letters with important, up-to-date information on the safety of the medicines, as well as educational materials for both doctors and patients providing information on the prevention or reduction of the risks of the prescribed medicines.

Healthcare professionals were regularly updated on the latest developments following the monthly meetings of the working group of the European Committee for the Pharmacovigilance Risk Assessment Committee (PRAC), where a representative of Latvia participated and presented the evaluations of pharmacovigilance experts. Medical associations and medical specialists in Latvia were regularly informed of the PRAC's decisions on the safety of the medicines and recommendations to mitigate the risks.

Information on pharmacovigilance issues has also been exchanged with EMA and European national medicines agencies, characterised by replies to 19 information request documents for EU Member States (NUIs -Non urgent information).

COMPENSATION FOR DAMAGE FROM ADVERSE REACTIONS TO COVID-19 VACCINES

Inārs Švarcs,
Head of COVID-19 vaccine adverse reactions damage compensation division

"In 2024, the Agency received 44 applications for compensation for serious or moderate damage to health or life caused by adverse reactions of a vaccine against COVID-19 infection. This is 51 submissions less than in 2023. The decrease in the number of submissions received reflects a reduction in the impact of the pandemic, a possible drop in vaccination volumes and increased public confidence."

A causal link between the adverse reactions of a COVID-19 vaccine and moderate or severe damage to health was established in two cases where compensations of €5,000 and €10,000 were granted and paid.

A compensation programme for moderate and severe health damage caused by COVID-19 vaccines' adverse reactions in Latvia was established in May 2022. Since the start of the programme, 261 applications for compensation have been received by the Agency. In a total of 13 cases, a causal relationship has been established between the adverse reactions of the vaccine and moderate or severe harm to the patient's health.

The total amount of compensation paid is EUR 364 580. Of these, the maximum amount specified in regulatory enactments has been disbursed in two cases – EUR 142 290, in five cases – EUR 10 000, and in six cases – EUR 5 000.

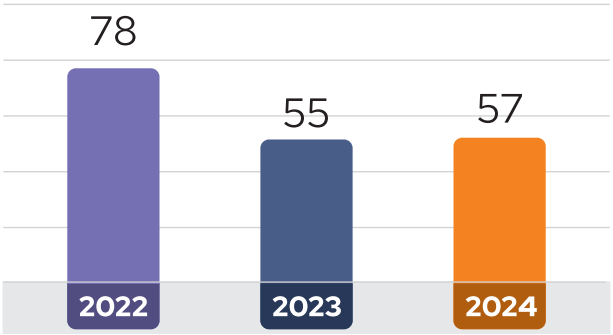
Compensation may be claimed within two years from the date of the discovery of the damage, but no later than three years from the date of vaccination.

In order to apply for compensation, an application for compensation must be submitted to the Agency, which must be accompanied by medical documents confirming the damage caused to health or life, as well as a doctor's conclusion on the possible causal link with the adverse reactions of the COVID-19 vaccine and the damage caused to the patient's life or health. Received applications are evaluated within six months to a year.

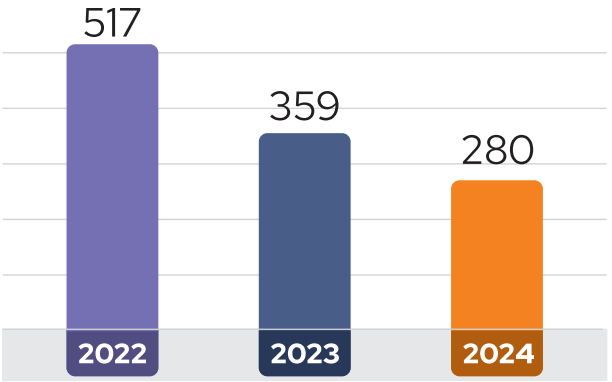
QUALITY CONTROL OF MEDICINES

Guntars Kaspars,
Head of the Medicines Examination Laboratory

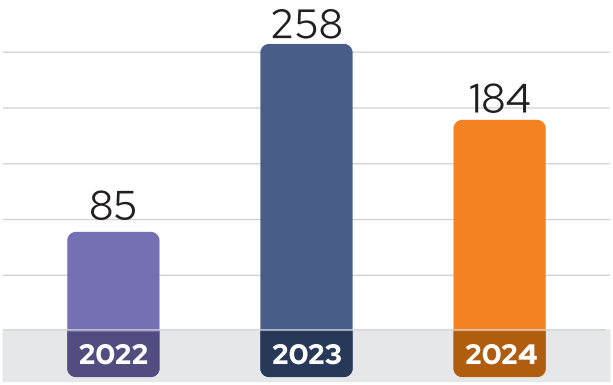
"In 2024, the Latvian National Accreditation Bureau (LATAK) carried out a monitoring visit, during which the Agency's Medicines Examination Laboratory (hereinafter "the Laboratory") maintained its accreditation regarding compliance with the requirements of the LVS EN ISO/ IEC 17025:2017 standard in the following areas: physical and physicochemical testing of medicinal products, pharmaceutical active ingredients and excipients (fixed and flexible fields) and physical testing of purified water (fixed field)
On 7-11 October 2024, an audit of the Joint Audit Programme (JAP) of the European Medicines Agencies took place at the Agency. The Laboratory actively participated in the audit preparation process, as well as participated in the audit process itself and provided answers to the auditors' questions within the scope of its competence. Successful audits are important proof of the quality of the Agency's professional performance. The compliance certification ensures that our clients can remain confident in our work – industry professionals, business partners in Latvia and abroad, and people in Latvia can rely on the quality of the Agency's performance."



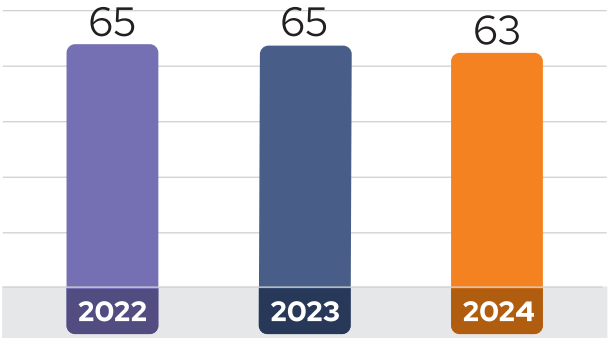
Number of medicinal product samples tested



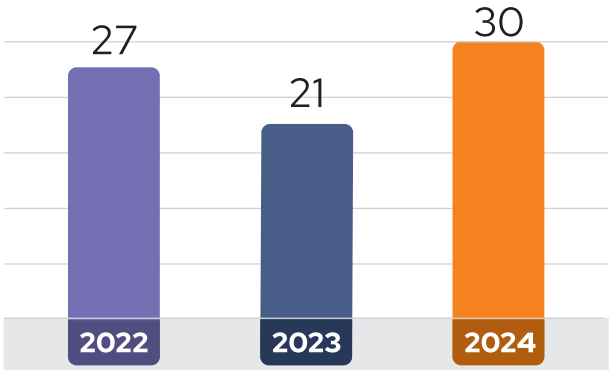
Number of medicinal product quality parameters tested



Number of volumetric solutions, indicators and reagents tested upon request from pharmacies



Number of purified water samples tested



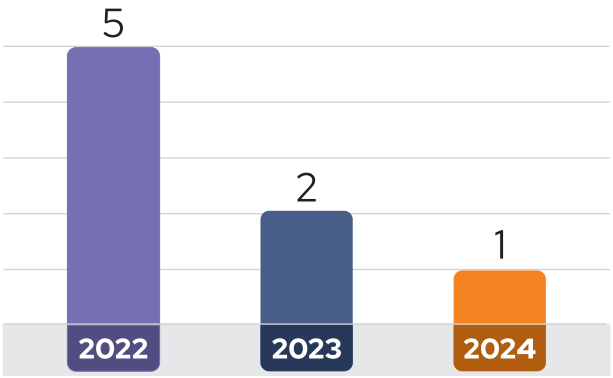
The conducted expertise for medicinal products upon request from the Agency's Medicines Marketing Authorisation Department, assessing the methods for analysis of active substances and/ or end-products and their validation

The Laboratory's specialists participated with good results in the professional-level testing programmes offered by EDQM and the Royal Dutch Society of Pharmacists, as well as in the European market surveillance (MSS063) testing programme 'Rosuvastatin Tablets and APIs'.

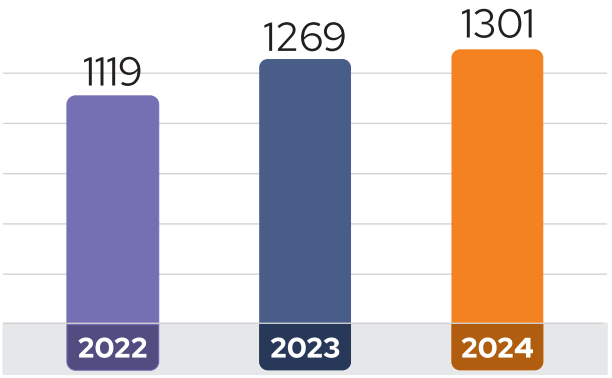
MONITORING, CLINICAL RESEARCH AND VIGILANCE OF MEDICAL DEVICES

Andis Viļums,
Head of Medical Devices Division

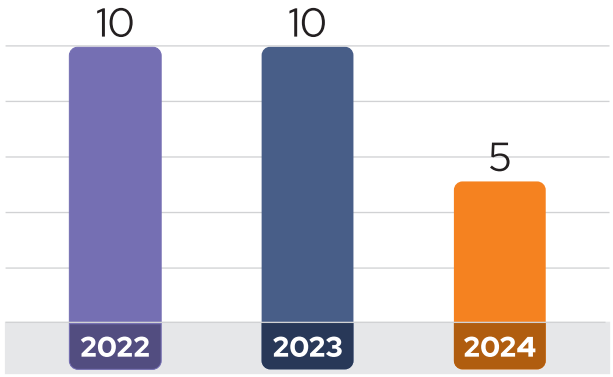
"2024 marked the end of an important transition from the framework of the European Medical Devices Directives to the new legal framework provided by the Regulations. Since 26 September, only medical devices that comply with the Medical Devices Directives may be placed on the market if their manufacturer has signed an agreement with a notified body (certification body) for complianse assessment in accordance with the requirements of the new framework. Furthermore, such devices must fulfil the condition that they do not present an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health. This guarantees that the medical devices used in the treatment and care of patients and residents comply with modern requirements, are safe, effective and are able to ensure a high level of health protection for the inhabitants of Latvia."



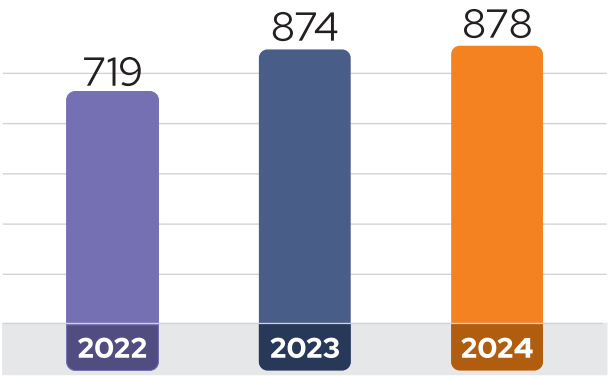
Latvian medical device manufacturers and their medical devices: information analysed and included in the Medical Device Database LATMED



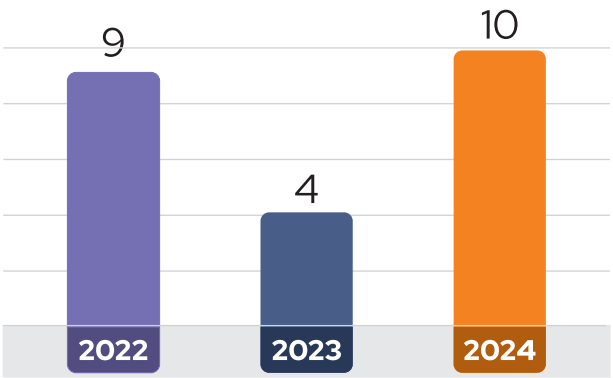
Vigilance[2] reports regarding medical devices (total number of reports received by the Agency)



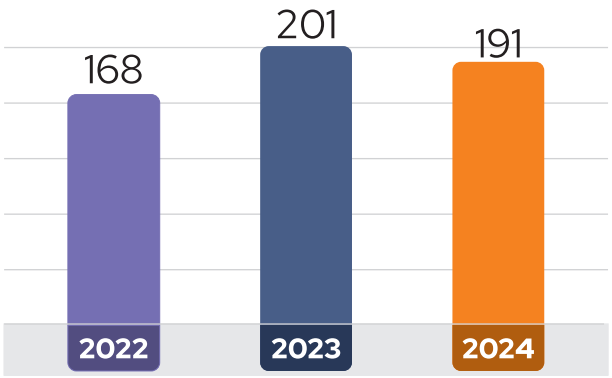
Authorised representatives of third country medical device manufacturers in the EU who have registered business in Latvia: information evaluated and included in the Medical Device Database LATMED



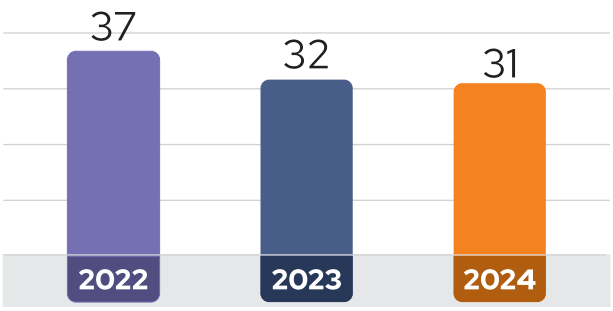
Primary vigilance[2] reports regarding medical devices (number of primary reports received by the Agency)



Authorisations for clinical trials with medical devices (permits issued)[1]



Primary vigilance[2] reports regarding medical devices located in Latvia and implementation of safety monitoring measure



Free trade certificates issued for medical devices

[1] Authorisations for conduct of clinical trials with medical devices and authorisations for amendments to the research plans of clinical trials already being conducted.

[2] The medical device vigilance system is a unified EU reporting system for incidents involving medical devices, corrective measures taken by manufacturers or competent authorities and for evaluation of reports and information. The objectives of the vigilance system are 1) to prevent repeat incidents, 2) to protect patients by using the medical device incident reporting system in all EU member states, 3) to ensure that member states may simultaneously identify non-compliant medical devices on the market and in use

HEALTH TECHNOLOGY ASSESSMENT

Antra Fogele,
Health Technology Assessment Division

"In 2022, Regulation 2021/2282 of the European Parliament and of the Council of Europe on health technology assessment (HTA) entered into force, providing for a joint clinical assessment of new medicinal products for the treatment of tumors as well as advanced therapy medicinal products in the EU as of 12 January 2025. In 2024, intensive preparations continued for the implementation of the Regulation, the development of health technology assessment tools, methodologies and guidelines necessary for its implementation,

aimed at faster clinical evaluation of new health technologies (including innovative medicinal products and high-risk medical devices with a high impact on patients, public health and EU health care systems) and subsequent availability to patients of the European Community and Latvia."

To ensure the presence and cooperation of all parties involved, the EC organized information events on the HTA Regulation in several European regions. In April 2024, in cooperation with the Agency, such a regional event took place in Riga. Patients' associations, healthcare professionals, representatives of the pharmaceutical industry and decision-makers from Latvia, Lithuania, Estonia and Poland participated in the event. The information event discussed issues related to:

- the main elements of the HTA Regulation;
- Challenges and opportunities in the implementation process of the Regulation;
- the involvement of stakeholders in the implementation of the Regulation.

The experts of the unit are involved in the work of the Regulation Implementation Coordination Group and the HTA Committee, as well as subgroups for joint clinical assessments, joint scientific consultations, guidelines on methodologies and procedures, and the identification of new technologies.

The implementation of the Regulation in the future will affect certain stages of the clinical and cost-effectiveness assessment process of new medicines established in Latvia. Therefore, amendments were made to Cabinet Regulation No 899 'Procedures for the Reimbursement of the Costs of Acquisition of Medicinal Products and Medical Devices Intended for Outpatient Treatment' in 2024, stipulating that the Agency, when preparing its opinion, will evaluate the results of the joint clinical assessment report drawn up by the Coordination Group as part of the medical assessment: the Agency will indicate in its opinion the results corresponding to the circumstances of Latvia (depending on the patient group submitted by the manufacturer of the medicinal product and the comparator therapy), as well as draw conclusions on the therapeutic effectiveness of the medicinal product on the basis of these results.

OPINION ON CLINICAL AND COST-EFFECTIVENESS OF NEW NONPROPRIETARY NAMES OR NEW COMBINATIONS OF MEDICINES

In 2024, the Agency received 51 applications and prepared 47 opinions.

Opinions provided according to diagnostic groups (according to the International Classification of Diseases (ICD-10))

- Tumors – 23 opinions (49%)
- Endocrine, nutritional and metabolic diseases – 5 opinions
- Nervous system diseases – 7 opinions
- Diseases of the digestive system – 2 opinions
- Infectious and parasitic diseases – 2 opinions
- Diseases of the blood and hematopoietic organs and disorders of the immune system – 4 opinions
- Skin and subcutaneous diseases – 1 opinion
- Musculoskeletal and connective tissue disorders – 1 opinion
- Congenital malformations, deformities and chromosomal abnormalities– 1 opinion
- Diseases of the genitourinary system – 1 opinion

Of the opinions issued in 2024, 21 (45%) concerned the treatment of rare diseases. This compares to 47 opinions issued by the

Agency in 2023, including 18 (38%) for rare diseases.

As the opinion of the Agency is a necessary step towards the possibility of paying for a new medicinal product from the State budget, according to the information available on the National Health Service of Latvia website, 23 applications have been submitted within one year for inclusion in the reimbursement system for the purchase of medicinal products, for which the opinion of the Agency has been issued.

Involvement of the public in the process of evaluating medicines has been launched since 2021. Following the collection of experience in other countries and consultations with patient organizations and professional associations of doctors, separate questionnaires have been established for medical practitioners and patients, where interested parties have the opportunity to express their views on the specific role of new medicines in the treatment of a particular disease, the expected benefits and unmet medical needs. Particularly important information is related to the comparative therapy currently available and applied in Latvia. Completing such a questionnaire is voluntary for both patients and professionals, but provides important information in the Agency's evaluations. Initially, in the pilot project, questionnaires were prepared only for medicines for oncological diseases, but since 1 September 2021, such questionnaires have been prepared and sent out for each applications received. In 2024, 46 questionnaires were sent to patient organizations through the Patient Organizations Network, with 2 replies received. Questionnaires were sent to doctors' professional associations on 49 new generic names or new diagnoses/groups of patients. Responses from specialists were received in 20 cases. The information provided in these questionnaires feeds into the resulting opinion on the clinical and cost-effectiveness of the medicinal product.

In autumn 2024, during a meeting with the Latvian Association of Oncologist Chemotherapists and the Latvian Association of Hematologists, the established questionnaires were revised, transforming them into shorter and more targeted ones, making it easier for specialists to fill them in.

Name of MT group	Approved MT	Supplemented MT	Cancelled MT	Case closed	Rejected
Medical services in internal medicine and functional diagnostics	2				
Medical services relating to anesthesia, resuscitation, transfusiology and intensive care		1	2		
Ophthalmology and optometry medical services		6			
Cardiovascular surgery medical services		1			1
Pathological medical services	1				
Physical medicine and rehabilitation medical services		1		3	
Additional (complementary) medical services	1				

APPROVAL, SUPPLEMENTATION AND WITHDRAWAL OF MEDICAL TECHNOLOGIES (MT) AND UPDATING OF THE DATABASE OF MEDICAL TECHNOLOGIES FOR THERAPEUTIC USE

In 2024, the Agency received 20 applications for the approval, supplementation or withdrawal of new medical technologies (MTs). 19 decisions were prepared (see table below), 7 of which were adopted within 30 days.

By comparison, in 2023, the Agency received 10 applications for approval, supplementation and cancellation of new MT and prepared 11 decisions on MT approval.

Using the possibilities provided by regulatory enactments, an opinion was requested from the Latvian Medical Association and the Latvian Association of Professional Organizations of Medical Practitioners regarding one medical technology submitted for approval, as well as in two cases, taking into account the complexity of administrative cases, it was necessary to extend the time period for taking a decision to one year.

In 2024, work continued on improving the content of the database of medical technologies used in medical treatment:

- in collaboration with the National Blood Donor Centre, a new title was created for the section 'Anesthesia, Reanimatology, Transfusiology and Intensive Therapy Medical Services' related to the preparation of blood and blood components, changing it from 'Preparation and Quality Control of Blood and Blood Components' to 'Transfusion Medical Technology', and its content was completely restructured and updated;
- 19 answers have been provided to questions/requests from customers (public authorities, insurance companies, medical institutions, media, private individuals, etc.) related to MT approval and MT already registered.

Preparation and submission of applications to the Agency is the competence and choice of medical institutions and professional associations of doctors. In 2024, the Agency has approached 17 different organizations with a call to review the already existing approved technologies in the Medical Technologies Database, update them if necessary and reflect on the approval of new MTs. The chosen directions for this year were pediatrics, cardiology and orthodontics. As a result of this initiative, successful cooperation has been started with the Riga Stradiņš University Institute of Dentistry and the Latvian Orthodontist Association on launching the process of updating the section "Dental Medical Services" next year.

The Medical Technology Assessment Commission, which aims to assess the compliance of the documentation submitted to the Agency regarding the approval, supplementation and cancellation of medical technologies with the requirements set out in regulatory enactments and to provide an opinion to the Director of the Agency, held 6 meetings in 2024. In addition to experts from the Agency, representatives from NSAs and MAs also participate in the Commission.

LICENSING OF PHARMACEUTICAL ACTIVITY COMPANIESCOMPANY

"To the extent that you build and beautify your own life, you also work for all of humanity – you fulfill your mission."

A. Brigadere

Signe Čudare,
Pharmaceutical Activity Licensing Division

"The aim of the Agency has always been to provide the necessary service to the client as quickly and qualitatively as possible, to explain unclear issues and to advise on the documents to be submitted.

In our daily work we provide services to pharmaceutical clients: We issue (renew) special permits (licenses) for the opening (operation) of a general and closed-type pharmacy, for the operation of a medicinal product wholesaler, for the manufacture or importation of medicinal products and for the manufacture of active pharmaceutical ingredients, issue authorizations certificates to manufacturers, importers and distributors of active ingredients, evaluate the documentation of

the broker with the medicinal product, ensure the issuance of good manufacturing and distribution certificates using the EUGDRAGMDP information system of the European Medicines Agency.

We would like to thank every client of the Agency for their cooperation and understanding in providing legal services in the field of pharmaceutical activity. ".

In 2024, the Agency carried out activities related to updating, renew the data of licensed subjects of pharmaceutical activity and legal addresses, aligning the address data with the data indicated in the National Address Register and the Enterprise Register Information System. The current data are reflected on the Agency's website, in the Register of Pharmaceutical Companies, in the Pharmacies' Map, where information can also be obtained on general-type pharmacies distributing medicinal products to residents' homes if it is not possible for them to reach the pharmacy, as well as information on the only general-type pharmacies, branches of pharmacies located in a particular administrative area and the only ones distributing medicinal products to residents in that region. Such a service has become very useful for both citizens and the Agency's clients.

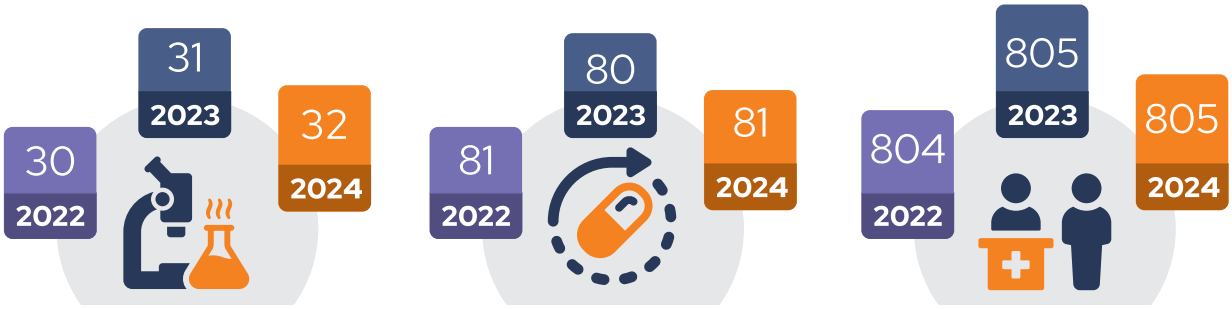
Last year, amendments to the Pharmaceutical Law were adopted, which brought changes to the activities of wholesalers of medicinal products and manufacturers of medicinal products, active ingredients, importers, who, in addition to the field of medicinal products for human use, also worked with veterinary medicinal products. The Agency took all steps to enable these customers to obtain their licensing services from the Food and Veterinary Service of Latvia in the future from 2025. The Agency continues to assess compliance and issue a special permit (licence) for the manufacture or import and wholesale distribution of veterinary narcotic and psychotropic medicinal products in accordance with Cabinet Regulation No 35 of 11 January 2011 on the procedure for issuing, suspending, re-registering and revoking special permits (licences) for veterinary pharmaceutical activities.

In 2024, the Agency renewed or issued licenses to 309 pharmaceutical companies (including 11 new companies):

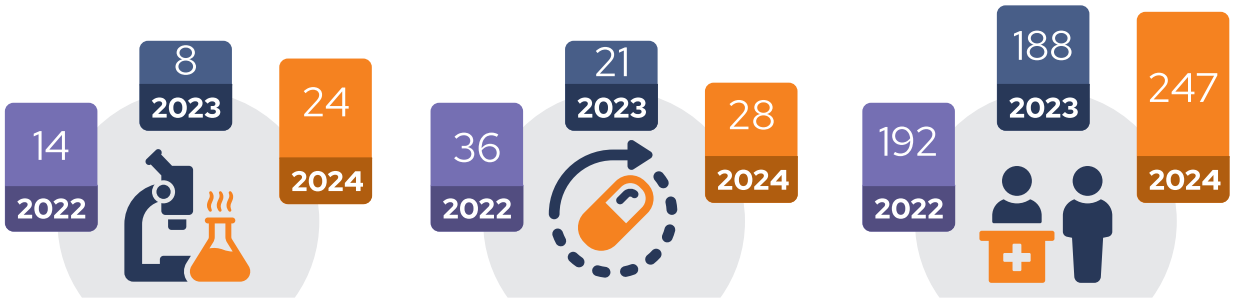
- 247 general-type pharmacies (including for 3 licenses new general-type pharmacies)
- 7 closed-type pharmacies
- 28 medicinal product wholesalers (including 6 licenses for new medicines wholesalers)
- 24 companies manufacturing or importing medicines (including 1 new manufacturer of medicines)
- 1 active pharmaceutical ingredients manufacturing company
- 2 veterinary medicinal product wholesalers. (including 1 new)

In 2024, the Agency issued 13 authorizations for manufacturing, import, distribution company of active pharmaceutical ingredients (including 2 new ones).

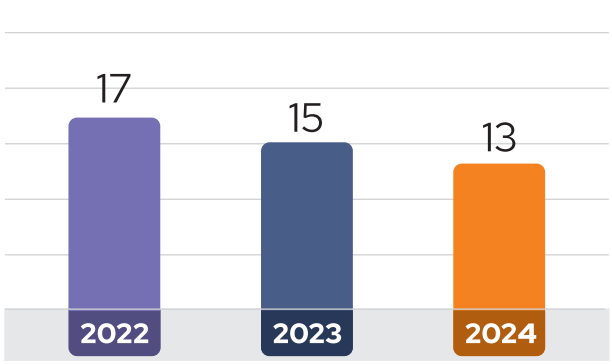
In 2024, there were 63 branches of pharmacies. In 2023, there were 70 branches of pharmacies. 72 branches of pharmacies in 2022.



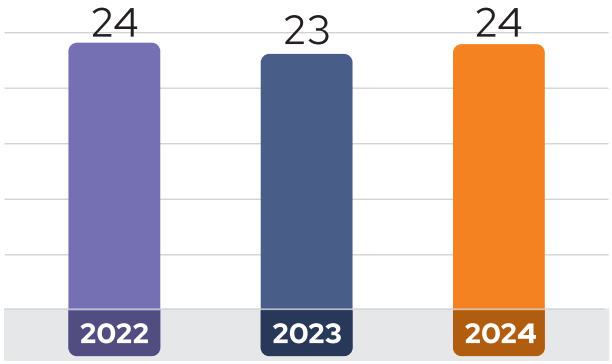
Total number of licensed pharmaceutical companies in Latvia. Data: 31 December 2024.



Changes in licences for pharmaceutical activity



Total number of licensed of active substance manufacturers, importers and distributors (APIs) (including new and renewed authorizations)



Total number of APIs registered in Latvia.

Data: 31 December 2024.

Comparing the data with 2022 and 2023, an equal number of pharmaceutical companies remains.

In 2024, new pharmaceutical outlets (addresses) of general-type pharmacies (branches of pharmacies) were assessed, i.e. 45 cases.

Last year, 15 meetings of the Agency's Commission for Licensing of Pharmaceutical Activity Companies (hereinafter – Commission) were held, at which issues were considered and decisions of an advisory nature were adopted on the issuance, renewal and suspension of pharmaceutical activity licenses and special activity permits in accordance with the procedure for the consideration of issues set out in the Commission's Rules of Procedure.

To facilitate a faster process for renewal of licenses and providing a service to merchants is ensured by the procedures laid down in the Rules of Procedure of the Commission regarding cases that are examined without a meeting of the Commission.

In 2024, the following special permits (licenses) were annulled:

- 4 licenses for opening a general-type pharmacy (activity);
- 4 licenses for medicinal product wholesaler operation;
- 1 license for manufacturing, import, distribution company of active pharmaceutical ingredients

COMPLIANCE EVALUATION OF PHARMACEUTICAL ACTIVITY COMPANIES, HEALTHCARE AND HIGHER EDUCATION INSTITUTIONS

Iveta Vilcāne,
Head of the Compliance Assessment Division

"2024 was very important for maintaining the international recognition status of the Agency's GMP inspection function, as a regular audit under the Joint Audit Programme (JAP) took place in October 2024. This time it was combined with an audit by the Health Canada and was observed by the Food and Drug Administration of the USA. A successful outcome of the audit is an essential prerequisite for the recognition of the results of our GMP inspections within the framework of Mutual Recognition Agreements (MRAs) concluded by the EU with third countries, while reducing the burden of inspections on Latvian manufacturers exporting their medicines to Switzerland, Australia, New Zealand, Japan, Canada, the USA and Israel. Such assessment and recognition is a significant achievement not only for the State Agency of Medicines and the Health Inspectorate, but also for Latvia as a country, as it strengthens its export capacity and significantly reduces the administrative burden on the pharmaceutical industry."

The functions of the Conformity Assessment

Division of the Agency are to perform conformity assessment of manufacturers of medicinal products, contract laboratories, wholesalers of medicinal products and manufacturers, importers and distributors of active substances in relation to the issue or renew certificates for special authorizations (licences) for pharmaceutical activities (except pharmacies) and manufacturers, importers and distributors of active substances, as well as to supervise the compliance of these merchants.

In 2024, the Agency carried out on-site inspections of 13 medicines and active substances manufacturing companies and contract laboratories of good manufacturing practice, 2 remote inspections of Ukrainian medicines manufacturing companies and an additional 8 document checks related to the renew a special permit (licence). After a longer interruption, inspections of companies in countries outside the EEA were resumed (two remote and one on-site). A total of 17 active substances were inspected during inspections of establishments manufacturing active substances. Cooperation with the Food and Veterinary Service of Latvia on the training of inspectors is ongoing.

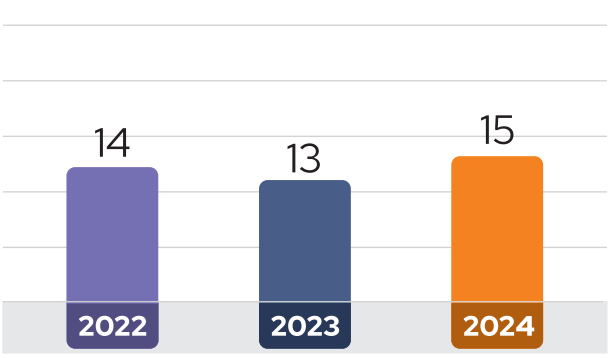
The Agency also carried out 24 inspections of good distribution practice at medicine wholesalers, 9 of which related to the issue or re-registration of a special permit (licence) for wholesale distribution of medicinal products.

In addition, support was provided to the Pharmaceutical Activity Licensing Division (PALD) in relation to the takeover and simplification of the process of issuing certificates of Good Manufacturing Practice and Good Distribution Practice: from June 2024, certificates are created only in the EudraGMDP database, companies are issued a printout from the database, which reduces the administrative burden for AVA, including in relation to questions from regulatory authorities of other countries regarding minor differences in information in the database and documents issued by the Agency.

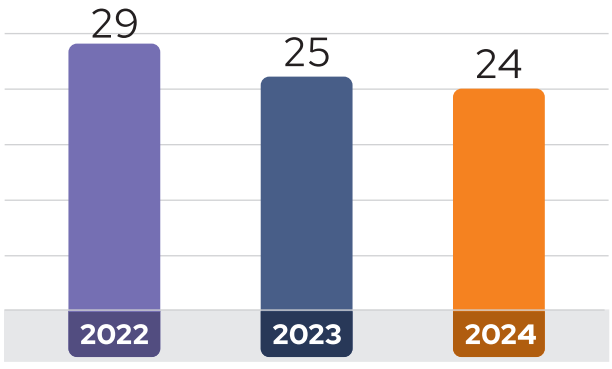
The functions of the Compliance Assessment Division are also to carry out compliance assessment and issue permits for the use of human blood, tissues, cells, organs in medical treatment institutions and higher education institutions that implement medical study programmes. The Agency is also responsible for regular compliance monitoring and biovigilance monitoring of the holders of these authorisations.

in 2024:

- 2 applications for compliance assessment and authorization of tissue establishments in relation to changes in activities and 2 applications for assessment and authorization of higher education institutions in relation to changes in activities were received;
- 3 authorizations were issued for tissue establishments and 3 for changes in university



Good Manufacturing Practice inspections



Good Distribution Practice inspections

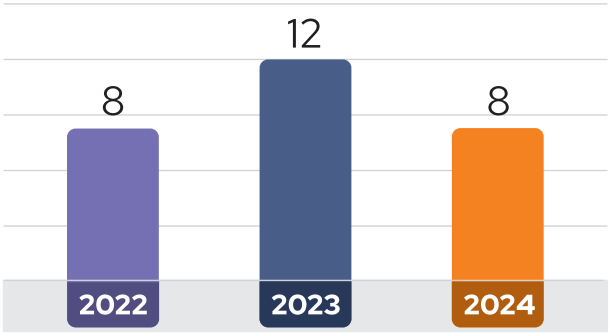
activities (draft decisions on the authorisation of 1 tissue establishment and university were prepared and issued at the end of 2023);

- an application for compliance assessment has been received and a new certificate of compliance has been issued to the State Blood Donor Center (SBDC) in connection with the commencement of a new activity (issuance of blood components for transfusion to a specific recipient in the case of emergency medical assistance);
- 3 certificates of compliance for blood establishments have been withdrawn after receipt of information regarding termination of work of the unit.

Permits have been issued in accordance with the deadlines for taking a decision laid down in laws and regulations.

Last year, 2 tests on the conformity of human blood and blood components preparation and 5 tests in tissue establishments (including 2 tests in tissue and cell procurement sites), 3 tests in institutions of higher education implementing medical study programmes were also carried out. 5 compliance assessment document checks were also carried out – in 2 tissue establishments due to operational changes, 1 at the NSADC and 2 at the university.

In 2024, no inspection was planned or carried out at the human organ transplantation centre.

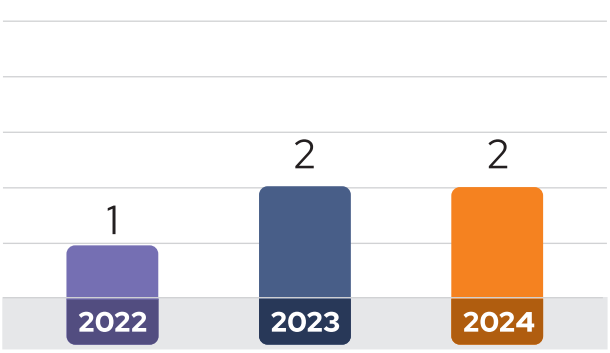


Inspections of tissue centers (and an organ transplantation center)

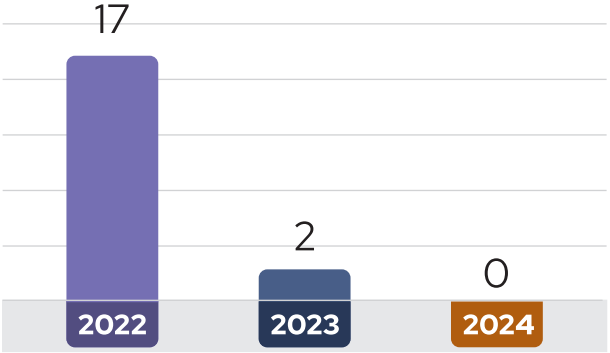
In 2024, the experts of the Compliance Assessment Division prepared annual review reports for the EC on serious adverse drug reactions and serious adverse events in the areas of blood and tissues and cells, as well as ensured communication with medical institutions both in relation to the Urgent notifications of serious adverse drug reactions and events received online and in relation to notifications in the Rapid Alert Systems maintained by the EC in the areas of tissues and cells (RATC) and blood (RAB).

Experts ensured communication with the Centre for Disease Prevention and Control (Latvia) and SBDC on the first detection of West Nile virus infection in a bird in Latvia and its potential impact on blood donor selection and testing.

The Agency was represented in the EMA's GMP and GDP inspectors' working group, PI-



Compliance inspections of human blood banks and blood establishments.
Blood establishments



Compliance inspections of human blood banks and blood establishments.
State Blood Donor Centre Blood banks

C/S activities and working groups on human blood and blood components, tissues, cells and organs organised by DG-SANTE of the EC, working group meetings organised within the Joint Action projects (JA11). The specialists of the unit also ensured the necessary communication with the specialists of the SBDC and the Latvian Transplantation Centre regarding the provision of vigilance data within the framework of the EC pilot projects, and with the Latvian Human Reproduction Society - regarding the provision of data for the survey on germ cell donors. The unit's experts also prepared responses to a number of SoHO Regulation-related surveys - on national IT systems in the SoHO Regulation area; the 'critical SoHOs' and the criteria for their determination; on vigilance requirements in the SoHO Regulation and their application; GAPP Pro project on nationally prepared SoHO products and their compliance with EDQM monographs.

Experts from the divison were involved in the revision of the translation of the SoHO Regulation, comments and suggestions were made on the translation of terminology.

During the reporting period, work has started on the implementation of the SoHo Regulation in Latvia. An information section on the Agency's website on the SoHO Regulation and ECDC's work in the field of biological material of human origin was set up, and the authorities were informed of the requirements of the SoHO Regulation during routine surveillance inspections. The unit's experts developed an initial concept for legislative amendments, including requirements for SoHO structures. A discussion was initiated with the SPDC on regulatory allocation (Blood Service/SoHO Regulation requirements for registration/authorisation, inspections, vigilance, data collection). The SBDC was informed about the SoHO platform and encouraged to assess the possibility of providing the data required by the SoHO Regulation on blood components for all medical establishments directly from the ProSang system maintained by the SBDC.

Information has been sent to all medical institutions on the READERSHIP project survey on the implementation of the SoHO Regulation requirements by institutions implementing SoHO for human use, as well as on the EDQM free courses for staff involved in the maintenance of the quality system on the requirements of the Good Practice Guidelines, which will be applied by the SoHO Regulation.

At the end of the year, steps have been developed on how to transfer the authorisation process to the FTT, a proposal for related changes to the FTT Case Nomenclature, SoHO facility documents have been prepared for transfer to the FTT.

Specialists of the unit were also actively involved in drafting laws and regulations and amendments thereto, including as technical expert in connection with the adoption of the new SoHO Regulation and the commencement of work in the EP working group on reviews of pharmaceutical regulation. The requested comments and proposals were provided to the MoH and their coordination within the Agency was ensured. During the reporting period, the experts of the department developed a proposal for regulation of the ATMP hospital exemption, including traceability, education of the qualified person, conditions under which a medical institution does not need permission to acquire autologous biological material in order to prepare a hospital exemption ATMP, as well as participated in the working group on drafting the Cabinet Regulation on the ATMP hospital exemption.

INTERNATIONAL COLLABORATION

The Agency is a member of the European Network of National Medicines Agencies and the fulfilment of the Agency's functions and tasks is closely linked to participation in a single European Network of Medicines Agencies – the EMA, the European Commission and more than 47 pharmaceutical regulators in the EEA.

This network provides access to a wide range of experts, allowing it to provide the best possible scientific expertise to the medicines regulatory environment in the EU. National experts, including experts from the Agency, participate in the work of the EMA as members of working groups and scientific advisory groups, as well as in scientific committees.

In 2024, the Agency's staff have been involved in cooperation with EMA's scientific committees, EC and Council of Europe working groups, working groups established by the EDQM and the European Medicines Regulators Network (HMA), etc.

EMA committees in which the Agency participates

- Committee for Medicinal Products for Human Use (CHMP)
- Co-ordination 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)

The Agency participates in more than 30 international working groups, including EMA working groups dedicated to specific regulatory aspects, e.g., Agency representatives participate in the EMA CHMP Working Group on Biological Products, EMA Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and Executive Steering Group on Shortages and Safety of Medical Devices (MDSSG), EMA Working Group on Document Quality Review, the Working Group on Phar-

macovigilance Inspectors, the Working Group on Good Clinical Practice Inspectors, the Working Group on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) Inspectors, the International Cooperation Platform of the European Medicines Regulatory Network, etc. Last year, the management of the State Agency of Medicines participated in the Steering Group of the European Medicines Agencies.

In 2024, the Agency's participation in the Drug Precursors Expert Working Group was also ensured, as well as participation in the 62nd session of the UNODC Drug Control Committee. For several years, the Agency has been involved in international collaboration on the surveillance of medical devices and blood and blood components, tissues and cells through working groups such as the Competent Authorities Task Force on Organ Donation and Transplantation set up by the EC Health and Food Safety Directorate-General, the Competent Authorities Task Force on Tissues and Cells set up by the EC Health and Food Safety Directorate-General, and the Competent Authorities Task Force on Blood and Blood Components set up by the EC Health and Food Safety Directorate-General.

The Agency is the competent authority in Latvia with regard to the issuing of clinical trial authorisations and the monitoring of safety in use. The responsible specialists of the Agency shall regularly attend meetings of representatives of the European national competent authorities for medical devices.

The regular audits carried out under the Joint Audit Programme (JAP) are a tool used to ensure proper supervision of the industrial production of medicinal products in the EEA. The Agency's Good Manufacturing Practice (GMP) monitoring was audited in the JAP programme in October 2024, with a particular focus on cooperation with the MA and the ability to successfully cope with the challenges of the pandemic. The audit lasted five days and included the observation of an inspection carried out by the Agency. The audit covered the evaluation of the regulatory framework laid down in legislation, as well as the market surveillance of medicinal products and independent testing of medicinal products, as well as cooperation with the MA in relation to the management of quality defects of medicinal products and the organisation of recall of medicinal products from the market, as well as cooperation in cases of violations of pharmaceutical activity.

The results of the Agency's audit are also used to maintain the Mutual Recognition Agreement (MRA) between the EU and third countries. During the audit, the Agency and the MA received some recommendations to improve their GMP monitoring. The final audit report was received in early 2025.

The Agency is also bound by a cooperation agreement with the Medicines Agencies of Estonia and Lithuania, which promotes closer cooperation between Medicines Agencies of the Baltic States in regulatory matters. Last year, a joint working meeting was also held between the Baltic States and Polish Medicines Agencies.

There is a clear need for qualified human as well as financial resources in order to be able to fully participate in the common European working procedures, which are an additional responsibility of the Agency.

For more information on the results of international cooperation, please see Chapter 2.

COMMUNICATION AND COLLABORATION

The Agency's external communication is embedded in the institution's medium-term operational strategy and its performance indicators are among the Agency's key strategic performance indicators. The Strategy states that the public health interest strand aims to ensure the provision of evidence-based and independent information to citizens and healthcare professionals.

Last year, a new Agency Communication Strategy 2024-2026 was developed and the Annual Communication Plan was also prepared.

PUBLICATIONS AND MEDIA

In 2024, the Agency responded to 120 media requests, providing answers to more than 600 journalists' questions. Last year, the Agency produced 21 press releases.

Examples of press releases distributed by the Agency include:

- Adverse effects of medicines can be reported by scanning the QR code
- During the campaign, 70 reports of medicine side effects were received
- We urge that antibiotics be used with caution
- 180 new medicines authorized by the Agency
- A map of pharmacies and home delivery of medicines
- The Agency calls for external automatic defibrillators, installed in public places to be notified, etc.

Top topics for media requests:

- Medicine shortages and imports from other countries
- Use of medicines and their contents
- Safety, side effects
- Consumption of medicines
- Regulation, etc.

INFORMATION ON AGENCY`S WEBSITE

In total, 118 news items were published last year on the Agency's website in "News" section (133 published in 2023), confirming that informing citizens, the public, healthcare professionals and the industry was a key priority for the Agency.

The Agency provided objective, reliable, and up-to-date information on its website about medicinal products, medical devices, and other services it offers. Last year, over 720 additional changes and improvements were made to various sections of the website.

Website traffic parameters:

- 1.2 million visits (views) were made to the Agency's website in 2024.
- The Register of Medicinal Products and other databases of the Agency were visited approximately 9 million times in total.

CAMPAIGNS

- Public awareness campaign "Taking medication? Experiencing the side effects? Report!"

Several informative materials have been developed as part of the campaign – a video, an informative leaflet for citizens and pharmacists, posters and stickers with a QR code for more convenient reporting of adverse reactions to medicines. During the campaign, a discussion of specialists was organised online on the news website DELFI, posts and videos were published on social media (Facebook and X) – in total more than 200 thousand social network users were reached, informative materials were distributed to Latvian pharmacies and hospitals, environmental advertising posters were placed with an invitation to report side effects

and other activities were carried out. The campaign included more than 100 publications in the media, including national news media.

- Social media campaign "Medicines Safety Week"

In November 2024, the Agency, together with 107 medicines safety monitoring organisations from around the world, carried out a public information campaign called "Medicines Safety Week" (#MedSafetyWeek), which called for the reporting of suspected adverse reactions to medicines, i.e. disorders observed following the use of any medicines, including vaccines, and possibly related adverse reactions. In order to facilitate the reporting of suspected adverse reactions, the Agency disseminated information videos and infographics as well as a press release on social networks.

- World Antimicrobial Awareness Week

In support of World Antimicrobial Awareness

Week activities, the Agency informed about the correct and prudent use of antibiotics to draw attention to bacterial resistance to antibiotics.

SOCIAL NETWORKS

Social networks are growing and it is essential that public authorities also communicate with citizens in these networks. Last year, the Agency published a total of 194 posts on social networks.

INFORMATION FOR HEALTHCARE PROFESSIONALS AND PHARMACISTS

Last year, the Agency published two newsletters for doctors, pharmacists and other healthcare professionals, Cito!, which provide important information on the safety of medicines and medical devices. The main purpose of the publication is to introduce Latvian healthcare professionals with the latest science-based information and recommendations on the safety of the use of medicines provided by the Agency, the EC, EMA, WHO, medicines agencies of other countries and independent scientific medical publications.

COLLABORATION WITH THE INDUSTRY

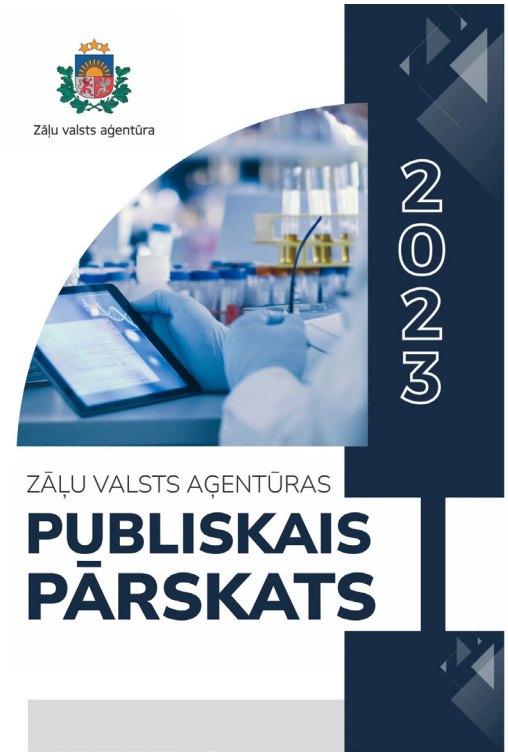
In implementing one of the Agency's priorities – to provide explanations of the requirements of regulatory enactments, last year the Agency organised three informative seminars for the pharmaceutical industry. 15 video recordings have been prepared on seminar topics, which have been provided to clients and are independently available on the Agency's website. Last year, several meetings were held with representatives of the industry.

Explanatory information of the Regulator is also provided in informative news and letters, also providing explanations of the requirements of regulatory enactments.

In total, the Agency's experts and the Public Relations Division participated in 8 conferences last year. In April 2024, the Agency participated in the organisation of an international event on health technology assessment organised by the EC in Riga.

INFOGRAPHICS AND INFORMATION MATERIALS

The information was also prepared in a visually easy-to-understand way – in infographics and informative materials. Two infographics were produced last year to invite medical device dis-



tributors to register in the LATMED database and on the evaluation of medicines and medical devices. Last year, the annual public report on the activities and achievements of the institution in 2023 was prepared (both in Latvian and Englih).

INTERNATIONAL COLLABORATION

The activities of the Agency's Public Relations Division in two international working groups – the HMA Working Group of Communication Professionals (WGCP) and the International Cooperation Platform of the European Medicines Regulators Network – should be noted. This cooperation ensured a proactive transfer of information provided by EMA to the Latvian public, providing important information on EU centrally authorised medicines, their authorisation and safety, side effects and other aspects.

CLIENT AND COLLABORATION PARTNER SURVEYS

Client and collaboration partner survey – objective: to obtain an evaluation of the Agency's work and services in order to improve customer service, information, cooperation with customers and the quality of the services provided by the Agency on the basis of the data received;

Employee survey – objective: to find out employees views on work organisation, environment and cooperation, job satisfaction and other relevant aspects.

A total of 11 surveys were conducted last year (including a survey of hospital pharmacists on the use of electronic package leaflets in hospitals, customer seminar evaluation surveys, a survey of MAHs, etc.). The Agency's communication activities shall, as far as possible, be based on data and studies.

CRISIS COMMUNICATION, PUBLICATION OF INFORMATION AND ASSESSMENT OF COMMUNICATION

During the reporting period, a new Crisis Communication Plan has been developed, based on the experience and solutions gained during the COVID-19 period, as well as an Institution's Internal Communication Plan has been established.

Last year, recommendations (guidelines) were prepared for the content of information intended for publication on the Agency's website, providing customers with information on the Agency's services and requirements.

An audit of the Agency's Public Relations Division took place in 2024. In the evaluation of the communication function of public administrations, the communication function performed by the Agency reached the highest score – level of maturity 4, which indicates that the Agency has an institutionalised, mature, full-fledged and professional communication function and it corresponds to the highest level of maturity.

Last year, up-to-date information was provided on the information platform for employees – the intranet "Agency Pulse". For more information on what has been done, please see the section on what has been done last year in this public report.

IMPLEMENTATION OF AND AMENDMENTS TO NORMATIVE ACTS

Decisions adopted by the State Agency of Medicines are balanced, legal and compliant with the requirements of normative acts. In 2024, only 16 of the 8 768 decisions adopted by the Agency were contested at the Ministry of Health. In 2024, two of the contested decisions adopted by the Agency in 2024 were annulled by the MoH.

In 2024, the Agency, in collaboration with the Ministry of Health prepared amendments to several normative acts that were reviewed and approved in 2024, such as the most significant of them:

- On 20 June 2024, the Saeima adopted amendments to the Pharmaceutical Law, which entered into force on 18 July 2024. Amendments to the law improve regulation at the level of the Pharmaceutical Law on issues that have not been regulated, such as:
  - authorisation of the manufacture and use of advanced therapy medicinal products (gene therapy medicinal products, tissue engineered products and somatic cell therapy medicinal products) exempted from registration under EU law;
  - surveillance of the movement of medicinal products in customs warehouses, which prevents medicinal products entering the EU and not intended to be placed on the EU market from entering into circulation.

Amendments to the Pharmaceutical Law also include amendments to other legal norms, including specifying certain norms in relation to the distribution of medicinal products, including radiopharmaceuticals, non-registered medicinal products and samples of medicinal products and substances, as well as specifying the functions of the Agency, including strengthening the supervision of medical devices.

The Pharmaceutical Law includes amendments to legal norms in relation to the licensing of production and wholesale distribution of veterinary medicinal products, if veterinary medicinal products are produced and distributed by a manufacturer of medicinal products and a wholesaler of medicinal products, which produces and distributes both medicinal products for

human use and veterinary medicinal products, as well as other amendments to the clarity of legal norms in relation to the field of veterinary medicinal products, without introducing new regulation on the substance, including improving the procedures for issuing certificates of good manufacturing practice and distribution practice, as well as at the same time specifying the functions of the Agency and the Food and Veterinary Service. Taking into account that the provision of Article 3 of the Pharmacy Law stipulates that the Ministry of Agriculture is responsible for the supervision and control of pharmacy in the field of veterinary medicinal products, and the provision of Article 4 stipulates that the Food and Veterinary Service supervises and controls the production and distribution of veterinary medicinal products, following a new initiative of the Ministry of Agriculture, the Food and Veterinary Service will carry out the conformity assessment and licensing, as well as certification, of all veterinary medicinal products (previously this was regulated in the Pharmacy Law as a function of the Agency). By 31 December 2024, the Agency has transferred files related to the issuance of a special permit (licence) and certificates in the field of veterinary medicinal products to the Food and Veterinary Service.

- Cabinet Regulation No 895 on the price list for paid services of the State Agency of Medicines was adopted on 18 December 2024 and entered into force on 1 January 2025.

With the entry into force of the rules, amendments have been made to the Agency's price list for paid services in order to facilitate the availability and placing on the market of medicinal products immediately after authorisation, to reduce the administrative burden for customers, as well as to provide new services, for example in the field of clinical trials of medicinal products, by complying with the requirements of EU legislation. The changes to the Price List provide that from 1 January 2025, MAHs will not be required to pay an annual pharmacovigilance fee, making it easier for customers to also administer their invoices, and also include a 50% reduction in the annual post-authorisation renewal fee for the MAH for the second year after the marketing authorisation, as well as the waiving of rebates on the annual post-authorisation renewal fee. The price list for paid services also includes new services relating to the registration of medicinal products, clinical trials of medicinal products, distribution of medicinal products and medical devices and in vitro diagnostic medical devices.

In the future, the Agency plans to offer a new service - scientific advice to medical device manufacturers on issues affecting the clinical and performance evaluation of medical devices and in vitro diagnostic medical devices.

The Agency's price list for paid services reviews and updates services relating to the distribution of medicinal products, the conformity assessment and monitoring of the place of collection, testing, processing, storage and distribution of human blood and blood components and the place of utilization of tissues, cells and organs, clinical trials of medicinal products, quality control of medicinal products and medical devices.

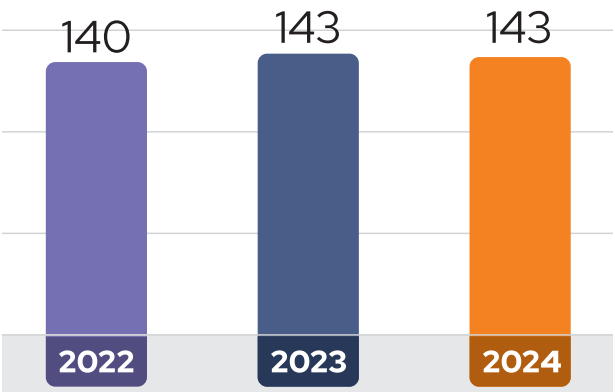
The new price list for paid services of the Agency was developed in close cooperation with industry representative associations, with the support of the industry, and is focused on the development of the Agency and its services.

In 2024, amendments were reviewed for more than 24 regulatory laws and regulations and proposals and opinions were prepared and provided to the Ministry of Health and other state administration institutions.

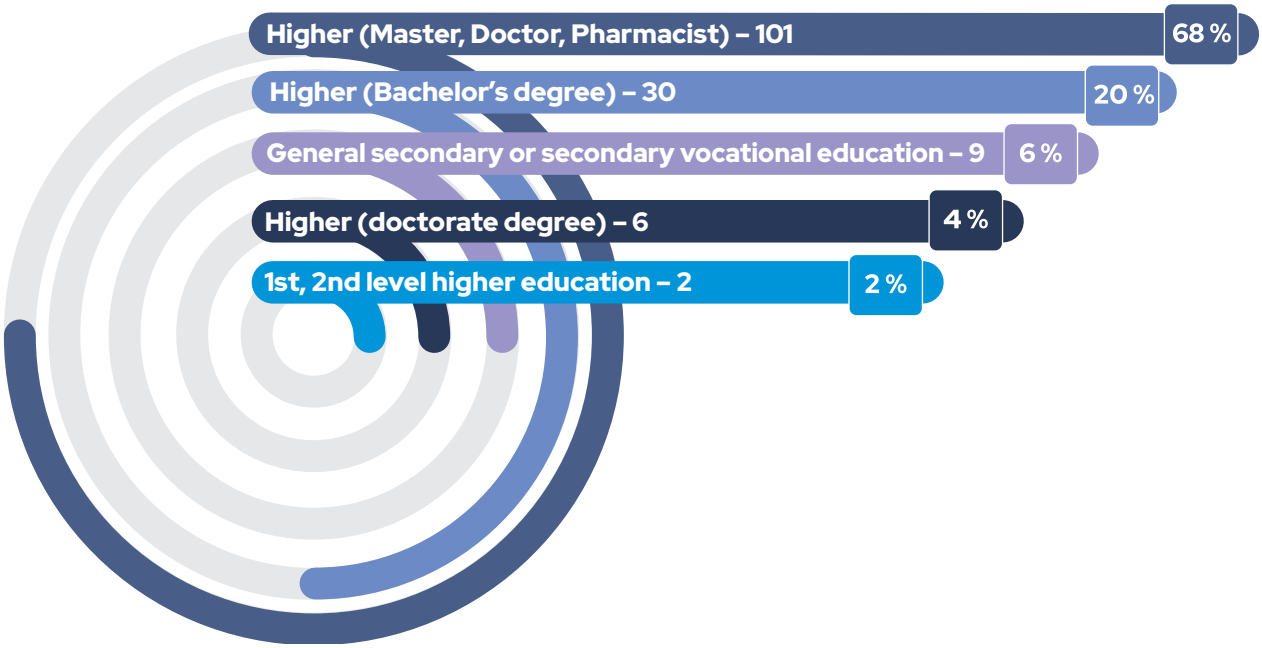
PERSONNEL MANAGEMENT AND TRAINING

There were 148 employees under employment or civil service at Agency. Staff turnover [1] - 11%.

The overall level of education among Agency's staff is high, with 137 staff or 92% having a higher education degree, of which 6 have a doctorate degree.



Actual number of employees



Breakdown of employees by level of education

[1] Proportion of officials and other servants who have left the service in relation to the average number of persons actually working.

Participation in further training courses and seminars, conferences of international organisations

Employees participation in trainings and international events in 2022-2024 is effectively ensured to the extent of demand. Training and international cooperation activities are organised both in person and remotely, part of the training is free of charge. In order to ensure the development of future-oriented competences and continuity of personnel competences, it is ensured that each employee attends at least two training activities during the year, in addition, training is carried out under the guidance of a mentor, special attention is paid to the acquisition of those competences that only one of the employees has. In 2024, employees had extensive opportunities to acquire new knowledge through training offered by the School of Public Administration and the EMA Training Centre.

2024 RESULTS OF THE EMPLOYEE SURVEY IN 2024:

92 %	of employees are satisfied with the progress of HR solutions and the availability of relevant information (request for leave and other absences, organisation of missions, consultations and support in dealing with various staff issues);
94.5 %	of employees are satisfied with the support provided for solving economic issues, satisfied with the working environment, which is assessed as safe and convenient.

INTEGRATED MANAGEMENT SYSTEM AND AUDITS

In order to implement the principles defined in the Agency's quality policy and achieve the objectives set, the quality management system continued to be maintained and improved in 2024, providing certification in accordance with the standard ISO 9001 'Quality management system', ISO/IEC 27001 '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 'Control of production, distribution and technical supervision of medical devices', launched by the MH in 2024, was concluded. It ended without recommendations or instructions. The audit 'Audit of personnel management functions and

improvement of personnel processes' launched in 2024 continued.

In addition to external audits, the Agency has carried out 13 internal audits focusing on the efficiency of internal processes, the management of pharmaceutical activities and information security.

An integrated management system helped coordinate and manage the Agency's activities to meet clients and regulatory requirements and continuously improve its organisational efficiency. One of the results – 93% of respondents to the client survey give a positive assessment of the quality of the services provided by the Agency.

Changes to the structure of the Agency, the approval of a new strategy and the consideration of future challenges led to a decision to revise the concept of quality indicators and gave particular importance to the optimisation of processes.

It should be noted that the total volume of services provided by the Agency has increased by 5% over the year. In addition, it is important to highlight the high level of digitalisation of the Agency - only 0.005% of cases are provided to clients on paper.

Particular attention was paid to the Agency's security - despite the difficult geopolitical situation, last year the Agency managed to ensure that the operational availability of the Information Systems was ensured 99.7% of the total time in working days.

It is important to highlight that:

- The Agency, in cooperation with the MA, successfully passed the JAP (Joint Assessment Process) and MRA (Mutual Recognition Agreement) audits. This confirms the competence of the regulatory authorities and strengthens the image of the country. It should be noted that mutual recognition opens global markets to Latvian pharmaceutical manufacturers without additional checks.
- The Agency received a certificate of compliance with the new standard 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 standard LVS EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" and that it is competent to perform testing.
- The Agency participated in the assessment together with the other European medicines agencies, which led to the recognition by the WHO of the European Medicines Regulatory Network (EMRN) as a 'single entity' to be included in the regulatory functions of the WHO Global Benchmarking Tool (GBT) for both medicines and vaccines.

Actions planned for the next period:

- Work on the implementation of the International Organisation for Standardisation (ISO) standards for the identification of medicinal products (IDMP) started in 2024 and will be actively pursued in 2025.
- Provision of new services and participation in the State-provided service environment improvement plan, improving service management.

MANAGEMENT OF INFORMATION AND COMMUNICATIONS TECHNOLOGY

In 2024, work continued on the development and improvement of information systems and ICT solutions, accessibility and governance. Last year, 1511 IT support works of various complexity and resource capacity were implemented, of which 20 applications for ICT changes, which contributed to the increase of work efficiency and provided significant support to enterprises, society and employees.

A number of significant changes have been made to the Agency's website:

- ▷ Automatic publication of data on the Agency's website
  - a list of medicinal products for which financial participation has been contracted between the National Health Service of Latvia (NHS) and the marketing authorization holder or wholesaler of medicinal products and whose export to EU Member States or export has been authorized only after authorization by the Agency.
  - a list of decisions taken on the non-removal of medicinal products from the Latvian Register of Medicinal Products (Sunset clause) in connection with exemption from the requirements of points 125.1 and 125.2 of Cabinet Regulation No 376 of 9 May 2006 on the procedure for the registration of medicinal products.
  - a list of the medicinal products for which the Agency has received notifications from the marketing authorization holders on the basis of paragraphs 6.3 and 7.6 of Regulation No 57 or for which the Agency has authorized the distribution of the medicinal product in packaging intended for another national market.
- ▷ Changes have been made to the Register of Medicinal Products to display additional

information for medicinal products on the presence, type of risk minimization materials, additional search conditions have been established for the selection of such medicinal products.

- Substantial additions and improvements to the adverse drug reaction reporting form (BZIS) to allow reporting of other vaccines than only COVID-19 vaccines and medicinal products, as well as to make the reporting more user-friendly.
- Establishment of a database of National Contact Points (NCPs) on pharmacovigilance by the MAHs.

In 2024, measures were implemented to mitigate IT security-related risks, as well as the introduction of new security monitoring solutions and the introduction of a computer management tool. Including implementation of CERT - LVRTC DDOS agreement, implementation of new data network connection. A security audit on compliance has been carried out and an opinion on it has been received. Several system and infrastructure improvement works have been carried out:

- Arranged EURS files, transferred to a new server, in a new environment.
- Updated Power BI report server to a new release of software.
- A solution has been developed that performs a quality check of the SAMIS/ Medicinal Product Register data under defined conditions every night.
- Changes have been made in the SAMIS in order to collect information about the only pharmacy or pharmacy branch and transfer this information to e-Health according to a pre-defined data structure together with other pharmaceutical activity data.
- New addition formulas and recalculated prices of prescription medicines have been introduced in the SAMIS in relation to the calculation of new prices of prescription medicines, which will come into force from 01.01.2025. The SAMIS has been supplemented to collect information on temporarily closed pharmacies and to collect information on the opening hours of officials responsible for pharmacies and the opening hours of pharmacies.
- Updates have been made to the SAMIS in relation to the maintenance and more convenient review of the marketing authorizations information for medicinal products by the Agency's experts.

Last year, the maintenance of the ICT infrastructure used by the MoH and its subordinate institutions was continued, as well as support to the ICT specialists of these institutions was provided. In 2024, cooperation also continued in the exchange of electronic information with various European institutions, competent authorities of other countries through common ICT solutions, such as the European clinical trials database EudraCT, the secure e-mail EudraMail and the data exchange system Eudralink, the pharmacovigilance system EudraVigilance and the data analysis system EVDAS, the European database for medical devices EUDAMED, the mutual recognition registration procedures for CTS solutions for medicinal products, the European common portal for submission of registration dossiers for medicinal products to CESP, as well as the Common Repository for Centralised Procedures for Registration of Medicinal Products, the PSUR Repository for Periodic Safety Update Reports. The next generation EURSnext software of the drug documentation evaluation system EURS has been introduced, and users are switching to its daily use, allowing them to work more conveniently and quickly with the data they need every day.

Priorities for 2025

1. Preparation to standardize the data structure of the ISO IDMP project in the EU for the launch required for EU cross-border data interoperability.
2. Receipt of distribution notifications for unauthorized medicinal products – development of a system for receiving distribution notifications (automation possible), data validation, easy browsing and processing of data by employees.
3. Modernization of the system of interruptions of supply of medicinal products – development of a system to make it easier to deal with received interruptions of supply notifications, so that data can be more easily processed and analyzed.

Development of a tool to manage changes to the marketing authorizations documentation to facilitate the handling of changes by experts of the Medicines Marketing Authorization Department of the Agency.

ENERGY EFFICIENCY AT THE AGENCY

The Agency has a heating system with condensation-type gas heating equipment, which provides hot water preparation and heating of buildings, as well as a 270 kW diesel generator, which ensures the continuity of the Agency's operation in case of power supply interruptions. There is also a solar microgeneration plant and heat pumps installed in the Agency's administrative building, which provide small electricity savings and energy autonomy.

The Agency shall continuously ensure the efficient use of the resources under its responsibility by ensuring the sorting of waste paper, glass, metal and PET and the collection and recycling of end-of-life batteries. Also, only energy-efficient lighting solutions are used to ensure the lighting of buildings.

Currently, the implementation of the reconstruction project of the Agency's archive building has started, which is planned to be completed by 2025, increasing the energy efficiency of the building.

OVERVIEW ON AGENCY'S ACTIVITIES IN THE REPORTING YEAR

MAIN EVENTS THAT AFFECTED THE AGENCY'S ACTIVITIES DURING THE REPORTING YEAR:

- **The audit of the Joint Audit Programme (JAP) at the Agency has been carried out. The JAP is an essential component of the quality system adopted by Good Manufacturing Practice (GMP) inspections**in the EEA, which aims to ensure consistency of GMP standards and a harmonised approach across Europe.
- Advising **sponsors, sponsor representatives, academic sponsors and ethics committees on their work in the EU's single Clinical Trials Information System (CTIS)** has continued. Given that, as of 31 January 2025, clinical trials can only take place in accordance with the requirements of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (CTR), the transition of clinical trials initiated in accordance with the requirements of Directive 2001/20/EC to the requirements of the CTR was **facilitated.**
- **Proactive solutions have been taken to ensure access to medicines:** The Agency issued marketing authorisations for non-registered medicinal products, parallel import authorisations, allowed the supply of medicinal products to Latvia in packaging intended for the market of another country, and addressed marketing authorisation holders in cases of potential interruptions in the supply of medicinal products with a request to provide the Latvian market with the necessary medicinal products, including centrally authorised medicinal products.
- The Agency actively continued **its work on the evaluation and authorisation of medicinal products,** promoting the availability of authorised medicinal products with appropriately proven and evaluated quality, efficacy and safety for the population of Latvia and providing a medicinal product authorisation service to economic operators, which is a precondition for the full distribution of medicinal products on the EU market.
- **Participation in EMA's Executive Steering Group on Disruptions of Supply and Safety of Medicinal Products (MSSG) and EMA's Executive Steering Group on Disruptions of Supply and Safety of Medical Devices (MDSSG),** set up to take EU-harmonised actions in the event of disruptions of supply of medicinal products caused by major events or public health emergencies, is ensured.
- Continued **participation in EMA's scien-**

tific committees and working groups, where the Agency assessed information and data to ensure the availability of medicines, including vaccines, and participated in and prepared assessment reports in centralised marketing authorisation procedures.

- Continued **monitoring of the safety of medicines, including vaccines,** assessment of adverse reaction reports received and awareness raising among healthcare professionals on the management of the use of medicines and their adverse reactions.
- Work has continued on the implementation of Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council, **ensuring a robust, transparent, sustainable and internationally recognised regulatory framework for medical devices and *in vitro* diagnostic medical devices,** thereby improving the clinical safety of those devices and guaranteeing fair market access for device manufacturers.
- **Participation in the development of the new European database on medical devices EUDAMED electronic system for authorisation of medical devices/ unique identification of medical devices (UDI) and electronic system for authorisation of economic operators, as well as in the development and testing of the electronic system on vigilance and post-market surveillance and electronic system on clinical trials,** which will improve the monitoring and coordination of information on medical devices available on the EU market.
- **Participation in the establishment of the implementation framework of Regulation (EU) 2021/2282 on health technology assessment (HTAR) to facilitate access to innovative technologies, including medicines and certain medical devices, for EU patients in the health sector.** Participation in the development and adoption of implementing acts on inter-institutional cooperation, management of conflicts of interest, joint clinical evaluation of medicinal products and medical devices and scientific advice in the field of health technology assessment.
- In the context of Russia's invasion of Ukraine, **the Agency worked on crisis preparedness issues by** reviewing the list of critical medicines, participating in an exchange of experience, including a study visit to Ukraine.
- **Independentand scientifically based information was provided** on new medicines authorised in the EU, their safety and authorisation process, **as well as the latest information was disseminated to the EMA on the progress of medicines research, evaluation and the role of regulatory bodies in the authorisation of medicines,** ensuring awareness of the Latvian public on the safe and rational use of medicinal products.
- **The public and healthcare professionals have been provided with up-to-date and evidence-based information on the availability, safety and use of medicinal products and other matters within the Agency's remit.** In general, publications and the preparation of information for doctors, the public and citizens on topical issues related to vaccines and medicines have been provided. Regularly provided EMA news on medicines and vaccines in Latvian and developed intensive cooperation with the media and health sector organisations, providing information on

medicines and vaccines;

- **A public awareness campaign on adverse drug reactions and their reporting has been carried out.** As part of the campaign, the Agency has simplified and made it easier to report adverse drug reactions. Citizens can submit adverse drug reaction reports to the Agency by scanning the QR code and filling in the report electronically. As part of the campaign, several information materials have been developed for the public – a video clip, an information leaflet for citizens and pharmacists, posters and stickers with a QR code for more convenient reporting of adverse drug reactions.
- **In the evaluation of the communication function of public administrations, the communication function performed by the Agency scored highest at level 4, indicating that the Agency has an institutionalised, mature, full-fledged and professional communication function and corresponds to the highest level of maturity.**
- **Information materials have been prepared for the public and healthcare professionals on antimicrobial resistance and prudent use of antibiotics,** raising awareness among the public and medical practitioners on the prudent use of antibiotics.
- Improvement of **the working environment has been implemented and remote working solutions have been maintained** in order to ensure continuity of work, reduce health risks for employees and clients, as well as to implement the promotion of well-being and ensure a motivating work-life balance.
- Taking into account the changes in the regulatory enactments providing for the development and change of certain services of the Agency, as well as changes in internal processes implemented in order to ensure efficiency of work and efficient use of staff resources, the structure of the Authority was reviewed and the Pharmacovigilance Unit with the posts included therein was abolished with effect from 1 July 2024 by Order No 1-6/46 of 27 May 2024 "On Amendments to Order No 1-6/78 of 4 October 2023 "On the List of Posts of the State Agency of Medicines" and the Medicines Safety Unit was established by combining functions and tasks.
- **In order to increase the efficiency of the work in the future and to ensure the improvement of the level of digitalisation of processes in the public administration, the Agency was actively involved in the implementation of the process of centralisation of accounting and personnel records of the public administration already in 2024** in order to transfer part of the accounting functions to the Single Service Centre in 2025.
- In order to gain assurance on the compliance of the activities and processes implemented by the Agency with the national and EU requirements, quality and safety requirements standards, **the Agency carried out a second surveillance audit in accordance with the requirements of ISO 9001:2015 standard, a surveillance/transition audit in accordance with the requirements of ISO/IEC 27001:2022**.

ACTIONS TO IMPLEMENT THE LINES OF ACTION SET OUT IN THE AGENCY'S STRATEGY

The medium-term operational strategy up to 2027 developed by the Agency, approved

in 2024, which includes the objectives and tasks set for the period 2024-2027, the priority axes for action, the operational results to be achieved and the resources and financial envelope expected to achieve them. The strategy analyses the external and internal environment of the Agency's activities, the factors influencing the fulfilment of the planned tasks and services, and the interaction between the parties involved. The Agency's strategy has been developed taking into account the priorities and objectives set for the health sector in ensuring public health, the current tasks (e.g. HMA, EMA, EDQM), as well as the opportunities for further development and improvement of the priority objectives set out in the Agency's operational strategy for 2020-2022 and the activities undertaken. The Agency provides an overview of the fulfilment of strategic objectives, their analysis and changes in current affairs once a year, compiling performance indicators for the tasks performed in a given year and producing an annual public report.

- In order to ensure public health as a priority, a strategic development of the Agency focused on future needs, high-quality and efficient implementation of national delegated functions and long-term service provision and management, as well as public information and the development of the Agency as a workplace, the Agency prioritises the following lines of action for the 2024-2027 strategy period:
- **Direction of public health interest** to promote the availability of effective, high-quality and safe treatments, as well as the provision of evidence-based and independent information to citizens and healthcare professionals.
- **The aim of the service development direction** is to provide services that correspond to the needs of the target groups, harmonizing and improving them, taking into account the applicable requirements set at the EU level and the latest technological trends, as well as developing and improving the quality management implemented in the Agency, ensuring its compliance with the selected ISO standards and the unified requirements of the EU Agencies Network.
- **Sustainable development direction of the Agency** with the aim to create a modern working environment, to promote the well-being and motivation of employees to work in the Agency, strengthening the capacity and ability to perform the functions delegated to the Authority in the long term, as well as ensuring the improvement of the skills and abilities of the staff in accordance with the future needs and changes in the regulation of the sector.

ACTION FOR THE IMPLEMENTATION OF THE PUBLIC HEALTH INTEREST DIRECTION

In 2024, as the Agency's medium-term strategy period continues, the **issue of ensuring access to medicines has remained a priority in the area of public health interest** since the previous strategy period, with the following operational tasks:

- Strengthen the role of the Agency in the European Regulatory Network.
- Strengthen the role of the Agency in supporting the development of innovative medicines.
- Promote the use of the Multilingual Medicines Packaging (MLP) solution.
- To ensure that requests for distribution authorisations for medicinal products not authorised in Latvia and imported in pa-

rallel are dealt with in the shortest possible time and to facilitate the obtaining of annual authorisations.

- Ensure participation in the assessment of clinical trials under the CTIS system as reporting Member State (RMS) and ensure coordination of the assessment.
- Participate in EMA-initiated inspections and carry out national Good Clinical Practice inspections.
- Ensure safety monitoring of investigational medicinal products and participate in the Safe-CT project.

One of the Agency's main priorities is to provide public and healthcare professionals with up-to-date information on the safety of medicinal products through the following tasks:

- Provide up-to-date information on the safety of medicines to the public and healthcare professionals.
- Promote compliance of the MAHs with good pharmacovigilance practice.
- Manage adverse drug reaction reports.

Today, when everyone has free access to a wide range of information, the question of the veracity and reliability of the information available is crucial. In 2024, **in line with the direction of providing reliable information set out in the Agency's strategy,** the Agency has actively continued to inform doctors, healthcare professionals, pharmacists and the public at large about the services provided by the Agency and the decisions taken by regulators, about topical issues that are important and also passed on to the public by the EMA, as well as continued to participate in joint European national information campaigns.

In order to implement the action direction set out in the strategy **Ensuring reliable information,** the following tasks are implemented:

- Provide reliable information to pharmaceutical companies on the Agency's services.
- Provide up-to-date, timely, accurate, evidence-based and easily understandable information to the public.
- Increase public confidence in the Agency.
- Provide up-to-date and easily accessible information on pharmaceutical companies and their activities.

OPERATION FOR THE IMPLEMENTATION OF THE SERVICE DEVELOPMENT DIRECTION

Since the main task included in the Agency's mission is the provision of high-quality services, the performance and quality of which can significantly affect the performance of the pharmaceutical industry, the quality of healthcare and public interests, the Agency is committed to promoting client satisfaction by improving the quality of the services provided and implementing appropriate solutions.

In order to ensure quality of service management, the Agency shall carry out the following tasks:

- Develop the SAMIS by implementing the creation of a client portal and the availability of automated services.
- Ensure up-to-date ISO 9001 and ISO /IEC 27001 certification and ISO IEC 17025 accreditation.
- Optimise service delivery processes.
- Maintain a consistently high level of quality and rule of law in the Agency's decisions.

The new period of the Agency's strategy in the field of health technologies is related to the implementation of Regulation (EU)

2021/2282 of the European Parliament and of the Council of 15 December 2ssment tools, methodologies and procedures for its implementation. The development of services in the field of health technology assessment shall be related to the following tasks:

- Prepare and make proposals for the necessary legislative changes to the common EU health technology assessment procedure.
- Contribute to the preparation of the reviews of the clinical part of the Joint EU Health Technology Assessment.
- To inform the Agency's clients about the regulatory framework in the field of health technology assessment.

In 2024, the Agency participated in the development and adoption of the implementing acts laid down in Regulation (EU) 2021/2282 of the European Parliament and of the Council and created two new posts to ensure Latvia's participation in the joint clinical assessment processes.

In the field of medical devices, the new strategic period involves changing the requirements for the provision of services from the regulatory framework. Work on the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, which had already started, continued in 2024. How are the main tasks implemented:

- To prepare and make proposals for regulatory enactments regarding medical devices, *in vitro* diagnostic medical devices and procedures for conducting clinical studies of medical devices intended for humans and performance studies of *in vitro* diagnostic medical devices.
- Contribute, in cooperation with the competent authorities of other EU Member States, to the evaluation of the risks arising from reported serious incidents and to the evaluation of any related field safety corrective actions.
- Participate in the preparation of a coordinated assessment procedure for clinical investigations of medical devices, including pilot projects and the preparation of experts for the application of that procedure.
- Plan and organise targeted information activities on the need to report suspected serious incidents involving medical devices.

The Agency registered more than 150 distributors of medical devices, carried out an information campaign on their responsibilities, device classes and other issues, as well as made proposals for amendments to regulatory enactments – for the national position on amendments to regulations of the European Parliament and of the Council and proposals for Cabinet Regulations on medical devices, *in vitro* diagnostic medical devices, clinical and performance studies.

In the areas of conformity assessment, the new strategic period involves changing the requirements for the provision of services in the context of initiatives at European level to revise the regulatory framework in the areas of both pharmaceuticals and the use of biomaterials of human origin. In 2024, one of the main tasks on which work has been carried out is: to prepare and make proposals for regulatory enactments in the fields of pharmaceuticals and the use of biomaterials of human origin. In 2024, the Agency successfully carried out the Single Audit Programme process, which allows the recognition of licences and certificates issued in Latvia in other countries of the world.

On 27 May 2024, the Council of the Europe-

an Union adopted a regulation on standards of quality and safety for substances of human origin (SoHO), new rules aimed at improving the safety and quality of blood, tissues and cells used in healthcare and facilitating their cross-border circulation in the EU. The Regulation entered into force on 7 August 2024 and is to apply 3 years after its entry into force, unless otherwise provided for in Article 87(2) of the Regulation. In preparation for its implementation, the Agency created a new Organic Products Unit – Product Assessment and Monitoring, as well as an additional post in the Compliance Assessment Unit – to strengthen the compliance assessment and monitoring capacity of SoHO institutions.

ACTION FOR THE IMPLEMENTATION OF THE SUSTAINABLE DEVELOPMENT DIRECTION OF THE AGENCY

As the Agency performs its functions and tasks in an environment subject to innovation and rapid technological development, the knowledge and competence of its staff, as well as the regulatory framework, do not always keep pace with the development of the sector. In order to overcome these challenges and implement a future-oriented development of staff competences, work continued in 2024 on the development of the competences required for each position, mentoring programmes and targeted replenishment of the necessary knowledge. In order to ensure future-oriented development of staff competences and continuity of staff competences, the following tasks shall be implemented:

- Implement an effective use of human resources to strengthen the capacity to perform functions.
- Implement targeted staff qualification development according to future needs.

A well-organised work environment, a good atmosphere and a sense of cohesiveness in the team help the employee to feel better, increase resilience to stress, give motivation to work more efficiently and feel belonging to a particular workplace. In order to increase the productivity of the Agency's staff, their loyalty to the institution, as well as their work-life balance, the Agency is modernising its office premises, while thinking about the environment and the necessary reduction in the use of resources, developing a strong corporate culture, ensuring sufficient, convenient and easy-to-use access to information and IT resources, working both in person and remotely.

The following tasks set out in the strategy are implemented for the development of the working environment:

- Modernise working spaces by reducing the use of necessary resources.
- Build a time-appropriate working environment and strengthen corporate culture.
- Develop IT infrastructure in line with changing requirements in the field of IT security.
- To develop a common understanding of the data available in the Agency, its quality and to promote its multi-purpose use.

FUTURE DEVELOPMENT OF THE AGENCY AND KEY EVENTS IN 2025

- Within the scope of its competence, submit proposals to the MoH and participate in the national pharmaceutical and health care regulation (incl. In the development of amendments to the Pharmaceutical Law) and in the development of the international pharmaceutical regulation.
- Involvement in the development of the EU pharmaceutical reform and subsequent implementation of the policy, which the European Commission intends to implement with new regulatory enactments:
  - a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human use and laying down rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 2014 and repealing Regulations (EC) No 726/2004, (EC) No 141/2000 and (EC) No 1901/2006;
  - Directive of the European Parliament and of the Council on the Community code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

- Development of requirements for the use of an exceptional advanced therapy medicinal product in medical treatment and issuance of a permit to a medical treatment institution for the use of such medicinal product, as well as ensuring of these requirements from 1 July 2025.
- In the field of biomaterials of human origin (hereinafter 'SoHO'), it is necessary to implement the requirements laid down in Regulation 2024/1938. The development of services in the SoHO area is related to the following tasks:
  - to prepare and make proposals for the necessary changes to laws and regulations;
  - participate in the SoHO Coordination Board (SCB);
  - ensure participation in the MoH SoHO working group in the context of the implementation of Regulation 2024/1938;
  - to provide information to the Agency's clients on the SoHO regulatory framework.
- Start and ensure laboratory monitoring of the quality of medicines. Within the framework of laboratory monitoring of the quality of medicinal products, it is planned that samples of medicinal products will be submitted to the Agency for quality control by a medicinal product wholesaler or a pharmacy (general type or closed type) at the request of the Agency.
- Follow and play an active role in reducing the risks of interruptions in access to medicines, including participating in the EMA Executive Group on Shortages and Safety of Medicinal Products (MSSG) and Medical Devices Shortages Steering Group (MDSSG) and other working groups, as well as continuing to implement projects such as the Electronic Product Information Leaflet (e-PIL) project.
- Participate in EMA scientific consultation procedures.
- Continue the ongoing development of the information system ZVAIS with a view to increasing its functionality and implementing automated services availability.
- Participate in the project "Improving the use of HTA in decision-making in Latvia" supported by DG REFORM at the end.
- Introduce the requirements of Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on Health Technology Assessment.

FUNDING AND ITS USE

Funding and use of the Agency's budget

Classification code	Item name	Plan for the year with changes	Implementation of the budget	
			In the reporting period	In the previous reporting period
I.	**REVENUE**	**6 663 088**	**7 442 535**	**6 736 473**
3	**Paid services and other own revenue**	**4 994 313**	**5 522 266**	**5 410 823**
21.4.0.0.	Other revenue of institutions not classified in group 21.3.0.0 for paid services provided by institutions and other own revenue	4 994 313	5 502 381	5 401 789
4	**Foreign financial assistance**	**1 585 384**	**1 835 753**	**1 202 039**
21.1.0.0.	Revenue for the institution from foreign financial assistance	1 585 384	1 835 753	1 202 039
5	**Transfers**	**83 391**	**84 516**	**123 611**
17.4.0.0.	Transfers received by derived public persons partly financed from the State budget and institutions not financed from the budget from other derived public persons partly financed from the State budget and institutions not financed from the budget		1 125	0
18.3.0.0.	Transfers received from the State budget by derived public persons partly financed from the State budget and institutions not financed from the State budget // Transfers received from the State budget by derived public persons partly financed from the State budget and institutions not financed from the State budget	83 391	83 391	123 611
II.	**EXPENSES TOTAL**	**7 993 475**	**7 841 007**	**7 331 727**
1000	Remuneration	5 856 784	5 856 779	5 127 452
1100	Salary	4 517 379	4 517 374	3 953 204
1200	State social insurance mandatory contributions calculated by employer, benefits and compensations	1 339 405	1 339 405	1 174 248
2000	Goods and services	1 325 065	1 172 602	1 048 132
1.3.	Subsidies, grants and social benefits	15 000	15 000	50 000
6000	Social payments and compensation	15 000	15 000	50 000
1.5.	Transfers within one budget type and maintenance expense transfers between budget types // Maintenance expense transfers	21 102	21 102	382 672
7810	Transfers of the maintenance expense of the derived public persons partially funded by state and non-budgetary institutions from state budget to state budget	21 102	21 102	382 672
2.1.	Formation of share capital	775 524	775 524	723 471
5000	Formation of share capital	775 524	775 524	723 471
5100	Intangible investments	67 566	67 566	106 687
5200	Fixed assets	707 958	707 958	616 784
III.	**REVENUE SURPLUS (+), DEFICIT (-) (I-II)**	**-1 330 387**	**-398 472**	**-595 254**
IV.	**Financing**	**1 330 387**	**398 472**	**595 254**

INDEPENDENT AUDITOR'S REPORT

Riga

The date of the document is the time of its electronic signing
No. 01/2025

To the State Agency of Medicines

Our Opinion on the Financial Statements
We have audited the financial statements included in the 2024 annual report of the State Agency of Medicines (hereinafter referred to as the "Agency"). The attached financial statements comprise:

- the statement of financial position as of 31 December 2024 (balance sheet);
- the statement of financial performance for the year ended 31 December 2024;
- the statement of changes in equity for the year ended 31 December 2024;
- the cash flow statement for the year ended 31 December 2024;
- the notes to the financial statements, including explanations of line items in the financial statements, a description of accounting principles, principles used in preparing the annual report, and a description of risk management for financial instruments.

In our opinion, the attached financial statements give a true and fair view of the financial position of the State Agency of Medicines as of 31 December 2024, and of its financial performance and cash flows for the year then ended, in accordance with Cabinet Regulation No. 652 "Procedure for Preparing the Annual Report" dated 28 September 2021.

Basis for Opinion
We conducted our audit in accordance with the Law on Audit Services and the International Standards of Supreme Audit Institutions (ISSAIs) recognized in Latvia. Our responsibilities under these standards are further described in the "Auditor's Responsibilities for the Audit of the Financial Statements" section of our report.

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

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

Reporting on Other Information
Management is responsible for the other information, which comprises:

- the management report included in the attached annual report;
- the budget execution report included in the attached annual report.

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 thereon, except as stated in the section "Other Reporting Requirements under the Laws of the Republic of Latvia."

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

If, based on the work we have performed and the knowledge we have obtained in the course of the audit, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Other Reporting Requirements under the Laws of the Republic of Latvia
Pursuant to the Law on Audit Services, we are required to evaluate whether the management report is prepared in accordance with Cabinet Regulation No. 652 "Procedure for Preparing the Annual Report" dated 28 September 2021.

Based solely on the procedures carried out within our audit, in our opinion:

- the information provided in the management report for the reporting year, for which the financial statements are prepared, is consistent with the financial statements; and
- the management report has been prepared in accordance with the requirements of Cabinet Regulation No. 652 "Procedure for Preparing the Annual Report" dated 28 September 2021.

Responsibilities of Management and Those Charged with Governance for the Financial Statements
Management is responsible for the preparation of financial statements that give a true and fair view in accordance with Cabinet Regulation No. 652 "Procedure for Preparing the Annual Report" dated 28 September 2021, and for such internal control as management determines is necessary to enable the preparation of financial statements that are 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, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting, unless management either intends to merge the Agency with another institution or liquidate it.

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 ISSAIs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, 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 ISSAIs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and

obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Agency's internal control;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management;
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Agency's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Agency to cease to continue as a going concern;
- Evaluate the overall presentation, structure, and content of the financial statements, including the disclosures in the notes, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation;

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

Līga Šķibele
Member of the Board
SIA "Auditorfirma Šķibele un Partneri"
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