Annual Report 2025

State Institute for Drug Control

SÚKL

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INTRODUCTION

Dear readers,

the State Institute for Drug Control presents its Annual Report which provides summary data, tabular and graphical overview of the results of the Institute's operation in 2025, along with accompanying texts.

For our Institute, last year was a time of intensive professional work, development of international cooperation, and enhancement of key activities that are essential for public health protection.

We were fulfilling the role of a modern national regulatory authority, whose primary mission is to safeguard the availability of and surveillance over the safety, efficacy, and quality of medicinal products, medical devices, and human tissues and cells intended for use in man for patients in the Czech Republic, and, at the same time, to act as a respected partner within the European regulatory network of drug agencies.

It is appropriate to express our appreciation for the constructive cooperation with the Ministry of Health of the Czech Republic. In 2025, we were jointly involved particularly in the preparations for the implementation of European legislation into the Czech legal order, specifically in the area of pharmaceuticals, human tissues and cells, and medical devices. The Institute also actively contributed to the preparation of new legal regulations and inter-ministerial comment procedures in areas relevant for the scope of the Institute's powers.

Cooperation with other state administration institutions, expert societies, professional chambers, the academia as well as the general public is of equal importance for us. In recent years, we have been significantly enhancing our dialogue with patient organisations that provide valuable patient insights during the establishment of regulatory processes, in communication about the safety of pharmaceuticals or in discussions focusing upon the availability of advanced therapies. We support expert education of patient representatives, and we are actively engaged in the process. We consider open communication with the public and involvement of patients in expert discussions as one of the primary pillars of transparent communication.

The Institute's operation is also firmly embedded in the European regulatory system. In 2025, our experts were actively involved in work of European Union's bodies, e.g., in areas associated with the approval of new medicines, safety of medicinal products on the EU market, medical devices regulation, pricing, healthcare technology assessment, laboratory control, or regulation of human tissues and cells, availability of medicines, and antimicrobial resistance (AMR). This concerned, in particular, working groups under the EU Council, working meetings of and participation in the committees of the European Commission, including the European Medicines Agency (EMA) or the Council of Europe, namely its European Directorate for the Quality of Medicines & HealthCare (EDQM).

Involvement in these structures allows the Czech Republic to take an active part in the development of European rules in the sphere of marketing authorisation and safety of pharmaceuticals, medical devices regulation, healthcare technology assess-

ment, regulation of human tissues and cells or in addressing antimicrobial resistance issues. Active participation of our experts in international working groups is also an important source of shared experience and enhancement of the Institute's expertise.

Another of the Institute's priorities for 2025 was the task of continuously safeguarding the availability of medicines for patients. The Institute, in cooperation with the Ministry of Health, monitored the situation on the medicinal product market on a continuous basis and evaluated information about suspended or terminated supplies. The amended Act on Pharmaceuticals had a positive practical impact, as it provided new instruments allowing for good-quality monitoring of availability and looking for timely solutions in case of medicinal product shortages, which stabilised the availability of medicines on the Czech market.

Surveillance over quality and over legislative compliance remains an essential part of the Institute's activities. In 2025, our inspectors carried out hundreds of inspections in pharmacies, at distributors as well as other regulated entities. The inspection activity included not only control of compliance with the rules governing the handling of medicinal products and medical devices, but also such areas as compliance with price regulation rules and surveillance over advertising for medicinal products and medical devices.

Much attention has been also paid to the safety of medicinal products.

Within the scope of the pharmacovigilance system, each year, the Institute receives and evaluates all reports of suspected adverse drug reactions. In 2025, we continued to strengthen our involvement in European pharmacovigilance procedures, and our experts were engaged in the evaluation of the safety of many active substances as well as centrally authorised medicinal products.

Equal attention has been paid to the safety of medical devices. In this sphere, we investigated each of almost 1,800 reported serious incidents potentially associated with the use of medical devices in the provision of healthcare services and we monitored compliance with adopted safety corrective actions.

The coming into force of Regulation (EU) 2024/1860 of the European Parliament and of the Council (and its implementation into Czech legislation) was an important milestone, as it introduced a new Article 10a effective from 10 January 2025, which sets forth the obligation of medical device manufacturers to provide competent authorities with timely information about planned interruption or discontinuation of supplies of selected devices, in respect of which it may be reasonably assumed that such interruption or discontinuation could result in serious harm or a risk of serious harm for patients or for public health.

An important role in the regulatory system is that of assessment of clinical studies and clinical investigations of medical devices. In this area, in 2025, the Institute was involved in European projects focusing upon the harmonisation of clinical trial assessment and upon coordinated evaluation of safety data. At the same time, in cooperation with partners in the Czech Republic, we drafted a proposal of national strategy for clinical trials, the aim of which is to increase the attractiveness of the Czech Republic for the conduct of clinical research and to enhance access to innovative therapies for patients.

In 2025, the Institute focused much of its efforts on consumer, or patient, protection. It carried out surveillance over compliance with the rules governing advertising for medicinal products, medical devices as well as *in vitro* diagnostic medical devices; it addressed tens of reports of suspected breaches of legal regulations; and conducted administrative procedures in order

to prevent misleading or illegal practices. It was also involved in the assessment of the nature of products in respect of which it was suspected that they might be placed on the market illegally outside the regimen governing medicinal products, and provided expert support to other state administration bodies, particularly customs authorities, in the control of shipments from third countries. As an integral part, this incorporated also the identification and publication of websites with illegal offers of medicinal products. These activities contributed to the enhancement of patient safety and market protection against illegal or potentially risky products.

2025 was also a year of significant development of information technologies and cybersecurity enhancement. The Institute continued the implementation of a project funded by the National Recovery Plan (NPO), the purpose of which is a pronounced enhancement of information system and infrastructure cybersecurity. We have significantly raised the security awareness of employees to sustain a high standard of data protection and to safeguard reliable operation of services and of the ePrescription system, which are essential for communication with professionals as well as with the patients. Our Institute much contributed to progress in health care electronisation through the introduction of an automated system of protective limit monitoring. From 2025, eligible out-of-pocket payments have been recorded in the ePrescription system, allowing for the real-time excess payment evaluation.

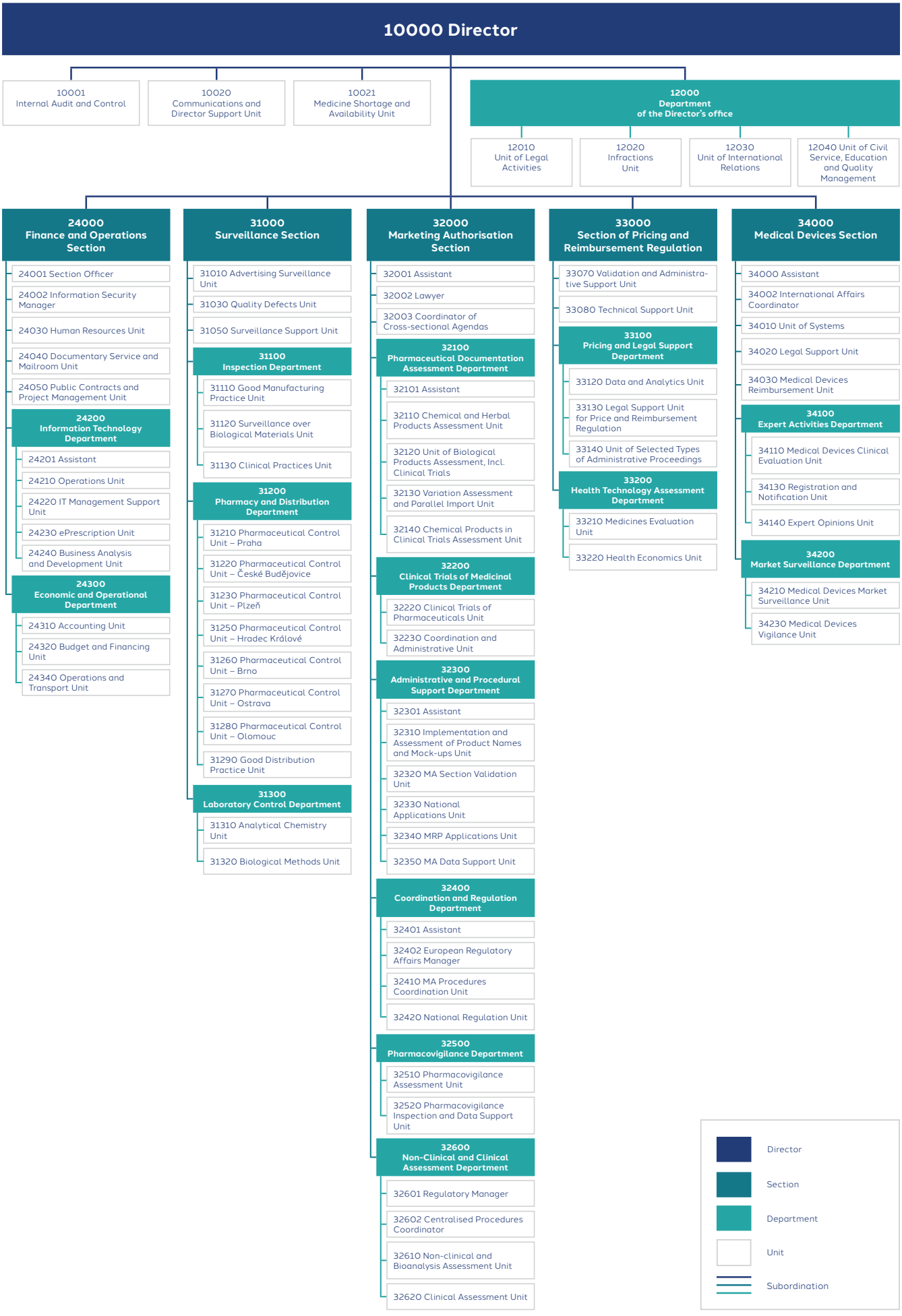
This broad range of activities of our Institute is conducted to warrant that patients can be sure that authorised medicines and medical devices are carefully monitored and that medicines and medical devices are distributed and dispensed in compliance with effective rules and in adequate quality and efficacy.

Dear readers, everything I have mentioned here is supported by specific data on the following pages. I would like to express my thanks for the achieved results that we can be rightly proud of to the employees of the Institute whose expertise, responsibility, and everyday work form the basis of the goodwill of our institution. My thanks also go to all partners – the Ministry of Health, other cooperating state institutions, healthcare professionals, the academia, pharmaceutical industry, and patient organisations.

I believe that through our joint efforts we will continue to enhance the safety, availability, and quality of pharmaceuticals for patients in the Czech Republic.

Tomáš Boráň
Director of the Institute

ORGANISATIONAL STRUCTURE



National and International Cooperation

Cooperation with the Ministry of Health in the Area of Legislation

Established cooperation with the Ministry of Health of the Czech Republic (hereinafter referred to as the "Ministry") in drafting of legislative proposals and other activities associated with legislation issues continued also in 2025. This concerned, in particular, the implementation of EU regulations governing the sphere of pharmaceuticals, human tissues and cells as well as medical devices. Furthermore, the Institute cooperated with the Ministry in the legislative process of adoption of new or amended legislation and, in respect of some legislative proposals, the Institute itself acted as the internal comments site. Within the scope of inter-ministerial comments procedures, the Institute helped formulate some of the comments relevant for the scope of its powers.

In the course of 2025, the Institute was invited by the Ministry to collaborate in the preparation of source materials for the planned amendment to the Act on Pharmaceuticals in connection with the considered mail-order dispensing of prescription-only medicinal products (Rx online). Allowing for mail-order supply of prescription-only medicinal products is one of the long-term plans of the Ministry. In the course of the year, the Institute assisted with the wording of basic argumentation and revised the proposed wording of individual sections. The proposed amendment has not been completed in 2025.

In early June 2025, amendment to Act No 40/2009 Coll., the Criminal Code, was adopted. Based on a motion to amend the Criminal Code, the possibility of using an individually prepared medicinal product (IPLP) containing psilocybin for medical use was embedded in the Czech legal order. The Institute cooperated with the Ministry in the preparation of the implementing legal regulation, Government Regulation No 552/2025 Coll., on the conditions for prescribing, dispensing, and use of individually prepared medicinal products containing medical psilocybin. With regard to the adopted amendment, it was necessary to amend also some other existing legal regulations, to prepare technical notification of the proposed Government Regulation, and to address comments arising from comments procedures. The Institute was actively involved in all of the aforementioned activities.

In the course of 2025, intensive preparation associated with the coming into force of Regulation (EU) 2024/1938 of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (so-called "SoHO Regulation") continued. The Ministry and the Institute established a Coordination Group and one of its objectives was to prepare a brand new draft act on substances of human origin. In parallel to drafting this new act, preparations of amendments to existing legal regulations begun, and these included also the Act on Pharmaceuticals, Act No 40/1995 Coll., on Advertising Regulation, and many others. Throughout the year, the Institute took active part both in preparatory and coordination works and significantly contributed to the preparation of the legislative proposals.

The Institute also continued its close cooperation with the Ministry in amending Act No 375/2022 Coll., on medical devices and ***in vitro*** diagnostic medical devices. In 2025, the amendment, which was by and large prepared as early as in 2024, moved forward in the legislative process and the Institute assisted in addressing comments arising from comments procedures as well as comments of the Department of Information for EU Law Compatibility.

NATIONAL AND INTERNATIONAL COOPERATION

One of the primary tasks of the Institute was amendment to Decree No 84/2008 Coll., on Good Pharmacy Practice, prepared in intensive cooperation with the Ministry. The amendment, ***inter alia***, specifies the principles and conditions of medicinal product preparation, complements basic rules governing the preparation of medicinal products posing an increased risk for healthcare professionals handling the product and for the surrounding environment, and clarifies the rules in the area of mail-order dispensing of medicinal products. The Institute was involved in the preparation of the draft, addressing of comments, and its representatives attended the working commission of the Legislative Council of the Government.

Last but not least, the Institute cooperated with the Ministry on an amendment to Decree No 376/2011 Coll., implementing some provisions of the Act on Public Health Insurance. The Institute was actively involved in the preparation of the amendment to this Decree to make sure it reflected amendments to Act No 48/1997 Coll. and subsequently contributed to addressing comments received as part of the comments procedures.

In addition to the aforementioned legislative work, the Institute also actively monitored discussions in both chambers of the Czech Parliament and was involved in the assessment of various proposed amendments to discussed Chamber or Senate documents of relevance. The representatives of the Institute also directly attended some of the meetings held by the Healthcare Committee of the Chamber of the Czech Parliament, particularly those where legislation relevant for the Institute's operation was being discussed.

The Institute was involved in comments procedures or submitted its comments via the Ministry, particularly in respect of legal regulations relevant for the operation of the Institute, such as a draft act amending Act No 325/2021 Coll., on Electronisation in Healthcare, as amended, and other related acts, draft decree on requirements for minimum technical and material equipment of healthcare facilities and contact centres, draft decree on regulated services, and many others.

The statutory requirements governing individual areas of regulatory activities were further explained by the Institute in the guidelines published thereby. In these guidelines, the Institute informed the public about guidance published by the European Commission (EC) and by the European Medicines Agency (EMA).

As in the previous years, close cooperation with the Ministry in the preparation of opinions of the Czech Republic on requests for preliminary rulings raised with the European Court of Justice and falling within the competence of the Institute continued also in 2025.

Cooperation with Other State Institutions

The Institute continued its cooperation with the Institute for State Control of Veterinary Biologicals and Medicines in Brno and with the National Institute of Public Health located within the same grounds as SÚKL also during 2025. In the area of market surveillance, its partners were primarily the Czech Agriculture and Food Inspection Authority (CAFIA) and the Customs Administration. As in the previous years, also in 2025, the Institute continued its highly intensive cooperation with public authorities through providing answers to their requests and questions falling within the scope of the Institute's powers. The majority of requests came from law enforcement authorities. A significantly increasing trend in the provision of information and data from information systems administered by the Institute, particularly from the ePrescription system, has been repeatedly obvious: 37 requests in 2021, 95 requests in 2022,

183 requests in 2023, 241 requests in 2024, and 306 requests in 2025.

In total, this involved 243 requests, of which 165 were raised by the Czech Police, eight by courts of justice, six by the General Directorate of Customs, four by revenue authorities, one by the General Financial Directorate, four by the General Inspectorate of Security Forces, one by the ombudsman, one by a Regional Public Health Office, three by the Ministry of Justice, one by the Military Police, three by the Czech Medical Chamber, two by the Fire Department of the Capital City of Prague, one by the Czech Chamber of Pharmacists, seven by the Supreme Audit Office, six by the National Cyber and Information Security Agency, three by local governments (regional governments, municipal authority), two by the Czech Telecommunication Office, three by District Offices of Czech Social Security Administration, two by Public Prosecutor's Offices, four by the Office for the Protection of Competition, and 16 by various other state institutions.

Cooperation with Patient Organisations

The Institute's cooperation with patient organisations represents an important part of the regulatory system in the Czech Republic. Patient organisations are key partners, as they bring in the perspective of those who are the most dependent on the outcomes of regulation – that is, of patients themselves.

On its website, the Institute keeps an up-to-date list of patient organisations, which includes tens of entities covering a broad range of diseases, from cancer diagnoses through rare diseases, chronic conditions, mental disorders to organisations focused on people with disabilities. Of these entities, 39 have concluded a memorandum of mutual cooperation with the Institute, which formalises bilateral exchange of information and involvement of patients in regulatory processes.

The Institute participates in the European Health Technology Assessment (EU HTA) as part of so-called PICO survey, where the patient perspective is absolutely irreplaceable in the process.

In 2025, the Institute continued its support of and contribution to education of patient organisation representatives within the scope of the prestigious European Patients Academy on Therapeutic Innovations (EUPATI) programme, which includes also contributions from the Institute's experts. The objective is to enhance expert competences in the area of pharmaceutical development, clinical trials, safety of medicines, and health technology assessment. Graduates thus gain in-depth knowledge of the pharmaceutical development and regulatory processes, thanks to which they can become involved in expert debates about new treatment methods and therapies as qualified patient representatives and equal debate participants.

The Institute's meetings with patient organisations form an important part of the dialogue. These meetings serve as a platform for direct communication, the Institute uses them to inform about current regulatory topics, upcoming changes, and outcomes of its activities; patient representatives then may share practical experience and highlight specific problems encountered by their members. Mutual feedback contributes to regulatory measures reflecting actual patient needs as much as possible. In 2025, such meeting took place on 23 October.

One of the specific outputs of the cooperation is, for instance, a practical brochure "How to Inform Patients about Medicines without Breaching the Law" published by the National Association of Patient Organisations (NAPO) with expert support provided by the Institute. The publication offers a clear explanation of the rules governing

advertising for prescription-only medicinal products. The brochure includes specific real-world examples from the everyday practice of patient organisations, which help the organisations navigate in what they can safely share when informing their members about treatment.

To make sure the information needed by patient organisations is readily and clearly available, the Institute dedicated a special section on its website to publishing materials from expert meetings as well as other information that patient representatives need for their work and that they can make use of, including an up-to-date list of cooperating organisations.

The Institute's cooperation with patient organisations is not only formal. It is a systematic dialogue that helps better set up the regulatory framework, taking into account actual patient needs, enhancing patient awareness, and empowering patients within the healthcare system.

Cooperation with EU Institutions and Other Foreign Partners

Within the scope of their expertise, the Institute's employees were actively involved in the activities of numerous committees and working or coordinating groups also in 2025. These concerned, in particular, bodies of the EU Council, EC, and EMA or the European Directorate for the Quality of Medicines and HealthCare (EDQM), specifically in areas associated with the approval of new pharmaceuticals, safety of medicinal products on the EU market, medical devices regulation, pricing, health technology assessment, laboratory control or regulation of human tissues and cells, availability of medicines, and antimicrobial resistance.

Activities in these groups involved scientific assessment, grounds for opinions, regulatory or coordination activities, including implementation of the European legislation. As part of the informal EU network of the Heads of Medicines Agencies (HMA) and EMA, close cooperation has been established in the sphere of law, enforcement, clinical trials, communication or information technologies, and joint HMA/EMA strategy is being fulfilled. Mutual cooperation includes also a broad offer of educational activities of the joint European Training Centre, which was greatly used by the Institute's employees in 2025.

In 2025, also cooperation with our Slovak colleagues continued. A meeting of a Czech-Slovak Working Party on Drug Policy took place as well as a visit of the representatives of the Slovak State Institute for Drug Control (ŠÚKL) in the Czech Republic to share experience in the sphere of medical devices regulation and price regulation of medicines.

Within the scope of the TAIEX study programme, the Institute hosted a two-day lecture marathon for colleagues from Ukraine, focused upon sharing of experience in the area of regulation of medicines, vaccines, human blood and blood components.

In cooperation with the European Directorate for the Quality of Medicines & HealthCare, preparatory works in connection with hosting the European medicines control laboratories symposium focused upon counterfeit medicinal products were commenced; the symposium is to be held in June 2026 in Prague.

In 2025, the Institute was involved also in the process of adoption of new European legislation, where discussion concerning revised pharmaceutical legislation continued, with the objective to improve availability of medicinal products for EU patients, to support innovations, and to ensure environmental sustainability of pharmaceuticals.

The Institute also engaged in debates concerning the EU legislative proposal of the

Critical Medicines Act (CMA), the aim of which is to address the chronic shortage of key medicines.

A healthcare package including, *inter alia*, the Biotech Act or a targeted revision of the Medical Devices Regulation and of the *In Vitro* Diagnostic Medical Devices Regulation, entered the early stage of discussions.

Involvement in International Projects within the EU

The Institute has been actively involved in international grant projects (so-called joint actions) within the scope of the EU4Health programme funded by the EC. In 2025, it took part in the seven below-listed projects.

JAMS 2.0.

The purpose of this project is to enhance surveillance over the medical devices and *in vitro* diagnostic medical devices market throughout Member States, to harmonise approaches across the EU, and to create a space for more intensive dialogue and future coordination among competent authorities by adopting harmonised and consistent working methods. The content of the project is sharing of information, best practices, knowledge and resources, support of information exchange in the sphere of market surveillance among competent authorities via data collected from the entire EU market, development of standard control procedures, support of inspection method development, and creation of training tools for skill development and enhancement of technical knowledge in the sphere of vigilance and surveillance over the medical devices and *in vitro* diagnostic medical devices market. In 2025, the total of 30 inspections of distributors/importers took place as part of the WP6 package and this part of the project was completed.

The total project budget is 80,303 EUR.

EU4H 11

The objective of the joint action on quality of medicines and implementation of the pharmaceutical legislation/strategy is to enhance the capacity of Good Manufacturing Practice and Good Distribution Practice inspectorates in EU/EEA countries with the aim to achieve global mutual reliance on inspection data to be able to better ensure the quality of medicinal products and public health protection. The project has been undertaken by 39 EU/EEA drug inspectorates from the total of 29 EU/EEA countries. One of the main objectives of the EU4H 11 project is to enhance the Joint Audit Programme (JAP) for Good Manufacturing Practice inspectorates in the EU/EEA; to prepare a proposal for the inclusion of Good Distribution Practice in the current Joint Audit Programme; and, moreover, to introduce harmonised training and qualification processes for GMP inspectors in cooperation with the PIC/S Inspectorates Academy (PIA).

The total project budget is 43,870 EUR.

CHESSMEN

The objective of the project is to support personnel and technical infrastructure of the EU Member States in the sphere of harmonisation of monitoring, communication, and new solutions preventing medicinal product shortages in the EU and sharing of approaches of EU Member States to the evaluation of the causes, IT applications, and solutions of medicinal product shortages as such. Another task of the project is to complement and support activities in the area of medicines shortages with the tasks of other working groups and newly adopted legislation, such as the implementation of Regulation (EU) 2022/123 of the European Parliament and of the Council. Participating medicines agencies present to each other their internal structure and

organisation by means of presentations as well as mutual short-term study stays.

The total project budget is 384,986 EUR.

CT-CURE

The project associated 15 EU Member States responsible for the assessment of clinical trials in the EU with the aim to cater for harmonised and accelerated assessment of international clinical trials on anti-COVID-19 therapeutic agents with the utilisation of the Clinical Trials Information System (CTIS). The project aimed at improving the availability and affordability of medicinal products intended for the treatment of COVID-19 and at supporting innovations concerning such products. The project was completed at the end of 2025.

The total project budget was 56,905 EUR.

IncreaseNET

The project associates 29 partner organisations from 27 EU/EEA countries and Ukraine. The purpose of the project is to enhance the capacity and competence of European national medicines agencies in the sphere of assessment of medicines, and hence ensure better patient access to innovative, high-quality, effective, and safe medicinal products. One of the project objectives is to train 50 new assessors (mostly at their workplaces) using a new training programme. All of the activities are coordinated in cooperation with EMA, HMA, EU-NTC, the "Accelerating Clinical Trials in the EU" (ACT EU) initiative, Committee for Human Medicinal Products (CHMP), CMDh Coordination Group, Committee for Advanced Therapies (CAT), BWP, and EU-IN. The project has been split into eight separate work packages. The Institute is actively involved in three of them.

The total project budget is 165,332 EUR.

SAFE CT

The purpose of the project is to develop expert knowledge in the field of safety assessments in clinical trials and to support cooperation in the sphere of safety surveillance over clinical trials, and implementation of Regulation (EU) 536/2014 of the European Parliament and of the Council.

The content of the project is the proposal of measures to increase the capacity for the assessment of safety data from clinical trials in EU Member States through training of new safety assessors, increasing the competence of all safety assessors, as well as harmonisation and consistence of evaluation in clinical trial safety assessments among the Member States. In 2025, two SÚKL assessors were engaged in the project.

The total project budget is 79,697 EUR.

STOCKPILE

This extensive joint action includes 54 organisations from 25 Member States. The objective of the project is to contribute to improved preparedness in case of serious cross-border health threats, i.e., to ensure that countries are prepared to have more sustainable set of medical countermeasures (MCM). Another objective is to establish the principles of MCM development, distribution, maintenance, and usage as well as to improve cooperation among the Member States, to support proposals concerning supplies, and to strengthen European independence in crises.

The project is based upon lessons learnt from medical emergencies and it strives to develop a coordinated and multi-level supply system. The supply concept will be developed not only for the purposes of defining the amounts and availability of stockpiles in case of emer-

gencies, but also for the purposes of supporting sustainable stock management and ensuring prompt MCM deployment and application. The aim is to use medical measures effectively, both within the European Union and on the global level.

The project objectives are fully consistent with the European Health Union framework, the "One Health" approach, and the EU global health strategy. Along with the aforementioned, this initiative contributes to practical implementation of EU strategies in the sphere of supplies and medical countermeasures. At the same time, close cooperation with EU competent authorities and international bodies will take place, e.g., with the Health Emergency Preparedness and Response Authority (HERA), European Civil Protection and Humanitarian Aid Operations (ECHO), the European Centre for Disease Prevention and Control (ECDC), EMA, and WHO.

The total project budget is 193,627 EUR.

Business Trips Abroad

In 2025, the conditions for business travel abroad were stable and allowed for the completion of most of the scheduled activities. In total, 264 business trips abroad took place, of which 133 were partially or fully reimbursed by the organising institutions (EC, EU Council, EMA, EDQM). Of the total number of completed trips, 17 were educational events, 18 were trips within the scope of joint European projects, and 21 trips were undertaken to conduct inspections abroad, particularly in India. Other trips were associated primarily with the routine agenda of the Institute. The employees travelled mostly to Brussels and Amsterdam.

Regulatory Activities of the Institute

Marketing Authorisation of Medicinal Products

Prior to their placement onto the market in the Czech Republic, most proprietary medicinal products are subject to marketing authorisation. Within the scope of the marketing authorisation procedure, the Marketing Authorisation Section assesses dossiers, in which the future marketing authorisation holder evidences the safety, efficacy, and quality of the product.

The therapeutic indications, contraindications, posology, prescription status, name of the medicinal product as well as the package leaflet intended for patients, and proposed labelling of the medicinal product are subjected to assessment. Upon the issuance of the marketing authorisation, the Institute sends the following to the marketing authorisation holder: the approved Summary of Product Characteristics, approved package leaflet, approved labelling of the medicinal product, and an identification sheet with the allocated medicinal product codes (so-called SÚKL codes) allowing for the identification of each presentation of the medicinal product. The Marketing Authorisation Section also assesses submitted applications for variations to marketing authorisation, marketing authorisation renewals, transfers, and revocations as well as applications for the authorisation of parallel import and variations to, renewals or revocations of parallel import authorisations. At the same time, the Section is responsible for the implementation of the results of European assessments into the marketing authorisations of medicinal products, such as referrals, uniform Periodic Safety Update Report (PSUR) assessments, and Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on pharmacovigilance signals or paediatric work-sharing; it is also responsible for the development of lists of medicinal products jeopardized by or ceased to be valid due to the sunset clause provision, and for the conduct of administrative procedures granting exemptions from the application of sunset clause provision.

Applications for New Marketing Authorisation

In 2025, 795 applications in total were forwarded for expert assessment following successful validation. Most of them were applications for MRP/DCP marketing authorisations. The total number of submitted applications for marketing authorisation increased from 748 applications in 2024 to 825 applications in 2025. In the sphere of MRP/DCP marketing authorisations, the number of applications where the Czech Republic acts as the Reference Member State is essential. In 2025, the number of received applications for DCP marketing authorisation with the Czech Republic acting as the Reference Member State was slightly higher than in 2024.

Marketing Authorisation Renewals

In 2025, the total of 298 applications were forwarded for expert assessment following successful validation. Most of them were applications for MRP/DCP marketing authorisation renewals; the total number of received applications for marketing authorisation renewal increased from 234 applications received in 2024 to 303 in 2025.

Variations to and Transfers of Marketing Authorisations

In 2025, the number of received applications for variations to MRP/DCP marketing authorisations was higher than that in the previous year; the number of received applications for variations to national marketing authorisations was slightly higher. The number of submitted applications

for MRP/DCP marketing authorisation transfers slightly decreased in 2025, while the number of applications for transfers of national marketing authorisations slightly increased compared to 2024.

Parallel Import

In 2025, the number of submitted applications for parallel import authorisation slightly decreased compared to 2024. The number of submitted applications for variations to parallel import authorisations increased compared to the previous year. At the same time, the number of submitted applications for parallel import authorisation renewals increased compared to 2024.

Marketing Authorisation Revocations

In 2025, 264 applications for revocation of marketing authorisation were decided compared to 308 applications in 2024; the total number of decided applications for revocation hence dropped.

Table 1 Marketing authorisation (MA) applications agenda

Process of marketing authorisation of medicinal products	Submitted in 2025	Decided in total in 2025	Total pending as at 31 December 2025
New marketing authorisations	**825**	**675**	**1,315**
of which national	8	32	17
of which MRP-RMS	49	28	95
of which DCP-RMS	131	148	221
of which CMS (MRP and DCP)	637	467	982
MA renewals	**303**	**275**	**147**
of which national	13	18	25
of which RMS	43	43	8
of which CMS	247	213	114
National variations to MAs	**1,692**	**1,494**	**457**
of which MA transfers	64	57	8
of which PIL and labelling	98	106	11
of which grouped national variations	1,530	1,331	438
MRP-RMS variations	**861**	**784**	**151**
of which MA transfers	41	34	0
of which PIL and labelling	30	26	4
of which grouped MRP-RMS variations	790	724	147
MRP-CMS variations	**4,180**	**3,893**	**1,262**
of which MA transfers	65	80	3
of which PIL and labelling	124	129	31
of which grouped MRP-RMS variations	3,991	3,684	1,228
MA revocations	**262**	**264**	**7**
Parallel import	**28**	**33**	**22**

Table 1 Marketing authorisation (MA) applications agenda

Process of marketing authorisation of medicinal products	Submitted in 2025	Decided in total in 2025	Total pending as at 31 December 2025
Parallel import variations	**84**	**108**	**14**
Parallel import renewals	**43**	**25**	**24**
Parallel import revocations	**0**	**3**	**0**

Note: The Table does not reflect the numbers of pending applications from the previous period.

Explanatory notes on the Table:

RMS – Reference Member State
CMS – Concerned Member State
MRP – Mutual Recognition Procedure
DCP – Decentralised Procedure

Expiry/Non-expiry of Marketing Authorisations

In 2025, the Institute conducted 145 administrative procedures concerning the granting of an exemption from the sunset clause (marketing authorisation expiry for medicinal products not placed on the market for the period of three years).

In the course of 2025, the sunset clause as referred to under Section 34a of the Act on Pharmaceuticals was applied to 79 marketing authorisation (MA) numbers and the marketing authorisation of these medicinal products was terminated.

Table 2 Applications for exemption from the sunset clause

	Conducted in 2025
Administrative procedures for exemption from the sunset clause	**145**
of which submitted applications	145
of which *ex officio* initiated administrative procedures	0
granted	126
declined	4
suspended as undue	15
suspended as unjustified	0
suspended for failure to provide amendment	0
withdrawal of application	0

Note: The table does not reflect the numbers of pending applications from the previous period.

Consultations and Seminars in the Sphere of Marketing Authorisation of Medicinal Products

In 2025, the Marketing Authorisation Section provided nine oral consultations (including consultations held in the form of a teleconference) and issued 17 written opinions on process-regulation and expert requests for consultations. Furthermore, 20 written opinions on requests for consultations concerning

medicinal product names and 20 opinions for active substances forming an integral part of a medical device were issued.

On two various days in May 2025, the Marketing Authorisation Section held a seminar on news in the area of marketing authorisations of medicinal products. Thereafter, in December 2025, the Marketing Authorisation Section organised a seminar concerning the update to the Classification Guideline and approach of the Institute to handling variations to marketing authorisations from 15 January 2026 onwards, intended for representatives of marketing authorisation holders.

Cooperation with the European Medicines Agency and CHMP

As part of its cooperation with the European Medicines Agency (EMA) and the Committee for Medicinal Products for Human Use (CHMP), in 2025, the Institute was involved in the assessment of centralised marketing authorisations as follows: 11 times as rapporteur/co-rapporteur; 34 times it assessed type I and II variations to centralised marketing authorisations; once it assessed a CHMP re-examination; 23 times it assessed pharmaceutical documentation for scientific advice procedures.

Along with the aforementioned, the Institute provided comments on other centralised procedures. It regularly and actively participated in discussions held during meetings of the CHMP and other committees (Committee for Orphan Medicinal Products – COMP; Paediatric Committee – PDCO; CAT; PRAC; Committee on Herbal Medicinal Products – HMPC), the CMDh coordination group and working groups where it has its representatives (BWP, BMWP, NcWP, QRD, NRG, EU-IN, CTS, and others). Via its representative, the Institute leads the Quality Working Party (QWP), which is involved in the preparation of guidance in the area of quality assessment, addresses disputable issues as part of medicinal product assessment, and safeguards a harmonised approach to quality assessment of active substances and products in the EU.

Clinical Trials

The Clinical Trials on Medicinal Products Department carries out assessment of applications for clinical trial authorisation/notification, surveillance over the conduct of clinical trials, and assessment of applications for hospital exemptions; it assesses non-interventional efficacy studies and in respect of study projects, it assesses whether the project is a clinical trial on pharmaceuticals or not.

31 January 2025 was the last day of the transition period within which sponsors were obliged to terminate nationally approved/authorised clinical trials or transition them to the regimen governed by Regulation 536/2014. In the course of January 2025, the Institute transitioned the last authorised clinical trial, and thus fully met the requirement stipulated by Regulation 536/2014. At the same time, the previous version of the Act on Pharmaceuticals expired, and all clinical trials began to be governed by Regulation 536/2014 on clinical trials, and by the currently effective amendment to the Act on Pharmaceuticals.

Statistics

In 2025, the total of 380 applications for clinical trial authorisation were submitted via the CTIS. Of this total number, 314 were initial applications, 63 were applications with the Czech Republic added as a new Member State accessing a previously authorised clinical trial, two applications constituted resubmission, and one application concerned transition from a clinical trial previously authorised/approved nationally pursuant to Directive 20/2001/EC to the regimen governed by Regulation 536/2014. Also, 26 applications constituting solely of the IMPD with reference to other submitted

applications for clinical trial authorisation were submitted; these applications are not included in the total number of applications for clinical trial authorisation. Furthermore, 388 substantial modifications to documentation Part I, 850 substantial modifications to documentation Part II, and 215 substantial modifications to both Part I and II of documentation were submitted.

Of the submitted applications for clinical trial authorisation, 213 applications were authorised, 131 clinical trials were conditionally authorised, 23 applications were withdrawn, two applications were declined, four applications lapsed due to sponsor's failure to observe a timeline or due to CTIS non-functionality. Of the total number of authorised clinical trials, 15 clinical trials were submitted by non-commercial entities (academic research), 46 concerned orphan medicinal products, 35 were clinical trials which planned also child enrolment or which were directly intended for paediatric population (paediatric trials), 14 authorised clinical trials concerned advanced therapy products (five somatic cell therapies and nine gene therapies), and two were first-in-human (FIH) trials.

Table 3 Clinical trials in 2025

Applications for clinical trial (CT) authorisation	
Initial applications (INIT)	314
Czech Republic added to a previously approved CT as additional Member State (AM)	63
Resubmission	2
Transition trial (TTR)	1
Concluded applications for CT authorisation	
Authorised	213
Authorised with condition	131
Lapsed	4
Declined	2
Withdrawn by sponsor	23
Czech Republic acting as the RMS	
Submitted applications	76
Concluded as authorised	42
Concluded as authorised with condition	25
Concluded as lapsed	2
Concluded as withdrawn by sponsor	4
Submitted applications for substantial modification (SM) authorisation	
Documentation PART I only	388
Documentation PART II only	850
Documentation PART I & II	215

REGULATORY ACTIVITIES OF THE INSTITUTE

Table 3 Clinical trials in 2025

Concluded applications for substantial modification (SM) authorisation		
Documentation PART I only	351	
Documentation PART II only	861	
Documentation PART I & II	242	
Other classification – by CT type	**Submitted**	**Concluded**
National	39	33
International	341	340
Low-intervention	8	6
Cluster	0	0

Table 4 Numbers of applications submitted via CTIS in 2025 by clinical trial phase

	Received	**Concluded**
Phase I – bioequivalence study	21	19
Phase I – first-in-human (FIH)	4	5
Phase I – other	10	10
Phase I/II	14	12
Phase II	92	91
Phase II/III	24	19
Phase III	206	208
Phase III/IV	4	4
Phase IV	5	5

Table 5 Indication groups of clinical trials submitted via CTIS and authorised in 2025

Indication	**Approved**
C01 Bacterial Infections and Mycoses	11
C02 Virus Diseases	3
C04 Neoplasms	73
C05 Musculoskeletal Diseases	11
C06 Digestive System Diseases	32
C08 Respiratory Tract Diseases	18
C09 Otorhinolaryngologic Diseases	1
C10 Nervous System Diseases	26
C11 Eye Diseases	7
C13 Gynaecology and Pregnancy	2
C14 Cardiovascular System	43
C15 Hemic and Lymphatic Diseases	9
C16 Congenital, Hereditary, and Neonatal Diseases	4

Table 5 Indication groups of clinical trials submitted via CTIS and authorised in 2025

Indication	Approved
C17 Skin and Connective Tissue Diseases	17
C18 Nutritional and Metabolic Diseases	13
C19 Endocrine System Diseases	1
C20 Immune System Diseases	44
C23 Pathological Conditions, Signs and Symptoms	2
F02 Psychiatry and Psychology – Mental Phenomena	1
F03 Psychiatry and Psychology – Mental Disorders	16
Cannot be specified	5
Including multiple diagnoses	34

Also in 2025, the Institute actively participated in the activities of HMA and EC working groups concerning clinical trials. The prevailing topics of all meetings were the decreased number of clinical trial applications throughout the EU, the need to increase the attractiveness of the EU for clinical trial sponsors, continued efforts to harmonise clinical trial assessment across EU/EEA, and addressing issues of potential reduction of the application assessment duration. The employees of the Institute were involved in the completion of numerous EC, EMA and HMA questionnaires on specific national requirements for documentation, on assessment harmonisation, and on presented proposals for initial application assessment timeline reductions. The Institute actively participated in meetings of international groups; the Clinical Trials Coordination Group (CTCG) held 65 meetings, the Clinical Trials Advisory Group (CTAG) held six meetings; and four online CTIS meetings took place. In the course of the year, regular online meetings of medicines agencies representatives, EMA, and EC on CTIS issues and on clinical trial assessment harmonisation based on submitted specific questions (so-called Assessors' Round Table) continued. As part of cooperation with EDQM, three toxicology assessment reports for the Pharmacopoeia Conformity Certification Unit and one scientific advice were prepared. Furthermore, the Institute has been involved in the activities of the Committee for Advanced Therapies (CAT), where it attended ten meetings.

The Clinical Trials Department continued its involvement in two international EU4Health grant projects. The CT-CURE project for accelerated assessment of clinical trials focusing upon the treatment of COVID-19 was completed in January 2025. The Department continued its involvement in the EU4Health SAFE-CT project focused upon joint assessment of safety data in clinical trials. In this project that focuses particularly on coordinated assessment of active substance safety in clinical trials, the Department acted as the Safety Assessing Member State (saMS) for 122 active substances and prepared 129 assessment reports for annual product safety reports that are shared with other Member States. In 2025, new EU4Health projects were launched; the Institute became involved in two of them: Project HS-g-25-27 and Project HS-g-25-28.

In 2025, the Institute continued its active involvement in the activities of the Ministry's Clinical Trial Working Group. Seven meetings were held in the course of the year and the Institute actively contributed to the preparations of the National Strategy for Clinical Trials proposal, which was

submitted to the Minister of Health for approval. In the Working Group, the Institute had already been working on certain specific objectives, such as changes to the conditions governing clinical trials on GMO-containing products and radiopharmaceuticals so that the sponsors do not have to apply for approval with the Ministry of Environment or the State Office for Nuclear Safety along with the application for clinical trial authorisation.

In 2025, the Institute participated in two meetings of the Ethics Committee Forum, providing a clinical trial news update, and in two CZECRIN BOARD meetings.

In 2025, the Institute organised one seminar on clinical trial monitoring in cooperation with the Institute's inspectors and two seminars on revision 3 of the ICH E6 guideline on Good Clinical Practice. Furthermore, seven lectures were held outside the grounds of the Institute, of which two were lectures for academic researchers and study team members (one for paediatricians and one for pharmacists from hospital pharmacies); two lectures for pharmaceutical faculty students; one lecture for a course for pharmacists; two lectures for sponsors and Contract Research Organisations (CROs); one lecture for investigators as part of a Good Clinical Practice course; one lecture on GMOs prepared for a meeting held at the Ministry of Environment; one lecture for the Technical University of Liberec on advanced therapy medicinal products (ATMPs); one lecture for patient organisations; and one lecture for the Clinical Trials National Day.

In 2025, the Institute gave 16 consultations on clinical trial issues, of which nine were for pharmaceutical companies and seven for non-commercial entities (the academia, researchers, representatives of healthcare service providers); nine took the form of an oral consultation and seven were in the form of a written opinion issued upon request. Furthermore, the Institute issued 62 written opinions upon request for project distinction to advise whether a particular project was a clinical trial on a medicinal product or not.

Pharmacovigilance

The Pharmacovigilance Department is in charge of ensuring medicinal product safety and of benefit/risk ratio assessment. The pharmacovigilance activity consists of collection of data on potential risks of pharmaceuticals (from the system of spontaneous reports of suspected adverse drug reactions, from various types of post-marketing studies, from scientific literature, etc.); evaluation of any available data on potential risks; implementation of regulatory measures to minimise risks; and provision of new safety information both to professionals and the general public.

In compliance with the Act on Pharmaceuticals, the Pharmacovigilance Department operates a system of spontaneous reports of suspected adverse drug reactions (ADR) from the Czech Republic. In 2025, the Institute received the total of 3,181 suspected ADR reports. Of the total number of reports received in 2025, 1,424 reports were from medicinal product marketing authorisation holders (pharmaceutical companies) and 1,757 were reports sent to the Institute directly by healthcare professionals and patients (of which 990 were reports from healthcare professionals and 863 were reports from patients; some of them were submitted by multiple reporters). Of the total number of 3,181 received reports, 554 concerned vaccines. All of the received reports are classified as suspected ADRs and they serve for the identification of possible new ADRs on the basis of evaluation of a large amount of collected similar reports. To be able to conduct a detailed evaluation, adequate report quality is necessary – i.e., important information about the patient's medical history, concomitant medication, a good clinical description of the reaction, its detailed progress, etc. When the report is received, it is often necessary to contact

the reporter again and ask for additional missing important data, especially where a very serious or unexpected ADR is suspected. In 2025, it was necessary to contact the reporter in 348 cases to obtain important additional information concerning the report (so-called follow-up), allowing for proper evaluation of the report.

Each individual spontaneous report delivered to the Institute is processed, individually assessed, entered into the database of adverse drug reactions from the Czech Republic (CDNÚ), and, at the same time, sent to the EudraVigilance Pan-European database as well as to the WHO global database. Records in ADR databases are regularly checked and evaluated using statistical as well as qualitative methods for the purposes of new pharmacovigilance signal detection. In addition to thorough continuous assessment of all reported adverse drug reactions from the Czech Republic, pharmacovigilance assessors are responsible for the evaluation of signals regarding 89 active substances on the Pan-European level. In 2025, the Pharmacovigilance Assessment Unit assessed 261 ADR extracts from the EudraVigilance database regarding substances in respect of which the Czech Republic acts as the pharmacovigilance signal rapporteur for the EU.

The Pharmacovigilance Assessment Unit keeps enhancing its involvement in international pharmacovigilance procedures. In the area of Periodic Safety Update Reports (PSURs) for individual products, in the course of 2025, the Institute assessed the total of 35 PSUSA procedures (i.e., PSUR single assessment for a particular substance) from the position of so-called PSUSA – Lead Member State (LMS). The Institute acts as the PSUSA LMS for the total of 88 substances, for which the respective PSUR reports are submitted in regular intervals of various duration. In the course of 2025, the Institute, as the EU PRAC rapporteur (the chief pharmacovigilance assessor) for centrally authorised medicinal products, prepared 76 assessment reports in procedures concerning centrally authorised products. In 2025, the Institute was appointed PRAC rapporteur for 25 centrally authorised medicinal products in total.

In late 2024, the Institute was appointed the chief rapporteur in the finasteride PRAC referral.

The referral was conducted successfully, the assessment was completed in 2025 and it resulted in new recommendations concerning safer use of finasteride. The Pharmacovigilance Department keeps enhancing its involvement in pharmacovigilance activities on the European level on a continuous basis. During 2025, its representatives took active part in all of the eleven regular PRAC meetings; furthermore, ten one-day virtual PRAC meetings were held. The Institute acts as the Lead Member State in numerous procedures; at the same time, it actively monitors and provides comments on ongoing procedures led by other countries. In the course of 2025, the Institute sent written comments on procedures led by other countries 123 times in total and at meetings, it presented eleven procedures led by the Institute.

In addition to regular PRAC meetings, there were two extraordinary meetings organised under the auspices of the state holding Presidency of the EU Council (Poland and Denmark in 2025); the representatives of the Institute also took an active part in these meetings; in Poland, they presented the topic of medicinal product use during lactation. Furthermore, the Institute was actively involved in the European group of pharmacovigilance inspectors (PhV IWG), an expert group for the EudraVigilance system (EV EWG), and EMA's PhV Business Team. The Institute is an active member of the group for harmonisation of risk management plans (HARP). The Institute has been, moreover, actively represented in several PRAC working groups – the group for follow-up questionnaires, i.e., questionnaires

used to obtain additional important information on reported suspected ADRs; the opiate risk communication group; and the group which prepares the update to EMA Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling, where SÚKL's representatives led the group updating information on lactation. We also actively participated in a group preparing a new Good Pharmacovigilance Practice (GVP) module for special populations – pregnant and lactating women. This module was launched as early as in late 2025.

In cooperation with other units of the Marketing Authorisation Section, conclusions adopted by CHMP and PRAC were being transferred to Czech clinical practice on an ongoing basis. In 2025, the Institute published on its website eight communications intended for healthcare professionals or for the general public concerning medicinal product safety. In cooperation with marketing authorisation holders, the Institute published new or updated educational materials on safer use of 56 active substances in total and seven letters to healthcare professionals focused upon enhanced safety of medicinal product use. Assessors from the Pharmacovigilance Assessment Unit were involved in the assessment of marketing authorisation dossiers of nationally authorised medicinal products or products authorised via MRP/DCP; in 2025, they prepared the total of 2,005 reports on the pharmacovigilance part of the dossier.

The Pharmacovigilance Department continues to publish the Adverse Drug Reactions Bulletin (Nežádoucí účinky léčiv), where it publishes up-to-date information on suspected adverse drug reactions reported in the Czech Republic in the course of the previous year, other pharmacovigilance news, a regular column "You Reported to Us" which provides specific cases of adverse drug reactions reported from the Czech Republic, as well as quarterly reviews of important pharmacovigilance outputs. In 2025, four issues were published.

In 2025, 26 notifications (of commencement, termination, or update) of post-marketing safety studies conducted in the Czech Republic were processed.

In 2025, the Pharmacovigilance Inspection and Data Support Unit carried out the total of twelve inspections of pharmacovigilance systems of marketing authorisation holders (MAHs). Of the conducted inspections, seven were inspections of the complete pharmacovigilance system, where the MAH's PSMF is kept in the Czech Republic (of which two were carried out as inspections requested by CHMP as part of the CAP programme and one as a national inspection as part of the CAP programme).

According to the new set-up of CHMP-requested inspections required by EMA, such inspections must be conducted by two or more authorities. With regard to this requirement, cooperation with the Slovak ŠÚKL was initiated and ŠÚKL inspectors cooperated as the representatives of the second authority in the conduct of both CHMP-requested inspections. Due to the fact that no PSMF covering a centrally authorised product is kept within the territory of the Slovak Republic, for new ŠÚKL's pharmacovigilance inspectors this was the first opportunity to take part in CHMP-requested inspections and gain new experience.

Furthermore, four inspections focused upon the pharmacovigilance activities of the local representative of a marketing authorisation holder in the Czech Republic and one inspection of a marketing authorisation holder whose PSMF is kept outside the Czech Republic were carried out. During the conducted inspections, the following findings were made.

One critical finding (for one MAH) in the area of regulatory affairs, 13 major findings (for six MAHs) in the areas of suspected ADR reporting (3), regulatory affairs (2), written procedures (2), signal management (2), company organisation (1), PSMF (1), QPPV (1), and quality system (1).

The inspectors personally attended an IWG PhV training in Amsterdam. In the course of 2025, a pharmacovigilance inspector participated as an observer in two inspections in the Netherlands and in Spain as part of the PIC/S programme (above the scope of the Institute's inspection plan) and she organised a visit of inspectors from these countries at one inspection within the CAP programme.

In 2025, the Pharmacovigilance Department continued its communication with the public, answered questions from healthcare professionals, the general public as well as pharmaceutical companies and answered 294 questions in writing or by phone. In order to disseminate information on the safety of medicines and to enhance suspected adverse drug reaction reporting, the employees of the Pharmacovigilance Department gave ten presentations at professional congresses or seminars for doctors and pharmacists, during courses of the Institute for Postgraduate Medical Education (IPVZ) or as part of student education and they organised one one-day seminar for marketing authorisation holders.

In the course of 2025, a questionnaire for doctors and pharmacists was prepared and published on the Institute's website. The purpose of the questionnaire was to find out which communication channels are preferred by healthcare professionals for the communication of important information on the safety of medicines. It rendered more than 1,400 replies which will help to optimise the communication of pharmacovigilance information to healthcare professionals.

Surveillance in the Sphere of Preparation, Dispensing, Sale, and Distribution of Pharmaceuticals

The Pharmacy and Distribution Department carries out inspection activities in pharmacies, at vendors of selected medicinal products for human use, in healthcare facilities (including their specialised workplaces), and at distributors and brokers of medicinal products. It is also in charge of the conduct of price controls for medicinal products and foods for special medical purposes, control of the conditions of dispensing of medicinal products classified as prescription-only products by the Act on Public Health Insurance, and control of handling of dependency-producing substances and precursors, incl. products containing such substances in pharmacies. Furthermore, the Pharmacy and Distribution Department keeps and regularly updates publicly accessible overviews of the aforementioned regulated entities, with the exception of healthcare facilities.

By the end of 2025, the Institute kept a record on 2,449 pharmacies in total, of which four were within the scope of powers of the Ministry of Defence of the Czech Republic; the Institute also kept a record on 201 detached pharmaceutical and medical device dispensing units (hereinafter referred to as "OOVL"), 3,624 outlets of vendors of selected medicinal products for human use, 42 nuclear medicine departments in healthcare facilities, 394 wholesale distributors, and 44 brokers of medicinal products for human use. Compared to 2024, the total number of pharmacies increased by five pharmacies and the number of OOVLs increased by five units (Table 6 on page 23 refers).

In 2025, the inspectors of the Pharmacy and Distribution Department conducted the total of 632 inspections in pharmacies, of which 22 were hospital pharmacies of inpatient care providers.

Table 6 Number of pharmacies and OOVLs in the last 5 years

	2021	2022	2023	2024	2025
Pharmacies	2,476	2,480	2,461	2,444	2,449
OOVLs	210	204	198	196	201

Note: The status is always given as of the last day of the given year.

Of the total number of completed inspections, 27 were targeted inspections, which were carried out on the basis of reports or complaints.

Separate inspections of handling of dependency-producing substances and precursors were performed in 382 pharmacies.

Price controls focused upon compliance with the Act on Prices and rules of price regulation were conducted in 88 pharmacies and at ten wholesale distributors.

On the basis of facts identified during the conducted inspections and controls, the total of 61 final decisions on imposition of a fine for breach of obligations stipulated by the Act on Pharmaceuticals in the total amount of 35,703,000 CZK, incl. aggregate fines (see below) and finalised administrative procedures based on inspections and controls completed in the previous period were adopted in respect of pharmacy operators. Two fines with final effect amounting to the total of 120,000 CZK were imposed for failure to cooperate during the inspection/control. In eleven cases, the preparation of medicinal products was suspended for a pharmacy; in ten cases it was due to non-verified weights and in one case for a workplace lacking validation of clean premises, laminar flow hood and verification of performance of a steriliser used in preparation of medicinal products.

The main reasons for the issuance of a decision imposing an administrative penalty included very serious shortcomings in the proper record-keeping and archival of the medicinal products received, stocked, and dispensed with the aim of illegal medicinal product re-export (41 % of decisions and 95 % of the financial volume of imposed fines); dispensing of medicinal products with a quality defect for which they should have been recalled; dispensing of medicinal products without medical prescription or on invalid prescriptions and dispensing of medicinal products with limited availability for veterinary purposes; failure to comply with the principles of Good Pharmaceutical Practice in the preparation of medicinal products, in particular, the use of expired active substances and excipients or active substances and excipients without quality documentation, failure to carry out proper record-keeping, preparation using non-verified weights and failure to provide complete and proper reports on dispensed medicinal products.

Within the scope of inspections focused on the handling of dependency-producing substances in pharmacies, in 2025, identification of major breaches of the Act on Dependency-Producing Substances resulted in the issuance of one final decision on fine imposition in the amount of 15,000 CZK and the total of four aggregate fines for concurrent breaches of obligations implied by the Act on Pharmaceuticals imposed on pharmacy operators.

In 2025, controls of precursor handling did not result in any final decision on fine imposition pursuant to the Act on Precursors.

The main reasons for the issuance of a decision on fine imposition included serious and repeated breaches of the Act on Dependency-Producing Substances concerning record-keeping and documentation of dependency-producing substances and

shortcomings in reporting the stock levels and movements of dependency-producing substances and products.

Conducted inspections focusing upon compliance with price regulation rules governing medicinal products in pharmacies identified 30 cases of a price regulation breach in total. In 2025, the total of eight decisions on administrative penalty imposition became final, of which six cases involved fines amounting to 295,300 CZK in total and the other two cases were admonitions imposed for price offences concerning failure to comply with the binding procedure for the determination of the sale price of individually prepared medicinal products and proprietary medicinal products treated prior to dispensing, failure to keep or store evidentiary price records, failure to observe officially fixed maximum prices during sale and failure to observe the conditions and procedures for their application.

Within the scope of the Institute's regular inspection activities, two breaches of the ban on the offering and provision of advantages in the dispensing of prescription-only medicinal products reimbursed from the public health insurance were identified in 2025. Two decisions on administrative penalty imposition became final, of which one was an admonition and one was an aggregate fine for a breach of the Act on Public Health Insurance and of the Act on Prices in the amount of 46,300 CZK.

Furthermore, in 2025, 202 inspections concerning the handling of medicinal products in healthcare facilities were carried out in 17 inpatient departments of healthcare service providers and in 185 separate outpatient offices of general practitioners and medical specialists and in other healthcare facilities. On the basis of reports received by the Institute in respect of the operation of healthcare facilities where health care is provided, 23 targeted inspections in total took place; in 15 cases, the report was rated as justified.

In 2025, the total of five final decisions on fine imposition in the total amount of 415,000 CZK were issued.

The main reasons for the issuance of the decision on administrative penalty imposition included shortcomings associated with the handling of medicinal products contrary to the summary of the product characteristics, medicinal product dispensing in the doctor's office, taking medicinal products from the patient, and serious or multiple breaches of obligations governing the handling of medicinal products stipulated by the Act on Pharmaceuticals and its implementing legal regulations.

In 2025, inspections of vendors of selected medicinal products concerned 119 outlets in total. For breach of the obligations implied by the Act on Pharmaceuticals, twelve final decisions on fine imposition in the total amount of 205,000 CZK were issued; in one case, the vendor's operation was suspended.

In other healthcare facilities authorised to prepare medicinal products (Nuclear Medicine Departments [ONM] and workplaces preparing autogenous vaccines for human use [HAV]), 18 inspections in total were performed. The findings from these inspections did not constitute any reason for offence procedure commencement.

Summary results from inspections conducted in 2025 are provided in Table 7 on page 25.

In 2025, inspectors from the Pharmacy and Distribution Department collected the total of 209 samples of medicinal products during inspections in pharmacies, of which 62 were samples of pharmaceutical products intended for the preparation of magistral formulas in the pharmacy. Out of 147 pharmacy samples (medicinal products prepared in pharmacies), only two were out-of-specification – inadequate microbiological safety

(absence of declared antimicrobial ingredient) and out-of-specification content of the active substance were identified. In the total of four samples intended for dispensing, defects in their labelling were identified.

Table 7 Inspection surveillance over pharmacies, nuclear medicine departments, healthcare facilities and vendors of selected medicinal products

Inspected entity	Inspection type	Number	Classification of defects						Penalties		
			1	%	2	%	3	%	A	B	C
Pharmacies	Regular inspections*	632	386	61.6	175	27.9	66	10.5	11	0	63
	Price controls	88	Not rated as per classification of defects						0	0	8
	Inspections of dependency-producing substances and precursors	382	336	87.9	40	10.5	6	1.6	0	0	5
ONMs		17	13	76.5	4	23.5	0	0	0	0	0
HAVs		1	0	0	1	100.0	0	0	0	0	0
Healthcare facilities*		202	156	78.0	33	16.5	11	5.5	0	0	5
Vendors of selected medicinal products*		119	90	76.3	12	10.2	16	13.5	0	1	12

Note: * Some of the targeted inspections were not rated.

Classification of defects
1 – None or minor defects identified
2 – Major or recurring defects identified
3 – Critical defect or serious breach of law identified

Penalties
A – Suspended preparation /activity
B – Suspended operation
C – Penalty imposition (final decision)

Other activities of the Pharmacy and Distribution Department include issuance of binding opinions on the technical and material equipment of pharmacies for the purposes of obtaining authorisation for the provision of healthcare services. In 2025, the total of 246 requests for issuance of an opinion were received from pharmacy operators and 244 favourable binding opinions were issued.

In 120 cases, the issuance of the binding opinion was associated with an inspection in the pharmacy (on-the-spot check of the technical and material equipment) and in 14 cases, with an inspection of the OOVL (Table 8). Furthermore, in this context, 177 consultations on the instrumentation of existing pharmacies or the construction of new pharmacies, and 587 consultations concerning the obligations of inspected entities implied by the Act on Pharmaceuticals, Act on Dependency-Producing Substances and on Precursors, their implementing regulations, and SÚKL guidelines took place. Table 8 also provides data on newly established and defunct pharmacies/OOVLs.

Table 8 Other activities of the Pharmacy and Distribution Department

Initial pharmacy inspections	Establishment of a new pharmacy/ OOVL	Defunct pharmacies/OOVLs
120	76/13	71/8

Initial OOVL inspections	Consultations on material and technical equipment	Other consultations
14	177	587

Distribution of Medicinal Products

In 2025, the number of distributors exhibited a year-to-year increase by 14 entities to the total of 394 medicinal product distribution authorisation holders. Of the total number of authorised distributors, 75 entities are both a distribution authorisation holder and a pharmacy operator.

In 2025, 29 new distribution authorisations and 96 decisions on variations to distribution authorisations were issued and 15 authorisations were revoked upon request of their holders. In respect of two entities, the distribution authorisation was revoked by the decision of the Institute in compliance with Section 76(3) of the Act on Pharmaceuticals.

In 2025, the total of 19 entities applied for entry into, variation to entry in, variation to or deletion from the Registry of Brokers of Human Medicinal Products; as of 31 December 2025, the Registry contained 44 brokers in total.

Table 9 provides an overview of received applications and issued decisions concerning distribution authorisations, variations thereto or revocations thereof, and the registration of brokers of medicinal products.

Table 9 Distribution and brokerage of pharmaceuticals

	Received applications	Decisions issued/ Registry entries made
Application for distribution authorisation	24	29
Application for variation to distribution authorisation	98	96
Application for revocation of distribution authorisation	14	15
Application for entry in the Registry /variation to entry in the Registry/deletion from the Registry	19	19

Note: The table does not include the numbers of pending applications from the previous period.

In 2025, the total of 222 inspections of distributors and 14 inspections of brokers were performed; of these, seven were targeted inspections conducted on the basis of internal and external reports. In total, 37 reports on the operation of distributors were received, in relation to which serious shortcomings in the observance of Good Distribution Practice (GDP) were identified in two cases.

The top priorities of the surveillance activities included a complex control of the medicinal product distribution chain and associated compliance with GDP principles, of the quality assurance system, and analysis of risks associated with the distribution activities, conditions of storage and transport of medicinal products, including control of records kept on the distribution activities carried out, controls of proper and complete provision of data on the volume of distributed medicinal products, control of compliance with the distributor's obligation to notify in advance of their intention to export a medicinal product placed on the list of the Ministry abroad and of observation of the ban on distribution and export as well as control of compliance with the distributor's obligations associated with the verification and checks of safety features in respect of those medicinal products that bear such features.

Of the total number of 168 rated inspections of distributors (follow-up and targeted inspections), 84.5 % were rated with grade 1 (good), 8.9 % with grade 2 (satisfactory), and 6.5 % with grade 3 (not satisfactory). On the basis of identified facts,

in 18 cases in total it was proposed to initiate an administrative procedure concerning fine imposition for major breaches of obligations implied by the Act on Pharmaceuticals and its implementing regulations and related GDP guidance.

Following the completed inspections, the total of 131 post-inspection GDP Certificates were issued, of which six Certificates were issued a limitation, specifically, two Certificates with scope limited to storage and four Certificates with validity limited to two years. Similar to distribution authorisations and variations thereto, all of the issued Certificates are regularly entered into the European EudraGMDP Database.

Under the authority of the Strasbourg EDQM inspectorate and the Institute's Laboratory Control Department, the Good Distribution Practice Unit was conducting sampling of authorised medicinal products in the distribution chain for the purposes of laboratory control of the product quality.

As part of its consultation activities, the Unit gave the total of 51 consultations concerning the application of GDP principles and, on an ongoing basis, has been providing opinions and source materials upon request from other bodies and organisations, including those from abroad (the Ministry, revenue authorities, courts of justice, the Czech Police, the National Antidrug Centre (NPC), EMA).

In 2025, ten price controls of distributors focused upon compliance with the Act on Prices and with effective Pricing Regulations issued by the Ministry of Health for the regulation of prices of medicinal products and foods for special medical purposes took place. A breach of pricing regulations was identified in three cases and these consisted of failure to comply with the procedure set forth in accordance with material conditions, rules or procedures governing the determination of official prices, changes thereto, and the method of their negotiation and application stipulated by the pricing authority pursuant to Section 5(5) of the Act on Prices. In 2025, five fines in the total amount of 2,717,725 CZK were imposed with final effect upon distributors for committed pricing offences.

On the basis of findings from inspections/controls, in 2025, the total of nine final decisions were imposed upon distributors on fines for breaches of obligations stipulated by the Act on Pharmaceuticals and its implementing regulations amounting to 1,415,000 CZK in total (including also finalised administrative procedures based on inspections completed in the previous period). One final decision on a fine amounting to 100,000 CZK was imposed for failure to provide cooperation during the inspection/control.

In addition to failure to comply with GDP rules, the main reasons for the proposed fine imposition included distribution of medicinal products outside the territory of the Czech Republic contrary to a measure issued by the Ministry; failure to notify of the intention to distribute a medicinal product placed on the list of the Ministry abroad; as well as failure to submit an application for variation to the distribution authorisation in case of changes concerning the distributor; and submission of incorrect or incomplete reports on the volumes of medicinal products distributed to clients.

In two cases, the distribution authorisation was suspended and declaration of non-conformity with GDP rules was issued due to serious breaches of the obligations implied by the Act on Pharmaceuticals and conditions of Good Distribution Practice.

The results of inspections at distributors' in 2025 are provided in Table 10.

A comparison of the number of regulated entities, conducted inspections/controls, and imposed penalties for the last four years is provided in Table 11.

Table 10 Inspection surveillance over distributors

Number of inspections					Inspection rating			Measures	
Total	Initial	Follow-up	Targeted	Variation	1	2	3	NCR	Proposed fine
222	30	161	7	24	142	15	11	2	18

Inspections are rated on the basis of the identified shortcomings and their severity, and according to the achieved point score, the overall level of com pliance with the principles of Good Distribution Practice is expressed by the following rating: 1 – Good, 2 – Satisfactory, 3 – Not satisfactory.

Table 11 Information on surveillance activities

Operator	Number of entities	Number of inspections/controls	Total number of penalties (final)
Pharmacies + OOVLs	2,650	1,102	76
Distributors	394	222	15
Brokers	44	14	0
Vendors	3,624	119	12
Nuclear medicine departments	42	17	0
Healthcare facilities	-*	202	5

Note: *SÚKL does not keep any registry or database of these entities.

Surveillance in the Area of Manufacture of Pharmaceuticals, Human Tissues and Cells, and Good Laboratory and Clinical Practices

The Inspection Department safeguards surveillance activities in the sphere of manufacture of pharmaceuticals (including the manufacture of blood components and starting materials for further manufacture of pharmaceuticals for human use – hereinafter referred to as "TP"), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP). Furthermore, it carries out surveillance over the donation, procurement, examination, processing, storage, and distribution of human tissues and cells (hereinafter referred to as "HTC") aimed at the assurance of their quality and safety. It issues authorisations to engage in the manufacture of medicinal products, in the operation of a control laboratory, in the manufacture of blood components for human use, in the operation of a tissue centre, donation centre, HTC distributor or diagnostic laboratory, and variations to these authorisations. The Inspection Department also issues Good Manufacturing Practice (GMP) Certificates, Good Laboratory Practice Certificates, Good Clinical Practice Certificates, and medicinal product certificates in the WHO format. It also issues licences for the growing of cannabis for medical use and it conducts Good Agricultural and Collection Practice (GACP) inspections. It is in charge of the haemovigilance agenda and monitoring of serious adverse events and reactions concerning HTC.

Surveillance in the Area of Manufacture of Pharmaceuticals

The Good Manufacturing Practice Unit of the Inspection Department safe-

guards surveillance activities in the sphere of manufacture of medicinal products, active substances, and active substance distribution and import. It issues authorisations to engage in the manufacture of medicinal products and in the operation of a control laboratory, and GMP Certificates published in the EudraGMDP database administered by EMA. In 2025, Health Canada completed a review of the system of surveillance over the manufacture of pharmaceuticals for human use in the Czech Republic and declared this surveillance to be adequate to the Canadian one.

Authorisation of Manufacture

In 2025, the total of 53 various applications were received (Table 12 refers). The quality of the submitted applications and applicant preparedness have significantly worsened compared to the past. In 2025, the number of declined applications and discontinued procedures was the highest since 1998, when the Institute began to issue manufacturing authorisations and authorisations to engage in the operation of a control laboratory. The number of cases brought forward to the next year corresponds to the application handling timelines.

Table 12 Applications for authorisation to engage in manufacturing/operation of a control laboratory, for variation thereto/revocation thereof

Application type	Received applications	Issued decisions/ authorisations	Declined/ discontinued
Application for medicinal product manufacturing authorisation	3	4	2
Application for variation to medicinal product manufacturing authorisation	43	41	4
Application for revocation of medicinal product manufacturing authorisation	4	4	0
Application for authorisation to engage in operation of a control laboratory	0	1	0
Application for variation to authorisation to engage in operation of a control laboratory	2	2	0
Application for revocation of authorisation to engage in operation of a control laboratory	1	1	0

Good Manufacturing Practice Certificate Issuance

An overview of GMP Certificate issuance for manufacturers of active substances in 2025 is provided in Table 13 on page 30.

In 2025, 100 GMP and GDP inspections concerning active substances were carried out in total. One breach of law was identified and two reports of failure to comply with GMP requirements were issued. In two cases, where the requirements stipulated by legislation and GMP guidance were not complied with, the authorisation was not issued.

An overview of inspections by type and entity is provided in Table 14.

Table 13 Certificate issuance for manufacturers of active substances

	Received applications	Issued certificates	Declined/ discontinued application
Application for issuance of a GMP Certificate for active substance manufacturer	9	8	2

Table 14 Inspections by type and entity

	Number of inspections				Inspection rating			
	Initial	Follow-up	Targeted	Variation	Compliant	Non-compliant	Breach of law	Not rated
Manufacturers of medicinal products	5	25	0	4	33	1	0	0
Manufacturers of investigational medicinal products	0	15	1	4	17	2	0	0
Manufacturers of active substances	3	10	0	5	17	1	0	0
Control laboratories	0	15	0	3	18	0	0	0
Control laboratories for investigational medicinal products	0	1	0	0	1	0	0	0
Active substance importers and distributors	3	4	1	1	6	0	1	3

Foreign Inspections

In 2025, ten GMP inspections at foreign entities took place, of which two were conducted upon EMA's request. In all cases, GMP Certificates were issued.

Surveillance over Medicines Development

Good Laboratory Practice

In 2025, 15 holders of Good Laboratory Practice Certificates issued by the Institute were listed in total, with prevailing scope of activities in toxicological studies; these are included in the National GLP Programme. One testing facility applied to be taken out of the National Programme. In the same year, six follow-up inspections took place.

Good Clinical Practice

In the course of 2025, 25 national GCP inspections were carried out in total. Of the said number, 22 concerned a targeted inspection of a clinical trial site (a GCP inspection at the investigator's site); one was an inspection of compliance with the obligations of the sponsor taken over by the CRO; and two were inspections on the basis of an application for the issuance of a GCP Certificate performed at a healthcare service provider where a first-in-human (FIH) clinical trial is conducted. In three cases, a potential breach of legislation was identified.

Furthermore, in 2025, six inspections (four at the investigator's site and two at the sponsor's) were conducted as part of two EMA inspection procedures associated with marketing authorisation of a medicinal product.

Blood Establishments and Hospital Blood Banks

In total, 24 applications for authorisation to engage in the manufacture of blood components for human use or variations thereto and two applications for authorisation revocation were received in 2025. The number of cases brought forward to the next year corresponds to the application handling timelines. See Table 15.

Table 15 Overview of applications

Application type	Received applications	Issued decisions
Application for manufacturing authorisation for blood components for human use	1	1
Application for variation to manufacturing authorisation for blood components for human use	23	22
Application for revocation of manufacturing authorisation for blood components for human use	2	2

In 2025, 82 inspections of blood establishments and hospital blood banks were carried out in total. The standard of GMP in blood establishments was mostly rated as good and no breach of law was identified. The follow-up inspection plan was fulfilled.

Table 16 Overview of inspections of blood establishments and hospital blood banks

	Number of inspections				Inspection rating			
	Initial	Follow-up	Targeted	Variation	Compliant	Non-compliant	Breach of law	Not rated
Blood establishments	1	66	1	5	66	0	0	7
Hospital blood banks	0	9	0	0	9	0	0	0

Haemovigilance

In 2025, 53 reports of suspected serious adverse reactions (hereinafter referred to as "SAR") experienced by donors of blood and blood components or recipients of blood components for human use were received, of which five reports are still pending and in nine cases, the suspected SAR was not confirmed. Thirty SARs involved blood or blood component donors (three investigations are still pending, four suspected SARs were not confirmed) and 23 cases concerned post-transfusion reactions in blood components recipients (two investigations are still pending, five suspected SARs were not confirmed). Of the concluded suspected SARs affecting blood components recipients, in one case, death unrelated to the transfusion occurred; two SARs resulted in serious health effects for the blood components recipient; and other SARs completely resolved. Out of 30 suspected SARs in donors of blood or blood components, full donor recovery was confirmed in 22 cases and in one case the donor suffered serious health effects.

Furthermore, 14 reports of suspected serious adverse events (SAE) associated with blood donation, testing, processing, storage, and distribution of blood components or raw materials for further manufacture, or blood components dispensing were reported, of which five suspected SAEs were not confirmed, and one report is still

pending. Seven cases concerned reports associated with donor infection (one HBV, one HCV, one VHE, one HAV, one syphilis, and two HIV infection cases); two reports concerned a human error during collection (confusion of saline and citrate during plasmapheresis); four cases concerned a human error associated with blood components administration (three cases of blood components confusion in the department, one case of patient confusion during sample collection); and one case concerned bacterial contamination in the blood components.

Each report, which the Institute received, was processed, evaluated, and entered in the database of SARs and SAEs and, concurrently, processed to be incorporated in the Annual SAE and SAR Report for the Czech Republic intended for the European Commission.

As part of its involvement in the European Rapid Alert System for Blood (RAB), in 2025, the Institute received the total of 22 reports from eleven countries. Sixteen cases concerned an epidemiological situation (twelve were associated with the occurrence of the West Nile fever virus, two were associated with the occurrence of the dengue fever, and two with the occurrence of the chikungunya virus). Three reports concerned the implementation of measures in association with the occurrence of the West Nile fever virus and three pertained to quality defects of the collection material.

Surveillance in the Area of Human Tissues and Cells

In total, 41 applications for authorisation to engage in an operation or variations thereto and five applications for authorisation revocation were received in 2025. The number of cases brought forward to the next year corresponds to the application handling timelines (see Table 17).

Table 17 Overview of applications in the area of human tissues and cells

Application type*	Received applications	Issued decisions
Applications for authorisation to engage in a facility operation	5	3
Applications for variation to authorisation to engage in a facility operation	36	34
Applications for revocation of authorisation to engage in a facility operation	5	4

*The table provides summary data for tissue centres, donation centres, diagnostic laboratories, and HTC distributors.

Inspections in tissue centres, donation centres, diagnostic laboratories, and at HTC distributors are conducted pursuant to Decree No. 422/2008 Coll., on detailed requirements for the safeguarding of the quality and safety of human tissues and cells intended for use in humans, as amended. In 2025, 45 inspections of tissue centres, donation centres, diagnostic laboratories, and HTC distributors were conducted in total (see Table 18).

Table 18 Overview of inspections in the area of human tissues and cells

	Number of inspections				Inspection rating			
	Initial	Follow-up	Targeted	Variation	Compliant	Non-compliant	Breach of law	Not rated
TCs, DCs, DLs, HTC DIS	3	33	7	2	30	0	0	15

Monitoring of Actual and Suspected Serious Adverse Events and Reactions

In 2025, the total of 187 SAEs or SARs were reported. All of the reports came from tissue centres and in most cases, they pertained to the area of assisted reproduction. Reportable are those reactions and events that result in the hospitalisation of the donor, recipient or offspring from the assisted reproduction, their disease, extended hospitalisation, death, health injury or limitation of their capacity.

No death of the donor or recipient associated with HTC collection or use occurred in 2025. Most of the cases were adverse reactions of a woman to hormonal stimulation and egg (oocyte) collection, these included e.g., the ovarian hyperstimulation syndrome and haemoperitoneum, and also transfer of genetic disorders resulting in loss of pregnancy or disability and limited capacity of the offspring from assisted reproduction.

Medical Cannabis

In 2025, one licence to grow medical cannabis and five variations were issued and one licence was revoked upon the holder's request. Furthermore, four follow-up GACP inspections were carried out at licence holders.

Laboratory Control

Laboratory Control is performed by the Laboratory Control Department within the scope of requirements stipulated by the Act on Pharmaceuticals (the Department controls the quality of pharmaceuticals on the market in accordance with predefined projects and it releases batches of particular medicinal products) and on the basis of requests submitted by internal requesters (other organisational units of the Institute), which includes, in particular, addressing of quality defects of medicinal products, pharmacy sample analyses, suspected counterfeit and illegal medicines, adverse drug reactions, etc.

The Laboratory Unit of the Laboratory Control Department is an active member of the international Official Medicines Control Laboratories (OMCL) network under EDQM. The employees of both laboratory units attend the annual OMCL meetings, and they are members of working groups.

The Department has developed a quality management system compliant with the ČSN EN ISO/IEC 17025 standard. In 2025, further verification of the established quality system by a group of EDQM auditors took place. International recognition of the quality management system is a precondition for participation in international studies of control of centrally authorised medicinal products organised by EMA/EDQM, recognition of the results of MRP/DCP product analyses, and international recognition of batch release certificates for selected medicinal products (Official Control Authority Batch Release, OCABR) within the EU.

The results of sample analyses that were conducted in 2025 by both laboratory units of the Laboratory Control Department are summarised in the tables below.

Table 19 Surveillance over the quality of pharmaceuticals on the market by means of laboratory analyses by predefined projects – projects concluded in 2025

Project name	Number of analysed products	Number of analysed samples	Number of compliant samples	Number of non-compliant samples	Number of comments on MA dossier
Project BIO5/2023 Masking effect and subsequent Low Endotoxin Recovery (LER) effect of bacterial endotoxin in selected medicinal products	2	3	3	0	0

Table 19 Surveillance over the quality of pharmaceuticals on the market by means of laboratory analyses by predefined projects – projects concluded in 2025

Project name	Number of analysed products	Number of analysed samples	Number of compliant samples	Number of non-compliant samples	Number of comments on MA dossier
Project BIO 1/2024 Control of microbiological quality of herbal medicinal products for oral use and extracts for their preparation – categories B and C	25	42	42	0	0
Project 7/2023 Medicinal products containing budesonide	11	20	19	1	0
Project 3/2024 Pharmacy samples	74	216	202	14	0
Project BIO/3/2023 Quality control of medicinal products where SVUS Pharma a.s. is present in the manufacturing chain	6	9	9	0	0
Project BIO/4/2023 UVAXOVID vaccine relative efficacy monitoring	1	14	14	0	0
Total	**119**	**304**	**289**	**15**	**0**

Table 20 Batch release of predefined medicinal products

Product type	No. of medicinal products	No. of batch reports	Released on the basis of certificate	Released after laboratory control	Total number of released batches	Not released	Completed within timeline
Blood derivatives	47	703	703	0	703	0	703
Vaccines	39	398	396	2	398	0	398
Other products	1	2	0	2	2	0	2

Table 21 Laboratory control of pharmaceuticals and excipients requested by other organisational units of the Institute, other state administration organisations or EDQM

	Number of samples	Of which compliant	Of which non-compliant
Suspected quality defect of a pharmaceutical	15	14	1
Suspected counterfeit products, illegal samples*	125	-	-
International OMCL studies	13	13	0
Internal quality control of purified water	124	124	0
Other analyses**	17	17	0
Total	**294**	**168**	**1**

* Sample compliance cannot be evaluated.
** For instance: requested microbiological controls, other requested analyses, etc.

Projects are prepared on the basis of a "risk-based" analysis. The criteria include, in particular, high consumption of the controlled products, less common pharmaceutical forms or routes of administration, target patient groups, or frequent complaints of patients or medical and pharmaceutical professionals. Proposed projects and reports on completed projects are approved by SÚKL's Quality Team. In 2025, works on the following projects were carried out: control of medicinal products containing mirtazapine, pioglitazone, carvedilol, dolyxan, and, moreover, verification of microbiological quality of selected medicinal products. Analytical control of influenza vaccines is also planned and, in cooperation with the Pharmaceutical Documentation Assessment Department, a proposal for continued project "Masking effect and subsequent LER (low endotoxin recovery) effect of bacterial endotoxin in selected medicinal products" has been prepared. Furthermore, pharmacy samples of medicinal products continue to be controlled and analyses of identified counterfeit and illegal samples continue to be conducted, particularly upon request of the Czech Police.

The tables above indicate that the Laboratory Control Department completed 604 sample analyses (see Figure 1). The number of samples rated as non-compliant (ex. counterfeit and illegal products) was 2.5 % (3.4 % in 2024; 1.7 % in 2023; 2.6 % in 2022; 3.0 % in 2021) as refers Figure 2.

Figure 1 Number of analysed samples in the period of 2021–2025

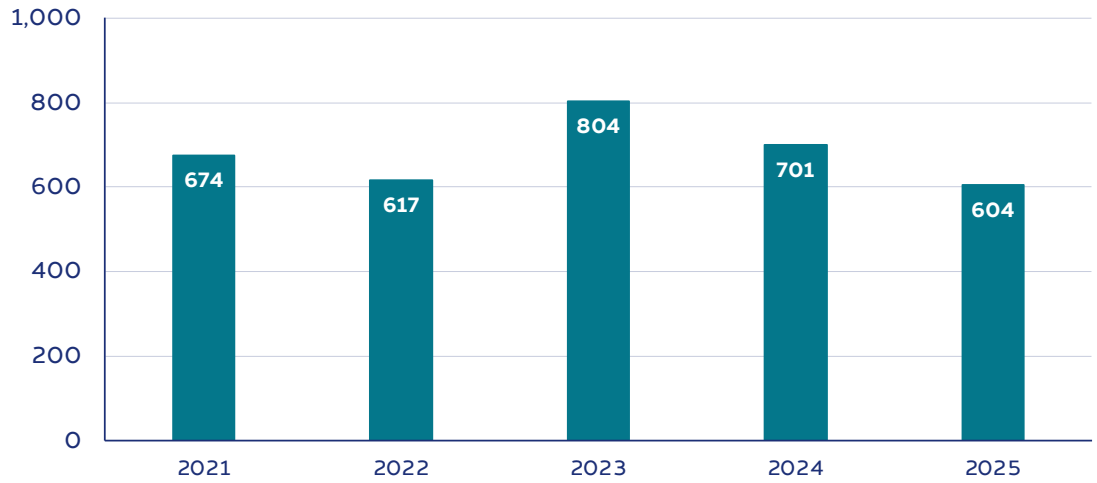
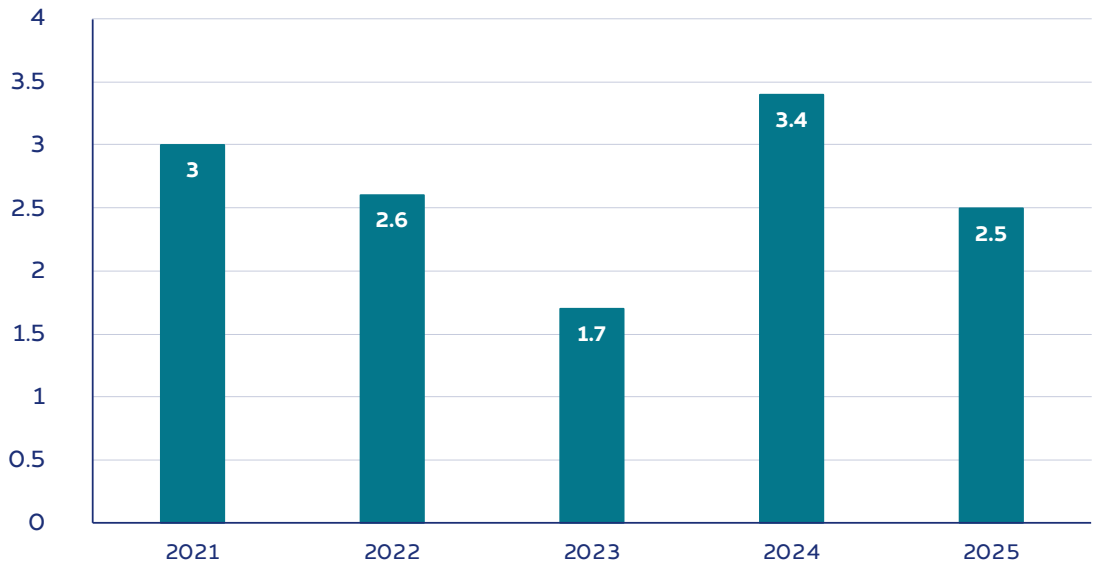


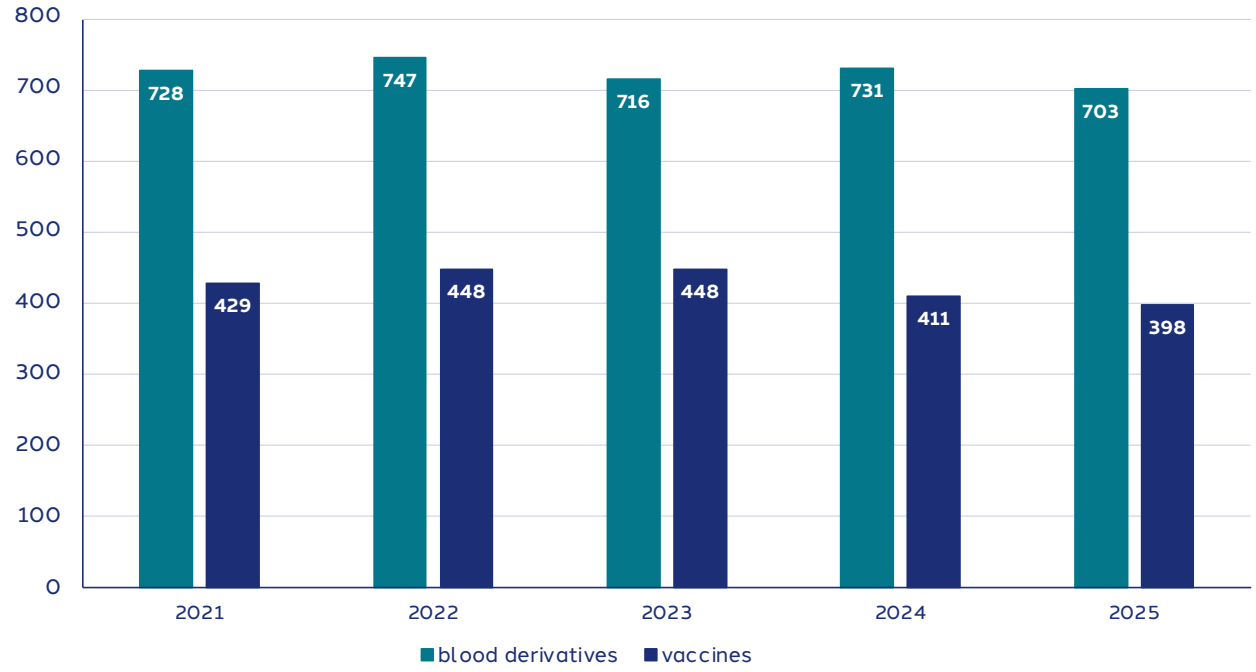
Figure 2 Non-compliant samples in the period of 2021–2025



Quality defects were confirmed particularly for pharmacy samples; furthermore, one medicinal product from the project was also rated as non-compliant. The quality of proprietary medicinal products available on the Czech market can be considered very good.

To the extent of the statutory task of batch release, all of the reported batches were released onto the market in time, i.e., within timelines stipulated by the law, which, in the last year, again concerned also COVID-19 vaccines. Figure 3 illustrates the number of released batches of blood derivatives and vaccines. For some vaccines, internationally recognised (OCABR) certificates were issued after laboratory testing.

Figure 3 Number of released batches in the period of 2021-2025



International Cooperation in the Sphere of Laboratory Control

The Department has been involved in joint studies on the control of the quality of marketed pharmaceuticals (this concerns, in particular, analyses of medicinal products authorised via the MRP or DCP), laboratory proficiency testing for the use of various analytical methods, and verification of the quality of reference substances for the European Pharmacopoeia. The laboratories typically also analyse one centrally authorised medicinal product per year on the basis of a contract with EDQM. As part of international cooperation, SÚKL laboratories are contract laboratories for the Slovak ŠÚKL and for the Irish HPRA, particularly in the area of microbiological and sterility tests.

In 2025, the Laboratory Control Department took part in collaborative international studies listed in Table 22.

Table 22 Participation in international studies

Study	Study title	Rating
PTS 249	Uniformity of mass of single dose preparations and dissolution	Good
PTS 255	Potentiometric determination of pH	Good
PTS 256	Liquid Chromatography	Good

Table 22 Participation in international studies

Study	Study title	Rating
PTS 257	Dissolution Test	Good
CRS	Labetalol hydrochloride CRS 6	Good
SUP 013	Suspected Unknown Product	Good
CAP 2025/31	Qinlock	Good

Legend to abbreviations:

PTS – Proficiency Testing Study organised by EDQM. Quality control of the work of the laboratory; EDQM provides the samples, reference substances, and method. Once the results are sent back to EDQM, they are statistically processed and the laboratory obtains the rating of the study.
CRS – Verification of the quality of the reference substance for EDQM / Chemical Reference Substance.
SUP – A comparative study to verify the laboratory's ability to analyse Suspected Unknown Products.
CAP – Analyses of samples of a centrally authorised medicinal product from the European market (Centrally Authorised Product).

Quality Defects of Pharmaceuticals and Counterfeit Products in Legal Distribution Chain

The Quality Defects Unit is in charge of addressing reports of suspected quality defects of pharmaceuticals, suspected occurrence of counterfeit medicinal products in the legal distribution network, and reports in the area of safety feature verification.

In 2025, the received reports concerned not only authorised and individually prepared medicinal products, but also non-authorised and investigational medicinal products and substances intended for the manufacture of medicinal products and preparation of medicinal products in pharmacies. There was an apparent increase in the number of received reports compared to the previous year, with the number of reports received from the Czech Republic comparable to the previous year, but a significant increase in the number of reports received from abroad. This growing number of reports received from abroad has been caused, *inter alia,* by a higher involvement of non-European regulatory agencies in the information system via which quality defect reports are received. Of the total number of 963 reports received in 2025, the Institute received and assessed 540 reports via the Rapid Alert System operated by EU, MRA, and PIC/S countries. Further 423 received reports on quality defects of pharmaceuticals came from the Czech Republic.

Table 23 Number and origin of reports received in 2025

Year	Total	From the Czech Republic	From abroad
2024	832	425	407
2025	963	423	540

As part of addressing quality defects, effective actions aimed at the market in the Czech Republic have been taken to reduce the impact of quality defects of pharmaceuticals upon patient health also in 2025 (Table 24 Overview of measures implemented in 2025 refers); in 2025, the total of 52 medicinal products (expressed in SÚKL codes) were recalled. Five reports were submitted to the international Rapid Alert System.

Table 24 Overview of measures implemented in 2025

Year	Recalled medicinal products (in SÚKL codes)	Reports submitted via Rapid Alert System	Administrative procedure	Information letters for operators	Counterfeit products in legal distribution network	Stolen pharmaceuticals
2024	77	6	79	37	57	0
2025	52	5	79	39	55	2

Reports received from foreign countries include also reports on GMP non-compliance on the part of the manufacturer of a pharmaceutical. In 2025, the Quality Defects Unit received and evaluated 246 such reports in total, which is 50 reports more than in 2024, consistent with the growing trend from the previous years.

In case of a quality defect of a pharmaceutical not constituting a jeopardy to the life or health of people, the Quality Defects Unit issues a decision on allowing the distribution, dispensing, placement into circulation, and use of such pharmaceutical or its particular batch in the provision of healthcare services. In 2025, 79 final decisions were issued in total, which is a number consistent with the previous year.

In those cases, where it is necessary to specify a quality defect not constituting a jeopardy to the life or health of people in more detail for the field, the Quality Defects Unit, in cooperation with the marketing authorisation holder, has been publishing information letters for operators. In 2025, 39 information letters have been published, some of them updated, including those cases where the quality defect affected also other batches.

Furthermore, the Quality Defects Unit addresses cases concerning the presence of counterfeit medicinal products in the legal distribution chain or theft of medicinal products. In 2025, the Quality Defects Unit addressed 55 reports of suspected presence of a counterfeit medicinal product in the legal distribution chain and two reports of theft of medicinal products from the legal distribution chain. The presence of a counterfeit product in the legal distribution chain in the Czech Republic was not confirmed in any case.

The Quality Defects Unit also monitored the recall of two medicinal products for marketing authorisation reasons. Both cases concerned a recall due to reduced shelf-life.

An overview of measures adopted in 2025 in respect of individual medicinal products (related to SÚKL codes) is provided in Table 25.

Table 25 Detailed break-down of measures adopted in 2025

Implemented measures	Number (in SÚKL codes)
Recall from distributor level	1
Recall from healthcare facility level	50
Recall from patient level	1
Suspended distribution, dispensing and/or use	13
Released distribution, dispensing, and use	10
Permitted distribution, dispensing, marketing, and use in the provision of healthcare services through an administrative procedure	104 (number of batches: 187)

All of the cases concerned measures adopted by marketing authorisation holders or by operators. The institute only monitored or adjusted these measures.

The Quality Defects Unit was involved in the adaptation of Commission Regulation 161/2016, supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (Safety Feature Regulation). The representatives of the Institute participated in the meetings of the expert group for safety features, in international teleconferences as well as in regular meetings with the National Organisation for Medicines Verification (Národní organizace pro ověřování pravosti léčiv, z. s.; NOOL). The Unit was also providing information from the National System for Medicines Verification audit trail to state institutions of the Czech Republic.

Since the coming into force of the aforementioned Regulation, the Institute has seen a gradual decrease in the number of reports on unsuccessful safety feature verification. In 2025, the Institute recorded the total of 10,868 such reports, which is three thousand reports less than in 2024. In the course of 2025, the Unit issued favourable recommendations for the total of seven medicinal products (eight batches), on the basis of which a temporary measure as referred to under Section 11(r) of the Act on Pharmaceuticals was issued by the Ministry so as to safeguard the availability of medicinal products in the Czech Republic. The said number of permitted medicinal products and batches is comparable to that in 2024. The Quality Defects Unit also carried out investigations into 19 reports concerning suspected broken anti-tampering devices (ATDs), including other cases of non-compliances with Commission Regulation No 2016/161.

Surveillance in the Area of Illegal Offers and Handling of Medicinal Products

In 2025, active surveillance in the sphere of illegal handling of medicinal products focused primarily upon the identification, investigation, and penalisation of cases of illegal offers of medicinal product sale on the internet, particularly through various advertising portals. In the area of enforcement, the Institute closely cooperates with the Czech Customs Administration, Czech Police, Czech Trade Inspection, and the Czech Agriculture and Food Inspection Authority (CAFIA). These institutions forward to the Institute, ***inter alia,*** cases of illegal handling of medicinal products they encounter in the execution of their control activities. Furthermore, this cooperation has been extended also to foreign partners within the Working Group of Enforcement Officers operating under the Heads of Medicines Agencies (HMA WGEO), not only in the exchange of information, but also in the investigation of specific cases with potentially international impact.

In 2025, the Institute received 14 reports from the public, of which four reports were forwarded to the locally competent Regional Authority and the remaining ones were investigated within the scope of the Institute's powers Two of the reports received from the public resulted in physical inspections of the outlets and identified illega sale of medicinal products carried out in these outlets. The illegally offered medicinal products were seized by the Institute.

From the Customs Authorities, the Institute took over the total of 14 handed-over shipments of confiscated unauthorised medicinal products in 2025. These cases resulted primarily from tax inspections, during which also illegal medicinal products were found at the inspected

entities, as well as from x-ray controls conducted upon the entry of shipments into the territory of the Czech Republic. The most often confiscated medicinal products included medicines for the treatment of erectile dysfunction or body weight reduction.

The Czech Police forwarded to the Institute the total of 19 cases, in respect of which the Police had not identified grounds for the commencement of criminal proceedings, but which were associated with medicinal products, and for this reason, they were passed on to the Institute to consider an offence referred to under the Act on Pharmaceuticals.

Through its own investigations, the Institute identified 86 cases of illegal offers of medicinal products on the internet (concerning the total of 2,965 advertisements), of which 61 cases (112 advertisements in total) were forwarded by the Institute to the Czech Police, as the offered medicinal products contained dependency-producing substances and constituted the suspected criminal deed of illegal manufacture and other handling of narcotic or psychotropic substances. The remaining cases (2,853 advertisements in total) were investigated by the Institute within the scope of its own powers; among other actions, the Institute sent the total of eleven demands to cease the illegal offering of medicinal products for sale to various advertising portals, which resulted in the removal of the illegal advertisements (in this manner, the total of 2,839 advertisements were removed).

Thirteen cases of illegal handling of medicinal products were of such degree of potential harm to the society that they resulted in the Institute's decision to initiate an administrative procedure concerning an offence and penalty imposition; some of these have already commenced, others will be initiated in the near future.

Surveillance in the Area of Regulation of Advertising for Medicinal Products

Surveillance in the Area of Regulation of Advertising for Medicinal Products, Medical Devices, and *in vitro* Diagnostic Medical Devices

In the area of surveillance over advertising for medicinal products, in 2025, the Institute investigated the total of 110 reports of suspected breaches of Act No. 40/1995 Coll., on Advertising Regulation, as amended. The subject of investigations into advertising was printed advertising matter (62 %), websites (36 %), and promotional samples of medicinal products (2 %). Pharmaceutical companies or their legal representatives filed 2 % of reports on suspected breaches of the Act, 25 % of reports were lodged by private individuals, 3 % by state administration authorities, and 70 % by SÚKL employees. Upon request, the Institute issued/provided 44 expert opinions/consultations on issues concerning proposed advertising for medicinal products for human use. The inspectors of the Advertising Regulation Unit completed 14 inspections of compliance with the Act on Advertising Regulation and the Act on Pharmaceuticals and identified shortcomings in one inspected person. Twenty-two administrative procedures were completed and these resulted in the imposition of 22 fines for breaches of the Act on Advertising Regulation in the aggregate amount of 5,589,000 CZK.

In the area of regulation of advertising for medical devices and *in vitro* diagnostic medical devices, in 2025, the Institute addressed the total of 42 reports concerning breaches of the Act on Advertising Regulation. Of these, 40 % were external reports and 60 % were submitted by the employees of the Institute. Upon request, the Institute provided four expert opinions/consultations on these issues.

Two administrative procedures were concluded and resulted in the imposition of two fines for the breach of the Act on Advertising regulation amounting, in total, to 3,000,000 CZK.

Surveillance in the Area of Decision-Making about Product Classification

In 2025, the Institute initiated investigation in respect of 121 various products, most often dietary supplements and cosmetic products, for suspected classification as a medicinal product. In nine cases, an administrative procedure regarding product classification was initiated *ex officio* or upon-request. In 2025, the Institute reclassified two products to the category of medicinal products. Upon request, the Institute provided three expert opinions/consultations on these issues.

Opinions for Customs Authorities on Shipments from Third Countries

In 2025, the Institute completed the total of 356 opinions for customs authorities on shipments from third countries for the purposes of release/non-release of medicinal products imported from third countries. The Institute assessed whether products that were the object of non-commercial import in mail shipments, express shipments, and in other shipment channels were medicinal products as defined by the provision of Section 2 of the Act on Pharmaceuticals.

List of Websites with Illegal Offers of Medicinal Products

In compliance with the provision of Section 13(3)(s) of the Act on Pharmaceuticals, the Institute keeps a list of websites offering medicinal products contrary to this Act (hereinafter referred to as the "list of websites with illegal medicinal product offer"); the list is being published by the Institute on its website. In 2025, the Institute investigated 242 cases of websites with illegal medicinal product offer and included them in the list.

Standardisation and Pharmacopoeial Activities

During the first half of 2025, the second supplement to Czech Pharmacopoeia 2023 – Supplement 2025 (hereinafter referred to as "Suppl. 2025") was prepared for print. Suppl. 2025 was published in cooperation with the Grada Publishing house in two volumes as binding from 01 September 2025 and it is available also in electronic format.

The European part of Czech Pharmacopoeia contains translations of 148 texts and it has been updated to reflect four supplements of the European Pharmacopoeia – 11.5 to 11.8 (Suppl. 11.5, which is binding with effect from 01 July 2024; Suppl. 11.6 binding with effect from 01 January 2025; Suppl. 11.7 binding with effect from 01 April 2025; and Suppl. 11.8 binding with effect from 01 July 2025). It contains translations of 137 new and amended general monographs, general chapters, and selected texts of the special part. Furthermore, 141 texts from the previous editions of the European Pharmacopoeia were included on the basis of requirements raised by professionals. The General Part contains translations of all texts of the General Part of the European Pharmacopoeia published in Suppl. 11.5 to 11.8. The Special Part contains 88 selected texts. Other monographs from the Suppl. 11.5-11.8 Special Part of the European Pharmacopoeia have been published only in the form of a table; their translations have not been provided.

The National Part of Suppl. 2025 contains 17 texts in total. Part III, Introductory Texts, provides an updated List of monographs from the Special Part of the European Pharmacopoeia, containing an overview of all Ph. Eur. articles with basic information. The monographs shown in bold in this list are provided in full text in the Czech language in Ph. Cz. 2023, Suppl. 2024

or in Suppl. 2025. On the basis of the results of the "Shelf-Life of Individually Prepared Medicinal Products IV" project, monographs for the following products were included in the National Part: *Argenti nitratis unguentum compositum, Unguentum molle, Zinci oxidi suspensio, Zinci oxidi suspensio cum levomentholo*. The results have been also incorporated in revised Table XVI: Storage and shelf-life of products prepared in pharmacies.

Along with the proof-reading and print preparation of Suppl. 2025, the preparation of another, this time third supplement to Ph. Cz. 2023 – Supplement 2026 (hereinafter referred to as "Suppl. 2026") was under way. In its European Part, Suppl. 2026 will contain translations and revisions of monographs from the 12th edition of Ph. Eur. (Issue 12.1 to 12.3). For the purposes of consistency with the new publication format of European Pharmacopoeia, one edition of the Czech Pharmacopoeia (or Supplement) will always contain one annual edition of the European Pharmacopoeia.

In its European Part, Suppl. 2026 will contain translations of 120 texts. This includes 95 new and revised general monographs, general chapters, and selected texts from the Special Part. Furthermore, with regard to the requirements raised by professionals, 25 texts from the previous editions of the European Pharmacopoeia will be included and translated into the Czech language.

A list of all monographs from the Ph. Eur. Special Part, updated with Ph. Eur. – Issue 12.1 to 12.3, has been published on the Institute's website.

The National Part will contain 24 texts, with three new monographs: ***Cremor leniens*** (CZ 152), ***Unguentum leniens*** (CZ 153), and ***Unguentum Whitfield*** (CZ 151), which have been prepared cooperation with the Faculty of Pharmacy of Charles University, the laboratories of the Ministry of Defence, and the Institute's laboratories.

In cooperation with the laboratories of the Institute and the pharmacy section of the Pharmacopoeial Commission, the "Shelf-Life of Individually Prepared Medicinal Products VII" project was almost completed in late 2025 (the project concerned ten products from the National Part of Czech Pharmacopoeia and the final testing of one of them was scheduled for January 2026). The results were incorporated in the relevant monographs and revised Table XVI: Storage and shelf-life of products prepared in pharmacies. These revisions will be reflected in Suppl. 2026.

Cooperation with the European Pharmacopoeia Commission in the preparation of further Ph. Eur. editions and in the preparation of the Czech translations of standard terms of pharmaceutical forms, methods of administration, and packaging and their inclusion in the EDQM database continued in the course of the year.

The employees regularly attended the meetings of the European Pharmacopoeia Commission and meetings of secretariats of national pharmacopoeia commissions.

Information about the binding nature of individual Ph. Eur. editions was published in the Institute's information media.

Determination of Prices and Reimbursements of Medicinal Products

In compliance with the provisions of Act No 48/1997 Coll., on Public Health Insurance and Amendments to Some Related Acts (hereinafter referred to as the "Act on Public Health Insurance"), the Section of Pricing and Reimbursement Regulation decides on maximum prices and reimbursements of medicinal products and foods for special medical purposes. In respect of proprietary

medicinal products, this is done via administrative procedures that fully comply with the principles of procedure transparency stipulated by the European legislation. In cases specified by law, administrative procedures are conducted ex officio (most often, so-called in-depth and abbreviated revisions) or they are initiated upon request of persons authorised to file such requests by law (marketing authorisation holders in the case of authorised medicinal products; importers or domestic manufacturers of medicinal products if the medicinal product imported or manufactured thereby is used in the territory of the Czech Republic within a specific therapeutic programme or other persons applying for a specific therapeutic programme; importers or domestic manufacturers of foods for special medical purposes; or health insurance companies). A request for the initiation of an ex-officio administrative procedure may be submitted by any person.

The primary legal regulation governing the sphere of pricing and reimbursement regulation of medicinal products and foods for special medical purposes, the Act on Public Health Insurance, did not change in 2025 compared to the previous year.

An amendment to the Act on Public Health Insurance (Act No 289/2025 Coll.) that entered into force on 12 August 2025, took effect as of 01 January 2026, and therefore did not exert any legal effect in 2025.

Maximum Ex-Factory Prices

In the sphere of price regulation, the applicable directive for 2025 was Price Regulation of the Ministry of Health no. 2/2024/OLZP of 29 November 2023, on the regulation of prices of medicinal products and foods for special medical purposes, effective as of 01 January 2024. Price regulation governed producer prices, through the maximum price determined by the Institute or through material price regulation, and the profit margin through determining the maximum profit margin amount. Medicinal products listed under Art. II(8) of the Price Regulation of the Ministry of Health No. 2/2024/OLZP continued to be regulated only in terms of profit margin.

Table 26 Overview of administrative procedures in 2025

	Number of SÚKL codes
Applications for maximum ex-factory price determination	
Initiated	22
Decided	20
Appeal procedure pending	0
Became final	16
Applications for maximum ex-factory price change	
Initiated	113
Decided	107
Appeal procedure pending	0
Became final	105
Applications for maximum ex-factory price reduction – abbreviated procedure	
Initiated	0
Decided	0

Table 26 Overview of administrative procedures in 2025

	Number of SÚKL codes
Appeal procedure pending	0
Became final	0
Applications for maximum ex-factory price revocation	
Initiated	8
Decided	6
Appeal procedure pending	0
Became final	6

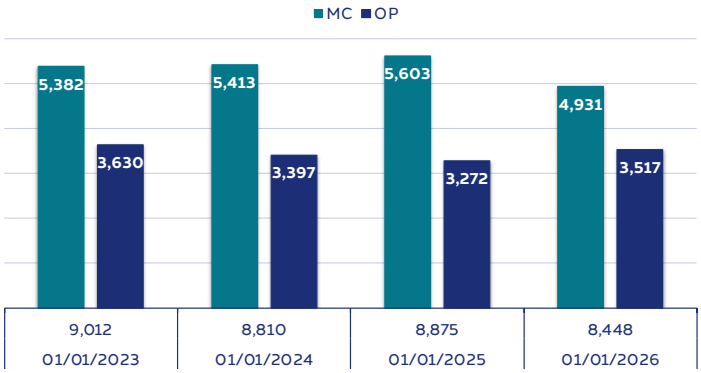
Another relevant directive in the area of price regulation was the Price Decision of the Ministry of Health no. 3/2024/CAU of 29 November 2023, effective as of 01 January 2024, laying down a list of ATC groups that are not subject to price regulation by setting the maximum price in the specified pharmaceutical form. The said Price Decision contains also a list of ATC groups of medicinal products with relevant routes of administration, which are important for the provision of healthcare services and the shortage of which on the market in the Czech Republic would jeopardise the availability of healthcare services. Medicinal products with concluded pricing agreement concerning maximum ex-factory price falling within these ATC groups are then not subjected to regulation via maximum price, either.

Price Assessments of the Ministry of Health no. 1/2026/OLZP and 2/2026/OLZP, taking effect as of 01 January 2026, did not have any impact upon price regulation in 2025.

In 2025, 20 administrative procedures regarding maximum price determination were initiated (cf. 33 administrative procedures in 2024). For maximum price change, 82 administrative procedures were commenced (cf. 81 administrative procedures in 2024); applications submitted by marketing authorisation holders prevailed (19 applications were submitted by health insurance companies and 83 by marketing authorisation holders).

Recently, the trend from the previous years has changed and the number of medicinal products regulated by maximum price decreased in 2025 compared to 2024, while the number of medicinal products regulated by profit margin was slightly growing.

Figure 4 Structure of reimbursed products by the type of price regulation (number of codes of medicinal products/foods for special medical purposes)



Explanatory notes: MC – Regulation through maximum price and profit margin; OP – Regulation through profit margin only

Regarding the structure of medicinal products (Table 27 refers), it may be stated that in the individual months of 2025, the numbers of medicinal products in the aforementioned maximum price zones were decreasing in the lower price zones. The most significant decrease in the number of codes occurred in the zone of "More than 100 CZK up to 200 CZK incl." The number of codes increased particularly in the upper half of the price zones. The highest increase was seen in the "More than 1,000 CZK up to 2,000 CZK incl." zone.

Table 27 Overview of the number of codes of medicinal products/foods for special medical purposes in the maximum price zones as per the List of Prices and Reimbursements (SCAU) by month

Price regulation zone	1	2	3	4	5	6	7	8	9	10	11	12
Up to 20 CZK incl.	5	5	5	5	5	5	5	5	5	5	5	5
More than 20 CZK up to 50 CZK incl.	181	180	178	178	181	182	179	179	179	179	177	176
More than 50 CZK up to 100 CZK incl.	572	572	564	562	561	560	561	558	557	555	555	555
More than 100 CZK up to 200 CZK incl.	810	792	783	784	780	788	788	792	793	788	790	787
More than 200 CZK up to 300 CZK incl.	507	500	500	500	499	500	495	496	506	510	512	514
More than 300 CZK up to 500 CZK incl.	495	491	489	495	495	497	498	497	507	510	511	522
More than 500 CZK up to 1,000 CZK incl.	727	725	730	736	740	740	747	744	747	752	752	755
More than 1,000 CZK up to 2,000 CZK incl.	586	577	582	591	595	614	629	625	625	628	622	629
More than 2,000 CZK up to 3,000 CZK incl.	264	263	261	268	272	271	273	273	279	292	293	305
More than 3,000 CZK up to 5,000 CZK incl.	291	281	284	285	292	295	298	301	286	292	296	303
More than 5,000 CZK up to 10,000 CZK incl.	295	284	287	288	292	290	291	296	298	307	310	312
More than 10,000 CZK up to 20,000 CZK incl.	260	264	265	268	268	270	272	276	282	290	291	298
More than 20,000 CZK up to 30,000 CZK incl.	131	130	129	130	131	132	131	132	134	138	140	141
More than 30,000 CZK up to 50,000 CZK incl.	134	138	137	139	140	141	141	143	142	143	144	146
More than 50,000 CZK up to 100,000 CZK incl.	216	222	226	226	229	237	237	234	234	236	238	239
More than 100,000 CZK	129	130	133	140	147	146	149	149	157	166	170	172
Number of codes	**5,603**	**5,554**	**5,553**	**5,595**	**5,627**	**5,668**	**5,694**	**5,700**	**5,731**	**5,791**	**5,806**	**5,859**

Development of Average End-User Prices

In 2025, there was no change to profit margins or to the VAT rate for medicinal products regulated by the maximum price (maximum price determined by an administrative procedure and profit margin pursuant to the Price Regulation); the average end-user price increased by 11.5 %. The highest increase of average prices occurred in the 2,500 – 5,000 CZK price zone and the biggest decrease was seen in the 5,000 – 10,000 CZK price zone. In respect of medicinal products regulated by notified price and profit margin (pursuant to the Price Regulation and Price Decision), the average end-user price increased by 3.5 %, with the highest increase in the "More than 10,000 CZK" price zone.

The biggest decrease of notified prices was seen in the "More than 5,000 up to 10,000 CZK incl." price zone. The situation on ex-factory price level (ex. profit margin and VAT) with focus upon a more detailed comparison of the last quarters of 2024 and 2025 is illustrated by Figures 5 and 6.

Figure 5 Prices of pharmaceuticals regulated by maximum price – comparison of average prices in Q4 2024 and Q4 2025 by price zone

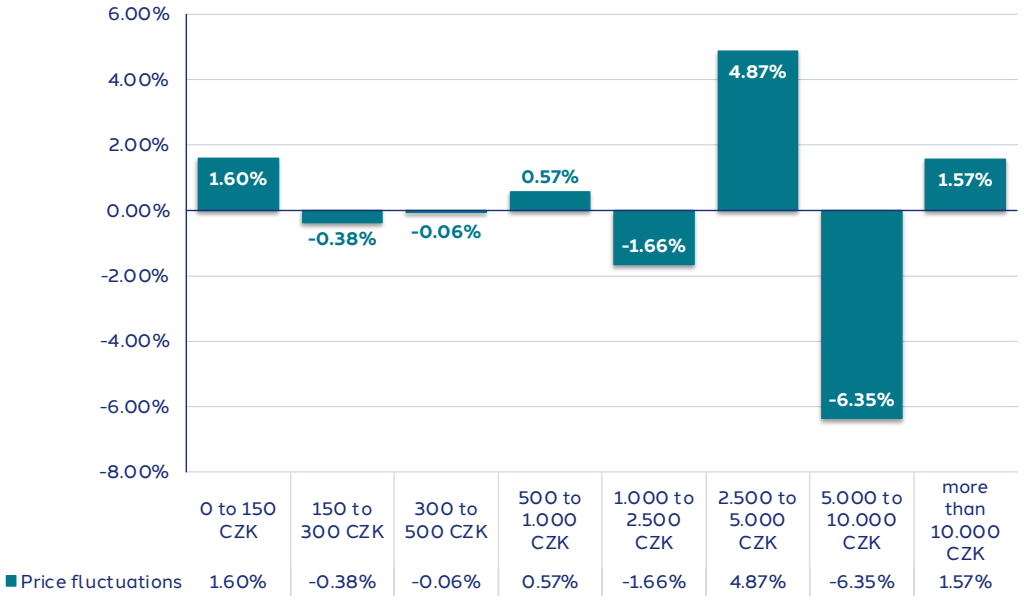
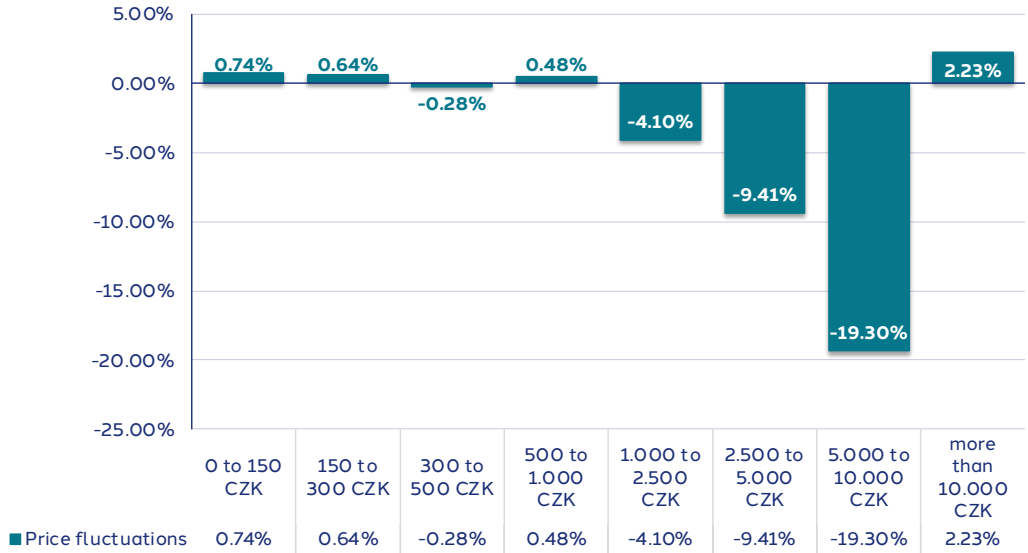


Figure 6 Prices of pharmaceuticals regulated by profit margin – comparison of average prices in Q4 2024 and Q4 2025 by price zone



Overview of the Most Commonly Distributed Medicinal Products Whose Maximum Price Changed

On the basis of periodical distributor reports on executed supplies of medicinal products, an overview of ten most commonly distributed medicinal products was compiled, along with an overview of ten products with the highest financial volume by the ex-factory price, in respect of which the maximum ex-factory price changed.

In 2025, the maximum prices both increased and decreased in the group of the most commonly distributed medicinal products whose maximum price changed. The biggest change in terms of maximum price increase occurred for medicinal product DUSPATALIN RETARD (Table 28 refers).

Medicinal products with the highest financial volume are found across all price zones, nevertheless, products from the highest price zone prevail (Table 29 refers).

Table 28 Ten most commonly distributed medicinal products by number of packages reported in compliance with DIS-13 Guideline whose maximum price changed

Code	ATC	Name	Name supplement	No. of packages	Original producer price (CZK)	New producer price (CZK)	Change to producer price (%)
0170760	R01AD09	MOMMOX	0,05MG/DÁV NAS SPR SUS 140DÁV	535,842	51.99	76.45	47.0
0002679	R03AL01	BERODUAL N	0,02MG/0,05MG/DÁV INH SOL PSS 200DÁV	533,626	129.01	135.38	4.9
0279264	A12BA01	KALNORMIN	1G TBL PRO 30	289,838	52.60	56.80	8.0
0279263	A12BA01	KALNORMIN	1G TBL PRO 90	261,299	156.75	169.30	8.0
0000168	C03AA03	HYDROCHLORO-THIAZID LÉČIVA	25MG TBL NOB 20	242,227	28.24	38.12	35.0
0090044	H02AB04	DEPO-MEDROL	40MG/ML INJ SUS 1X1ML	231,121	40.76	58.50	43.5
0200935	A12BA01	KALNORMIN	1G TBL PRO 30	226,648	52.60	56.80	8.0
0266450	A03AA04	DUSPATALIN RETARD	200MG CPS DUR MRL 30	183,511	111.67	168.74	51.1
0087299	L03AX	IMUNOR	10MG POR LYO 4	174,735	906.28	910.48	0.5
0047033	R05CB15	ERDOMED	35MG/ML POR PLV SUS 100ML	169,432	119.44	179.45	50.2

Table 29 Ten most commonly distributed medicinal products by financial volume in end-user prices reported in compliance with DIS-13 Guideline whose maximum price changed

Code	ATC	Name	Name supplement	Financial volume in end--user price	Original producer price (CZK)	New producer price (CZK)	Change to producer price (%)
0087299	L03AX	IMUNOR	10MG POR LYO 4	223,852,134	906.28	910.48	0.5
0238798	N02CD03	AJOVY	225MG INJ SOL PEP 1X1,5ML	163,060,073	10,648.13	8,168.97	-23.3
0222334	L04AC12	KYNTHEUM	210MG INJ SOL ISP 2X1,5ML	152,890,670	18,685.07	19,316.43	3.4

Table 29 Ten most commonly distributed medicinal products by financial volume in end-user prices reported in compliance with DIS-13 Guideline whose maximum price changed

Code	ATC	Name	Name supplement	Financial volume in end--user price	Original producer price (CZK)	New producer price (CZK)	Change to producer price (%)
0238546	J05AR25	DOVATO	50MG/300MG TBL FLM 30	122,359,865	14,935.48	12,497.41	-16.3
0185115	L03AB07	AVONEX	30MCG/0,5ML INJ SOL PEP 4X0,5ML+4J	110,836,035	15,217.99	11,703.61	-23.1
0002679	R03AL01	BERODUAL N	0,02MG/0,05MG/DÁV INH SOL PSS 200DÁV	106,930,931	129.01	135.38	4.9
0238362	N02CD02	EMGALITY	120MG INJ SOL PEP 1X1ML	95,694,379	10,155.29	8,006.88	-21.2
0168451	A10BH05	TRAJENTA	5MG TBL FLM 90X1	88,124,422	2,516.96	2,171.11	-13.7
0500512	L03AB07	REBIF	44MCG/0,5ML INJ SOL ZVL 4X1,5ML	76,448,428	16,168.07	13,550.78	-16.2
0214739	L03AX13	COPAXONE	40MG/ML INJ SOL ISP 12X1ML	74,982,448	14,284.16	11,538.62	-19.2

Amounts and Conditions of Reimbursements from Health Insurance Funds

In 2025, 34 applications for determination of temporary reimbursement of highly innovative medicinal products were submitted as well as 18 applications for determination of the amount and conditions of reimbursement of orphan medicinal products.

In the course of 2025, the Section continued to initiate in-depth reimbursement revisions in line with the schedule. Fifteen in-depth revisions were scheduled for 2025 and 14 of them (88 SÚKL codes) were initiated.

Table 30 Overview of administrative procedures in 2025

	Number of SÚKL codes
Applications for determination or change of the amount and conditions of reimbursement	
Initiated	461
Decided	162
Appeal procedure pending	1
Became final	160
Applications for determination or change of maximum price and the amount and conditions of reimbursement	
Initiated	162
Decided	67
Appeal procedure pending	0
Became final	61

Table 30 Overview of administrative procedures in 2025

	Number of SÚKL codes
Applications for reimbursement revocation	
Initiated	478
Decided	412
Appeal procedure pending	0
Became final	369
Applications for maximum price and reimbursement revocation	
Initiated	63
Decided	49
Appeal procedure pending	0
Became final	49
***Ex officio* initiated procedures**	
Initiated	767
Decided	596
Appeal procedure pending	0
Became final	562
Procedures concerning similar products	
Initiated	1,023
Decided	825
Appeal procedure pending	0
Became final	809

Pursuant to the provisions of Section 39l of the Act on Public Health Insurance, in in-depth-revisions, the Institute is obliged, *inter alia,* to review, and, where applicable, change the amount of the basic reimbursement, the consistency of the amounts of reimbursements for all principally therapeutically interchangeable medicinal products or foods for special medical purposes with the basic reimbursement, the uniformity and effectiveness of the determined conditions of reimbursement, and compliance of the determined amounts and conditions of reimbursement of medicinal products and foods for special medical purposes with the law, in particular, compliance with the expected results and reasons for pharmacotherapy and cost-effectiveness. Furthermore, the Institute initiates other types of administrative procedures *ex officio*, such as so-called abbreviated revisions or individual administrative procedures to change or revoke the amounts and conditions of reimbursement.

In 2025, savings of public health insurance funds were generated both by in-depth and abbreviated revisions of reimbursements. The total savings arising from abbreviated revisions enforceable in 2025 are estimated at 2,357,910,930.00 CZK, and those arising from in-depth revisions at 593,248,031.00 CZK (Table 31 refers).

Table 31 Overview of enforceable decisions on reimbursement revisions and the impact on public health insurance funds

Effective date	Number of SÚKL codes	Number of administrative procedures	Impact on public health insurance funds
01/2025	38	6	272,043,036.00 CZK
02/2025	112	4	239,883,087.00 CZK
03/2025	4	1	-12,281,568.00 CZK
04/2025	151	4	768,732,050.00 CZK
05/2025	650	1	870,162,980.00 CZK
06/2025	68	5	213,931,283.00 CZK
07/2025	8	4	51,891,884.00 CZK
08/2025	90	2	17,471,368.00 CZK
09/2025	120	5	264,064,317.00 CZK
10/2025	13	1	108,285,979.00 CZK
11/2025	7	2	11,213,825.00 CZK
12/2025	15	1	145,760,720.00 CZK

Note: Positive figures represent savings from health insurance funds, negative figures represent an increased impact upon the budget.

The overview of the number of medicinal product codes in the SCAU reimbursement price zones indicates that most commonly, medicinal products fall into the lower price zones, i.e., 3–8, in the reimbursement range of 50–2,000 CZK (Table 32 refers). The value distribution in 2025 is quite similar to that of 2024.

Table 32 Overview of the number of codes of medicinal products/foods for special medical purposes in the maximum price zones as per the List of Prices and Reimbursements (SCAU) by month

Reimbursement zone	1	2	3	4	5	6	7	8	9	10	11	12
Up to 20 CZK, incl.	147	149	149	150	151	151	152	152	150	150	147	146
More than 20 CZK up to 50 CZK, incl.	606	608	604	608	604	598	598	597	596	600	599	597
More than 50 CZK up to 100 CZK, incl.	1,129	1,124	1,105	1,109	1,104	1,109	1,110	1,109	1,105	1,109	1,111	1,113
More than 100 CZK up to 200 CZK, incl.	1,327	1,309	1,302	1,307	1,301	1,306	1,299	1,309	1,315	1,308	1,307	1,309
More than 200 CZK up to 300 CZK, incl.	864	860	863	875	877	888	894	895	889	884	879	889
More than 300 CZK up to 500 CZK, incl.	909	913	927	947	941	940	949	955	964	974	973	974
More than 500 CZK up to 1,000 CZK, incl.	1,012	1,018	1,025	984	987	982	983	986	990	1,012	1,007	1,016
More than 1,000 CZK up to 2,000 CZK, incl.	817	835	834	848	849	855	867	852	850	858	847	852

Table 32 Overview of the number of codes of medicinal products/foods for special medical purposes in the maximum price zones as per the List of Prices and Reimbursements (SCAU) by month

Reimbursement zone	1	2	3	4	5	6	7	8	9	10	11	12
More than 2,000 CZK up to 3,000 CZK, incl.	355	339	332	316	317	318	326	332	330	336	337	337
More than 3,000 CZK up to 5,000 CZK, incl.	320	309	313	313	328	329	332	334	331	340	341	343
More than 5,000 CZK up to 10,000 CZK, incl.	495	480	489	491	530	535	533	540	557	568	571	581
More than 10,000 CZK up to 20,000 CZK, incl.	384	378	376	379	339	340	341	341	322	325	327	345
More than 20,000 CZK up to 30,000 CZK, incl.	157	160	160	156	158	160	163	165	164	171	173	161
More than 30,000 CZK up to 50,000 CZK, incl.	127	131	133	138	137	140	141	143	146	146	150	155
More than 50,000 CZK up to 100,000 CZK, incl.	128	131	133	134	139	146	142	144	141	141	145	142
More than 100,000 CZK	111	112	114	118	123	116	119	120	127	135	131	132
Number of codes	**8,888**	**8,856**	**8,859**	**8,873**	**8,885**	**8,913**	**8,949**	**8,974**	**8,977**	**9,057**	**9,045**	**9,092**

Overview of the Most Commonly Distributed Medicinal Products for Which Reimbursement from Health Insurance Was Changed

The overview clearly indicates that in the group of medicinal products with the highest financial volume in end-user prices, there was quite a significant reduction in the reimbursement of individual packages of medicinal products. The biggest reduction of reimbursement occurred for medicinal products XARELTO and ELIQUIS. An increase in the reimbursement of these high-volume medicinal products occurred only in two cases, of which in one case the increase was by units of per cent only (Table 33 refers).

Table 33 Ten most commonly distributed medicinal products by financial volume in end-user prices reported in compliance with DIS-13 Guideline, for which reimbursement was changed

Code	ATC	Name	Name supplement	Financial volume in end-user prices	Original reimbursement (CZK)	New reimbursement (CZK)	Change in reimbursement (%)
0209484	L01FF02	KEYTRUDA	25MG/ML INF CNC SOL 1X4ML	4,258,629,720	66,210.12	67,893.06	2.5
0249566	L01FC01	DARZALEX	1800MG INJ SOL 1X15ML	1,378,731,015	105,557.96	118,642.18	12.4
0168904	B01AF01	XARELTO	20MG TBL FLM 98 II	893,721,038	2,426.62	1,481.76	-38.9
0219166	L01XX52	VENCLYXTO	100MG TBL FLM 112(4X28)	627,566,658	134,132.07	116,626.40	-13.1
0215956	J07BA01	FSME-IMMUN	0,5ML INJ SUS ISP 1X0,5ML+J	529,171,528	902.50	863.52	-4.3

Table 33 Ten most commonly distributed medicinal products by financial volume in end-user prices reported in compliance with DIS-13 Guideline, for which reimbursement was changed

Code	ATC	Name	Name supplement	Financial volume in end-user prices	Original reimbursement (CZK)	New reimbursement (CZK)	Change in reimbursement (%)
0193747	B01AF02	ELIQUIS	5MG TBL FLM 168	520,357,708	2,079.96	1,270.08	-38.9
0222937	L01XK01	LYNPARZA	150MG TBL FLM 56	461,125,184	58,897.30	49,920.90	-15.2
0238756	L04AF03	RINVOQ	15MG TBL PRO 28 KAL	355,913,548	14,766.92	14,702.86	-0.4
0022097	L04AB04	YUFLYMA	40MG INJ SOL PEP 2X0,4ML	343,262,459	10,788.43	7,714.41	-28.5
0238695	L04AB02	REMSIMA	120MG INJ SOL PEP 2X1ML	307,202,509	10,788.31	7,714.32	-28.5

The group of medicinal products for which reimbursement has changed and which are distributed in the highest volumes, includes, in particular, medicinal products from the lower price zones. In 2025, the increases and decreases of reimbursements of the aforementioned products were balanced. The most significant increase in reimbursement was seen for medicinal products EUTHYROX and LETROX; the most significant decrease occurred for medicinal product ROSUCARD. The response in distribution to changes of reimbursement amounts was not clear-cut, as both lower and higher levels of supplies were observed after the amounts of reimbursement of the above-mentioned products changed (Table 34 refers).

Table 34 Ten most commonly distributed medicinal products by number of packages reported in compliance with DIS-13 Guideline for which reimbursement was changed

Code	ATC	Name	Name supplement	A (no. of packages)	Original reimbursement (CZK)	New reimbursement (CZK)	B (no. of packages)	Note
0243240	A11CC05	VIGANTOL	0,5MG/ML POR GTT SOL 1X10ML	288,510	49.93	42.44	290,186	X*
0276445	H03AA01	EUTHYROX	50MCG TBL NOB 90 II	298,457	44.97	57.23	267,771	
0187425	H03AA01	LETROX	50MCG TBL NOB 100	207,772	49.98	63.59	207,731	
0241078	J01XE01	FUROLIN	100MG CPS DUR 30	175,594	248.60	255.48	188,507	
0193747	B01AF02	ELIQUIS	5MG TBL FLM 168	153,083	2,079.96	1,270.08	191,834	
0276448	H03AA01	EUTHYROX	75MCG TBL NOB 90 II	166,513	57.86	73.64	153,261	
0276545	H03AA01	EUTHYROX	100MCG TBL NOB 90 I	165,986	77.15	98.17	148,881	
0148074	C10AA07	ROSUCARD	20MG TBL FLM 90 I	153,667	437.86	259.11	180,069	
0193741	B01AF02	ELIQUIS	2,5MG TBL FLM 168	118,239	1,039.99	635.04	149,946	
0187427	H03AA01	LETROX	100MCG TBL NOB 100	143,068	85.71	109.08	139,998	

Note: X* – the period of 1/6 of a year

A – number of packages distributed during six months prior to the change
B – number of packages distributed during six months after the change

REGULATORY ACTIVITIES OF THE INSTITUTE

Table 35 represents a list of substantial changes in the reimbursement system in 2025 with impact upon clinical practice. The table provides a summary overview of new innovative pharmaceuticals that entered the reimbursement system for the first time, as well as previously reimbursed pharmaceuticals in respect of which reimbursement was newly extended to a new diagnosis or a broader patient population. Furthermore, the table provides an overview of highly innovative medicinal products entering the reimbursement system pursuant to Section 39d of the Act on Public Health Insurance, and of orphan medicinal products entering the reimbursement system pursuant to Section 39da of the Act on Public Health Insurance. For these selected administrative procedures the result of which may be important both for the general public and for professionals from the perspective of the addressed expert issue (application for determination of reimbursement for a new active substance, application for determination of reimbursement for a new indication, application for major change to the conditions of reimbursement), the Institute has been publishing so-called assessment report summaries on its website on an ongoing basis in order to facilitate access to basic data and information on the assessed pharmaceuticals for the general public.

Table 35 Overview of newly reimbursed original pharmaceuticals and significant reimbursement extensions with decisions issued in 2025

Medicinal product name (active substance)	Indication (clinical use)	Reimbursement effective date in 2025
Medicinal products with previously determined reimbursement		
SKYRIZI (risankizumab)	Treatment of Crohn's disease following failure or intolerance of at least one TNF-alpha inhibitor	January
LAGEVRIO (molnupiravir)	Treatment of mild and moderate COVID-19 in patients with high risk of progression to serious condition requiring hospitalisation (where treatment with other antiviral agents is not possible)	January
PAXLOVID (nirmatrelvir + ritonavir)	Treatment of mild and moderate COVID-19 in patients with high risk of progression to serious condition requiring hospitalisation	January
ILUVIEN (fluocinolon)	Treatment of diabetic macular oedema	February
SPRAVATO (esketamin)	Treatment of resistant depression in patients of up to 65 years of age	February
VELSIPITY (etrasimod)	Treatment of ulcerative colitis	March
REVLIMID (lenalidomid)	Treatment of adult patients with newly diagnosed multiple myeloma, who are not candidates for transplantation, in combination with bortezomib and dexamethasone (VRd)	April
NUBEQA (darolutamid)	Treatment of metastatic, high-volume or high-risk hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT) and docetaxel	April
KINPEYGO (budesonid)	Treatment of primary IgA (immunoglobulin A) nephropathy	May
DIPHERELINE (triptorelin)	Treatment of pubertas praecox	June
COSENTYX (sekukinumab)	Treatment of hidradenitis suppurativa	June

Table 35 Overview of newly reimbursed original pharmaceuticals and significant reimbursement extensions with decisions issued in 2025

Medicinal product name (active substance)	Indication (clinical use)	Reimbursement effective date in 2025
BEYFORTUS (nirsevimab)	Prevention of lower airway infection with respiratory syncytial virus (RSV) in newborns and infants during their first RSV season	July
RYEQO (relugolix, estradiol, norethisteron)	Treatment of endometriosis	July
LITFULO (ritlecitinib)	Treatment of severe alopecia areata (patchy baldness)	August
ALTUVOCT (efanesoktokog alfa)	Treatment and prophylaxis of bleeding in haemophilia A	August
OPDIVO (nivolumab)	Second-line treatment of advanced urothelial carcinoma	August
ALDARA (imiquimod)	Treatment of high-grade localised vulvar squamous intraepithelial lesions	September
TEPMETKO (tepotinib)	Treatment of advanced non-small cell lung carcinoma in the 1st line and in further lines of treatment following previous immuno-therapy and/or platinum-based chemotherapy	September
KEYTRUDA (pembrolizumab)	Treatment of early triple-negative breast carcinoma with high risk of recurrence in combination with chemotherapy in neoad-juvant treatment and following surgical solution in adjuvant treatment and, furthermore, first-line treatment of microsatellite instability high or mismatch repair deficient metastatic colo-rectal carcinoma	September
LAZCLUZE (amivantamab + lazertinib)	First-line treatment of locally advanced or metastatic non-small cell lung carcinoma with evidenced exon 19 deletion or substitu-tion in combination with lazertinib	September
RYBREVANT (amivantamab + lazertinib)	First-line treatment of locally advanced or metastatic non-small cell lung carcinoma with evidenced exon 19 deletion or substitu-tion in combination with amivantamab	September
LIBTAYO (cemiplimab)	Treatment of metastatic cervical cancer	October
BAVENCIO (avelumab)	First-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC), who have not progressed following platinum-based chemotherapy	November
COLISTIMETHATE ACCORD (colistimethatum)	Treatment of severe infections caused by selected aerobe gram--negative pathogens in patients with limited treatment options	November
DARZALEX (daratumumab)	Treatment of adult patients with newly diagnosed multiple mye-loma suitable for autologous stem-cell transplantation in combi-nation with bortezomib, lenalidomide, and dexamethasone	November
LYNPARZA (olaparib)	Treatment of adult patients with diagnosed HER2-negative loca-lly advanced or metastatic breast cancer with positive BRCA1/2 germline mutation and ECOG performance status 0-1, who have not been previously treated with chemotherapy for metastatic disease	December
OPDIVO (nivolumab)	First-line treatment of adult patients with advanced clear-cell renal cell carcinoma and favourable prognosis (in the absence of IMDC risk factors) in combination with cabozantinib	December

Table 35 Overview of newly reimbursed original pharmaceuticals and significant reimbursement extensions with decisions issued in 2025

Medicinal product name (active substance)	Indication (clinical use)	Reimbursement effective date in 2025
Highly innovative medicinal products		
JEMPERLI (dostarlimab)	Treatment of advanced or recurring endometrial cancer in combination with carboplatin and paclitaxel	January
ELREXFIO (elranatamabum)	Treatment of relapsing or refractory multiple myeloma in patients who have been previously treated with at least three treatment regimens	January
RETSEVMO (selperkatinib)	Treatment of advanced non-small cell lung carcinoma with RET fusion positivity	February
RETSEVMO (selperkatinib)	Treatment of advanced medullary thyroid cancer with a RET mutation	February
ENHERTU (trastuzumab deruxtecan)	Treatment of adult patients with non-resectable or metastatic HER2-low breast cancer	March
TALZENNA (talazoparib)	First-line treatment of asymptomatic or mildly symptomatic patients with metastatic castration-resistant prostate cancer (mCRPC) with evidenced homologous recombination repair deficiency (dHRR) in combination with enzalutamide	March
LYNPARZA (olaparib)	Treatment of metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone	April
ULTOMIRIS (ravulizumab)	Treatment of neuromyelitis optica spectrum disorder (NMOSD) with aquaporin-4 (AQP4) antibody positivity	April
RYBREVANT (amivavantamab)	First-line treatment of adult patients with locally advanced or metastatic non-small cell lung carcinoma with an EGFR exon 20 insertion mutation in combination with carboplatin and pemetrexed. Further treatment lines of locally advanced or metastatic non-small cell lung carcinoma with an EGFR exon 19 deletion (Ex19del) or exon 21 L858R substitution mutation in combination with pemetrexed and carboplatin	June
KEYTRUDA (pembrolizumab)	First-line treatment of locally advanced non-resectable or metastatic HER2-positive (IHC 3+) adenocarcinoma of the stomach or gastroesophageal junction in combination with trastuzumab and fluoropyrimidine- and platinum-based chemotherapy	July
TRODELVY (sacituzumab)	Treatment of adult patients with non-resectable or metastatic hormone-positive, HER-2 negative breast cancer who have undergone hormone therapy and at least two other systemic treatments for advanced disease	July
TAGRISSO (osimertinib)	First-line treatment of adult patients with locally advanced or metastatic non-small cell lung carcinoma with evidenced presence of EGFR exon 19 deletion or exon 21 L858R substitution in combination with pemetrexed and platinum-based chemotherapy	September
TALVEY (talquetamab)	Treatment of relapsing or refractory multiple myeloma in patients who have been previously treated with at least three treatment regimens	November
Orphan medicinal products		
AYVAKYT (avapritinib)	Treatment of advanced systemic KIT D816V-mutation mastocytosis following at least one systemic therapy	January
HEPCLUDEX (bulevirtid)	Treatment of chronic hepatitis delta viral infection with controlled liver disease	February

Table 35 Overview of newly reimbursed original pharmaceuticals and significant reimbursement extensions with decisions issued in 2025

Medicinal product name (active substance)	Indication (clinical use)	Reimbursement effective date in 2025
ASPAVELI (pegcetacoplan)	Treatment of adult patients with paroxysmal nocturnal haemoglobinuria and haemolytic anaemia	April
FINTEPLA (fenfluramin)	Add-on therapy to treatment of epileptic seizures associated with Lennox-Gastaut syndrome in patients over 2 years of age	April
PEMAZYRE (pemigatinib)	Treatment of adult patients with locally advanced or metastatic cholangiocarcinoma	July
KAFTRIO (elexacaftor, ivacaftor, tezacaftor)	Treatment of cystic fibrosis in paediatric patients from the age of 2 years up to less than 6 years, with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in combined regimen with ivacaftor	September
LIVMARLI (maralixibat)	Treatment of cholestatic pruritus in patients from the age of 2 months with Alagille syndrome	September
WINREVAIR (sotatercept)	Treatment of pulmonary arterial hypertension in combination with other PAH therapies in adult patients with WHO functional class (WHO FC) II to III upon sotatercept treatment initiation	October
QINLOCK (ripretinib)	Treatment of adult patients with advanced gastrointestinal stromal tumour (GIST), who have been previously treated with three or more kinase inhibitors	November
TAVNEOS (avacopan)	Treatment of adult patients with active and severe granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) in combination with a rituximab or cyclophosphamide containing regimen	December

Validation of Applications

In 2025, the total of 1,065 applications for determination, change or revocation of maximum price and/or the conditions and amount of reimbursement of medicinal products/foods for special medical purposes or for abbreviated reimbursement revision were submitted, which is a 20 % increase compared to 2024. The highest proportion included applications for determination of the amount and conditions of reimbursement or for determination of maximum price and the amount and conditions of reimbursement of medicinal products/foods for special medical purposes, on the basis of which administrative procedures conducted pursuant to the provisions of Section 39g(9) of the Act on Public Health Insurance were initiated (approx. 44 %); followed by applications for change of the maximum price and/or the amount and conditions of reimbursement of medicinal products/foods for special medical purposes (approx. 22 %) and applications for revocation of maximum price and/or the amount and conditions of reimbursement of medicinal products/foods for special medical purposes (approx. 21 %). In five cases, the decision on maximum price and reimbursement amount and conditions determination or change was based upon Section 32d of the Act on Public Health Insurance in order to maintain availability of irreplaceable reimbursed pharmaceuticals. In respect of 24 administrative procedures, an invitation to eliminate shortcomings of the application was issued. The primary reason was failure to reimburse the costs of expert activities, often associated with the failure to pay the administrative fee.

Table 36 Activities in the area of validation of applications for determination/change/revocation of maximum prices and/or reimbursement amounts and conditions, for abbreviated revision of maximum price or reimbursement system – 2025

Period	Submitted applications	Suspended due to defective submission and application shortcomings	Discontinued in the validation phase
January	69	2	2
February	74	0	0
March	104	4	0
April	79	1	1
May	80	0	0
June	103	2	3
July	89	2	0
August	82	3	1
September	62	1	0
October	85	2	0
November	77	2	0
December	161	5	0
Total	**1,065**	**24**	**7**

In 2025, 100 medicinal product SÚKL codes entered the reimbursement system on the basis of an application for the adoption of producer price and the amount and conditions of reimbursement from the reimbursed code of an identical medicinal product.

In respect of foods for special medical purposes, 90 label updates were carried out on the basis of an application submitted by the importer/domestic manufacturer of the food for special medical purposes.

Lists of Prices and Reimbursements of Medicinal Products and Foods for Special Medical Purposes

With regard to the amendment to the Act on Public Health Insurance, effective from 01 January 2026, which separated the categorisation and regulation of foods for special medical purposes into Part Eight thereof, along with separate publication of reimbursed foods for special medical purposes, the joint List of Prices and Reimbursements of Medicinal Products/Foods for Special Medical Purposes was divided into a Medicinal Products List and Foods for Special Medical Purposes List; their drafts and final versions were published in December 2025 separately in new data interfaces.

Individually Prepared Medicinal Products (IPLPs) and Other Products for Which Reimbursement is Determined by Means of General Measures

Individually prepared medicinal products (hereinafter referred to as “IPLPs”) are subjected to the conditions of material price regulation (hereinafter referred to as “VUC”) set forth by the Price Regulation (effective for 2025). This regulation applies to the following groups of medicinal products: individually prepared radiopharmaceuticals (RF), individually produced blood components and autologous blood components (TP), parenteral nutrition products for home therapy (DPV), medicinal products

individually prepared in pharmaceutical care facilities – magistral formulas (MAG), and advanced therapy medicinal products (ATMP), to which an exemption allowing for the use of a non-authorised advanced therapy medicinal product in a healthcare facility providing inpatient care applies.

The conditions governing the stipulation of the amount and conditions of reimbursement by means of a general measure (hereinafter referred to as the "OOP") are set forth by the provisions of Section 15(5) of the Act on Public Health Insurance. The drafting of an OOP and the method of its publication are further governed by the provisions of Sections 171-174 of Act No 500/2004 Coll., the Code of Administrative Procedure.

General Measures

In the course of 2025, eight General Measure (OOP) procedures in total were initiated and duly completed. For the TP group, OOP 07-24 was issued in 2024; it came into force on 01 September 2024, but the changes stipulated thereby took effect only from 01 January 2025, and for this reason, the OOP has been included in the assessed period of OOPs issued for 2025.

For the TP group, OOP 07-24 was issued and came into force on 01 September 2024. This OOP reflected suggestions for changes to the amounts and conditions of reimbursement and, at the same time, as of 01 January 2025, selected blood components (codes 0007901, 0007905, 0007917, 007956, 0007963, 0107930, 0107931, and 0107935) were deleted from the IPLP list.

As at 01 March 2025, OOP 01-25 for the DPV group, OOP 02-25 for the RF group, and OOP 03-25 for the TP group were issued. As at 01 June, OOP 04-25 for RFs, OOP 05-25 for the TP group, and complementary OOP 06-25 for the RF group were issued.

As at 01 September, complementary OOP 07-25 for TPs and, as at 01 November, complementary OOP 08–25 for the RF group were issued. All of these OOPs were issued in compliance with effective legislation.

On 01 March, OOP 01-25 for the DPV group came into force; this OOP reflected the change to the minute rate for professionals performing procedures in the L3 category (specialists) pursuant to Decree No 347/2024 Coll., amending Decree No 134/1998 Coll., setting forth the list of healthcare procedures and their point values, as amended. The OOP reflected the legislative change arising from Government Regulation No 466/2024 Coll., amending Government Regulation No 341/2017 Coll., on emoluments of employees in public services and administration, as amended, and Government Regulation No 304/2014 Coll., on emoluments of civil servants, as amended.

OOP 02-25 for the RF group and OOP 03-25 for the TP group reflected a change to the overhead minute rate in the amount of 4.47 points per minute of time performance, which is consistent to Decree No 347/2024 Coll., amending Decree No 134/1998 Coll.

Furthermore, with regard to Decree No 314/2024 Coll., setting forth point values, amounts of reimbursement for reimbursed services, and regulatory restrictions effective in 2025, the point value was changed from the original amount of 1.04 CZK per point to the new value of 0.94 CZK per point in the RF group and to 0.96 CZK per point in the TP group. In respect of the RF and TP groups, the legislative change arising from Government Regulation No 466/2024 Coll., amending Government Regulation No 341/2017 Coll. and Government Regulation No 304/2014 Coll., was also reflected. OOP 02-25 reflected a suggestion to amend the conditions for radiopharmaceutical 18F Fluordopa, code 0002119, product FLUORODOPA (18F).

As at 01 June, OOP 04-25 took effect; in this OOP, the Institute reflected new pricing background materials for radiopharmaceuticals (regular price reports) and the average annual €/CZK exchange rate published by the Czech National Bank (ČNB) for 2024, on the basis of which it determined the amounts of reimbursements. As at the same date, the following OOPs took effect: OOP 05-25 for the TP group, which reflected a suggestion to complement material costs for procedure 97111 and to reflect the purchase price of apparatuses and equipment of transfusion departments in the last two years; and OOP 06-25 for the RF group, in which the Institute extended the IPLP list by product (131I) IODOMETHYL NORCHOLESTEROL CIS BIO INTERNATIONAL (NORCHOL-131), radiopharmaceutical 131I Norcholesterol inj., code 0002079, in the specific therapeutic programme mode.

Complementary OOP 07-25 for the TP group was issued with effect from 01 September 2025, which included a Surcharge for the test of WNV nucleic acid by direct detection, code 0407951.

As at 01 November 2025, complementary OOP 08-25 was issued for the RF group, which extended the IPLP list with a new radiopharmaceutical 18F-PSMA, code 0002120 (product PYLCLARI).

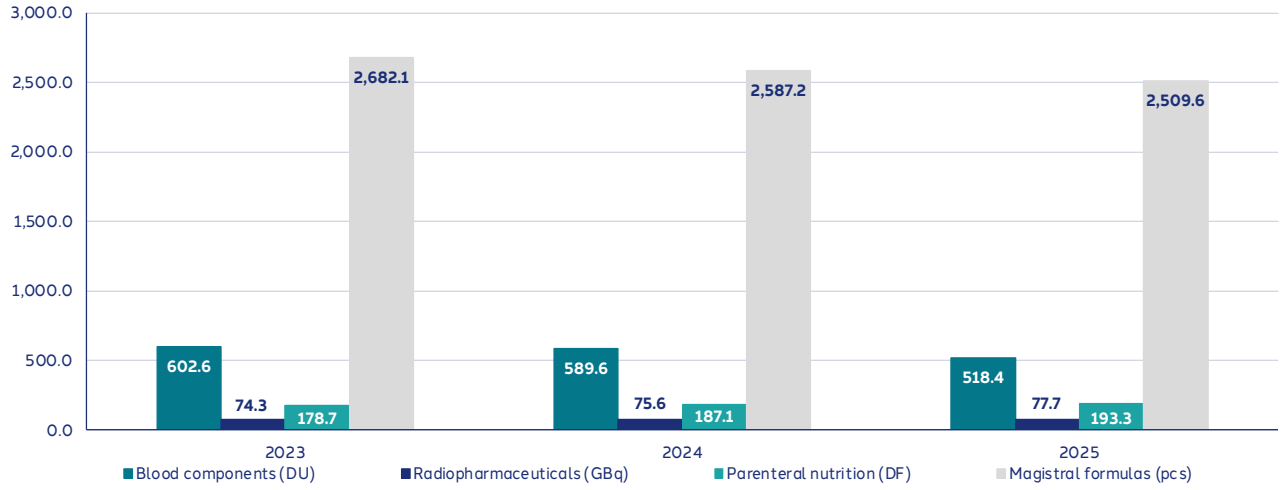
Consumption and Costs of Individually Prepared Medicinal Products Incurred by the Public Health Insurance System

The consumption of individually prepared medicinal products is evaluated in defined units (hereinafter referred to as "DU") by individual IPLP subgroups.

In case of the TP and MAG subgroups, in 2025, the consumption decreased, while in respect of the DPV and RF subgroups, consumption slightly increased in comparison to the previous period. The values specified for 2024 were updated as of 06 January 2026 and may slightly differ from the data originally published in the Annual Report for 2024. An overview of the consumption of individually prepared medicinal products in DU for the period of 2023 to 2025 is illustrated by Figure 7.

Figure 7 Overview of consumption of individually prepared medicinal products in the period of 2023–2025

in thous. DU



In 2025, expenses incurred for individual IPLP groups were influenced by the change to the minute overhead rate per one minute of time performance from the original value of 4.04 points to the value of 4.47 points in compliance with Decree No 347/2024 Coll., amending Decree No 134/1998 Coll., with effect from 01 January 2025.

In compliance with Decree No 314/2024 Coll., the point value changed from the original amount of 1.04 CZK per point to the new amount of 0.94 CZK per point in the RF group and to 0.96 CZK per point in the TP group At the same time, a legislative change arising from Government Regulation No 466/2024 Coll., amending Government Regulation No 341/2017 Coll. and Government Regulation No 304/2014 Coll., was reflected in the RF, DPV, and TP groups.

In 2025, new items from the RF group were placed on the IPLP List. With effect from 01 June 2025, radiopharmaceutical 131I Norcholesterol inj., code 0002079 (product (131I) IODOMETHYL NORCHOLESTEROL CIS BIO INTERNATIONAL (NORCHOL-131)) was included in a specific therapeutic programme until 31 October. With effect from 01 September 2025, the IPLP List was extended with radiopharmaceutical 18F-PSMA, code 0002120 (product PYL-CLARI), to be reported with procedure codes 47351, 47353, 47355, and 47357. In the TP group, Surcharge for test of WNV nucleic acid by direct detection, code 0407951 was added to the List with effect from 01 November 2025.

The distribution of expenses in the IPLP group in 2025 by individual subgroups is illustrated by Figure 8.

Figure 8 Distribution of total expenses in the IPLP group in 2025

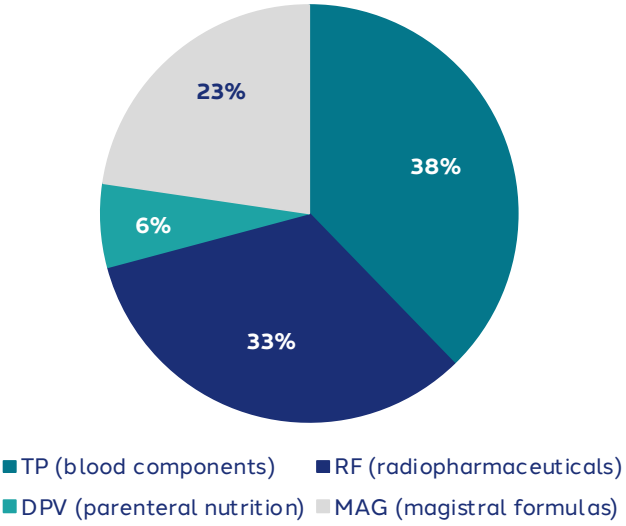
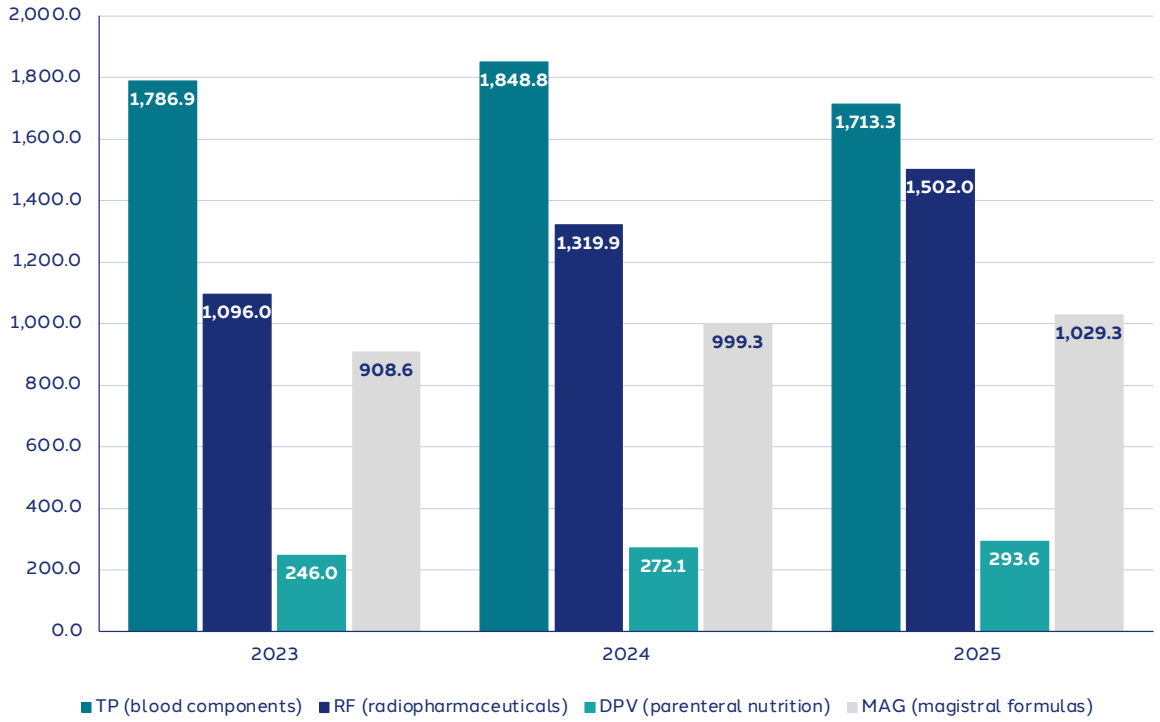


Figure 9 illustrates also a comparison of expenses for individual IPLP subgroups in the period of 2022-2025. A mild increase in the expenses incurred by the public health insurance funds was seen in the DPV, RF, and MAG subgroups; only the TP subgroup exhibited a decrease compared to 2024, which corresponds also to the lower consumption in this subgroup.

Figure 9 Comparison of expenses by IPLP group in the period of 2023–2025 in mil. CZK



The total expenses for the IPLP group reimbursed from public health insurance funds amounted to 4,440.1 mil. CZK in 2024; in 2025, they amounted to 4,538.2 mil. CZK, which represents an increase of expenses by 98.1 mil. CZK, i.e., by 2.21 % compared to 2024.

Involvement in European Health Technology Assessment

On the basis of Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment, a cooperation agreement in the assessment of medicinal products and medical devices was concluded on the EU level for the purposes to accelerate the entry of innovations onto the EU market and to prevent duplicities in work.

In 2025, 13 joint clinical assessment (JCA) procedures were held on the European platform. In all of them, in 2025, the Czech Republic was involved in the preparation of 13 national PICO frameworks (i.e., the determination of population, intervention, comparator, and outcomes relevant for the Czech Republic). A proper PICO definition is, at this stage, necessary for the set-up of the scope of the assessment and incorporation of national requirements for joint assessment. Patients and professional societies are also involved in the process of national PICO definition.

Table 37 Involvement in European Health Technology Assessment

Active substance	Indication	ATMP/ biological therapy	Orphan
Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Melanoma	ATMP	-
Tovorafenib	Low-grade glioma (LGG), paediatric population	-	Yes
Sasanlimab	Urinary bladder carcinoma	Biological therapy	-
Onasemnogene abeparvovec	Spinal muscular atrophy (SMA)	ATMP	Yes
Lurbinectedin	Small-cell lung carcinoma (ES-SCLC)	-	Yes
Camizestrant	Breast cancer	-	-
Tarlatamab	Small-cell lung carcinoma (ES-SCLC)	Biological therapy	Yes
Catequentinib	Synovial sarcoma; leiomyosarcoma	-	Yes
Senaparib	Epithelial carcinoma of the ovaries, fallopian tubes, or primary perito-neal carcinoma	-	-
Relacorilant	Epithelial carcinoma of the ovaries, fallopian tubes, or primary perito-neal carcinoma	-	Yes
Ensartinib	ALK-positive non-small cell lung carcinoma (ALK+ NSCLC)	-	-
Zopapogene imadenovec	Respiratory papillomatosis	ATMP	Yes
Sintilimab	Non-small cell lung carcinoma (NSCLC)	Biological therapy	-

Medicinal Product Shortage and Availability

In 2025, the Medicine Shortage and Availability Unit (DAN) continued to represent the Institute in activities set forth by the Act on Pharmaceuticals in areas of medicinal product monitoring and evaluation of availability. At the same time, the Unit was fully cooperating with the Ministry as the entity of primary responsibility for safeguarding medicinal products availability within the Czech Republic.

Market Report Administration – Mandatory Reports from Marketing Authorisation Holders on the Medicinal Product Placement on the Market and Suspension, Renewal or Termination of Supplies thereof as Referred to by the Provision of Section 33(2) of the Act on Pharmaceuticals

Marketing authorisation holders are obliged to report to the Institute the placement of a medicinal product onto the market in the Czech Republic as well as its suspended, renewed, or terminated supplies via an electronic application on the Institute's portal. Data from these reports are copied to the Database of Medicinal Products and presented in publicly available overviews. As a new feature, the system enables marketing authorisation holders to electronically amend previously submitted reports and all of the changes may be viewed by the public.

Market Report Statistics for 2025

In 2025, a total of 2,127 reports of suspended supplies of medicinal products were recorded as part of mandatory reporting. In 60 % of these cases, supplies were renewed during the same year. The termination of supplies was reported in 712 cases.

At the same time, 1,862 reports of renewed supplies and 964 reports of initiated supplies of medicinal products were recorded. Special attention was given to irreplaceable medicines. In this category, 104 reports of suspended supplies and 12 reports of terminated supplies were recorded.

In 2025, a significant, 55 % decrease in the number of submitted reports of suspended supplies was seen. This is associated with the generally improved situation on the market and with the new reporting system launched in late 2024, which no longer includes changes to supply renewal dates in the reported suspension counts.

Letters to Healthcare Professionals Concerning Medicinal Product Availability

Together with marketing authorisation holders, the Institute provides timely information on jeopardised medicinal product availability to professionals. One of the instruments for the dissemination of information provided in the Market Report are letters to healthcare professionals. In 2025, the Institute, with the involvement of marketing authorisation holders, assessed and published on its website the total of ten letters concerning medicinal product availability.

Addressing Medicinal Product Unavailability

Addressing Medicinal Product Shortages within the Institute

The current situation is being verified or addressed for each medicinal product individually.

Calls for Stock Level Reporting in Case of Suspected Jeopardy to Availability

This power, given to the Institute by the amended Act on Pharmaceuticals, has been exercised by the Institute since 2024. In 2025, the Institute issued calls regarding 21 SÚKL codes to marketing authorisation holders, 33 calls to distributors, and 25 calls to persons authorised to dispense medicinal products (namely pharmacies).

General Measures – Limited Availability

As of 01 June 2024, the Institute may flag a medicinal product with the "limited availability" flag and issue or cancel a general measure (OOP) under conditions stipulated by Sections 33b and 33c of the Act on Pharmaceuticals. The application of the "limited availability" flag implies a number of obligations for distributors and persons authorised to dispense medicinal products, particularly daily stock level reporting. Other obligations are also imposed upon the Institute and marketing authorisation holders.

In 2025, the Institute issued 186 general measures (in respect of 533 SÚKL codes flagged as "limited availability") and, during the same period, it revoked 139 general measures (the "limited availability" flag was removed from 337 SÚKL codes in total).

The "limited availability" flag is applied in a targeted manner and only within the framework stipulated by law. The DAN Unit analyses the relevance of the general measure on an ongoing basis following an internal methodology. In the long term, the number of included SÚKL codes has been ranging from 300 to 400, which indicates that the situation on the market is assessed dynamically.

Provision of Information about Medicinal Product Availability to the Ministry

In case of jeopardized availability of a medicinal product, the Ministry may temporarily adjust the conditions of its distribution, prescribing, and dispensing; this power is implied by Section 112c of the Act on Pharmaceuticals. In 2025, upon request of the latter, the Institute provided the Ministry with information about the availability of one medicinal product only (phenobarbital) and also with information on possible adjustment of the conditions of its distribution, prescribing, and dispensing, including a recommendation on the duration of such restriction. Throughout the year, the Institute was providing the Ministry with information about existing and potential shortages by means of written background materials for the Availability Working Group. Furthermore, the Institute was providing data analyses and proposed solutions of current cases to the Ministry. On the basis of an agreement, the Institute provided information to and held discussions with the concerned professional societies about the impact of suspended or terminated supplies.

Allowing for the Placement of a Foreign-Language Batch of a Medicinal Product on the Market in Order to Safeguard its Availability

Pursuant to Section 38 of the Act on Pharmaceuticals, the Institute, having regard to public health protection, may allow for the omission of certain data on the labelling and in the package leaflet of the concerned medicinal product; the Institute may also allow for the labelling and package leaflet to be partially or fully in a language other than Czech. When assessing such applications, the DAN Unit employees abide by the particulars stipulated by Section 3(6)(b) of Decree No 228/2008 Coll.

The amended Act on Pharmaceuticals now allows to file an application for import of a foreign-language batch also for medicinal products that may be dispensed without prescription, where serious availability problems arise. Nevertheless, in 2025, no such request was submitted to the Institute.

In 2025, the Institute issued the total of 304 decisions allowing for the placement of a foreign-language batch on the market, which copies the long-term trend in terms of the number of submitted applications and decisions issued by the Institute. The number of decided applications grew by 32 % compared to the previous year.

As part of a pilot project aimed at reducing administrative burden, the Institute has permitted to provide access to the package leaflet via a QR code instead of a paper copy. The pilot project was presented during a November seminar of the DAN Unit and thereafter, the information was published also on the Institute's website. At the end of the year, the first application for making use of this solution arrived.

Identifying the Possibilities of Individual Import of Non-Authorised Medicinal Products

Pursuant to the provision of Section 8(3) of the Act on Pharmaceuticals, the physician may prescribe or use a non-authorised medicinal product in cases when the authorised medicinal product is not available. The DAN Unit employees check the database referred to under Article 57 (EMA database, Regulation [EC] no. 726/2004 of the European Parliament and of the Council) for potential replacements of the medicinal products unavailable in the Czech Republic. The DAN Unit employees, moreover, use the regular market reports from distributors (guideline DIS-13) to see whether such medicinal products are imported to the Czech Republic, or, if applicable, they contact medicinal product distributors about possible import of non-authorised medicinal products.

In compliance with Section 77(1)(i) of the Act on Pharmaceuticals, and Section 46 of Decree No 229/2008 Coll., the DAN Unit assesses and issues approvals of import from third countries. In 2025, 209 approvals of import of non-authorised medicinal products from third countries were issued in total, which is 20 less than in the previous year.

Drafting of Opinions on Specific Therapeutic Programmes

Where the supply of a foreign-language presentation of a medicinal product cannot be organised and the Institute considers the product irreplaceable, the Ministry may authorise the Institute (within the meaning of the 51/2024/AMU Methodological Guidance Act – "Coordination of the activities of the Ministry of Health and SÚKL in addressing certain specific tasks in relation to safeguarding the availability of medicinal products important for the provision of health care services") to publish a communication about the emergency need and call for proposals of specific therapeutic programmes using non-authorised medicinal products for human use.

In compliance with Section 49 of the Act on Pharmaceuticals, and Section 2 of Decree No 228/2008 Coll., the DAN Unit prepares opinions on submitted proposals of specific therapeutic programmes using non-authorised medicinal products for human use (guideline UST-20), the purpose of which is the treatment, prophylaxis, or diagnosis of life-threatening conditions for a defined patient group.

On the basis of requests from the Ministry, the Institute drafts also opinions on special therapeutic programmes. In 2025, the Institute drafted opinions on 65 submitted applications for opinion on a specific therapeutic programme (of which seven were opinions on proposed special therapeutic programmes).

Processing of Expert Opinions on Emergency Measures Issued by the Ministry

On the basis of requests of the Ministry, in 2025, the Institute processed eight expert opinions on medicinal products for the purposes of issuance of emergency measures as per Section 8(6) of the Act on Pharmaceuticals, particularly in case of suspected or confirmed dissemination of pathological agents that could pose a major risk to public health.

Identifying the Possibility of Individual Preparation of Medicinal Products in Pharmacies

Individually prepared medicinal products (IPLPs) offer a way how to resolve a medicinal product availability problem on a temporary basis. Nevertheless, medicinal products prepared in this manner are not identical to authorised proprietary medicinal products. The DAN Unit employees consult such alternative options with pharmaceutical specialists.

Communication with the Public

Within the scope of their activities, the DAN Unit employees also address questions from professionals as well as from the general public concerning medicinal product availability and replaceability. In 2025, they answered more than 700 questions, mostly in writing.

Assessment of Medicinal Product Replaceability in Relation to the Activities of Other Institute's Units

The DAN Unit employees also assess medicinal product replaceability for the Quality Defects Unit and for the Marketing Authorisation Section. In 2025, the number of assessed requests increased by more than 20 %; specifically, this concerned 37 replaceability assessments for the Quality Defects Unit and 72 assessments of exemptions from the sunset clause for the Marketing Authorisation Section.

Preventive Measures Related to Restricted Re-export of Medicinal Products

In compliance with Section 77c of the Act on Pharmaceuticals, the Institute collects information on the volume of medicinal products on the market and on the volume of medicinal products dispensed in the provision of healthcare services from marketing authorisation holders, distributors, and pharmacies. The Institute assesses this information to see whether the quantities of irreplaceable medicinal products or of medicinal products mutually replaceable in terms of their therapeutic properties adequately meet the current needs of patients in the Czech Republic. Where the Institute arrives at a conclusion that the available stock level is no longer adequate, which could potentially jeopardize treatment of patients or affect the provision of healthcare services, it notifies the Ministry to this effect, providing also background materials on the basis of which the Institute arrived at this conclusion.

In case the Institute receives a report from a distributor as referred to under Section 77(1)(q) of the Act on Pharmaceuticals, concerning an intention to export a medicinal product placed on the list of medicinal products whose distribution abroad has to be reported by distributors to the Institute, the DAN Unit employees assess whether such distribution abroad would, in the coming period, cause a shortage of irreplaceable or mutually replaceable medicinal products for patients in the Czech Republic. In 2025, the Institute validated 2,538 applications from distributors intending to distribute listed products abroad, which is 7 % more than in the previous year. Should the export jeopardize treatment availability, the Institute would submit a motion to the Ministry for the issuance of a general measure as referred to under Section 77d of the Act on Pharmaceuticals, by means of which the distribution of the concerned medicinal product abroad can be prohibited.

In 2025, the DAN Unit availed of export regulation as a complement to other measures to ensure the restrictions were targeted and justified and to maintain the availability of medicinal products for patients in the Czech Republic. In total, 63 SÚKL codes were placed on the list and a similar number was also taken from the list in the course of the year. On SÚKL's instigation, export was prohibited for 40 SÚKL codes following

the assessment of more than 2,500 reports of intended export.

Inspection Activities of the Medicine Shortage and Availability Unit

The DAN Unit has two inspectors who, in 2025, focused upon compliance with all obligations concerning the availability of medicinal products imposed by the Act on Pharmaceuticals upon marketing authorisation holders, distributors, and operators authorised to dispense medicinal products. In 2025, the DAN inspectors carried out 21 inspections and 35 *ex-officio* investigations of regulated entities and addressed 22 received motions in total.

On the basis of shortcomings identified during the inspections and *ex-officio* investigations, grounds for the initiation of an administrative procedure concerning penalty imposition were handed over in respect of 51 entities, and 16 penalties became final through final decision. Most often, penalties were imposed for failure to report supplies to the market (REG-13), failure to supply a medicinal product with determined reimbursement from public health insurance or maximum price pursuant to Section 33a of the Act on Pharmaceuticals following suspended/terminated supplies, failure to report suspended/terminated supplies or late reporting, failure to report or incorrect reporting of stock levels, failure to safeguard supplies of a medicinal product with the "limited availability" flag on the list (limited-availability product) within two days of the receipt of the request ordering of limited-availability products in quantities higher than usual, and distribution/dispensing contrary to a general measure issued by the Ministry as referred to under Section 112 of the Act on Pharmaceuticals.

Preparation, Sharing, Communication, and Addressing of Availability on the European Level

In 2025, the Czech Republic was represented by the Institute in the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and the Single Point of Contact Working Party (SPOC WP), where the representatives of national agencies mutually share information on the availability of critical medicines and discuss adequate solutions. The Institute has been playing a significant role in negotiations concerning the supplies of medicinal products with limited availability on the European level, and, moreover, has substantially contributed to the development of methodology; on a continuous basis, it has been also involved in the compilation of the EU list of critical medicines.

Medical Devices

Medical Device Clinical Evaluation

On the basis of the obligation imposed upon the sponsors of clinical investigations on medical devices (hereinafter referred to as "CIMD") by Act No 375/2022 Coll. and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter referred to as the "MDR"), 44 individual applications for authorisation of CIMD conduct and 62 individual applications for modifications to CIMD conditions were submitted to the Institute in 2025 via the Registry of Medical Devices (RZPRO) Clinical Investigations module and via the Medical Device Information System (ISZP).

The number of applications for authorisation to conduct a clinical investigation remained practically unchanged, but the number of applications for authorisation

of clinical investigation modifications more than doubled compared to the previous year.

In compliance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter referred to as the "IVDR"), twelve applications for authorisation of the conduct of a performance study, 22 applications for authorisation of a modification of the conditions of a performance study, and eleven notifications of the conduct of a performance study were submitted.

Thirty-nine favourable decisions authorising the conduct of clinical investigation were issued; 14 procedures were stopped; and one application was declined.

Fifty-seven decisions authorising modifications to clinical investigations were issued; three procedures were stopped.

Twelve authorisations of the conduct of a performance study were issued and, at the same time, eleven notifications of the conduct of a performance study were assessed.

Seventeen decisions authorising modifications to the conditions of a performance study were issued; four procedures were stopped.

In respect of ongoing clinical investigations, 280 individual serious adverse event (SAE) reports were filed in total.

Within the scope of international cooperation in the sphere of clinical evaluations, in 2025, the representatives of the Medical Device Clinical Evaluation Unit (KHZP) attended regular (face-to-face as well as virtual) meetings of the WG on Clinical Investigation and Evaluation, Performance Studies Evaluation of the European Commission (hereinafter referred to as the "CIEPSE group"). A representative of the KHZP Unit was actively involved in the activities of two working groups under the CIEPSE group. The meetings focus upon the development, implementation, and uniform interpretation of implementing regulations and the European database of medicinal products (EUDAMED) that are associated with the MDR and IVDR. The KHZP Unit has been also involved in the project of coordinated assessment of applications for clinical investigations and performance studies on the EU level.

Medical Device Registration and Notification

In the course of 2025, the Registration and Notification Unit undertook preparations for the termination of its work in the area of medical device notification by manufacturers, authorised representatives, and importers, as this agenda was transferred to the EUDAMED database with effect from May 2026. As at 31 December 2025, this Unit was dissolved in line with government-approved systemisation. At the same time, it was, however, necessary to safeguard the operation of processes associated with full EUDAMED functionality, particularly the issuance of Free Sale Certificates (FSC), which are necessary for successful export activities of Czech manufacturers in third countries.

Medical Device Systems

In the course of 2025, the Systems Unit (SYS) safeguarded the development and support of information systems in the area of medical device regulation and, ***inter alia,*** also registration of persons in the RZPRO registry, in the ISZP system and in the EUDAMED database.

In the course of 2025, the Systems Unit focused upon further development and stabilisation of the ISZP system, particularly upon the adjustment of processes associated with the notification duty, in order

to be able to make use of data taken over from the European EUDAMED database. At the same time, works associated with the preparation of the mandatory launch of the electronic voucher (eVoucher) system were carried out and the production system was launched in January 2026.

In the RZPRO registry, a bulk renewal of medical device notification validity was performed. At the same time, process adjustments and optimisation took place in order to prepare for the mandatory launch of the EUDAMED database, scheduled for May 2026.

The Systems Unit was also involved in the organisation of seminars of the Medical Device Regulation Section which were held in compliance with the predefined schedule and focused upon systematic education of economic operators in the area of compliance with their statutory obligations pertaining to medical devices.

Expert Opinions

As of 01 January 2025, the original agenda of the Expert Opinion Unit, i.e., medical device assessment, was merged with the agenda of medical device assessment in the area of borderline products. The Unit is now in charge of the complete borderline agenda of the Institute.

Expert opinions are issued on the basis of requests for the issuance of an expert opinion received from external entities as well as on the basis of motions from other units of the Institute and in response to submitted applications for medical device notification in the RZPRO registry. Expert opinions are the outputs of product nature assessment, either with regard to the applicability of the MDR or IVDR to the product or in terms of the product compliance with the definition of a medicinal product. Expert opinions are also the outcome of medical device risk class classification assessment. In 2025, the Expert Opinion Unit issued 95 expert opinions concerning the nature of a product or medical device classification. Of the aforementioned number, 26 opinions were issued upon external request and 69 on request of other units of the Institute.

Medical Device Market Surveillance

Surveillance Activities

The Medical Device Control Unit (KON) safeguards the performance of surveillance over the medical device market. The controlled economic operators include healthcare service providers as well as manufacturers, importers, distributors, dispensing persons, and persons servicing medical devices.

The legislative framework of these surveillance activities in based upon the MDR, IVDR, and, moreover, Act No 375/2022 Coll., which governs the sphere of medical devices on the national level (Act No 375/2022 Coll.).

Surveillance activities include also the execution of surveillance pursuant to Act No 526/1990 Coll., on Prices, as amended, in respect of medical devices with regulated price, and, moreover, surveillance pursuant to Act No 634/1992 Coll., on Consumer Protection, as amended, in respect of medical device offers and sale to consumers.

The objective of both scheduled and ad hoc inspections carried out by the Institute is to ensure that medical devices supplied onto the market in the Czech Republic are safe and functional and that health care is provided using appropriate, safe, and effective medical devices in a manner preventing any damage to the health of users or patients, when used properly and for their intended purposes.

As at the end of 2025, 40,717 healthcare service providers, more than 5,000 distributors, importers and persons servicing medical devices were registered

in the Czech Republic. Furthermore, more than 1,800 medical device and IVD manufacturers are active on the Czech market.

In 2025, the inspectors of the Control Unit conducted the total of 226 inspections, they addressed 93 reports concerning medical device handling, and as part of other activities, they catered for more than 230 inquiries and consultations.

In 2025, the inspectors of the Control Unit attended regular meetings of the Post-Market Surveillance and Vigilance Working Group (PMSV) established under the Medical Device Coordination Group (MDCG). At the same time, they actively participated in the international EU4Health – JAMS 2.0 (signal detection and vigilance) grant project, within the scope of which they took part in five international inspections in the EU and performed four inspections with the participation of foreign inspectors in the Czech Republic.

A detailed overview of inspections of individual entities is provided in Table 38 and Table 39.

Table 38 Overview of inspections conducted in 2025

Total number of inspections	226
Number of inspections instigated by a motion	34
Number of inspected medical devices	976*
Number of forwarded proposals for administrative procedure initiation	72

Note: * Due to the fact that not all of the inspections have been concluded to date, this is a qualified estimate.

Table 39 Inspected entities

Entity	Number of inspections/controls
POS – providers	57
CEN – price control	30
DIS/DOV – distributors and importers	74
SER – persons servicing medical devices	27
VYD – persons dispensing medical devices	22
VYR – manufacturers	7
OS – consumer protection	9

Vigilance

On the basis of effective legislation of the Czech Republic, 1,787 serious incidents considered to be associated with the use of medical devices in the provision of healthcare services within the territory of the Czech Republic were reported to the Institute. In all of the cases, monitoring was initiated. Investigations into 1,704 serious incidents are carried out separately, while the remaining 83 serious incidents are subject to aggregate investigations.

The total number of received reports on safety corrective actions regarding medical devices from competent national authorities, manufacturers or their authorised representatives, distributors or importers, as applicable, amounted to 912. Of the total number of received reports, 450 concerned medical devices made available on the Czech market.

In 2025, 418 communications to medical device users – Field Safety Notices (FSN) were published via the RZPRO. FSNs are disseminated by the manufacturer, authorised representative or distributor in association with an adopted Field Safety Corrective Action (FSCA).

As part of monitoring of the implementation of a safety corrective action adopted by a Czech manufacturer, 13 reports for competent national authorities (NCAR), the European Commission, and the competent bodies of EU Member States were issued and disseminated via the EUDAMED 2 database.

On 10 January 2025, the provisions of Art. 1(1) and Art. 2(1) of Regulation (EU) 2024/1860 of the European Parliament and of the Council amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) came into effect. This Regulation introduces a new Article 10a, pursuant to which medical device manufacturers are obliged to inform competent authorities in a timely manner about planned interruption or discontinuation of supplies of selected devices, in respect of which it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States.

In 2025, the Institute received 47 reports of interruption or discontinuation of supplies of medical devices or in vitro diagnostic medical devices (IVDs). Of this number, 31 reports concerned termination of manufacture and 16 were reports of interruption of manufacture.

The investigations revealed that 26 reports affected the Czech Republic, and hence also impacted the Czech market, while for 21 reports, no such impact was detected. Of the reports affecting the Czech Republic, 16 cases of supply discontinuation and ten cases of supply interruption were noted. In the reports not affecting the Czech Republic, 15 cases of supply discontinuation and six cases of supply interruption were noted. In two cases, the Institute executed surveillance from the position of the coordinating competent authority.

In 2025, the Vigilance Unit inspectors also regularly attended the meetings of the PMSV as well as the meetings of a working group of the JAMS 2.0 international grant project, and teleconferences focusing upon the exchange of information among EU Member States on current vigilance cases and further course of action to be taken in their resolving.

Medical Device Reimbursement

The medical device reimbursement regulation system has been based on the principle of notification by the manufacturer or their authorised representative. Decisions on the inclusion of specific medical devices into particular reimbursement groups are primarily not taken via administrative procedures. Notifiers themselves notify the Institute of their medical device, which may result in a new inclusion of the medical device, change of or removal thereof from the reimbursement group, or exclusion from the reimbursement system. These facts have a direct impact upon the amount of the device reimbursement from the public health insurance funds and out-of-pocket payment for the patient, as applicable. Notifications, which are filed via the ISZP system, may be submitted at any time, without any time limitations. In 2025, the reimbursement limits for individual reimbursement groups were stipulated by the Act on Public Health Insurance.

In case a notification of a medical device inclusion in an improper reimbursement group is received, the Institute initiates an administrative procedure regarding non-inclusion in the reimbursement group. In respect of previously reimbursed medical devices, the Institute may, in situations

specified by law, initiate an *ex-officio* procedure regarding exclusion of the medical device from the reimbursement group.

An important part of the Medical Device Reimbursement Unit's operation is the agenda of the year-to-year producer price increase. The processes were implemented in compliance with Price Regulation 1/2024/OLZP of the Ministry of Health of 25 October 2023, on the regulation of prices of medical devices and *in vitro* diagnostic medical devices. The main output of the Medical Device Reimbursement Unit's operation is the process of issuing the list of all medical devices reimbursed on prescription voucher (hereinafter referred to as the "Medical Device List"). This is the primary price and reimbursement index for medical devices provided on prescription voucher and reimbursed from the public health insurance funds. The Medical Device List is published on a monthly basis via the Institute's electronic noticeboard, and it is also available in machine-readable formats in the public section of the ISZP system.

As at 31 December 2025, the Medical Device List contained the total of 12,777 reimbursement codes.

Table 40 Notifications submitted to the Reimbursements module of the ISZP system in 2025

Reimbursement notifications	Number
Total	**5,582**
Medical device inclusion in a reimbursement group	1,076
Change to medical device inclusion in a reimbursement group	6
Other changes	1,184
Year-to-year producer price increases	2,570
Removal of medical device from a reimbursement group	746

Table 41 Overview of administrative procedures in 2025

	Number
Conducted	87
Concluded	85

Legislative Activities in the Area of Medical Devices

In 2025, the Medical Device Legal Support Unit (PPZ) continued its legislative activities in the area of medical device legal framework. Initial rounds of discussions on the proposed legislation governing categorisation and reimbursement regulation of separately charged material took place. To date, the regulation of separately charged material reimbursement was governed only by the methodology issued by the General Health Insurance Company (VZP), but in the future, this will become part of the Act on Public Health Insurance. Furthermore, works on the preparation of amendment to Act No 375/2022 Coll., were carried out to reflect the new Article 10a of the MDR and IVDR, introducing a uniform system of anticipated medical device supply interruption or discontinuation reporting by manufacturers. Furthermore, suggestions from professionals concerning

the upcoming revision of Act No 375/2022 Coll. were collected and evaluated. Furthermore, the PPZ Unit was involved in the currently prepared amendment to Act No 40/1995 Coll., on Advertising Regulation, and it also prepared an accompanying amendment to the aforementioned Act within the scope of the newly proposed act on substances of human origin.

Penalties in the Sphere of Pharmaceuticals and Medical Devices

Penalties in the Sphere of Pharmaceuticals

In 2025, the Institute initiated administrative procedures concerning offences falling within the scope of its powers particularly on the basis of its own control and inspection activities. These were carried out in accordance with the Institute's control plan as well as on the basis of reports from individuals and legal entities. Another reason for initiating a procedure were cases forwarded or referred to the Institute by the Czech Police or other administrative authorities of the Czech Republic. As part of the conducted administrative procedures, the Institute was imposing measures and penalties that may be imposed thereby on the basis of effective legislation, in particular, monetary fines or administrative admonitions, as well as measures constituting of confiscation or forfeiture of things used in committing the offence. Even in 2025, the Institute continued to penalise systematic failure to enter medicinal products in stock, receipts and dispensing in pharmacies that were withdrawing the concerned medicinal products from the official distribution chain in this manner. The Institute has been disclosing such conduct during its controls for several years now, and considers it highly harmful for the society, as it may have direct negative impact upon the availability of medicinal products in the Czech Republic.

For this reason, the Institute, in cooperation with the Ministry, initiated an amendment to the Act on Pharmaceuticals, pursuant to which the upper limit of fines for such conduct has been increased from 2 to 20,000,000 CZK as of 23 August 2024. Such conduct may be, moreover, penalised by a ban on operation for the period of up to two years. In 2025, 25 final penalties were imposed for this conduct amounting to the total of 33,995,000 CZK, including the to date highest imposed penalty for this conduct in the amount of 17,000,000 CZK. Immediately after the increase of the maximum fine limit for this type of offence, the Institute noticed a relatively new phenomenon in procedures concerning these offences, where the offenders – business companies initiated complicated company transformations, resulting in the administrative procedure being held with several parties to the procedure at the same time. As a result, the Institute's decision-making practice has seen more and more procedures where the fine is imposed both upon the offenders and their legal successors. From 2021 until the end of 2025, the Institute imposed a fine for systematic withdrawal of medicinal products from the pharmacy stock levels in 70 cases in total.

Overall, in 2025, the Institute imposed the total of five admonitions and 169 fines in the total amount of 48,576,024.96 CZK for offences concerning human tissues and cells (Tables 42 and 43 refer). Most often, the penalties were imposed for breaches of the Act on Pharmaceuticals (125 fines and two admonitions), the Act on Prices (eleven fines and two admonitions), the Act on Advertising Regulation (22 fines), the Code of Control Procedure (four fines), and the Act on Dependency-Producing Substances (six fines). For breaches of the Act on Public Health Insurance, one fine and one admonition were imposed. As part of penalties for breaches of the Act on Pharmaceuticals, *inter alia,* 61 penalties were imposed upon pharmacy operators, most often for failure to enter medicinal products

in the pharmacy records, for breach of Good Pharmacy Practice rules, and for dispensing of recalled medicinal products; nine penalties were imposed upon distributors, most often for failure to provide reports on the volumes of distributed medicinal products, for breach of Good Distribution Practice rules, and for failure to notify of the intention to distribute a listed medicinal product abroad. Furthermore, twelve penalties were imposed upon vendors of selected medicinal products, most often for the sale of selected medicinal products by a person who had not completed the training required by the Act on Pharmaceuticals; and 26 penalties were imposed for illegal handling, offering, and sale of medicinal products, typically upon individuals offering medicinal products for sale on the internet.

Furthermore, in 2025, the first decisions associated with the new legislation aimed at safeguarding the availability of medicines (e.g., the "limited availability" flag) became final, specifically, 15 finally imposed penalties, three of them imposed upon pharmacy operators, four upon distributors, and eight upon marketing authorisation holders for the medicinal products.

Table 42 Amounts of finally imposed penalties in the area of pharmaceuticals in the period of 2021–2025 (in thous. CZK)

Year	2021	2022	2023	2024	2025
Total	**65,733**	**39,303**	**38,222**	**36,381**	**48,576**
Act on Pharmaceuticals	62,237	26,757	29,674	29,329	39,238
Act on o Dependency-Producing Substances	160	60	145	90	65
Act on Prices	872	9,141	238	772	3,013
Act on Advertising Regulation	1,330	2,370	5,970	5,040	5,940
Act on Public Health Insurance	374	0	95	50	0
Code of Control Procedure	760	930	2,100	1,100	320

Table 43 Number of finally imposed penalties in the area of pharmaceuticals in the period of 2021–2025

Year	2021	2022	2023	2024	2025
Total	**256**	**196**	**182**	**178**	**174**
Act on Pharmaceuticals	178	138	125	123	127
Act on o Dependency-Producing Substances	18	11	7	6	6
Act on Prices	32	19	13	20	13
Act on Advertising Regulation	13	13	19	19	22
Act on Public Health Insurance	7	1	2	2	2
Code of Control Procedure	8	10	16	8	4

Administrative Procedures and Penalties in the Sphere of Medical devices

The Institute, as the first-instance administrative authority, conducts administrative procedures regarding offences in the area of medical devices and IVDs, particularly with reference to the inspection activities carried out at entities subjected to the surveillance. In 2025, the Institute imposed fines

amounting to the total of 5,261,000 CZK, issued 41 orders and five decisions, and the PPZ Unit received the total of 22 appeals which were forwarded to the appellate body, i.e., the Ministry of Health. The highest proportion of fines were fines imposed upon medical device distributors and healthcare service providers and fines for the breach of the Act on Advertising Regulation.

The Institute, moreover, decides on granting exemptions upon request lodged by the manufacturer, authorised representative, or importer, for placement on the market, into operation or use of a specific device within the territory of the Czech Republic in case the conformity assessment procedures stipulated by the MDR or IVDR were not carried out for the device and if the use of such device is in the interest of public health protection or the safety or health of patients. In 2025, the stable trend in received applications continued; specifically, nine applications were submitted, and it may be summarised that this procedure is used rather commonly, with positive feedback and without any appeals filed.

Processing and Provision of Information

Information Technologies

For the Information Technology Department, 2025 was marked by cybersecurity enhancement and modernisation of infrastructure elements that are necessary for reliable and secure operation of the Institute's systems. Key activities concerned both the area of technologies and the area of employee education to ensure complex protection from the growing security risks.

National Recovery Plan Project – Enhancing Cybersecurity

In 2025, the Institute continued to implement a project funded by the National Recovery Plan (NPO) aimed at pronounced enhancement of system and infrastructure cybersecurity. Within the scope of the project, selected security features were upgraded, security incident monitoring was extended, some incident detection processes were automated, and back-up and recovery mechanisms were enhanced.

The project much contributes to the development of a more robust and resilient infrastructure and its outputs closely reflect the current legislative requirements as well as recommendations in the area of IT security.

Education in the Sphere of Cybersecurity

As part of a project focused upon the enhancement of cybersecurity, the implementation of an extensive educational programme aimed at increasing the awareness of security risks and proper procedures when working with information technologies was initiated in 2025. The programme is structured to accommodate various user levels, from basic user training through specialised courses for administrators. It focuses primarily upon practical security situations, phishing attack prevention, sensitive data handling, and secure use of advanced technologies.

The implementation of the programme was commenced in 2025 and it will continue also in 2026. The trainings that took place in 2025 outside the scope of this project (such as events concentrating on general cybernetic threats) were separate in terms of their organisation and content and they do not form part of the aforementioned programme.

The initiated educational programme is an important element for the Institute's security culture development, and, once completed, it will contribute to further strengthening of the organisation's ability to prevent security incidents and to respond to such incidents adequately.

End Station Protection

In 2025, the Institute strived to significantly strengthen the protection of computers and notebooks used by the employees in their everyday work. These stations may become the target of attacks, and for this reason, their protection is one of the main elements of general cybersecurity. The existing security method was no longer adequate to the current types of threats that tend to appear more and more often in the form of fraudulent e-mails, malicious attachments or new types of malware.

For this reason, the deployment of advanced security solution was initiated; this solution is able to monitor suspicious computer behaviour and to provide a timely alert of an attempted attack. The system is able to detect malicious activities that would be difficult to recognize for a common antivirus program, and, at the same time, it helps to quickly determine the way the incident arose and what steps are needed to resolve it. The newly deployed technologies also reduce the risk of computer abuse, e.g., for dissemination of further attacks.

The modernisation, moreover, included a mass update of computers to the Windows 11 operating system. This step contributed to a higher security standard, unification of working procedures, and ensuring long-term technical support. The update was finalised in most machines; at several specialised workplaces it will take place with regard to the special software used thereby.

These measures collectively resulted in a significantly enhanced end-station protection and increased general security of the systems operated in the Institute. Furthermore, they respond to the long-term trend of growing cybernetic threats and support stable and secure operation of advanced information technologies.

Security Perimeter and Firewall Feature Upgrades

Within the scope of the activities carried out by the Information Technology Department, the Institute in 2025 implemented an extensive upgrade of the security perimeter aimed at strengthening the protection of key information systems and safeguarding their long-term stable and secure operation. The security perimeter is the essential protection layer between the Institute's internal network and the outer environment and its technical condition has a principal impact on the organisation's ability to face current cybernetic threats as well as operational risks.

An important part of this upgrade was a complete replacement of firewall elements that form the key perimeter protection component. The existing equipment was approaching the end of its service life and was no longer adequate to the current requirements regarding performance, reliability or security level. The newly deployed technologies cater for a more advanced network operation control, more effective security rule management, and timely detection of potential security incidents. The implementation included, moreover, migration and revision of existing configurations, introduction of high availability of key elements and their incorporation in the central monitoring and security surveillance system.

The security perimeter upgrade was implemented in association with a project funded from the NPO that focused upon the overall enhancement of cybersecurity of the Institute's information infrastructure as part of the project preparation, detailed documentation describing the as-is perimeter technology and defining the to-be technical and organisational requirements was drawn down. Emphasis was placed upon maintaining smooth operation without scheduled outages and upon compliance with internal security rules and effective standards.

The implemented measures provided an enhanced standard of protection from advanced cybernetic threats, improved overview of the network operation, and quicker response to suspicious activities. At the same time, the stability and performance reserves of the network infrastructure were increased and audit and security surveillance options were improved. The security perimeter and associated firewall feature upgrade hence significantly contributed to the fulfilment of the Institute's strategic objectives in the sphere of cybernetic security and to safeguarding reliable operation of its electronic services.

Along with cybersecurity enhancement, the development and deployment of new information systems and their advancement continued also in 2025.

In mid-2025, a new API (HZv2) version was deployed for information on quality defects of pharmaceuticals. The new version was developed with the aim to provide more detailed and accurate information on quality defects of pharmaceuticals to pharmacists and distributors.

In late 2025, the log-in options for some of the electronic forms were extended with log-in via citizen identity. This step contributed to the availability of identification and signing of electronic submissions without the need to have an electronic signature.

In 2025, we managed to complete the prepared information system for administrative procedures regarding prices and reimbursements (ASTERx) and to launch its pilot version.

As part of the system for work with marketing authorisation dossiers (Lorenz eCTD), an adjustment for dossiers submitted via Grouping and Worksharing was implemented. This adjustment simplified and increased the effectiveness of the process of received marketing authorisation dossier processing and assessment.

In the second half of the year, preparations for a new economic system (JASU) were under way to ensure that it was ready for productive launch on 01 January 2026. This system provides for the automation of activities concerning the circulation of accounting documents and it is fully compliant with the legislation governing accounting in state organisations.

ePrescription

Since 01 January 2018, the ePrescription system has been operated in the mode of mandatory electronic prescription. Throughout 2025, as well as in the previous years, its operation was not hindered by any major problems. Health insurance companies routinely download batches of ePrescriptions and eVouchers for their insureds, which provides the former with a complete overview of dispensing. Since the launch of the mandatory electronic prescription, applications for patients and healthcare professionals have been also made available.

In 2025, the electronic delivery of the ePrescription identifier – via SMS or e-mail messages – amounted to approx. 60.6 million SMS messages and more than 987 thousand e-mail messages. The number of eVoucher identifier deliveries via SMS messages exceeded one million and almost 150 thousand e-mail messages were sent.

Since the launch of the electronic prescription, the https://epreskripce.gov.cz/ website is being continuously updated.

In 2025, almost 86 million ePrescriptions were issued and more than 85 million were dispensed. In 2025, the borderline of 600 million ePrescriptions issued since the start of mandatory electronic prescription was overcome. The ePrescription system has become an indispensable instrument in the area of healthcare service provision.

As of 31 December 2025, 51,227 doctors, 18,550 healthcare facilities, 8,778 pharmacists, and 2,773 pharmacies were actively involved. The numbers of active entities and healthcare professionals are stable and reflect only common changes in the sector, i.e., retiring individuals, arrivals of new graduates, establishment or dissolution of healthcare service providers.

On the basis of Act No 89/2021 Coll., on Medical Devices, and in compliance with Communication No 54/2022 Coll., on the launch of the central repository of electronic vouchers, as at 01 May 2023, the electronisation of prescription vouchers for medical devices (eVouchers) was launched as one of the ePrescription system components. The registration of eVouchers was not mandatory until 31 December 2025.

In 2025, the non-mandatory operation was evaluated and on the basis thereof, minor adjustments to the system were made and, as of 01 January 2026, it was transferred to the mandatory mode.

In 2025, almost 1,685 thousand eVouchers were issued; the number of prescribers was

close to 15 thousand and the number of dispensing persons exceeded 10 thousand.

Since as early as 2018, SÚKL has been involved in the Deployment of Cross Border Services in the Czech Republic (ePrescription/eDispensation) NIX-ZD.CZ II. project, where the main project partner is the Vysočina Region. The NIX-ZD.CZ II project focuses upon cross-border exchange of ePrescriptions and information about dispensed medicinal products, which, as a result, offers increased safety and quality of provided health care and patient comfort.

In 2025, production operation with Croatia, Estonia, Finland, Greece, Latvia, Lithuania, Poland, Portugal, and Spain was carried out. In these countries, 1,170 Czech ePrescriptions were dispensed in the course of 2025. Step-by-step extension to other EU countries is planned in the coming years.

As of 01 January 2025, the task of insureds' out-of-pocket payment limit determination and record-keeping was transferred from health insurance companies to the Institute on the basis of an amendment to the Act on Public Health Insurance and Act on Pharmaceuticals. For this reason, intensive preparation of the new module for eligible out-of-pocket payment record-keeping in the ePrescription system begun as early as in 2024. Since 2025, the only binding data on the insured's limit utilisation has been kept in the ePrescription system.

Eligible out-of-pocket payments are recorded in the ePrescription system within the Central Repository of Out-of-Pocket Payment Limits (CÚLD). The moment when the patient/insured exceeds the limit, is evaluated in real time in the ePrescription system. When dispensing or downloading the identifier of a dispensed ePrescription, the pharmacies always get the information about the remaining limit amount of the insured. The out-of-pocket payments not paid by the patient in the pharmacy (due to exceeded limit) are charged by the pharmacy to the insurance company. The data source for the set-up of the protective limit amount is primarily the Central Registry of Insureds administered by the General Health Insurance Company of the Czech Republic (VZP). Other sources are the Czech Social Security Administration (CSSA), which provides the ePrescription system with information on insureds granted grade 2 and 3 disability status, and so-called "power" ministries (the Ministry of Interior, Ministry of Justice, and Ministry of Defence) that administer their own registries of insureds granted grade 2 and 3 disability status.

The new eligible out-of-pocket payment record-keeping system via the ePrescription system eliminates redundant financial flows (when the patients paid the full amount even if they had exceeded the protective limit and then they waited for settlement and refund from the health insurance company). At the same time, the ePrescription system gives any patient/insured the possibility to monitor their protective limit and its utilisation via the ePrescription application. In 2025, almost 1.4 million insureds reached their protective limit. Their savings amounted to more than 2.25 billion CZK.

On the basis of amendment (no. 12/2025 Coll., with effect from 01 April 2025) to Decree No 236/2015 Coll., on the conditions for the prescribing, preparation, distribution, dispensing, and use of individually prepared medicinal products containing medical cannabis, as amended, the limit for prescribed medical cannabis was changed to 3 months and the maximum of 540 g (90 g reimbursed by the health insurance company). Since 01 April 2025, it is hence possible to prescribe medical cannabis for up to 90 days. Cannabis may be dispensed in quantities remaining to the limit after deduction of previous dispensing over the last 90 days. The monitored period is the 90 days during which actual dispensing

is recorded in the Registry of Restricted Medicinal Products (RLPO). The logic of entries into the RLPO, calculation, and control remains unchanged. Only the amount and the monitored period have been tripled. At the same time, the number of prescribed material codes was reduced to mere two, one for dry matter and one for the extract. As a new feature, medical cannabis may be prescribed also by medical specialties 001 and 002, i.e., the general practitioners for adults and paediatricians.

The importance of the ePrescription system may be evidenced also by numerous awards gained thereby since 2018. In 2022, ePrescription was pronounced the most beneficial project in the sphere of eHealth and digitisation of Czech health care and won an award of the INMED conference organised by EEZY Publishing, s. r. o. In 2023, the "The National eHealth Point of Contact – Cross-border ePrescription and eDispensing" came 3rd in the "Egovernment The Best" competition.

Database of Medicinal Products and Monitoring of Supplies to Pharmacies

On the basis of the obligation set forth by the Act on Pharmaceuticals, the Institute keeps a registry of authorised medicinal products and arranges for the publication of selected information in its information media. For the purposes of this registry, an internal database of medicinal products (DLP) is used; this database is updated on an ongoing basis. The mandatory disclosure information from DLP is displayed in the database of medicinal products available on the Institute's website.

Registry of Active Substances

At present, the DLP Component Library contains 21,076 components (incl. combined components). In 2025, 84 new components were entered.

In 2025, the flagging of components as prohibited substances in terms of doping and flagging of products containing such substances was updated in compliance with "The 2025 Prohibited List – The World Anti-Doping Code", effective as of 01 January 2025. Thereafter, flagging was carried out on a weekly basis and a list of all authorised medicinal products with doping components was being sent to the Czech Antidoping Committee on a monthly basis.

Furthermore, new components were entered and components were amended as per Czech Pharmacopoeia 2023 – Supplement 2025 and as per European Pharmacopoeia – Supplements 11.7 and 11.8. Components from the Proposed and Recommended INN WHO lists issued in 2025 were also entered or amended.

Registry of Medicinal Products

In 2025, the Institute granted 559 marketing authorisations (3,627 SÚKL codes). Authorisation was revoked for 368 marketing authorisation numbers, which corresponds to 3,525 SÚKL codes. The authorisation was revoked either upon request of the marketing authorisation holder (79 marketing authorisation numbers), or due to the fact that the marketing authorisation holder did not apply for marketing authorisation renewal (24 marketing authorisation numbers). The validity of 3,182 SÚKL codes in total expired (the period of the code final sale expired or marketing authorisation was revoked).

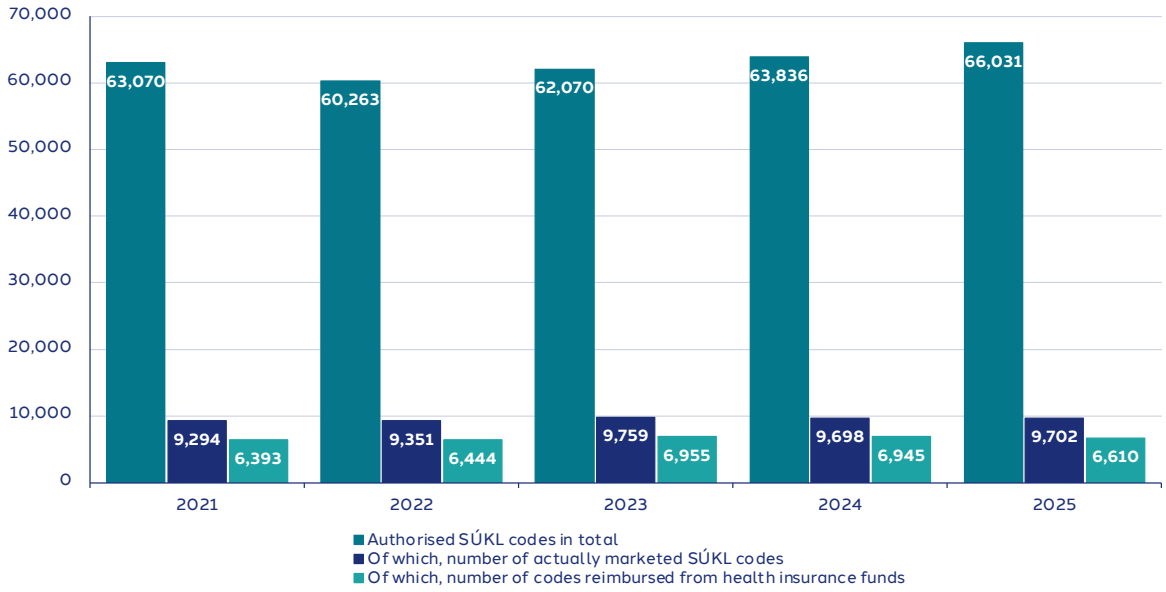
Authorised medicinal products contain 2,756 various active substances in total.

In the course of 2025, no distribution was reported for 56,329 SÚKL codes (85.3 %) of medicinal products, excluding homeopathic preparations. Hence despite having a valid marketing authorisation, these products were not being placed on the market.

Table 44 Selected subgroups of authorised medicinal products entered in SÚKL's database as of 31 December 2025

	Total no. of MA numbers / marketed MA numbers	Total no. of SÚKL codes / marketed SÚKL codes
Medicinal products in total (excl. homeo--pathic preparations)	20,008/6,600	66,031/9,702
Of which by MA numbers		
MA numbers granted by the Institute	6,839/4,809	52,795/7,408
MA numbers of products authorised via Central-ised Procedure	13,169/1,790	13,220/1,803
Of which by content		
Single-component	16,329	54,155
Multi-component	3,681	11,870
Of which by type of dispensing		
Prescription-only medicinal products	19,192/5,957	62,216/8,191
OTC medicinal products	887/665	3,785/1,026
Restricted OTC medicinal products	4/3	12/3
Restricted prescription-only medicinal products	4/3	17/3
Homeopathic preparations	282/278	835/361

Figure 10 Authorised medicinal products in the period of 2021–2025



Regular Outputs from the Database of Medicinal Products

For professionals as well as for the general public, the Institute regularly publishes information about authorised medicinal products, approved specific therapeutic programmes, and foods for special medical purposes with allocated SÚKL codes, providing all details in the database of authorised medicinal products.

PROCESSING AND PROVISION OF INFORMATION

Since 2008, the Institute has been publishing the "List of Prices and Reimbursements of Medicinal Products and Foods for Special Medical Purposes", including updates thereof, on its website. In 2010, the system of so-called "Control List" publication was established. The List notifies professionals in advance of possible changes to maximum prices and reimbursements implied by final decisions. In 2011, the title "Control List" was changed to "Draft List" in compliance with Act No. 298/2011 Coll.

Information from the database is, moreover, utilised for the market report overview (reports on placements on the market or suspension or termination of supplies of medicinal products onto the market) as well as for the overview of non-interventional post-marketing studies.

Evaluation of Deliveries of Distributed Medicinal Products

In 2025, evaluation of deliveries of distributed medicinal products based upon the mandatory reporting from entities authorised to distribute medicinal products in the Czech Republic was conducted on a monthly basis. The subject-matter of the reports were deliveries of medicinal products to pharmacies and to other healthcare facilities both in the Czech Republic and abroad. In addition to authorised medicinal products, products included in specific therapeutic programmes and non-authorised products supplied on medical prescription for a specific patient were also being evaluated.

Data on the volumes of distributed medicinal products in the number of packages, in financial volumes (CZK), and in the number of daily defined doses (DDD) were being evaluated. Due to the need to compare the financial cost values over the years, data on financial costs are provided in producer prices, i.e., in ex-factory prices excl. VAT (VAT rates were changing over the years), and excl. profit margin. Since 2020, the Institute has been receiving data about the price of a medicinal product only for medicinal products in respect of which reimbursement from the public health insurance funds has been determined. Since 2008, the Institute's website contains a table showing deliveries for each individual active substance (further broken down by route of administration, where applicable). Furthermore, on a monthly basis, the Institute publishes also summary information from monthly reports of entities authorised to distribute medicinal products in the Czech Republic on its website.

In 2025, 267.61 million packages of medicinal products were distributed, which corresponds to approx. 7,945.96 mil. DDDs. The value of these deliveries amounted to 104 billion CZK (based on ex-factory prices).

Figure 11 Deliveries of medicinal products in the period of 2021–2025

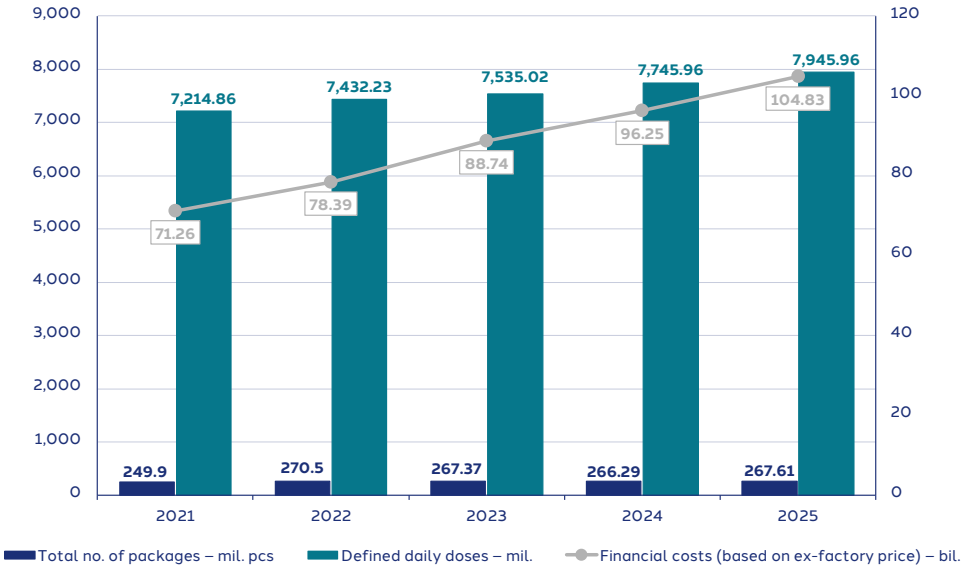


Table 45 Deliveries of distributed medicinal products in 2025

	Number
Medicinal products in total	
Deliveries to pharmacies and healthcare facilities (mil. packages)	267.608
Deliveries to pharmacies and healthcare facilities (mil. CZK based on ex-factory price)	104,826.16
Deliveries to pharmacies and healthcare facilities (mil. DDD)	7,945.96
DDD/1,000 inhabitants/day	1,991.74
Prescription-only medicinal products	
Deliveries to pharmacies and healthcare facilities (mil. packages)	186.356
Deliveries to pharmacies and healthcare facilities (mil. CZK based on ex-factory price)	104,590.61
Deliveries to pharmacies and healthcare facilities (mil. DDD)	7,320.17
DDD/1,000 inhabitants/day	1,834.88
OTCs and selected pharmaceuticals	
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuti-cals (mil. packages)	80.927
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuti-cals (mil. CZK based on ex-factory price)	235.544
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuti-cals (mil. DDD)	625.79
DDD/1,000 inhabitants/day	156.861
Restricted OTCs	
Deliveries to pharmacies and healthcare facilities (mil. packages)	0.324
Homeopathic preparations	
Deliveries to pharmacies (mil. packages)	1.91

Information Activities

Most of the information activities are catered for by the Communications and Director Support Unit in cooperation with other units across the Institute. Major administered information channels are following sources.

Websites

The most commonly employed channel for the communication of expert information is the Institute's website. It informs about the activities of the Institute and also shares data intended for professionals. Since late 2024, the website is available in a new version compliant with the uniform gov.cz system graphic design used by state institutions. The website reflects the needs of various user groups – patients, healthcare professionals or representatives of pharmaceutical companies and industry.

In 2025, further development took place and access to information for individual user groups was made easier.

Social Media

The Institute uses Facebook, Instagram, and LinkedIn to reach out to the general

public and to communicate current topics, calls, and notices. These social media were used, *inter alia,* for the presentation of the international "MedSafety Week" campaign or a campaign focused upon safe use of medicines called "Medicines Are Not Candies", which was initiated and prepared in cooperation with EMA.

Expert Library

The information agenda of the Institute includes also the administration of the expert library and publications activities, specifically the preparation and publication of the monthly "Bulletin" ("Věstník"), quarterly publication of the "Adverse Drug Reactions Newsletter" ("Informační zpravodaj – Nežádoucí účinky léčiv"), and publication of eleven issues of the "Pharmacotherapeutic Information" ("Farmakoterapeutické informace") per year, a bulletin belonging to the group of the International Society of Drug Bulletins (ISDB). All of the aforementioned publications are available in electronic format from the Institute's website at sukl.gov.cz. Pharmacotherapeutic Information is also published in printed format as a magazine supplement of the Časopis českých lékárníků (Journal of Czech Pharmacists) and Zdravotnictví a medicína (Healthcare and Medicine).

Expert Seminars and Lectures

Seminars and lectures form an important part of expert information provision. In 2025, 67 requested lectures for commercial entities and healthcare facilities took place. Furthermore, the Institute organised 19 expert seminars in total (eleven less than in 2024) attended – either face-to-face or via online connection – by 3,968 professionals (almost 25 % more than in 2024, when seminars were attended by 3,017 professionals) who gained a certificate of completion of the expert seminar. The increased attendance was primarily due to the frequent use of a hybrid form of the seminar.

Thanks to the REENIO application, attendees can comfortably reserve their place online. The reservation system enables electronic check-in on the basis of reservation confirmation containing a QR code, a method currently used for all seminars.

In 2025, all Sections of the Institute contributed to the organisation of seminars, particularly the Marketing Authorisation Section and the Medical Device Regulation Section.

Table 46 Number of organised seminars by sections in 2025

Section	Number of seminars
Pricing and Reimbursement Regulation	1
Surveillance	2
Marketing Authorisation	8
Director	2
Business Operation	1
Medical Device Regulation	5
Total	**19**

Figure 12 Number of seminars in the period of 2021–2025

PROCESSING AND PROVISION OF INFORMATION

Inquiries

This agenda includes responding to inquiries from media, arriving at e-mail box tiskove@sukl.gov.cz, as well as to inquiries from the general public and professionals, submitted to e-mail box infs@sukl.gov.cz, via data mailbox or via post. In 2025, the number of answered inquiries from the general public and professionals amounted to 3,114; the telephone info line handled 2,009 inquiries. In total, 279 media inquiries were answered in writing and tens of other inquiries were handled by phone.

In addition to the aforementioned, the Institute organised two workshops for media, separate press conferences or joint press conferences with the Ministry and it published or shared 20 press releases in total. The representatives of the Institute provided dozens of statements for television or radio broadcasting.

ePrescription Media Information Campaign

In the first half of 2025, a media information campaign presenting the ePrescription took place, introducing its mobile and web applications and its important component – the Medication Record. The campaign reached out both to the general public and professionals. It aimed at promoting the installation and use of the ePrescription application as the primary source for the hand-over of the electronic medicinal product prescription identifier. Last but not least, it intended to reduce the number of electronic prescriptions sent via SMS messages. Within the scope of the television campaign, three various TV spots reaching 170 TRP were broadcasted. Using 1,100 LCD screens in doctor's waiting rooms, 358 spots in three various versions were shown; 302 size B1 posters were put up in healthcare facilities; and eleven advertisements were published in specialised medical periodicals. On-line advertising achieved 12,437,140 impressions.

Information Disclosure Pursuant to Act No 106/1999 Coll., on Free Access to Information

Annual Report on Information Disclosure pursuant to Section 18 of Act No 106/1999 Coll., on Free Access to Information, as amended (hereinafter referred to as the "Act on Free Access to Information")

Paragraph 1(a)

In 2025, the State Institute for Drug Control received 165 requests for information submitted in compliance with the Act on Free Access to Information. In 25 cases, a decision declining the request was issued, and in 15 cases, a decision declining some part of the request was issued.

Paragraph 1(b)

In five cases, an appeal against the decision declining the request was filed.

Paragraph 1(c)

Three court procedures regarding the Institute's decisions pertaining to information disclosure pursuant to the Act on Free Access to Information were held. All of the procedures were initiated by the same applicant concerning similar matters. The Ministry, as the appellate body, was party to all of the court hearings.

Substantial excerpts from judgement of the Municipal Court in Prague, ref. no. 11 A 37/2025–64 of 16 October 2025

"I. Decision of the Ministry of Health dated 13 February 2025, ref. no. MZDR 1292/2024-2/PRO, and decision of the State Institute for Drug Control dated 11 October 2023, file no. SUKLS236130/2023, is hereby annulled and the matter is returned to the defendant for continued procedure."

"II. The defendant is obliged to pay to the applicant reimbursement of costs of the

proceedings concerning the Application in the amount of 33,674 CZK, to be disbursed to the applicant's representative JUDr. Jakub Kadlec, lawyer, within thirty days of this Judgement becoming final."

"33. Should the administrative authorities in the continued procedure insist that the processing of the requested information constitutes creation of new information, they will have to explain, in a reviewable manner, the operation of the ePrescription system and specify what assessment consideration they undertook in respect of the requested information that exceeds the ePrescription system settings allowing to filter the required data. If the administrative authorities come to a conclusion that they have not undertaken such assessment consideration, and the matter constitutes solely the issue of programming of the ePrescription system functionalities and subsequent mechanical data collection, they shall assess the request for information from a perspective to see whether the information disclosure is prevented by other statutory reasons (e.g., the reference to jeopardy for the critical state infrastructure, repeatedly voiced by the administrative authorities). Such consideration shall be properly justified by the administrative authorities, so that it may be challenged by the applicant using legal remedies intended for such purposes. If the administrative authorities come to a conclusion that there is no other reason to decline the information disclosure, and hence the case does not constitute deviation from the right to information, as contested by the defendant in their Response to the Application, they shall provide the requested information. The Municipal Court hereby adds that this "instruction" does in no way preconceive the decision to be taken by the administrative authorities the case."

Substantial excerpts from judgement of the Municipal Court in Prague, ref. no. 5 A 39/2024-44 of 24 March 2025

"I. Decision of the Defendant dated 15 February 2024, ref. no. MZDR 31699/2023-2/PRO, is hereby annulled and the matter is returned to the defendant for continued procedure."

"II. The defendant is obliged to pay to the applicant reimbursement of costs of the proceedings concerning the Application in the total amount of 13,200 CZK, to be disbursed to the applicant's representative Mgr. Michal Hrnčíř, lawyer, within thirty days of this Judgement becoming final."

"28. Should the administrative authorities in the continued procedure insist that the processing of the requested information constitutes creation of new information, they will have to explain, in a reviewable manner, the operation of the ePrescription system and specify what assessment consideration they undertook in respect of the requested information that exceeds the ePrescription system settings allowing to filter the required data. If the administrative authorities come to a conclusion that they have not undertaken such assessment consideration, and the matter constitutes solely the issue of programming of the ePrescription system functionalities and subsequent mechanical data collection, they shall assess the request for information from a perspective to see whether the information disclosure is prevented by other statutory reasons (e.g., the reference to jeopardy for the critical state infrastructure, repeatedly voiced by the administrative authorities). Such consideration shall be properly justified by the administrative authorities, so that it may be challenged by the applicant using legal remedies intended for such purposes. If the administrative authorities come to a conclusion that there is no other reason to decline the information disclosure, and hence the case does not constitute deviation from the right to information, as contested by the defendant in their Response to the Application, they shall provide the requested information. The Municipal Court hereby adds that this "instruction" does in no way preconceive

the decision to be taken by the administrative authorities the case."

Substantial excerpts from judgement of the Municipal Court in Prague, ref. no. 5 A 118/2024-43 of 25 March 2025

"I. Decision of the Defendant dated 13 September 2024, ref. no. MZDR 140308/2024-2/PRO, is hereby annulled and the matter is returned to the defendant for continued procedure."

The defendant is obliged to pay to the applicant reimbursement of costs of the proceedings concerning the Application in the total amount of 13,200 CZK, to be disbursed to the applicant's representative Mgr. Michal Hrnčíř, lawyer, within thirty days of this Judgement becoming final."

"29. Should the administrative authorities in the continued procedure insist that the processing of the requested information constitutes creation of new information, they will have to explain, in a reviewable manner, the operation of the ePrescription system and specify what assessment consideration they undertook in respect of the requested information that exceeds the ePrescription system settings allowing to filter the required data. If the administrative authorities come to a conclusion that they have not undertaken such assessment consideration, and the matter constitutes solely the issue of programming of the ePrescription system functionalities and subsequent mechanical data collection, they shall assess the request for information from a perspective to see whether the information disclosure is prevented by other statutory reasons (e.g., the reference to jeopardy for the critical state infrastructure, repeatedly voiced by the administrative authorities). Such consideration shall be properly justified by the administrative authorities, so that it may be challenged by the applicant using legal remedies intended for such purposes. If the administrative authorities come to a conclusion that there is no other reason to decline the information disclosure, and hence the case does not constitute deviation from the right to information, as contested by the defendant in their Response to the Application, they shall provide the requested information. The Municipal Court hereby adds that this "instruction" does in no way preconceive the decision to be taken by the administrative authorities the case."

Paragraph 1(d)

The Institute did not grant any exclusive licence for information disclosure pursuant to the Act on Free Access to Information.

Paragraph 1(e)

In association with information disclosure pursuant to the Act on Free Access to Information, one complaint concerning the course of action taken when addressing the request for information was lodged.

Record System

In 2025, the electronic record system of the Institute, incl. its regional workplaces, registered 90,489 delivered documents and 112,321 dispatched documents (Table 47).

Table 47 Registration of documents in the period of 2023–2025

	2023	2024	2025
Received documents	93,363	78,336	90,489
Dispatched documents	72,443	83,480	112,321

PROCESSING AND PROVISION OF INFORMATION

The increase in the number of sent documents is associated with the operation of the Medical Device Information System (ISZP) in accordance with Act No 375/2022 Coll. This system automatically generates and sends e-mail notifications upon any act carried out in respect of the reporter, which ensures that immediate information is provided to all parties involved, and it also sends certificates of digital acts.

In the course of 2025, more than 97 % of all documents were sent electronically. Of the total amount of 112,321 sent documents, 57,499 documents were sent via data mailbox (Table 48 refers). The communication channel overview indicates that the Institute continues electronisation of its agendas, confirming its dedication to innovative and modern approach in public administration.

Table 48 Overview of communication channels in 2025

	Mailroom	E-mail messages	Data messages	–	Total
Received documents	25,033	53,134	12,322	–	90,489
	Dispatch room	**E-mail messages**	**Data messages**	**Electronic notice board**	**Total**
Dispatched documents	2,605	41,425	57,499	10,792	112,321

Financial and Material Resources of the Institute

The 2025 Income and Expenditure Account

Income

In 2025, extra-budgetary income amounted to the total volume of 701,641 thousand CZK. The main part of this income was generated by the reimbursement of costs of expert activities that were performed by the Institute upon requests raised by marketing authorisation holders, manufacturers, distributors, vendors, and other legal entities as well as natural persons. The largest proportion of the total volume was represented by income from applications in the sphere of marketing authorisations of medicinal products and in the sphere of maintenance payments. The income from completed expert activities was used piecemeal by the Institute in compliance with the Act on Pharmaceuticals, Act No 296/2008 Coll., on Human Tissues and Cells, as amended, Act on Public Health Insurance, as amended, Act No 167/1998 Coll., on Dependency-Producing Substances, as amended, and Act No 375/2022 Coll. for the funding of payroll, operating, and investment expenditures not covered by financial resources allocated from the state budget. In 2025, the total amount of 652,102 thousand CZK was used in this manner through permissible excess expenditure. Of this amount, 613,142 thousand CZK was used for non-investment expenditure and 38,959 thousand CZK for the funding of investment needs.

In addition to income from the reimbursement of costs of expert activities, another part of income came from the revenues of the state budget, such as collected administrative fees for submitted applications amounting to 20,887 thousand CZK, income from imposed fines amounting to 7,260 thousand CZK, income from lease in the amount of 350 thousand CZK, compensations of administrative procedure costs and refunds of excess advance payments made, related fully to the previous budgetary years, in the amount of 314 thousand CZK, etc. The Transfers from the reserve fund line shows the volume of extra-budgetary income used for the funding of expenditures in 2025. Investment transfers received from the EU amounted to 9,528 thousand CZK in 2025. An overview of the budget income as of 31 December 2025 is provided in Table 49.

Table 49 State budget income (thous. CZK)

Item	Approved budget	Actual amount
Administrative fees	24,800	20,887
Received penalty payments	4,000	7,260
Income from lease	-	350
Income from service provision	-	56
Received non-capital contribu-tions and compensation	-	314
Transfers from the reserve fund	-	652,102
Investment transfers received from the EU	-	9,528
Total	**28,800**	**690,497**

FINANCIAL AND MATERIAL RESOURCES OF THE INSTITUTE

Expenditure

Data on expenditures incurred in 2025 broken down by individual categories are provided in Table 50.

The total investment expenditure incurred in 2025 amounted to 72,874 thousand CZK; 31,080 thousand CZK came from extra-budgetary resources. The funds were used, in particular, to finance the development of the Institute's process electronisation, information technology modernisation, office space reconstruction as well as the renewal of laboratory instruments.

Table 50 Expenditures (thous. CZK)

Indicator	Approved budget	Final budget	Actual amount
Regular employee salaries	25,435	56,758	56,758
Civil servant salaries	96,883	349,224	349,224
Other payments for completed work, severance pay, surrenders	3,604	17,604	17,604
Mandatory insurance premium	42,561	141,342	141,342
Fund of Social and Cultural Needs contribution	1,223	4,060	4,060
Operating acquisitions and related expenditure	967	210,923	205,040
Acquisition of long-term tangible and intangible fixed assets	-	109,548	72,874
Total	**170,672**	**889,457**	**846,901**
of which Operating expenditure	170,672	779,910	774,027
of which Capital expenditure	-	109,548	72,874

The expenditures incurred by the "Shared medication record – extended service in the sphere of consent management and access log" and "Enhancement of the Institute's Infrastructure Cybersecurity" projects implemented as part of the National Recovery Plan, amounted to 41,794 thousand CZK and came from the state budget funds and EU resources.

Non-investment expenditures were utilised in the total amount of 774,027 thousand CZK, of which 162,910 thousand CZK came from the state budget and 607,431 thousand CZK were taken from extra-budgetary resources, and funds provided to the Institute as part of the "Shared medication record – extended service in the sphere of consent management and access log" project in the amount of 3,687 thousand CZK. Extra-budgetary resources included resources from abroad provided for international projects within the EU.

Assets

The total assets as of 31 December 2025 amounted to 1,282,657 thousand CZK, of which fixed assets were in the volume of 446,894 thousand CZK and current assets in the volume of 835,763 thousand CZK. Of the total liabilities of 1,282,657 thousand CZK, equity amounted to 1,222,932 thousand CZK and borrowed capital to 59,725 thousand CZK. Selected types of assets and liabilities are shown in Table 51.

FINANCIAL AND MATERIAL RESOURCES OF THE INSTITUTE

Table 51 Overview of selected types of assets and liabilities of the organisation (thous. CZK)

	Past period 2024	Current period 2025
ASSETS	**1,196,957**	**1,282,657**
A. Total fixed assets	**408,287**	**446,894**
of which: Long-term intangible fixed assets – total	109,898	133,842
Long-term tangible fixed assets – total	298,388	313,052
of which: Lots	4,530	4,530
Buildings	257,586	251,944
Separate tangible movables and sets of tangible movables	31,644	51,366
Unfinished long-term tangible fixed assets	4,628	5,211
B. Total current assets	**788,670**	**835,763**
of which: Inventory – total	158	27
Short-term receivables – total	26,221	15,707
Short-term financial assets – total	762,292	820,029
LIABILITIES	**1,196,957**	**1,282,657**
C. Equity	**1,144,709**	**1,222,932**
of which: Assets of the accounting entity and adjustments	226,552	226,623
Funds of the accounting entity	720,658	775,020
of which Fund for Cultural and Social Needs	1,191	1,574
of which Reserve Fund	719,467	773,446
Economic result	-1,105,288	-1,237,902
of which Economic result for the current accounting period	148,689	-131,272
of which Economic result for the previous accounting periods	-1,253,977	-1,106,630
Income and expenditure account of the budget management	1,302,787	1,459,191
D. Total borrowed capital	**52,248**	**59,725**
of which: Reserves	-	-
Total long-term liabilities	-	-
Total short-term liabilities	52,248	59,725

Focus Upon Employees

Personnel Issues

Table 52 Number of registered employees as at 31 December 2025

Women	447
Men	102
Total	**549**

Table 53 Numbers of employees at local workplaces as at 31 December 2025

Brno	36
České Budějovice	3
Hradec Králové	5
Olomouc	4
Ostrava	5
Pilsen	3
Prague	493

Table 54 Age structure of employees as at 31 December 2025

Younger than 30 years of age	35
Aged 30–50 years	334
Above 50 years of age	180

Table 55 Qualification structure of employees by the highest achieved level of education

University graduates	447
Technical college graduates	6
Secondary school graduates	96

Table 56 Entries into/terminations of employment/civil service in the period from 01 January 2025 to 31 December 2025

Entries	56
Terminations	59

Staff Turnover

The overall staff turnover taking into account all entries into and terminations of employment/civil service amounted to 10.73 %, which was a slight decrease compared to 2024.

In the course of 2025, 125 tenders for vacancies were opened in total, of which 73 job openings were filled.

Overview of tenders completed pursuant to the Act on Civil Service (civil service positions) and pursuant to the Labour Code (employment positions) and associated entries into employment/civil service.

Table 57 Overview of tenders completed pursuant to the Act on Civil Service (civil service positions) and pursuant to the Labour Code (employment positions) and associated entries into employment/civil service:

Civil service		Employment	
No. of positions to be staffed through tenders	Staffed	No. of positions to be staffed through tenders	Staffed
102	55	23	18

Employee Education

In 2025, the employees again showed much interest in corporate education. Most of the educational events were personally attended by the employees, nevertheless, a growing trend of on-line education has been emerging, as this form is preferred for time savings. This fact was confirmed also by the apparent interest in courses on the SEDUO.cz educational platform.

FOCUS UPON EMPLOYEES

The Institute continued to provide initial introductory training for new employees in the form of e-learning. All of the new employees completed the initial training that included topics defined by the currently effective legislation and they also fulfilled the obligation to obtain follow-up initial education, either in the form of completing the civil-service examination or the "Follow-up Initial Education" course organised via the Institute for Public Administration Prague.

Throughout 2025, much emphasis was placed by the Institute upon deepening and increasing employee qualification and knowledge, particularly with a view to the high demands on expertise and implementation of legislative changes.

All of the employees were trained in cybersecurity issues, which was organised by the Information Security Manager in compliance with effective legislation. Furthermore, all staff completed the courses of Ethics, occupational safety and health (OSH) and fire protection.

In autumn 2025, a series of management trainings in soft skills for new managers, in the development of previously mastered soft skills (follow-up course) for last year's students, and trainings focused upon teamwork and communication for employees at positions with inherent communication with other Sections or across the Institute took place. These courses focused upon corporate culture and teamwork, major causes of problems in teamwork, effective communication and its establishment. Furthermore, a specialised lecture on social and mental security at work was organised for the employees.

Internal (English) language courses continued also in 2025. Most employees attended group courses; some of the employees completed individual language courses. The knowledge gained through language courses was applied in regular activities of the Institute as well as during participation in international and multinational organisations, institutions, congresses, and during foreign business trips where the employees gained also new knowledge in their field of expertise.

The total volume of financial costs incurred for all types of educational activities amounted to 2,058,124 CZK.

Table 58 Overview of educational activities in 2025

Type of event	Number of events	Number of attendees
Specialised courses & training	217	230
Mandatory courses	9	630
Management training	5	66
Language courses	571	79
Foreign specialised training	17	18

Civil-Service Examination in 2025

On 01 January 2025, changes in the area of civil-service examinations stipulated by the amended Act No 448/2024 Coll., on Civil Service, took effect. The civil-service examination was split into two separate parts, or which the general part is newly organised by the civil-service office where the civil servant serves, and the special part by the service specialty guarantor. Furthermore, the timelines for passing the examination were changed. A civil servant is obliged to successfully pass the general part of the civil-service examination no later than within nine months of entry into the civil service and the special part of the civil-service examination no later than within 18 months of entry into the civil service (or within 18 months of the date when the civil servant began his/her service in another or additional service specialty).

In 2025, the Institute organised the total of 13 dates for taking the general part

of the civil-service examination, typically in a monthly or two-weekly interval. The general part of the civil-service examination was taken by 26 employees in the Institute and all of them passed the exam successfully at first attempt.

Of the total number of received applications, the special part of the civil-service examination was taken by 17 employees from various civil-service specialties in 2025. The most common specialty was specialty 21 “Health care and health protection”. As with the general part, the employees successfully passed the examination at first attempt.

Charter Against Domestic Violence

In 2025, the Institute acceded to the Charter Against Domestic Violence. The Institute is fully aware of the severity of the problem as well as of the fact that a workplace may be the only safe space for victims of domestic violence. The Institute fulfils the duties of a signatory of the Charter Against Domestic Violence and strives to actively contribute to addressing this serious issue by helping its employees wherever necessary. In 2025, five trained Charter ambassadors recruited among the Institute’s employees commenced their work in the Institute.

Focus Upon Quality and Control

The Institute has an established and certified quality management system compliant with the requirements stipulated by the ČSN EN ISO 9001 standard and the Methodological Guideline for Quality Management in Civil-Service Authorities. Furthermore, the Laboratory Control Department uses a management system compliant with the ČSN EN ISO/IEC 17025 standard.

Quality assurance forms an integral part of all key and auxiliary processes of the Institute.

In May 2025, the Institute conducted an internal review of compliance with the improvement criteria defined by the Methodological Guideline for Quality Management in Civil-Service Authorities focused upon identification of opportunities for improvement.

In November 2025, the LL-C (Certification) Czech Republic, s.r.o., certification body carried out the second surveillance audit of the Institute's processes and confirmed that the quality management system continues to meet the requirements stipulated by the aforementioned standard.

Internal Audits

The Institute conducts internal audits in compliance with the ČSN EN ISO 9001 standard as well as in compliance with Act No 320/2001 Coll., on Financial Control.

Internal audit referred to by Act No 320/2001 Coll. is established as an independent and objective assurance and advisory activity. It is reportable directly to the Institute's Director and its scope is governed by the Internal Audit Manual and Statute. These activities are also governed by international internal audits standards. Internal audit verifies the functionality of the internal control system and handling of public funds in compliance with the principles of efficiency, economy, and effectiveness. It proceeds in line with an approved annual plan, derived from the mid-term internal audit plan established in the Institute for the period of three years. Both the mid-term and annual plans are based upon the requirements of the Institute's Director and risk analysis. In 2025, the Institute had one full-time internal auditor (1.0 FTE). No external evaluation of internal audit took place in 2025.

Internal audits as referred to by the ČSN EN ISO 9001 standard verify the functionality of the quality management system (QMS) and effectiveness of established processes on an ongoing basis. In 2025, 13 QMS internal audits took place. The QMS internal audit programme was based upon the audit strategy for the period of 2021–2025 and upon risk analysis.

QMS internal audits are carried out by a team of trained internal auditors from various units of the Institute, who conduct this activity above the scope of their standard work duties. Their involvement supports independent process evaluation and ongoing quality management system improvement. In 2025, there were eight active internal quality auditors in the Institute.

Furthermore, in 2025, an internal audit of a part of the Pharmacovigilance System of the Czech Republic was carried out, focusing upon the control of GVP requirements as per the GVP modules issued by EMA. Specifically, the audit concentrated on the following modules: GVP I, V, VII, VIII, IX, X, XV, and XVI.

In September 2025, the regular report on the results of the audit of the Pharmacovigilance System of the Czech Republic was submitted to the EC. It also reflected the results of the internal audit of the pharmacovigilance system conducted in 2024 as per modules GVP II and III.

Table 59 Development of internal audits in the period of 2021–2025

	2021	2022	2023	2024	2025
Number of completed QMS audits	21	12	17	12	13
Number of completed audits as per the Act on Financial Control	5	4	4	5	2
Number of identified nonconformities	4	15	6	0	1
Number of identified shortcomings	14	9	2	4	5
Number of recommendations for improvement	104	101	76	83	60
Number of new risks	23	14	24	15	7

Following internal audit completion, audit findings are discussed with the responsible organisational units and relevant corrective and preventive actions are determined. The fulfilment of these actions is monitored on an ongoing basis until their full conclusion. Internal audit results hence serve as an important input for process improvement, risk management, and enhancement of the internal control system of the organisation.

Complaints

In 2025, the Institute received and resolved 16 complaints referred to under Section 175 of Act No 500/2004 Coll., the Code of Administrative Procedure. All of the queries were resolved within statutory timelines. Two complaints were found partially substantiated. The identified shortcomings were communicated to the relevant Institute's units and corrective and preventive actions were adopted in order to prevent such situations from arising in the future.

Findings arising from complaints represent one of the feedback sources not only for internal audit. They help identify areas of increased risk and provide important signals of potential weaknesses in the Institute that may be subsequently targeted during internal audits.

Feedback

The Institute continuously strives to perform activities at a high standard, predictably, using transparent documentation, within as short timelines as practicable, and in the required quality, keeping an open mind to suggestions, observing ethical and AML rules, environmentally friendly style of conduct, and safety at work. All of these efforts are aimed at increasing stakeholder satisfaction, at enhancing the positive image of the Institute, and at achieving international recognition.

In 2025, SÚKL received 1,340 feedback reports from external entities, which were obtained from satisfaction surveys or other forms of communication. The received feedback indicates mostly high satisfaction of external entities. There is also a lower rate of suggestions concerning the availability of information, request handling speed, and employee availability. For seminars and presentations, there were isolated objections to the practical applicability of the presented findings or the level of their expertise (Table 60 refers).

Table 60 Feedback and suggestions obtained in the period of 2021–2025

	Activity questionnaire	Seminar questionnaire	Other feedback	Total feedback	Received suggestions
2021	65	30	17	112	Not collected
2022	139	112	58	309	32

FOCUS UPON QUALITY AND CONTROL

Table 60 Feedback and suggestions obtained in the period of 2021–2025

	Activity questionnaire	Seminar questionnaire	Other feedback	Total feedback	Received suggestions
2023	165	297	41	503	72
2024	132	1,003	31	1,166	185
2025	139	1,152	49	1,340	158

The obtained feedback is continuously evaluated and used for the identification of opportunities for improvement, process adjustments, and for the planning of educational activities for external entities. Also in 2025, suggestions for improvement concerned mostly the organisation of seminars. The employees of the Institute will organise a number of seminars also in the next year in order to educate external entities on good practices and to inform on new regulations or changes.

Strategy

Mission

Public health protection and support on the basis of effective regulation in areas within the scope of the Institute's powers, based on state-of-the-art scientific and research knowledge. The Institute fulfils its mission as part of its competences stipulated by legal regulations through medicinal products and medical devices regulation aimed at safeguarding their quality, efficacy, and safety in clinical practice.

Vision

The Institute as an independent, competent, professionally sound, economically stable regulatory authority respected both nationally and internationally, with high degree of transparency, flexibility, predictability of decision-making practice and independence, observing high standards of quality of work.

Strategy

For the fulfilment of its mission and achievement of its vision, the Institute has developed the Strategic Plan of the State Institute for Drug Control for the Period of 2021–2025, including strategic aims, the fulfilment of which is reviewed on an annual basis by the Institute's Management.

On its website, the Institute publishes a brief summary of Strategic Plan fulfilment.

In total, 10 % of unfulfilled or partially fulfilled specific objectives are brought forward to the next period.

Nine per cent of specific objectives have been partially fulfilled or unfulfilled in terms of their defined target values.

Most often, the failure to fulfil an objective within the predefined timeline was caused by incorrect planning, lack of capacities on the part of the Institute, workload or shortcomings on the part of suppliers and external factors.

Figure 13 Fulfilment of specific objectives in the period of 2021–2025

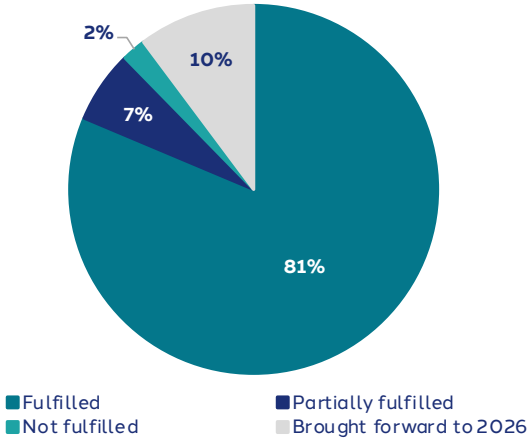


Table 61 Fulfilment of specific objectives in the period of 2021–2025

Total number of defined specific objectives in 2021–2025	284
Fulfilled	231
Partially fulfilled	18
Not fulfilled	6
Brought forward to 2026	29

Information Security Management Policy

Year by year, the demands on safeguarding an adequate level of cybersecurity keep growing not only in the Institute, and this trend continued also in the course of 2025.

The number of detected cybersecurity attacks targeting the Institute's information systems was substantial also in 2025; nevertheless, none of the attacks was successful. In cooperation with the Information Technology Department, several projects aimed at enhancing the Institute's cybersecurity were implemented.

With regard to the growing amount of socially engineered cybersecurity attacks, in 2025, much emphasis was placed upon enhancing the security awareness of the employees. For this reason, an instrument for the conduct of regular phishing campaigns was procured.

In April 2025, the Institute successfully passed a recertification audit of the information security management system (ISMS) pursuant to the ČSN EN ISO/IEC 27001:2023 standard, which means that it has been the holder of the relevant certificate for as long as 18 years. In mid-year, the role of the Cybersecurity Manager was re-staffed.

LIST OF ABBREVIATIONS

A	
ACT EU	Accelerating Clinical Trials in the EU
ADR	Adverse Drug Reaction
AP	Administrative Procedure
ASTERx	Information System for Administrative Procedures Concerning Pricing and Reimbursements
ATC	Anatomical Therapeutic Chemical
ATD	Anti-Tampering Device
ATMP	Advanced Therapy Medicinal Products
B	
BMWP	Biosimilar Medicinal Products Working Party
BWP	Biologics Working Party
C–Č	
CAFIA	Czech Agriculture and Food Inspection Authority
CAT	Committee for Advanced Therapies
CAU	Pricing and Reimbursement Regulation Section
CDNÚ	Central Database of Adverse Drug Reactions (Centrální databáze nežádoucích účinků)
CHESSMEN	Coordination and Harmonization of the Existing Systems against Shortage of Medicine – European Network
CHMP	Committee for Medicinal Products for Human Use
CIMD	Clinical investigation of medical devices
CKS	End-user price
CMDh	Co-ordination group for Mutual Recognition and Decentralised Procedures – human
CMS	Concerned Member State
COMP	Committee for Orphan Medicinal Products
CP	Price zone
CRO	Contract Research Organization
CRS	Chemical Reference Substance
CSSA	Czech Social Security Administration
CTAG	Clinical Trials Advisory Group
CTCG	Clinical Trials Coordination Group
CT-CURE	Clinical Trial Competitive multinational assessment timelines in the European Union ensuring Regulatory Excellence
CTIS	Clinical Trial Information System
CTS	Communication and Tracking System Working Group
CÚLD	Central Repository of Out-of-Pocket Payment Limits (Centrální úložiště limitů doplatků)
CZECRIN	Czech Clinical Research Infrastructure Network
ČR	Czech Republic
ČSN	Czech technical standard

LIST OF ABBREVIATIONS

C–Č	
ČSN EN ISO	Czech version of an international standard (adopted by the European Committee for Standardization – CEN)
ČSN EN ISO/ IEC	Czech version of an international standard published by the International Organization for Standardization (ISO) and by the International Electrotechnical Commission (IEC) (adopted by CEN)
D	
DAN	Drug Availability and Replaceability Unit
DCP	Decentralised Procedure (for marketing authorisations)
DDD	Daily defined dose
DIS	Distributor
DIS-13	Distributed human medicinal product supply and stock report
DL	Diagnostic laboratory
DLL	Importers of active substances
DLP	Database of medicinal products (Databáze léčivých přípravků)
DOV	Importers
DOZ	Surveillance Section
DPV	Parenteral nutrition products for home therapy
DU	Defined unit
E	
EC	European Communities
ECDC	European Centre for Disease Prevention and Control
ECHO	European Civil Protection and Humanitarian Aid Operations
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
EU	European Union
EUDAMED	European database of medical devices
EudraGMDP	European Community of Manufacturing Authorisations and of Certificates of Good Manufacturing Practice
EU-IN	EU Innovation Network (EU-IN) Working Group
EU NTC	EU Network Training Centre
EU4H 11	Joint Action on quality of medicines and implementation of the pharmaceutical legislation/strategy
EV EWG	EudraVigilance Expert Working Group
F	
FIH	First-in-human
FSC	Free Sale Certificate
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice

LIST OF ABBREVIATIONS

G	
GACP	Good Agricultural and Collection Practice
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMO	Genetically modified organisms
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practices
H	
HARP	Harmonisation of RMP Project
HAV	Human autogenous vaccines
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority
HTA	Health Technology Assessment
HTC	Human tissues and cells
I	
IMPD	Investigational Medicinal Product Dossier
IncreaseNET	Supporting the increased capacity and competence building of the EU medicines regulatory network
INN	WHO International Nonproprietary Name
IPLP	Individually prepared medicinal product
IPVZ	Institute for Postgraduate Medical Education
ISDB	International Society of Drug Bulletins
ISMS	Information Security Management System
ISO	International Organization for Standardization
ISZP	Medical device information system (Informační systém zdravotnických prostředků)
IVD	*In vitro* diagnostic medical device
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
J	
JAMS 2.0	Reinforced market surveillance of medical devices and *in vitro* devices
JAP	Joint Audit Programme
JCA	Joint Clinical Assessment as per Regulation EU 2021/2282
K	
KHZP	Medical Devices Clinical Evaluation Unit
KON	Medical Device Control Unit

LIST OF ABBREVIATIONS

L	
LER	Low Endotoxin Recovery
LMS	Lead Member State
M	
MA	Marketing authorisation
MAG	Magistral formula
MAH	Marketing authorisation holder
MC	Maximum price
MCM	Medical Countermeasure
MDCG	Medical Devices Coordination Group
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MP	Medicinal product
MRA	Mutual Recognition Agreements
MRP	Mutual Recognition Procedure
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
N	
NCAR	National Competent Authority Report
NcWP	Non-clinical Working Party
NOOL	Organisation for Medicines Verification (Národní organizace pro ověřování pravosti léčiv, z. s.)
NPC	National Antidrug Centre (Národní protidrogová centrála)
NPO	National Recovery Plan (Národní plán obnovy)
NRG	Name Review Group
O	
OCABR	Official Control Authority Batch Release
OLZP	Medicines and Medical Devices Department
OMCL	Official Medicines Control Laboratories
ONM	Nuclear Medicine Department
OOP	General Measure
OOVL	Detached pharmaceuticals dispensing unit
OP	Profit margin
OZ	Donation centre
P	
PDCO	Paediatric Committee
PhV	Pharmacovigilance

LIST OF ABBREVIATIONS

P	
PhV IWG	Pharmacovigilance Inspectors Working Group
PIA	PIC/S Inspectorates Academy
PICO	Population, Intervention, Comparator, Outcomes
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMSV	Post-Market Surveillance and Vigilance Working Group
POS	Providers
PPZ	Medical Device Legal Support Unit
PRAC	Pharmacovigilance Risk Assessment Committee
PSMF	Pharmacovigilance System Master File
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Single Assessment
PTS	Proficiency Testing Study
PZLÚ	Foods for special medical purposes
Q	
QMS	Quality Management System
QPPV	Qualified Person Responsible for Pharmacovigilance
QRD	Working Group on Quality Review of Documents
QWP	Quality Working Party
R–Ř	
RAB	Rapid Alert System for Blood and Blood Components
REG	Marketing Authorisation Section
RF	Radiopharmaceuticals
RLPO	Registry of Restricted Active Substances (Registr pro léčivé látky s omezením)
RMS	Reference Member State
RZPRO	Registry of Medical Devices (Registr zdravotnických prostředků)
Ř	Director of the State Institute for Drug Control Division
S–Š	
SAE	Serious Adverse Event
SAFE CT	Safety assessment cooperation and facilitated conduct of clinical trials
SCAU	List of prices and reimbursements of medicinal products and foods for special medical purposes reimbursed from health insurance funds
SER	Persons servicing medical devices
SoHO	Substances of Human Origin
SPE	Business Operation Section
SpLP	Specific therapeutic programme

LIST OF ABBREVIATIONS

S–Š	
SPOC	Single point of contact
SPOC WP	Single Point of Contact Working Party
SUP	Suspected unknown product
SYS	Systems, Education, and European Affairs Unit
SZP	Medical Device Regulation Section
ŠÚKL	Slovak State Institute for Drug Control (Štátny ústav pre kontrolu liečiv)
T	
TB	Tissues and Cells Group
TP	Blood components
TRP	Target Rating Point
TZ	Tissue centre
U	
UHR	Reimbursement
ÚZIS	Institute of Health Information and Statistics of the Czech Republic (Ústav zdravotnických informací a statistiky)
V	
VLP	Selected medicinal products
VŘ	Tender
VUC	Material price regulation
VYD	Dispensing persons
VYR	Manufacturers
W	
WHO	World Health Organization
Z	
ZNP	Serious incident
ZNR	Serious adverse reaction
ZNU	Serious adverse event
ZP	Medical device
ZTS	Blood establishment
ZUM	Separately charged material

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SÚKL