ANNUAL REPORT

2024

STATE INSTITUTE FOR DRUG CONTROL

SÚKL

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1. INTRODUCTION

Dear readers,

You are looking at the Annual Report of the State Institute for Drug Control (SÚKL), which provides a comprehensive summary of the Institute's activities throughout 2024 in data.

For SÚKL, 2024 was a period of significant changes and fulfilment of challenging tasks. When I assumed the role of the Institute's Director in May 2024, I set several priority goals, which included personnel stabilisation of the Institute, improved communication, and a smooth transition to new systems that enhance the effectiveness of our work and that will be beneficial for the patient as well as the entire healthcare sector.

It is my pleasure to say that in the last year, we managed to fulfil these objectives. In terms of personnel stabilisation, we have undertaken key steps to safeguard a highly professional leadership of all sections, which is the basis for quality work in our Institute. Improved communication has become a priority not only within the Institute and in relation to the Czech Ministry of Health, but also during cooperation with external partners, such as patient organisations, healthcare professionals or representatives of the pharmaceutical industry and entities operating in the field of medical devices.

2024 brought the launch of a new web portal and commencement of the migration to the new sukl.gov.cz domain, which represents an important step towards cybersecurity, modernisation, and unification of the Institute's online presentation and visual identity. In the course of the year, web portals as well as e-mail addresses were migrated to the new domain, which resulted in increased effectiveness of communication and creation of a uniform identity of the organisation, incl. compliance with the requirements governing the design of state administration websites.

Our Institute was also busy providing inputs in the field of legislation. In 2024, SÚKL continued its close cooperation with the Czech Ministry of Health in the implementation of EU regulations, both in the area of pharmaceuticals, human tissues & cells and medical devices, and it was also involved in the legislative process of the adoption of new legal regulations or amendments to existing legal regulations with relevance for the scope of the Institute's operation. In my opinion, the implementation of the amended Act on Pharmaceuticals in practice is another important milestone, as it has much contributed particularly to stabilisation in the sphere of safeguarding medicinal product availability.

In the last year, the Institute continued to carry out surveillance over pharmaceuticals, medical devices, and in the area of human tissues and cells within the scope of its responsibility.

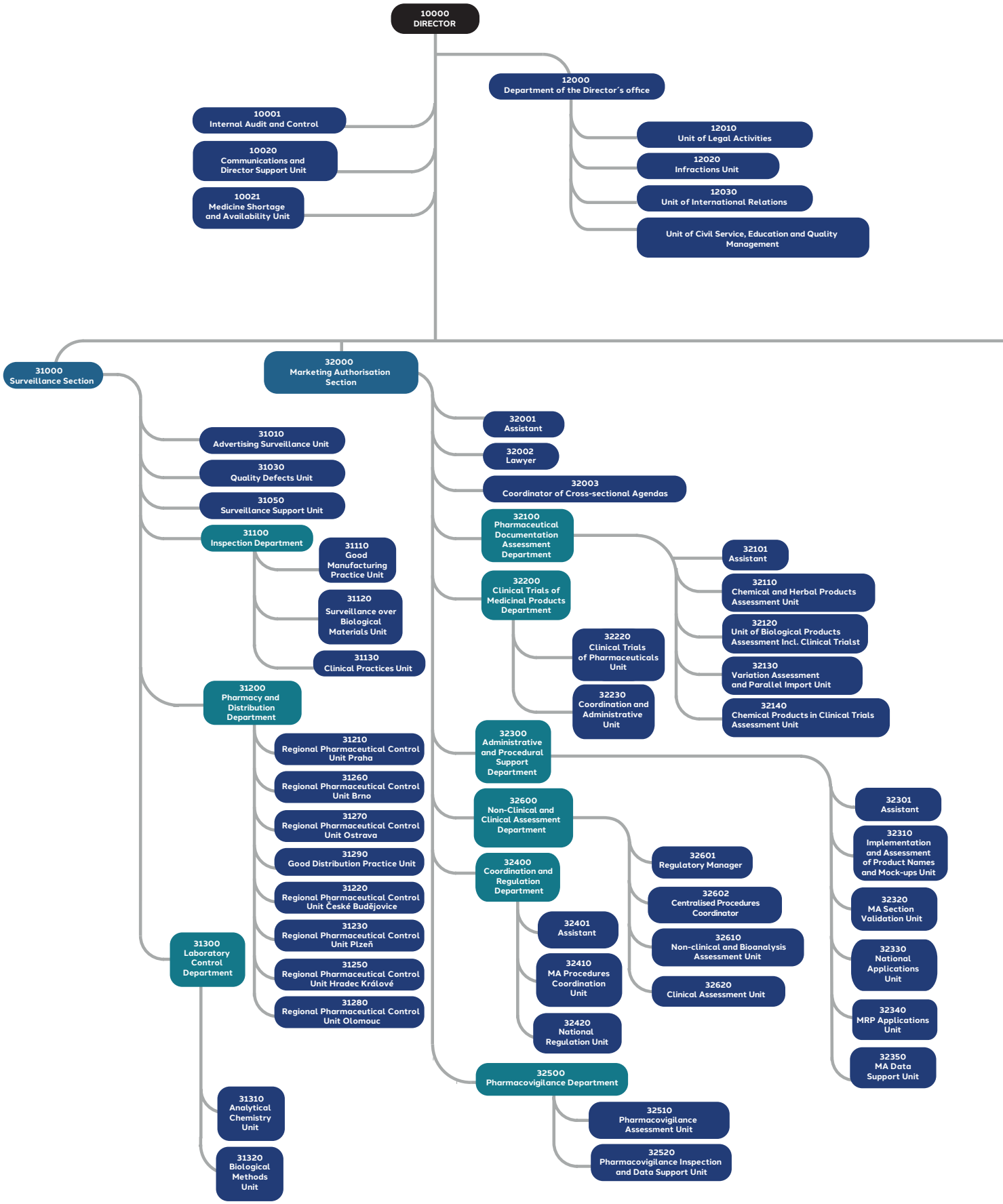
International cooperation and active involvement in more than one hundred working groups, subgroups and committees formed an integral part of the Institute's activities. These were primarily the bodies of the EU Council, European Commission, and the European Medicines Agency (EMA) as well as the working bodies of the World Health Organisation (WHO), the Council of Europe and its European Directorate for the Quality of Medicines and Health Care (EDQM) or the Organisation for Economic Cooperation and Development (OECD). One of the top priorities in terms of medicines regulation is primarily the membership of the Institute's experts in EMA scientific committees which address issues associated e.g., with the safety of medicinal products on the EU market or the approval of new pharmaceuticals. In addition to the area of pharmaceuticals, the Institute has been involved also in working groups focusing upon the field of pricing and reimbursement regulation and health technology assessment (HTA) and has been a member of HTA agency network (HAG). Furthermore, SÚKL participates in working groups in the field of medical devices and is also a member of the Competent Authorities for Medical Devices (CAMD) network.

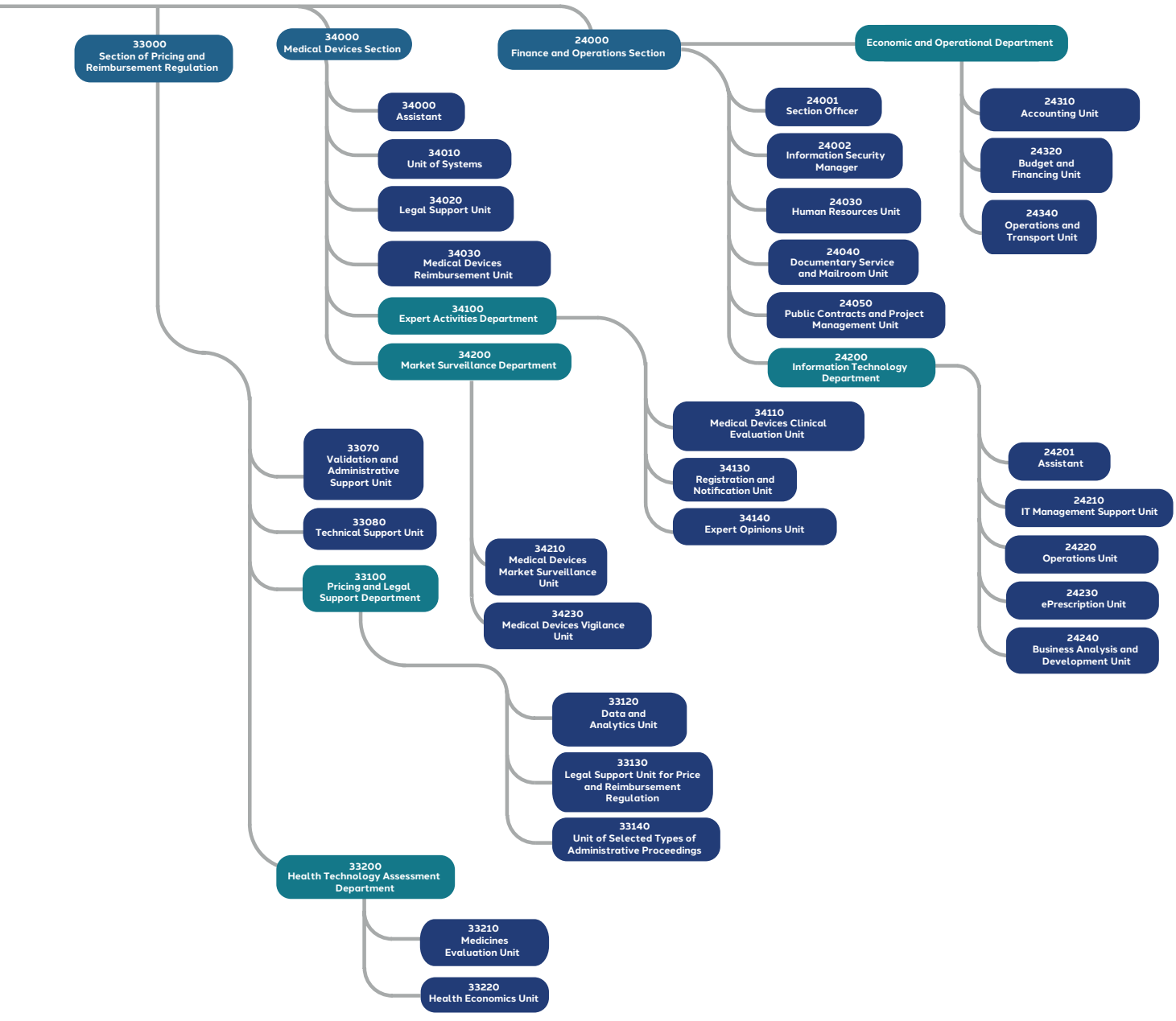
For detailed results of all activities, please refer to individual chapters of this Report.

Finally, let me thank all my colleagues, partners as well as external institutions for their cooperation and support which helped us in fulfilling our obligations. I believe that in 2025, we will carry on such positive dynamics and fulfil the mission of the State Institute for Drug Control, contributing to the protection of health of the citizens of the Czech Republic.

Tomáš Boráň
executive director

2. ORGANISATIONAL STRUCTURE AS OF 01.01.2025




33000
Section of Pricing and Reimbursement Regulation
34000
Medical Devices Section
24000
Finance and Operations Section
Economic and Operational Department
34000
Assistant
34010
Unit of Systems
34020
Legal Support Unit
34030
Medical Devices Reimbursement Unit
34100
Expert Activities Department
34200
Market Surveillance Department
24001
Section Officer
24002
Information Security Manager
24030
Human Resources Unit
24040
Documentary Service and Mailroom Unit
24050
Public Contracts and Project Management Unit
24200
Information Technology Department
24310
Accounting Unit
24320
Budget and Financing Unit
24340
Operations and Transport Unit
33070
Validation and Administrative Support Unit
33080
Technical Support Unit
33100
Pricing and Legal Support Department
34110
Medical Devices Clinical Evaluation Unit
34130
Registration and Notification Unit
34140
Expert Opinions Unit
34210
Medical Devices Market Surveillance Unit
34230
Medical Devices Vigilance Unit
24201
Assistant
24210
IT Management Support Unit
24220
Operations Unit
24230
ePrescription Unit
24240
Business Analysis and Development Unit
33120
Data and Analytics Unit
33130
Legal Support Unit for Price and Reimbursement Regulation
33140
Unit of Selected Types of Administrative Proceedings
33200
Health Technology Assessment Department
33210
Medicines Evaluation Unit
33220
Health Economics Unit

3. INVOLVEMENT IN THE NETWORK OF NATIONAL, EUROPEAN, AND OTHER INTERNATIONAL INSTITUTIONS

3. 1 Cooperation with the Ministry of Health in the Area of Legislation

In 2024, the Institute continued its close cooperation with the Ministry of Health of the Czech Republic, particularly in the implementation of EU regulations governing the sphere of pharmaceuticals, human tissues and cells, as well as medical devices, and, moreover, in the legislative process of adoption of new legal regulations or amendments to existing legislation with significant impact upon the scope of the Institute's operation.

From the beginning of 2024, the Institute, in cooperation with the Ministry of Health of the Czech Republic, continued the finalising works on the new Act on Pharmaceuticals, specifically the splitting of the existing Act No 378/2007 Coll., on Pharmaceuticals, to the human and veterinary parts. Following agreement between the Ministry of Health and the Ministry of Agriculture, it was decided to prepare a new act due to the need for the actual division of regulation of pharmaceuticals in the human and veterinary sectors, and also with a view to the excessive number of amendments made to the regulations. The Institute, as the regulator in the area of medicinal products, was significantly involved in drafting of the new wording of the basic standard governing medicinal products throughout 2024, including meetings with the representatives of the Ministry of Health of the Czech Republic. All SÚKL's regulatory organisational units concerned by the agenda of medicinal products were actively involved in this preparatory process.

Furthermore, in the sphere of medicinal products, in 2024, the Institute was actively cooperating in drafting of several amendments and in addressing of comments submitted in respect of these amendments. This concerned specifically an amendment that was adopted with effect from 23 August 2024 as Act No 241/2024 Coll., amending Act No 375/2022 Coll., on Medical Devices and in Vitro Diagnostic Medical Devices, and Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, concerning primarily Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (hereinafter referred to as "Regulation No 123"), the purpose of which is to enhance the effectiveness in the management of availability of medicinal products, medical devices, in vitro diagnostic medical devices, and their accessories. Moreover, as part of this amendment, the amount of penalty for the offence of failure to keep records in pharmacies from the current amount of 2 million to 20 million, and the possibility to impose administrative penalty of ban on operation were amended.

Another legislative change was amendment no. 338/2024 Coll., amending Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended; Act No 592/1992 Coll., on Public Health Insurance Premiums, as amended; and Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, applicable from 01 January 2025. This is an amendment implementing Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (HTA Regulation). HTA (health technology assessment) is a multidisciplinary process which collects and evaluates information on medical, social, economic, and ethical impacts of health technology usage. Its purpose is to enhance the effective capacity of the healthcare system and to maximise utility with limited resources. This amendment also adjusted the expert requirements for the conduct of inspections of compliance with obligations associated with medicinal product availability, and, first and foremost, a new out-of-pocket payment limit central repository system was set up.

In 2024, moreover, the Institute commenced activities associated with legislative cooperation with the Ministry of Health of the Czech Republic as part of the preparatory process for the coming into force (mostly as of 07 August 2027) of Regulation (EU) 2024/1938 of the European Parliament and of the Council 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 (hereinafter referred to as the "SoHO Regulation"). These activities are much intensive and demanding in terms of scope, as the SoHO Regulation will have

an impact on multiple expert units of the Institute. In 2024, the Institute already attended several working meetings with the representatives of the Ministry of Health of the Czech Republic; for 2025, regular coordination meetings with the representatives of the Ministry of Health of the Czech Republic have been scheduled. In order to enhance the effectiveness of the preparatory process for the implementation of this Regulation, the Institute has established a SoHO advisory body.

Upon call by the Ministry of Industry and Trade, as early as in 2023, the Institute drafted amendment to Act No 40/1995 Coll., on Advertising Regulation and on Amendment to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended, considered necessary thereby for the sphere of human medicinal products and medical devices. These works intensively continued also in 2024, when it was necessary to specify, in particular, requirements governing the area of advertising for medical devices. Following intensive discussions among the Ministry of Health of the Czech Republic, Ministry of Industry and Trade, and the Institute, in late 2024, this amendment was forwarded to all relevant government working commissions for discussion.

In the sphere of public health insurance, in 2024, the Institute continued its involvement in the preparation of a major amendment to Act No 48/1997 Coll., on Public Health Insurance and on Amendments to some Related Acts, both in relation to medicinal product pricing and reimbursement and in relation to medical devices (medical device categorisation). By the end of 2024, these amendments were included as Chamber documents 847 and 849. With regard to the Act on Public Health Insurance, the Institute was also involved in legislative activities concerning so called HTA vaccines; also this amendment was included as Chamber document 868.

Equally important legislative task for 2024 was the amendment Act amending Act No 375/2022 Coll., on Medical devices and on in Vitro Diagnostic Medical Devices, as amended by Act No 241/2021 Coll. This is an amendment adapting Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of EUDAMED, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices. The Institute was involved in intensive works on this amendment as well.

Furthermore, the Institute closely cooperated with the Ministry of Health of the Czech Republic in drafting amendment 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; this amendment has already been published in the Collection of laws as no. 12/2025 Coll., coming into force as of 01 April 2025.

In addition to direct legislative works, the Institute also monitored discussions in the Czech Parliament and Senate and was involved in the assessment of various draft amendments to discussed Chamber or Senate documents of relevance. The representatives of the Institute, along with the representatives of the Ministry of Health of the Czech Republic, also directly attended some of the meetings held the Healthcare Committee of the Czech Parliament, particularly those where legislation relevant to the Institute's operation was being discussed.

Along with the activities associated with these important legislative tasks, in 2024, the Institute continuously and actively monitored the preparation of all legal regulations with potential impact upon the interests protected by the Institute, and commented thereupon where necessary; these are, e.g., amendment to Act No 526/1990 Coll., on Prices, amendment to the Atomic Act No 263/2016 Coll., amendment to Act No 167/1998 Coll., on Dependency-Producing Substances and on Amendments to Some Other Acts, two amendments to Act No 372/2011 Coll., on Healthcare Services and Conditions of their Provision (Act on Healthcare Services), amendment to Act No 373/2011 Coll., on Specific Healthcare Services, amendment to Act No 325/2021 Coll., on Electronisation in Healthcare, amendment to Decree No 92/2012 Coll., on requirements for minimum technical and material equipment of healthcare facilities and homecare contact centres, and amendment to Decree No 373/2016 Coll., on the provision of data to the National Healthcare Information System. In addition to amendments to effective legal regulations, the Institute also cooperated in the preparation of completely new legal regulations, such as the draft Act on Critical Infrastructure Entity Resilience, new draft Decree on healthcare documentation (which has been published in the Collection of Laws as no. 444/2024 Coll.), new draft Decree on telemedical healthcare services.

The statutory requirements governing individual areas of expert activities were further explained by the Institute in the guidelines published thereby. In these guidelines, the Institute was also informing the public about guidance published by the European Commission and by the European Medicines Agency.

As in the previous years, close cooperation with the Ministry of Health of the Czech Republic in drafting of

opinions of the Czech Republic on requests for preliminary rulings raised with the European Court of Justice regarding the issues falling within the competence of the Institute continued also during the last year.

In terms of European legislation, the Institute actively cooperated with the Ministry of Health of the Czech Republic in issues concerning the AI Act, Ecodesign Regulation, CER Directive, and the aforementioned SoHO Regulation.

Due to the major increase in legislative works within the scope of cooperation with the Ministry of Health of the Czech Republic, as at 01 October 2024, a Legislation Advisory Body was established in the Institute, effectively cooperating with colleagues from the Legislative Department of the Ministry of Health of the Czech Republic.

3. 2 Cooperation with Other State Institutions in the Czech Republic

The Institute continued its cooperation with the Institute for State Control of Veterinary Biologicals and Medicines in Brno also during 2024. 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 2024, the Institute continued its highly intensive cooperation with public authorities through providing answers to their questions falling within the scope of the Institute's powers. The majority of requests came from law enforcement authorities and 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 obvious: 37 requests in 2021, 95 requests in 2022, 183 requests in 2023, and 241 requests in 2024.

In total, this involved 419 requests, of which 373 were raised by the Czech Police, twelve by courts of justice, two by the General Directorate of Customs, four by revenue authorities, four by the General Inspectorate of Security Forces, one by the ombudsman, five by the Military Police, two by a court enforcement officer, one by the Prison Service of the Czech Republic, one by the Czech Trade Inspection Authority, one by the Financial Analytical Office, three by insurance companies, two by Public Prosecutor's Offices, one by the Office for Personal Data Protection, and seven by local governments (regional offices, municipality).

3. 3 Cooperation with EU Institutions and Other Foreign Partners

The Institute has been actively involved in international cooperation through its participation in the activities of more than 100 working groups, subgroups, and committees. These represent, in particular, bodies of the EU Council, the European Commission, and the European Medicines Agency (EMA) as well as the working bodies of the World Health Organisation (WHO), the Council of Europe and its European Directorate for the Quality of Medicines and HealthCare (EDQM), or the Organisation for Economic Co-operation and Development (OECD). Namely the membership of the Institute's employees in EMA scientific committees that address e.g., issues associated with medicinal product safety on the EU market or the approval of new pharmaceuticals, is considered a matter of particular importance from the perspective of regulation of pharmaceuticals.

Furthermore, the Institute has been actively involved in working/coordination groups that bring together experts from various EU Member States specialised in the field of regulation of pharmaceuticals and medical devices, pricing and health technology assessment or the regulation of human tissues and cells. Involvement in these groups is invaluable in terms of implementation of new or updated European regulations governing the aforementioned expert areas.

One of the most important groups is the network of the Heads of Medicines Agencies (HMA) that, along with the EMA, forms the European medicines regulatory network. The Institute participates in its activities not only via the membership of the Institute's Director, but also through direct involvement of experts in the sphere of law, enforcement, clinical trials or communication or information technologies. As part of the activities of HMA working groups as well as their management structures, the Institute has been involved in the development and implementation of the joint HMA/EMA strategy.

The Institute has been regularly delegating its representatives, including top management members, senior staff as well as external experts, to attend the meetings of the aforementioned working bodies. Relevant strategic information from these groups is forwarded via membership in sectoral and cross-sectoral bodies also down to the national level. One of the key topics being addressed in the long term on the international level is particularly the availability of medicinal products or the issue of antimicrobial resistance (AMR).

For its employees, the Institute avails of the offer of education in the EU NTC HMA/EMA European training centre, the purpose of which is to harmonise scientific and regulatory practice across the EU and to enhance the qualification of employees of medicines agencies in the EU Member States.

In 2024, a working group of representatives of the Slovak and Czech ministries of health and medicines agencies with focus upon medicines policy issues was established. In August 2024, the first meeting of the group was hosted by the Slovak party, and in September, an online meeting was organised.

In October 2024, the Institute provided premises for a two-day MedDRA (standardised terminology for adverse drug reaction reporting and for other marketing authorisation activities) training event for domestic and foreign participants.

On the EU level, the Institute is also involved in the process of adoption of new European legislation and in discussions on non-legislative proposals in the EU Council falling within the scope of the Institute's responsibility. In 2024, intensive discussions on so called Pharmaceutical Package continued. The Pharmaceutical Package brings the most extensive reform of pharmaceutical legislation in the last 20 years, with the primary objective to improve the availability of medicines for EU patients, to support innovations, and to safeguard environmental sustainability of pharmaceuticals.

Business Trips Abroad

In 2024, the conditions for travel were standard and allowed for the completion of most of the scheduled activities. In total, 256 business trips abroad took place, of which 147 were partially or fully reimbursed by the organising institutions (the European Commission, EU Council, EMA, EDQM, etc.). Of the total number of completed trips, 15 were educational events, 18 were trips within the scope of international expert projects, 16 trips were undertaken to conduct foreign inspections (particularly in India), and 207 were routine business trips abroad. The Institute's employees travelled mostly to Brussels and Amsterdam, where they attended meetings held in European institutions.

4. REGULATORY ACTIVITIES OF SÚKL

4. 1 Record System

In 2024, the electronic record system of the Institute, incl. its regional workplaces, registered 78,336 delivered documents and 83,480 dispatched documents (Table 1). The decrease in the number of received documents was due to the transfer of part of the Medical Device Registry agenda to the Medical Device Information System, where the processes have been optimised to be compliant with currently effective legislation, which significantly contributes to administrative burden alleviation and allows for a more efficient management of agendas associated with medical device regulation.

The increase in the number of sent documents is also associated with the launch of the Medical Device Information system in accordance with Act No 375/2022 Coll., on Medical Devices and on in Vitro Diagnostic Medical Devices. This system has brought an important innovation to the sphere of communication, as it automatically generates and sends e-mail notifications upon any act for the reporter, which ensures that immediate information is provided to all parties involved.

The Institute's continued efforts in the area of electronisation of its agendas is evidenced also by the fact that in the course of 2024, more than 92.9 % of all documents were sent electronically. Of the total amount of 83,480 sent documents, 45,754 documents were sent via data mailbox (Table 2). The continued electronisation of individual processes contributes to a more efficient document management and enhanced transparency, while reducing the environmental burden by eliminating the need for extensive paper-based correspondence. Through this, the Institute confirms its dedication to innovative and modern approach in public administration.

Table 1 Registration of documents in 2022–2024

	2022	2023	2024
Received documents	92,515	93,363	78,336
Dispatched documents	71,700	72,443	83,480

Table 2 Overview of communication channels in 2024

	Mailroom	E-mail messages	Data messages	Medical device reimbursement notifications	Total
Received documents	16,877	49,347	11,614	498	78,336

	Dispatch room	E-mail messages	Data messages	Electronic notice board	Total
Dispatched documents	5,905	24,696	45,754	7,125	83,480

MARKETING AUTHORISATION SECTION

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 product 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 the Product Characteristics, which serves doctors and healthcare professionals as a key source of information about the medicinal product; approved package leaflet intended for patients; approved labelling of the medicinal product; and an identification sheet with the allocated medicinal product 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 trade and variations to, renewals or revocations of parallel trade 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 (e.g., referrals, uniform PSUR [Periodic Safety Update Report] assessments, PRAC [Pharmacovigilance Risk Assessment Committee] recommendations on pharmacovigilance signals or paediatric worksharing), for the development of lists of medicinal products jeopardized or extinct due to the sunset clause application, and for the conduct of administrative procedures concerning exemptions from the sunset clause application.

The Clinical Trials on Medicinal Products Department performs assessments of applications for authorisation/notifications of clinical trials, supervises the conduct of clinical trials, and assesses applications for hospital exemptions; it also assesses non-interventional efficacy studies and, for projects of studies, it assesses whether the study in question is a clinical trial on pharmaceuticals or not.

The Department of Pharmacovigilance is in charge of safeguarding the safety of medicinal products and conducting the evaluation of their risk/benefit ratios. The pharmacovigilance activities comprise of the collection of data about potential risks of pharmaceuticals (from the system of spontaneous suspected adverse drug reaction reporting, from post-marketing studies of various types, scientific literature, etc.), evaluation of any available data on potential risks, implementation of regulatory measures intended for risk minimisation, and of communicating new safety information both to healthcare professionals and to the general public.

4. 2 Marketing Authorisation of Medicinal Products

Applications for New Marketing Authorisation

In 2024, 716 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 applications for marketing authorisa-

Table 3 Marketing authorisation (MA) applications agenda

Process of marketing authorisation of medicinal products	Submitted in 2024	Decided in total in 2024	Total pending as of 31 December 2024
New marketing authorisations	748	610	1,192
- of which national	21	33	44
- of which MRP-RMS	24	16	82
- of which DCP-RMS	122	123	230
- of which CMS (MRP and DCP)	581	438	836
MA renewals	**234**	**391**	**123**
- of which national	9	27	33
- of which RMS	79	102	3
- of which CMS	146	260	87
National variations to MAs	**1,681**	**1,683**	**272**
- of which MA transfers	59	58	3
- of which PIL and labelling	91	76	19
- of which bulk NAT variations	1531	1549	250
MRP-RMS variations	**819**	**814**	**161**
- of which MA transfers	16	17	0
- of which PIL and labelling	33	36	1
- of which bulk MRP-RMS variations	770	761	160
MRP-CMS variations	**4,152**	**38,54**	**1,190**
- of which MA transfers	104	92	9
- of which PIL and labelling	169	36	35
- of which bulk MRP-CMS variations	3,879	3,726	1,146
MA revocations	**310**	**308**	**5**
Parallel trade	**34**	**36**	**27**
Parallel trade variations	**68**	**50**	**38**
Parallel trade renewals	**28**	**42**	**6**
Parallel trade revocations	**14**	**11**	**3**

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
NAT – national

tion increased from 606 applications in 2023 to 716 applications in 2024. 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 2024, the number of received applications for DCP marketing authorisation with the Czech Republic acting as the Reference Member State was similar to that in 2023.

Marketing Authorisation Renewals

In 2024, the total of 252 applications were forwarded for expert assessment following successful validation. Most of them were applications for MRP/DCP marketing authorisation renewals; the total number of applications for marketing authorisation renewal received in 2024 was slightly lower than that in 2023.

Variations to Marketing Authorisations

In 2024, the number of received applications for variations to MRP/DCP marketing authorisations was slightly higher than that in the previous year; the number of received applications for variations to national marketing authorisations was similar. The total number of received applications hence slightly grew. The number of submitted applications for MRP/DCP marketing authorisation transfers decreased in 2024, while the number of applications for transfers of national marketing authorisations slightly increased compared to 2023.

Table 4 Applications for exemption from the sunset clause

	Conducted in 2024
Administrative procedures for exemption from the sunset clause	**104**
- of which: submitted applications	**104**
- of which: ex officio initiated administrative procedures	**0**
- granted	95
- declined	5
- suspended as undue	4
- 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.

Parallel Trade

In 2024, the number of submitted applications for parallel trade authorisation was similar to that in 2023. The number of submitted applications for variations to parallel trade authorisations slightly decreased compared to the previous year. At the same time, the number of submitted applications for parallel trade authorisation renewals decreased compared to 2023.

Marketing Authorisation Revocations

In 2024, 310 applications for revocation of marketing authorisation were decided, which is a similar number as in 2023.

Expiry/Non-expiry of Marketing Authorisations

In 2024, the Institute carried out 104 administrative procedures concerning the granting of an exemption from the sunset clause (marketing authorisation expiry for products not placed on the market for the period of three years).

In the course of 2024, the sunset clause as referred to under Section 34a of the Act on Pharmaceuticals was applied to 53 marketing authorisation (MA) numbers and the marketing authorisation of these medicinal products was terminated.

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

In 2024, the Institute provided nine oral consultations (including consultations held in the form of teleconferences) and issued 19 written opinions on process-regulation and expert requests for consultations, 22 written opinions on requests for consultations concerning medicinal product names, and eleven opinions for active substances forming an integral part of a medical device.

4. 3 Cooperation with the European Medicines Agency and CHMP

Within the scope of its cooperation with the European Medicines Agency (EMA) and the Committee for Medicinal Products for Human Use (CHMP), in 2023, the Institute was involved in the assessment of centralised marketing authorisations as follows:

13 times as rapporteur/co-rapporteur;

23 times it assessed type I and II variations to centralised marketing authorisations;

once it assessed a CHMP referral;

26 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 (COMP, PDCO, CAT, PRAC) and working groups.

4. 4 Clinical Trials

Within the scope of its cooperation with the European Medicines Agency (EMA) and the Committee for

Medicinal Products for Human Use (CHMP), in 2023, the Institute was involved in the assessment of centralised marketing authorisations as follows:

13 times as rapporteur/co-rapporteur;

23 times it assessed type I and II variations to centralised marketing authorisations; once it assessed a CHMP referral;

26times 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 (COMP, PDCO, CAT, PRAC) and working groups.

Table 5 Clinical trials in 2024

Applications for clinical trial (CT) authorisation	
Initial applications (INIT)	294
Czech Republic added to a previously approved CT as additional Member State (AM)	48
Stand-alone application containing only IMPD	20
Resubmission	14
Transition trial (TTR)	418
Resubmission – TTR	2

Concluded applications for CT authorisation	
Authorised	489
Authorised with condition	255
Declined	6
Withdrawn by sponsor	33
Lapsed	6
Lapsed during validation	2

Czech Republic acting as the RMS	
Submitted applications	168
Concluded as authorised	79
Concluded as authorised with condition	80
Concluded as lapsed	4
Concluded as withdrawn by sponsor	8
Declined	1

Submitted applications for substantial modification (SM) authorisation	
Documentation PART I only	187
Documentation PART II only	144
Documentation PART I & II	639

Concluded applications for substantial modification (SM)	
Documentation PART I only	120
Documentation PART II only	112
Documentation PART I & II	433

Other classification – by CT type		
	Submitted	Concluded
National	62	55
International	732	736
Low-intervention	12	15
Cluster	0	0

Table 6 Numbers of applications submitted via CTIS in 2024 by clinical trial phase

	Received in 2024	Concluded in 2024
Phase I – bioequivalence study	13	14
Phase I – first-in-human (FIH)	11	6
Phase I – other	19	18
Phase I/II	29	25
Phase II	180	173
Phase II/III	37	34
Phase III	473	445
Phase III/IV	7	8
Phase IV	25	21

Table 7 Indication groups of clinical trials submitted via CTIS and authorised in 2024

Indication	Approved in 2024
C01 Bacterial Infections and Mycoses	6
C02 Virus Diseases	2
C04 Neoplasms	243
C05 Musculoskeletal Diseases	17
C06 Digestive System Diseases	43
C08 Respiratory Tract Diseases	43
C09 Otorhinolaryngologic Diseases	1
C10 Nervous System Diseases	55
C11 Eye Diseases	15
C12 Male Urogenital Diseases	2
C13 Female Urogenital Diseases and Pregnancy Complications	8
C14 Cardiovascular Diseases	70
C15 Hemic and Lymphatic Diseases	30
C16 Congenital, Hereditary, and Neonatal Diseases and Abnormalities	9
C17 Skin and Connective Tissue Diseases	25
C18 Nutritional and Metabolic Diseases	21
C19 Endocrine System Diseases	3
C20 Immune System Diseases	68
C23 Pathological Conditions, Signs and Symptoms	2
E02 Analytical, Diagnostic and Therapeutic Techniques and Equipment – Therapeutics	1
E04 Analytical, Diagnostic and Therapeutic Techniques and Equipment – Surgical Procedures, Operative	2
F03 Psychiatry and Psychology - Mental Disorders	12
F04 Psychiatry and Psychology - Behavioural Disciplines and Activities	1
F04 Psychiatry and Psychology – Behaviour and Behaviour Mechanisms	1
G03 Metabolism	3
G04 Cell Physiological Phenomena	1
G10 Digestive System and Oral Physiological Phenomena	1
G11 Musculoskeletal and Neural Physiological Phenomena	2
G12 Immune system processes	2
G14 Ocular Physiological Phenomena	1
Cannot be specified	4
Including multiple diagnoses	50

TRANSITION STATISTICS

Twelve ethics committees (SÚKL's Ethics Committee and eleven multicentric ethics committees) are involved in the process of assessment of applications for clinical trial authorisation submitted via CTIS. In the course of the year, three meetings with the representatives of multicentric ethics committees were organised. SÚKL's Ethics Committee held 16 meetings, regularly attended also by SÚKL employees. Regular working meetings will continue also in the course of the next year.

In 2024, the total of 794 applications for clinical trial authorisation were submitted via the CTIS. Of this total number, 294 were initial applications, 48 were applications with the Czech Republic added as a new Member State accessing a previously authorised clinical trial, 20 applications contained solely IMPD with reference to other submitted applications for clinical trial authorisation, 14 applications constituted resubmission, and 418 applications concerned transition from a clinical trial previously authorised/approved nationally pursuant to Directive 20/2001/EC to the regime governed by Regulation 536/2014. Furthermore, 187 substantial modifications to documentation Part I, 144 substantial modifications to documentation Part II, and 639 substantial modifications to both Part I and II of documentation were submitted via the CTIS.

Of the submitted applications for clinical trial authorisation, 489 applications were authorised, 255 clinical trials were conditionally authorised, 33 applications were withdrawn, six applications were declined, two applications lapsed during validations, and six applications lapsed for sponsor's failure to observe a timeline. Of the total number of authorised clinical trials, 33 clinical trials were submitted by non-commercial entities (academic research), 49 concerned orphan medicinal products, 58 were clinical trials which enrolled also children or which were directly intended for paediatric population (paediatric trials), eight authorised clinical trials concerned advanced therapy medicinal products (eight gene therapies), and six were first-in-human (FIH) trials.

Also in 2024, the Institute actively participated in the activities of the HMA and European Commission working group. The prevailing topic of all meetings was the current situation of CTIS and harmonisation of clinical trial assessment across EU/EEA. Outages and errors of the system were being addressed, looking for and setting up solutions of situations not covered by Regulation (EU) No 536/2014, arising in the course of the year, as well as procedures to harmonise assessment of PART I of clinical trial dossiers across the EU/EEA. The Section continued to be involved in the provision of comments on and updating of the European Commission's Q&A document on the requirements for submitted documents, with particular focus on clinical trials transitioned into the mode governed by Regulation (EU) No. 536/2014. The employees actively participated in meetings of international groups – the Clinical Trials Coordination Group (CTCG) held 27 meetings (eight online, three face-to-face, and 16 CTCG round tables); the Clinical Trials Advisory Group (CTAG) held eight meetings (six online and two face-to-face) – and also took part in three online meetings concerning the Clinical Trial Information System (CTIS). In the course of the year, regular online meetings of medicines agency representatives, EMA, and the European Commission on CTIS issues based on submitted specific questions (so called Assessors' Round Table) continued (see above). As part of cooperation with EDQM, seven toxicology assessment reports for the Pharmacopoeia Conformity Certification Unit and one scientific advice were prepared.

Furthermore, the Institute was involved in the activities of the Committee for Advanced Therapies (CAT); the employees attended 13 meetings, of which five were face-to-face and eight were online meetings.

In 2024, the Institute continued its involvement in two international projects – EU4Health CT-CURE for accelerated assessment of clinical trials focused upon the treatment of the COVID-19 disease, and EU4Health SAFE-CT, focusing 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 Institute acted as the Safety Assessing Member State (saMS) for 93 active substances.

In 2024, we also became a member of a newly established Clinical Trial Working Group under the Ministry of Health of the Czech Republic, the members of which are the representatives of the Ministry of Health of the Czech Republic, SÚKL, the Association of Innovative Pharmaceutical Industry (AIFP), the Association of Clinical Research Organisations (ACRO), the Czech Clinical Research Infrastructure Network (CZECRIN), General Health Insurance Company (VZP), healthcare facilities, and investigators. The purpose of the Working Group is to develop a strategy for the area of clinical trials, which would motivate sponsors to conduct clinical trials in the Czech Republic. In the course of 2024, six meetings were held.

In 2024, we actively participated in two meetings of the Ethics Committee Forum, providing a clinical trial news update, and in two CZECRIN meetings. In 2024, we organised two seminars for sponsors, CROs, monitors, and contact persons

on transition trials (TTR); two seminars focusing on clinical trial monitoring in cooperation with SÚKL's inspectors; two lectures for academic researchers and study team members (one for paediatricians and one for pharmacists from hospital pharmacies); two lectures for university students (Pharmaceutical Faculty Hradec Králové and Pharmaceutical Faculty Brno); one lecture for a course for pharmacists; two lectures for sponsors and CROs and 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 Technical University of Liberec on ATMPs; one lecture for patient organisations; and one lecture for the Clinical Trials National Day. In 2024, we gave 16 consultations: nine to pharmaceutical companies and seven to 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, we 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.

4. 5 Pharmacovigilance

In compliance with the Act on Pharmaceuticals, SÚKL's Pharmacovigilance Department (OFV) operates a system of spontaneous reports of suspected adverse drug reactions (ADR) from the Czech Republic. In 2024, SÚKL received the total of 3,524 suspected ADR reports (the Graph in the "Bulletin" may slightly vary with a view to the data cut-off for the Annual Report, as the report duplicity and validity checks continue to be performed on an ongoing basis). Of the total number of reports received in 2024, 1,342 reports were from medicinal product marketing authorisation holders (pharmaceutical companies) and 1,912 were reports sent to SÚKL directly by healthcare professionals and patients (of which 917 were reports from healthcare professionals and 1,995 were reports from patients).

Of the total number of 3,524 received reports, 574 concerned vaccines, of which 73 were reports concerning COVID-19 vaccines. In respect of medicinal products other than vaccines, 2,950 reports were received. Nevertheless, all of the reports concern merely suspected ADRs, which should 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 to ask for additional missing important data, especially where a very serious or unexpected ADR is suspected. In 2024, it was necessary to contact the reporter in 396 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 88 active substances on the Pan-European level. In 2024, the Pharmacovigilance Assessment Unit assessed 268 ADR extracts from the EudraVigilance database regarding substances in respect of which the Czech Republic acts as the pharmacovigilance signal rapporteur for the EU. This is a lower number of assessed extracts than in the previous years, the reason being prolongation of the monitoring period in early 2024, when extracts for the period of 3-6 months began to be evaluated instead of monthly extracts. Although the number of evaluated extracts dropped, the assessment has become more challenging as the new extracts contain many more reports.

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 2024, the Institute assessed the total of 27 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 85 substances, for which the respective PSUR reports are submitted in regular intervals of various duration. As the EU PRAC rapporteur (the chief pharmacovigilance assessor) for centrally authorised medicinal products, in the course of 2024, the Institute drafted 62 assessment reports in procedures concerning centrally authorised products. In 2024, 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.

It commenced the assessment of responses provided by the holders of marketing authorisations of products containing finasteride, who were answering questions asked within the scope of the referral. Further assessment is to continue also in 2025. SÚKL's Pharmacovigilance keep enhancing their involvement in pharmacovigilance activities on the European level on a continuous basis. We actively participated in eleven regular meetings of the PRAC pharmacovigilance committee of the European Medicines Agency (EMA); after the COVID pandemic, these meetings assume alternately a remote form and the form of face-to-face meetings in EMA. Furthermore, ten one-day virtual meetings of PRAC took place. SÚKL's active participation involves not only the role of the lead MS for numerous procedures, but also thorough monitoring of and provision of comments on ongoing procedures led by other countries. In the course of 2024, the Institute sent written comments on procedures led by other countries 144 times in total and at meetings, eleven procedures led by SÚKL were presented. In addition to regular PRAC meetings, there were two extraordinary meetings organised under the auspices of the state holding Presidency of the EU Council (Belgium and Hungary in 2024); the representatives of the Institute also took an active part in these meetings; in Hungary, they presented the topic of joint preparation of educational materials. Furthermore, they were 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), for which SÚKL's employees prepare our own assessments and provide comments on assessments drafted by other members. The Institute was, 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.

In cooperation with other units of the Marketing Authorisation Section, conclusions adopted by the CHMP and PRAC committees were being transferred to Czech clinical practice on an ongoing basis. In 2024, the Institute published on its website eleven communications intended for healthcare professionals or for the general public concerning medicinal product safety. In cooperation with marketing authorisation holders, the Institute published educational materials on the safer use of 73 active substances in total and twelve letters to healthcare professionals focused upon enhanced safety of medicinal product use. In the course of 2024, a new distribution method of Dear Healthcare Professional Letters was established – specifically, SÚKL sends the letters directly to professional societies whose members are authorised to use the medicinal product in question. Assessors from the Pharmacovigilance Assessment Unit were involved in the assessment of marketing authorisation dossiers of nationally authorised medicinal products, where they were reviewing the pharmacovigilance section; in 2024, they prepared 1,807 reports on pharmacovigilance documentation in total.

The Pharmacovigilance Department continues to publish the Adverse Drug Reactions Bulletin (Nežádoucí účinky léčiv). In 2024, four issues were published. The Bulletin provides 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 2024, 54 notifications (of commencement, termination, or update) of post-marketing safety studies conducted in the Czech Republic were processed.

In 2024, the Pharmacovigilance Inspection and Data Support Unit (FVIDP) conducted the total of twelve inspections of pharmacovigilance systems of marketing authorisation holders (MAHs). Of the conducted inspections, five were inspections of the complete pharmacovigilance system, where the MAH's PSMF is stored in the Czech Republic (of which two were carried out as inspections requested by CHMP). Three inspections were conducted at MA holders whose PSMFs are stored outside the territory of the Czech Republic. Four inspections were focused upon the pharmacovigilance activities of the MAH's local representation in the Czech Republic.

During the conducted inspections, the following findings were made:

Two critical findings (for one MAH) in the areas of quality management (1) and PSUR (1).

Ten major findings (for seven MAHs) in the areas of suspected ADR reporting (3), regulatory affairs (3), quality management (2), company organisation (1), and PSMF (1).

Furthermore, as part of their inspection activities, FVIDP inspectors were involved in reviewing

the operation of two MAHs in respect of which substantial doubts as to the functionality of their pharmacovigilance systems were raised.

In 2024, the Pharmacovigilance Department continued its communication with the public, answered questions from healthcare professionals, the general public as well as pharmaceutical companies. In 2024, we answered 443 questions in writing or by phone. In order to disseminate information on the safety of pharmaceuticals and to enhance suspected adverse drug reaction reporting, the employees of the Pharmacovigilance Department gave five presentations at professional congresses or seminars for doctors and pharmacists or courses of the Institute for Postgraduate Medical Education (IPVZ) or as part of student education; they gave one presentation for patient organisations; and they organised two one-day seminars for marketing authorisation holders.

Table 8 Surveillance over the quality of pharmaceuticals on the market by means of laboratory analyses by predefined projects – projects concluded in 2024

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
3/2023 – Pharmacy samples	74	218	208	10	0
1/2023 – Control of Braille on medicinal product labelling	122	122	118	4	0
2/2023 - Medicinal products containing betahistine dihydrochloride	7	12	12	0	0
4/2023 – Medicinal products containing aripiprazole	14	22	22	0	0
5/2023 – Medicinal products containing sertraline hydrochloride	12	23	22	1	0
6/2023 Medicinal products containing nimesulide, celecoxib and meloxicam	12	24	24	0	0
8/2023 Medicinal products containing gabapentin	11	24	24	0	0
9/2023 Medicinal products containing donepezil hydrochloride	7	24	24	0	0
BIO6/2023/MMR vaccines	2	21	21	0	0
BIO/1/2023 Determination of influenza vaccine efficacy by radial immunodiffusion	3	7	7	0	0
Total	**264**	**497**	**482**	**15**	**0**

Table 9 Batch release of predefined medicinal products

Product type	No. of medicinal products	No. of batch reports	Released on the basis of certificate	Released after lab. control	Total number of released batches	Not released	Completed within timeline
Blood derivatives	50	731	731	0	731	0	731
Vaccines	30	411	408	3	408	0	411

Table 10 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	32	23	9
Suspected counterfeit, illegal samples*	20	-	-
International OMCL studies	7	7	0
Internal quality control of purified water	126	126	0
Other analyses**	16	16	0
Total	201	172	9

** Sample compliance cannot be evaluated.*

*** E.g., requested microbiological controls, other requested analyses, etc.*

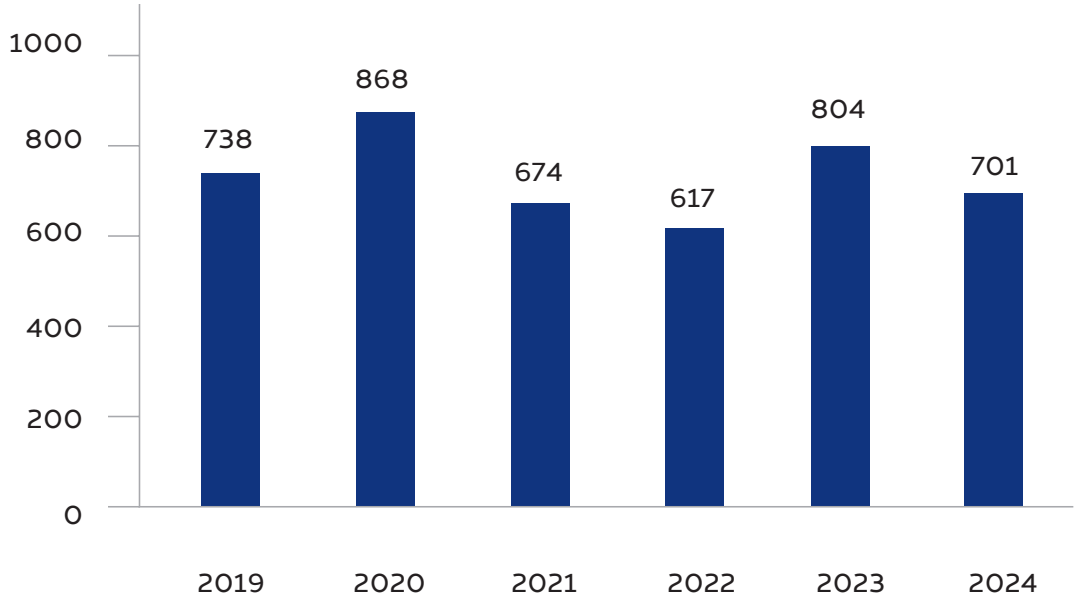
SURVEILLANCE SECTION

V The Laboratory Control Department performs analyses of pharmaceuticals required by law (e.g., from random controls of pharmaceuticals on the market or batch release) or requested by other organisational units of the Institute or state administration bodies, and those conducted as part of international cooperation. The laboratories are integrated into the international General Network of Official Medicines Control Laboratories. The laboratories do not carry out analyses upon request for any commercial entities (except for batch release pursuant to the Act on Pharmaceuticals). Furthermore, the Laboratory Control Department is involved in the publishing of the Czech Pharmacopoeia and the preparation of the European Pharmacopoeia.

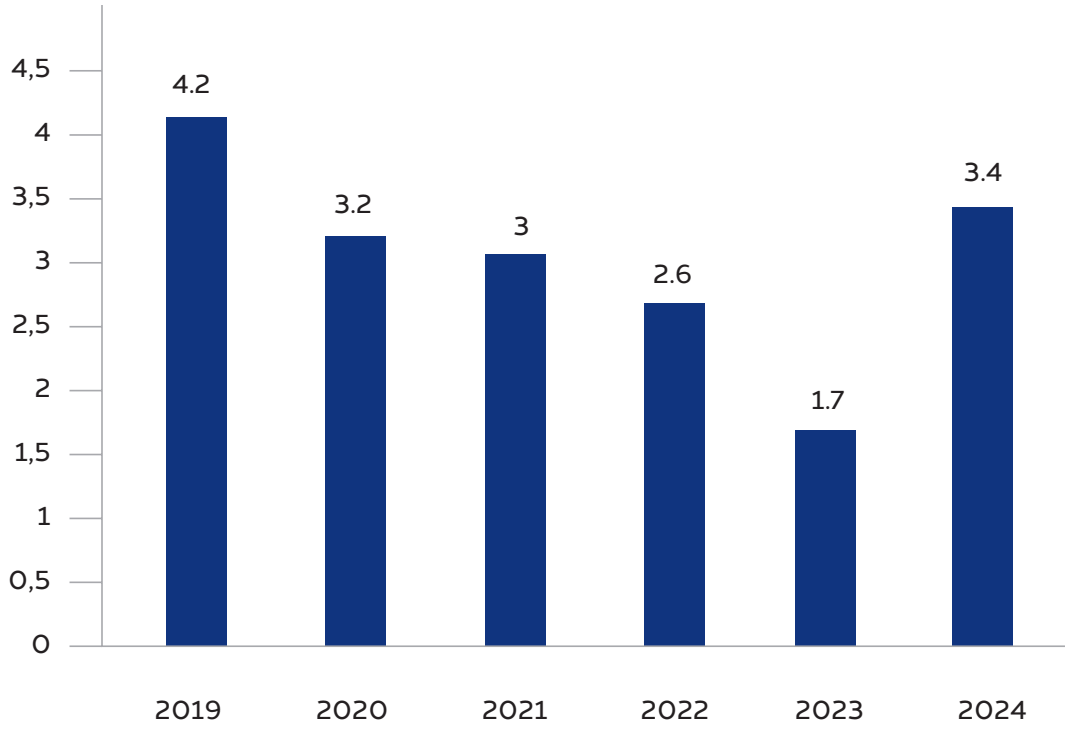
The Pharmacy and Distribution Department is in charge of surveillance over compliance with legislative requirements governing wholesale distribution of pharmaceuticals, with focus upon the principles of Good Distribution Practice and the issuance of authorisations for wholesale distribution activities, including the administration of a register of brokers of medicinal products, and, moreover, carries out surveillance over the area of dispensing, sale, and preparation of medicinal products. The inspected entities are wholesale distributors, pharmacies, vendors of selected medicinal products, and specialised workplaces of healthcare facilities. Inspections of medicinal product handling are carried out also in any other healthcare facilities. The inspections are performed by individual regional units of the Institute according to their territorial competence.

The Inspection Department is in charge of surveillance activities in the sphere of manufacture of pharmaceuticals, good clinical and laboratory practices, and issuance of binding opinions on the import and export of medicinal products, including cooperation with customs authorities. Furthermore, it oversees donation, procurement, testing, processing, storing, and distribution of human tissues and cells aimed at safeguarding their quality and safety. This activity includes the issuance of authorisations to engage in the activities of a tissue centre, donation centre or diagnostic laboratory, the conduct of inspections, monitoring of serious adverse events and reactions or suspected serious adverse events and reactions, and, in cases where doubts arise, issuance of decisions as to whether tissues and cells regulated by the applicable law are concerned.

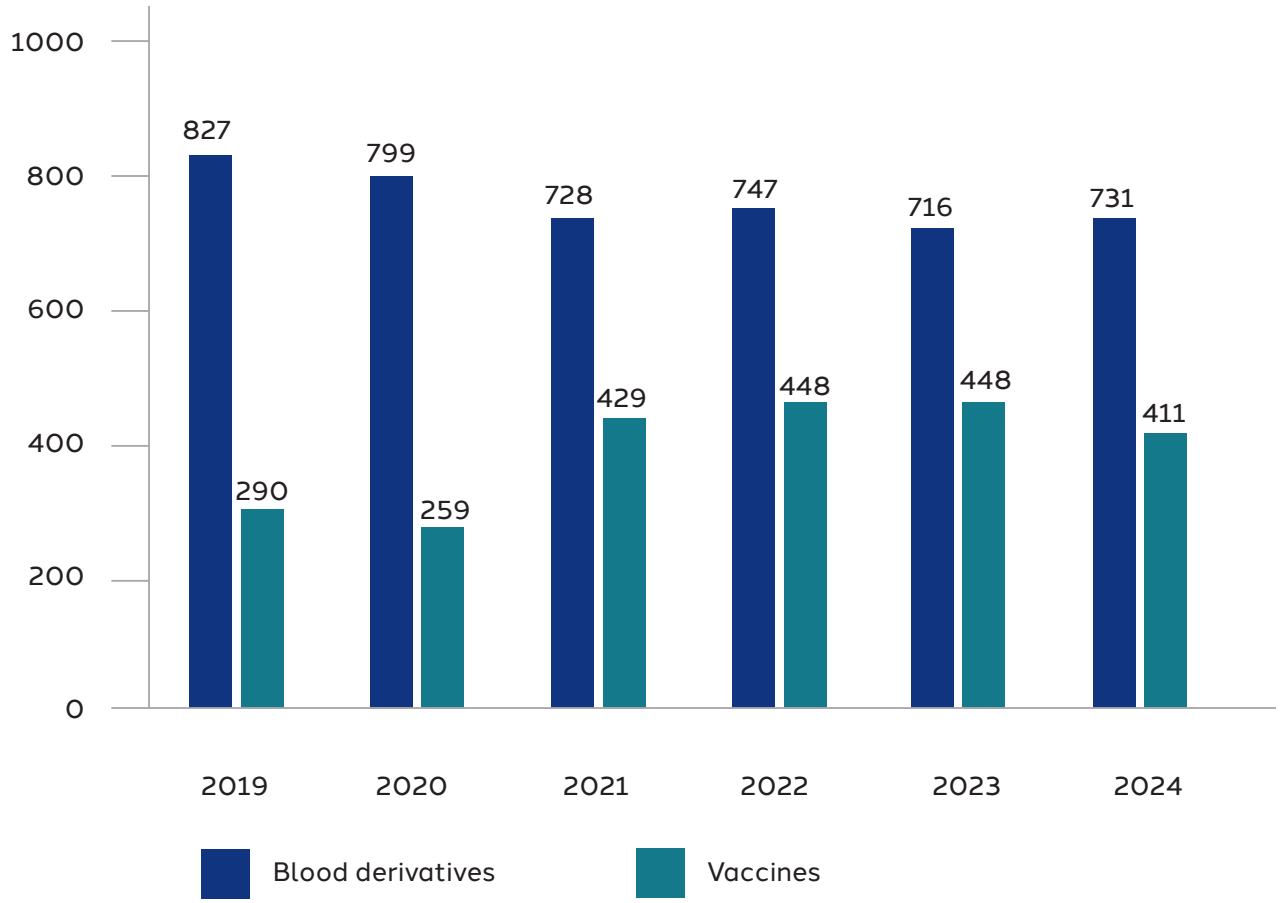
Graph 1 Number of sample analyses in 2019–2024



Graph 2 Development in the number of non-compliant samples in 2019–2024 (v %)



Graph 3 Number of released batches in 2019-2024



The Quality Defects Unit is in charge of addressing quality defects of pharmaceuticals and excipients available on the market in the Czech Republic and it safeguards activities aimed at eliminating a potential jeopardy caused by a pharmaceutical or an excipient of inadequate quality, including assessments of the measures proposed/adopted by regulated entities. Furthermore, it is in charge of issues of counterfeit and stolen medicinal products in the legal distribution chain and it addresses also cases of unsuccessful verification of safety features on medicinal products in compliance with effective legislation in order to protect the public from counterfeit medicinal products. This activity also includes assessment of requests submitted under the provision of Section 11(r) of the Act on Pharmaceuticals.

The exercise of surveillance over compliance with the Act on Advertising Regulation in the sphere of advertising for medicinal products for human use (HMPs) and sponsorship in this area (with the exception of radio and television broadcasting) is safeguarded by the Advertising Surveillance Unit. The Unit carries out investigations into complaints pertaining to inappropriate advertising for HMPs and provides expert opinions on advertising materials and on advertising regulation issues. Furthermore, the Unit is involved in enforcement in those cases where illegal situation has been identified – i.e., illegal handling of pharmaceuticals, and also in decision-making on whether a specific product is a medicinal product or not.

4. 6 Laboratory Control

Laboratory control is performed by the Laboratory Control Department both within the scope of requirements set forth by the Act on Pharmaceuticals, i.e., the Department controls the quality of pharmaceuticals in circulation pursuant to predefined projects and releases batches of predefined medicinal products, and on the basis of internally submitted requests (requirements from other organisational units of the Institute). This includes, in particular, addressing of quality defects of medicinal products, analyses of pharmacy samples, suspected counterfeit and illegal pharmaceuticals, adverse drug reactions, etc. Since 1995, the laboratory units of the Laboratory Control Department have been active members of the international Official Medicines Control Laboratories (OMCL) network under the European Directorate for the Quality of Medicines (EDQM). The employees of both laboratory units attend annual OMCL meetings and they are members of working groups.

Table 11 Participation in international studies

Study	Study title	Rating
Study title	Thin layer chromatography	Good
Rating	Liquid Chromatography	Good
PTS 246	Conductometry	Good
CRS	Cefapirin sodium CRS 3	Good
SUP 013	Suspected Unknown Product	Good
CAP 2024/45	Zejula (2 samples)	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 centrally authorised medicinal products from the European market (Centrally Authorised Product)

The Department has an established quality management system compliant with the ČSN EN ISO/IEC 17025 standard. In 2021 and 2022, further verifications 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.

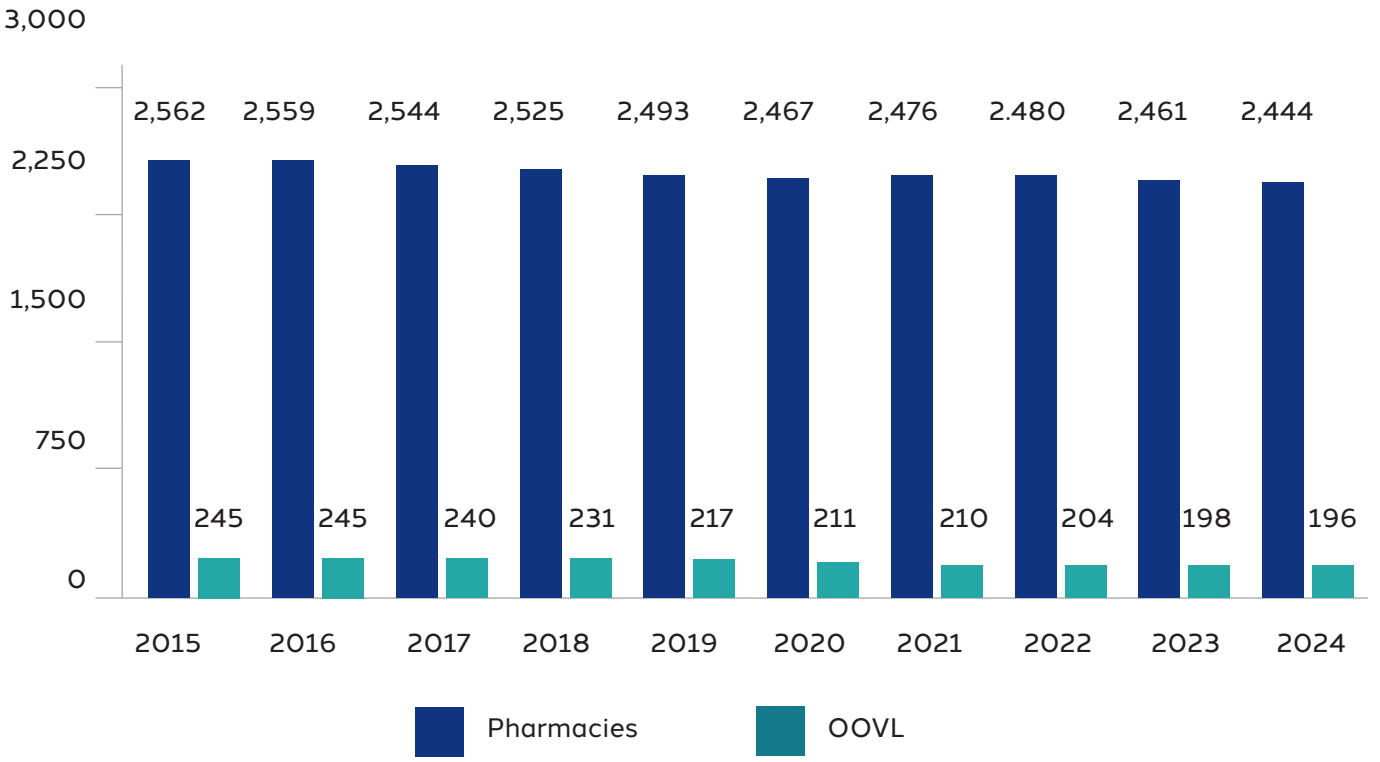
The results of sample analyses that were performed in 2024 by both laboratory units of the Laboratory Control Department are summarised in the tables below.

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 will be performed: control of medicinal products containing mirtazapine, pioglitazone, carvedilol, dolyxan, and, moreover, verification of microbiological quality of selected medicinal products. 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. Analytical control of influenza vaccines is also planned and the project of verification of the method of monoclonal antibody analysis by capillary electrophoresis is under way. In cooperation with the MA Dossier Assessment Department, the project of Masking effect and subsequent development of LER (low endotoxin recovery) effect of bacterial endotoxin in selected medicinal products is nearing completion.

The tables above indicate that in the Laboratory Control Department, 701 sample analyses were completed. Compared to the previous year, the number of samples rated as non-compliant (ex. counterfeit and illegal products) increased to 3.4 % (1.7 % in 2023; 2.6 % in 2022; 3.0 % in 2021; 3.2 % in 2020; 4.2 % in 2019; 5.8 % in 2018). Quality defects were confirmed particularly for pharmacy samples; furthermore, some medicinal products with errors in Braille were also rated as non-compliant. Otherwise, the quality of proprietary medicinal products available on the Czech market has been 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. Fig. 3 illustrates the number of released batches of blood derivatives and vaccines. For some vaccines, internationally recognised certificates (OCABR – Official Control Authority Batch Release) were issued after laboratory testing.

Graph 4 Number of pharmacies and OOVLs in the last 10 years (as at 31 December 2024)



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 conduct of various analytical methods, and verification of the quality of reference substances for the European Pharmacopoeia. In the laboratories, we typically also analyse one centrally authorised medicinal product per year on the basis of a contract with the EDQM. As part of international cooperation, SÚKL laboratories are contract laboratories for the Slovak State Institute for Drug Control (ŠÚKL) and for the Irish HPRA, particularly in the area of microbiological and sterility tests.

In 2024, the Laboratory Control Department took part in collaborative international studies listed in Table 11.

4. 7 Surveillance in the Area of Preparation, Dispensing, Sale, and Distribution of Pharmaceuticals

Surveillance in the area of medicinal product handling is one of the principal activities of the Pharmacy and Distribution Department. Control activities are carried out by the Institute in pharmacies, at vendors of selected medicinal products for human use, in healthcare facilities (including their specialised departments), and wholesale distributors and brokers of medicinal products. Furthermore, the Pharmacy and Distribution Department is in charge of the performance of price inspections of medicinal products and foods for special medical purposes, inspections of the conditions of dispensing of prescription-only medicinal products pursuant to the Act on Public Health Insurance, and inspections of handling of dependency-producing substances and precursors, including products containing the aforementioned, in pharmacies. The Pharmacy and Distribution Department, moreover, keeps and regularly updates publicly accessible lists of the aforementioned regulated entities with the exception of healthcare facilities.

By the end of 2024, the Institute kept a record on 2,444 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 196 detached pharmaceutical and medical device dispensing units (hereinafter referred to as "OOVL"), 3,522 outlets of vendors of selected medicinal products for human use, 42 nuclear medicine departments in healthcare facilities, 380 wholesale distributors, and 47 brokers of medicinal products for human use. Compared to 2023, the total number of pharmacies decreased by 17 pharmacies and the number of OOVLs decreased by two units (Graph 4 refers).

In 2024, the inspectors of the Pharmacy and Distribution Department conducted the total of 643 inspections in pharmacies, of which 22 were hospital pharmacies of inpatient care providers. Of the total number of completed inspections, 29 were targeted inspections, which were conducted on the basis of reports or complaints.

Separate inspections of handling of dependency-producing substances and precursors were carried out in 395 pharmacies.

Price controls focused upon compliance with the Act on Prices and rules of price regulation were performed in 87 pharmacies and ten wholesale distributors.

On the basis of facts identified during the conducted inspections, 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 26,940,000 CZK, incl. aggregate fines (see below) and finalised administrative procedures based on inspections completed in the previous period, and two admonitions were adopted in respect of pharmacy operators. Eight fines with final effect amounting to the total of 1,100,000 CZK were imposed for failure to cooperate during the inspection. **In six cases**, the preparation of medicinal products was suspended for a pharmacy due to non-verified weights used during the preparation of the 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; 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; 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 2024, identification of major breaches of the Act on Dependency-Producing Substances resulted in the total of six final decisions on fine imposition upon pharmacy operators; in total, the fines amounted to 90,000 CZK, incl. aggregate fines.

In 2024, 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 in terms of record-keeping and documentation of dependency-producing substances and shortcomings in reporting the stock levels and movements of dependency-producing substances and products.

The completed inspections focused upon compliance with **price regulation** rules governing medicinal products in pharmacies identified 29 cases of a price regulation breach. In 2024, the total of 17 decisions on administrative penalty imposition became final, of which eight cases involved fines amounting to 412,000 CZK in total and the other nine 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 2024. Two decisions on administrative penalty imposition became final, of which one was an admonition and one was a fine for a breach of the Act on Public Health Insurance identified in the previous period in the amount of 50,000 CZK.

Furthermore, in 2024, 216 inspections concerning the **handling of medicinal products in healthcare facilities** were carried out. The inspections took place in 14 inpatient departments of healthcare service providers and in 202 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, 15 targeted inspections in total took place.

In 2024, in total, four final decisions on fine imposition in the total amount of 150,000 CZK were issued for identified breaches of the Act on Pharmaceuticals (this includes also finalised administrative procedures based on inspections completed in the previous period).

The main reasons for the issuance of the decision on administrative penalty imposition included handling of medicinal products contrary to the

summary of the product characteristics; providing advantage to pharmacy care providers by directing the patient to a particular pharmacy; serious or multiple breaches of obligations governing the handling of medicinal products stipulated by implementing legal regulations (failure to keep storage temperature records, handling of medicinal products returned by patients, shelf-life checks, missing regulatory documentation, etc.).

In 2024, inspections of **vendors of selected medicinal products** concerned 107 outlets in total. For breach of the obligations implied by the Act on Pharmaceuticals, 13 final decisions on fine imposition in the total amount of 153,000 CZK were issued.

In other healthcare facilities authorised to prepare medicinal products (Nuclear Medicine Departments [ONM] and workplaces preparing autogenous vaccines for human use [HAV]), 15 inspections in total were carried out. The findings from the inspections did not constitute any reason for offence procedure commencement.

Summary results from inspections conducted in 2024 are provided in Table 12.

Table 12 Inspection surveillance over pharmacies, nuclear medicine departments, healthcare facilities, and vendors of selected medicinal products in 2024

			Classification of defects						Penalties		
Inspected entity	**Inspection type**	**Number**	**1**	**%**	**2**	**%**	**3**	**%**	**A**	**B**	**C**
Pharmacies	Regular inspections*	643	444	69.5	131	20.5	64	10.0	6	-	71
	Price controls	87	Not rated as per classification of defects						-	-	19
	Inspections of dependency-producing substances and precursors	395	334	84.6	46	11.6	15	3.8	-	-	6
ONMs		12	12	100.0	-	-	-	-	-	-	-
HAVs		3	1	33.3	2	66.7	-	-	-	-	-
Healthcare facilities*		216	165	77.1	35	16.4	14	6.5	2	-	4
Vendors of selected medicinal products*		107	76	71.7	18	17.0	12	11.3	-	-	13

**Some of the targeted inspections were not rated*

Classification of defects

1 – None or minor defects identified

2 – Major or recurring defects

3 – Critical defect or serious breach of law

Penalties

A – Suspended preparation

B – Suspended operation

C – Administrative penalty imposed (final decision)

Table 13 Other activities of the Pharmacy and Distribution Department

Initial pharmacy inspection	Establishment of a new pharmacy/ OOVL	Defunct pharmacies/OOVLs
109	65/10	82/12
Initial OOVL inspection	**Consultations on material and technical equipment**	**Other consultations**
13	150	498

In 2024, inspectors from the Pharmacy and Distribution Department collected the total of 216 samples of medicinal products during inspections in pharmacies, of which 63 were samples of pharmaceutical products intended for the preparation of magistral formulas in the pharmacy. Out of 153 pharmacy samples (medicinal products prepared in pharmacies), twelve were out-of-specification: six cases concerned inadequate microbiological safety, four cases constituted out-of-specification content of the active substance, and in two cases, the declared antimicrobial ingredient was missing or the pH value was inconsistent. In three samples intended for dispensing, defects in their labelling were identified.

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 2024, the total of 233 requests for issuance of an opinion were received from pharmacy operators and 229 favourable binding opinions were issued.

In 109 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 13 cases, with an inspection of the OOVL (Table 13 refers). Furthermore, in this context, 150 consultations on the instrumentation of existing pharmacies or the construction of new pharmacies, and 498 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 13 also provides data on newly established and defunct pharmacies/OOVLs.

Distribution of Medicinal Products

In 2024, the number of distributors exhibited a year-to-year decrease by five entities to the total of 380 medicinal product distribution authorisation holders. Of the total number of authorised distributors, 79 entities are both a distribution authorisation holder and a pharmacy operator.

In 2024, 25 new distribution authorisations and 98 decisions on variations to distribution authorisations were issued, and 22 authorisations were revoked upon request of their holders. For three entities, the distribution authorisation was revoked by the decision of the Institute in compliance with Section 76(3) of the Act on Pharmaceuticals.

In 2024, the total of ten entities applied for entry into, variation to entry in, or deletion from the Registry of Brokers of Human Medicinal Products; as of 31 December 2024, the Registry contained 47 brokers in total.

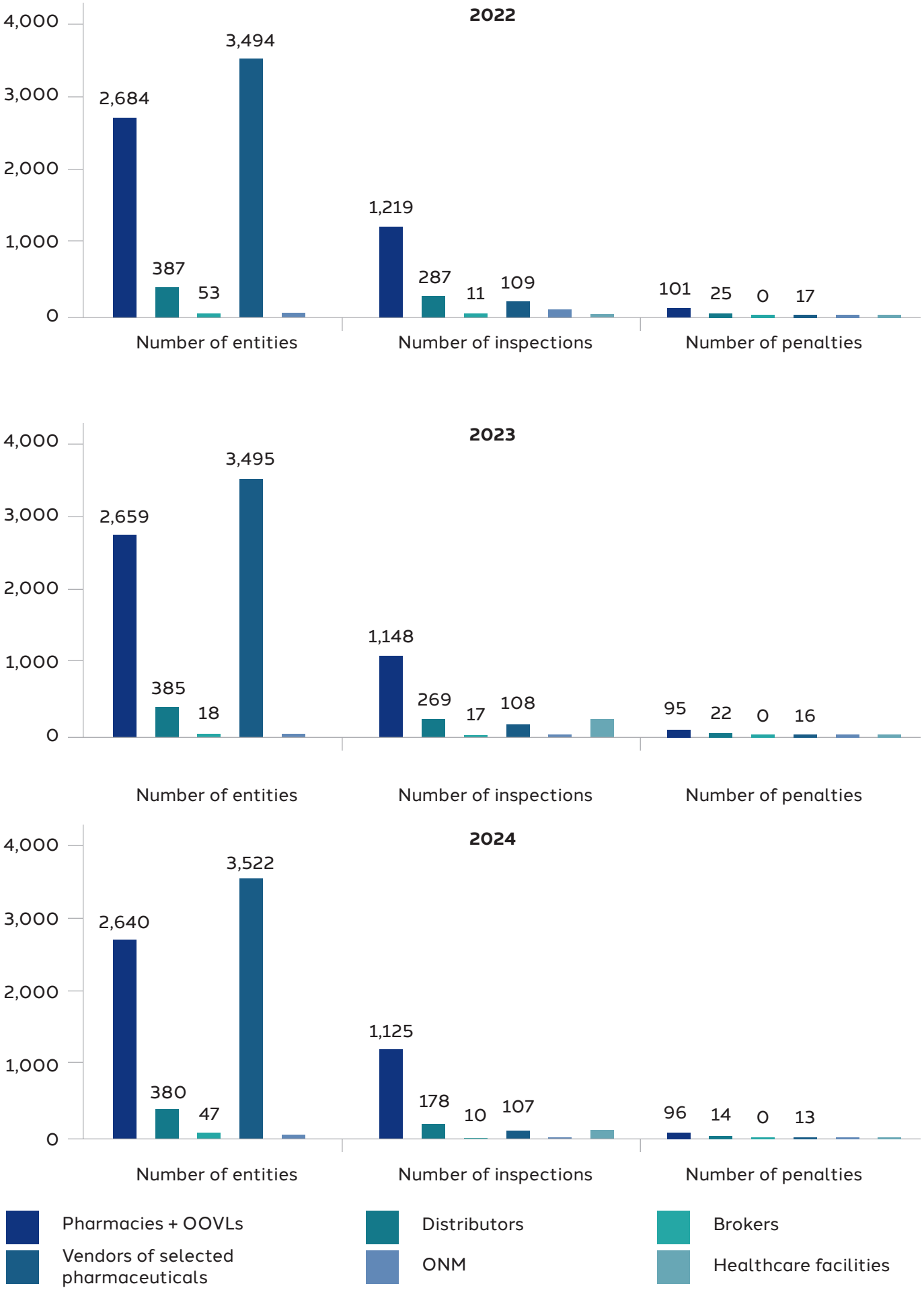
Table 14 provides an overview of received applications and issued decisions concerning distribution authorisations, variations thereto or revocations thereof, and the registration of brokers of medicinal products.

Table 14 Distribution and brokerage of pharmaceuticals in 2024

	Received applications	Decisions issued/ Registry entries made
Application for distribution authorisation	31	25
Application for variation to distribution authorisation	107	98
Application for revocation of distribution authorisation	23	22
Application for entry in the Registry /variation to entry in the Registry/deletion from the Registry	10	9

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

Graph 5 Information on surveillance activities in 2022–2024



In 2024, the total of 178 inspections of distributors and ten inspections of brokers were carried out, of which four were targeted inspections performed on the basis of internal and external reports. In total, 15 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 one case.

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 their intention to export a medicinal product placed on the list of the Ministry of Health of the Czech Republic 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 129 rated inspections of distributors (follow-up and targeted inspections), 81.4 % were rated with grade 1 (good), 13.9 % with grade 2 (satisfactory), and 4.7 % with grade 3 (not satisfactory). On the basis of identified facts, in three cases in total it was proposed to initiate an administrative procedure regarding 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 122 post-inspection Good Distribution Practice Certificates were issued, of which one Certificate was issued with scope limited to storage. Similar to distribution authorisations and variations thereto, all of the issued Certificates are regularly entered into the European EudraGMDP Database.

The Good Distribution Practice Unit, with the authorisation of the Strasbourg EDQM inspectorate and the Institute's Laboratory Control Department, was carrying out 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 59 consultations concerning the application of Good Distribution Practice principles and, on an ongoing basis, has been providing opinions and source materials upon request from other bodies and organisations, including those from abroad (Ministry of Health of the Czech Republic, revenue authorities, courts of justice, the Czech Police, the National Antidrug Centre (NPC), EMA).

In 2024, 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 four cases and these consisted of failure to comply with the procedure set forth by 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 2024, three fines in the total amount of 360,000 CZK were imposed with final effect upon distributors for committed pricing offences.

On the basis of findings from inspections, in 2024, distributors were imposed one admonition and the total of ten final decisions on fines for breaches of obligations stipulated by the Act on Pharmaceuticals and its implementing regulations amounting to 750,000 CZK in total (incl. also finalised administrative procedures based on inspections completed in the previous period).

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 of Health of the Czech Republic; failure to notify of the intention to distribute a medicinal product placed on the list of the Ministry of Health of the Czech Republic abroad; as well as failure to file an application for variation to the distribution authorisation in case of changes concerning the distributor; and provision of incorrect or incomplete reports on the volumes of medicinal products distributed to clients.

In one case, 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; this was entered in the EudraGMDP database.

The results of inspections at distributors in 2024 are provided in Table 15.

A comparison of the number of regulated entities, conducted inspections, and imposed penalties for the last four years is illustrated by Fig. 5.

Table 15 Inspection surveillance over distributors

Number of inspections					Inspection rating			Measures	
Total	Initial	Follow-up	Targeted	Variation	1	2	3	NCR	Proposed fine
178	26	125	4	23	105	18	6	1	3

Inspection Rating

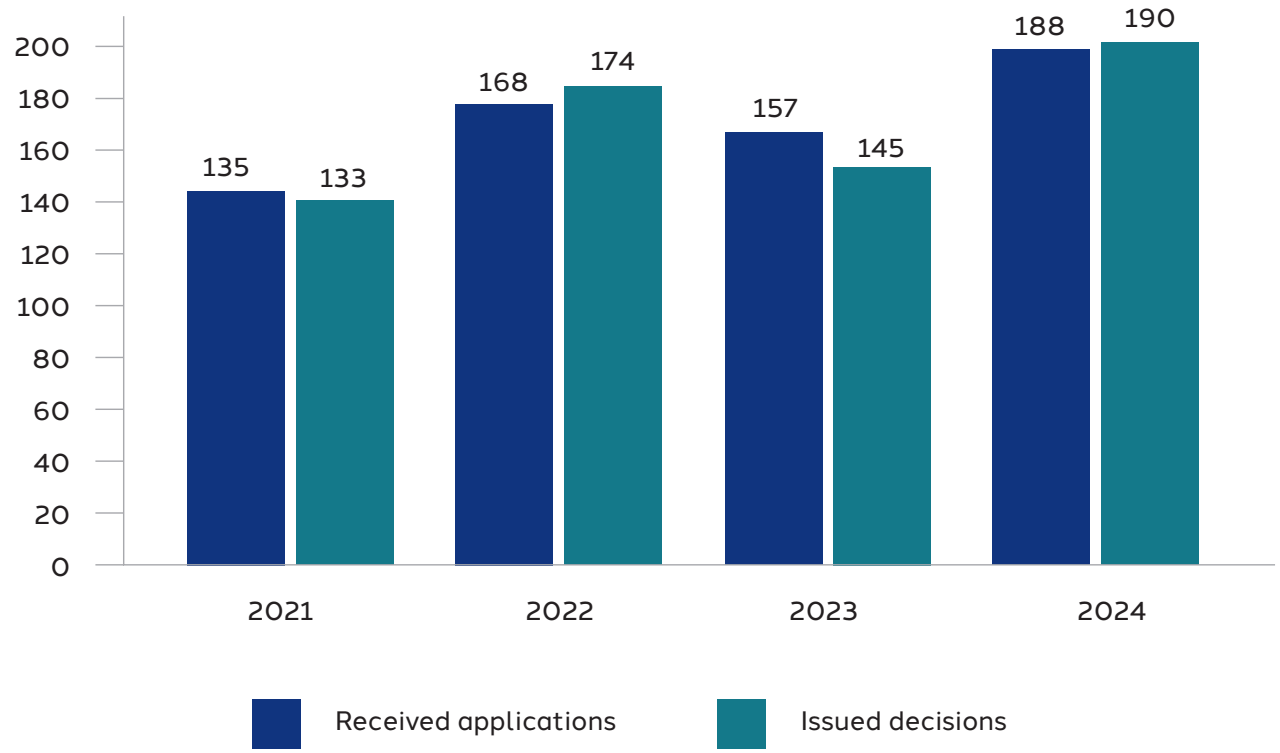
Inspections are rated on the basis of the identified shortcomings and their severity, and according to the achieved point score, the overall level of compliance with the principles of Good Distribution Practice is expressed by the following rating:

1 – Good *2 – Satisfactory* *3 – Not satisfactory.*

4. 8 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 transfusion products and starting materials for further manufacture of pharmaceuticals – hereinafter referred to as "TP"), Good Clinical Practice and Good Laboratory Practice, issuance of binding opinions on the import of active substances, including cooperation with the customs authorities. Furthermore, the Department exercises 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. This activity involves also the issuance of authorisations to engage in the operation of a tissue centre, donation centre, HTC distributor or diagnostic laboratory, the conduct of inspections, monitoring of actual or suspected serious adverse events and reactions, and, where doubts

Graph 6 Numbers of received and decided applications



arise, decision-making as to whether tissues and cells subjected to regulation by a particular act are concerned. It, moreover, safeguards activities in the sphere of haemovigilance, monitoring of serious adverse reactions experienced by transfusion product donors or recipients, and serious adverse events associated with blood collection, examination, processing, storage, and distribution of transfusion products or starting materials for further production or with transfusion product dispensing. The Department also receives and assesses reports from the European rapid alert systems for blood (hereinafter referred to as "RAB") and for HTC (hereinafter referred to as "RATC").

Manufacture of Pharmaceuticals

The updated lists of operators in the sphere of manufacture of pharmaceuticals subjected to surveillance are available from the Institute's website.

In the sphere of manufacturers (incl. blood centres), the total of 146 applications for the issuance of manufacturing authorisation or variations thereto were received (Table 16 refers). The number of cases brought forward from one year to another corresponds to the timelines governing the application processing.

Table 16 Administration of applications in the sphere of manufacture of pharmaceuticals and in the sphere of human tissues and cells

Application type		2021		2022		2023		2024	
		Received applications	Issued decisions	Received applications	Issued decisions	Received applications	Issued decisions	Received applications	Issued decisions
Application for manufacturing authorisation	Tissue centre	1	0	3	2	2	2	5	3
	Distribution of tissues and cells	1	1	1	1	3	2	2	1
	Donation centre	3	3	3	3	2	2	0	0
Application for variation to manufacturing authorisation	Diagnostic laboratory	53	53	52	55	43	43	48	47
	Tissue centre	2	2	6	6	10	9	7	6
	Distribution of tissues and cells	39	43	47	46	33	32	84	85
Application for manufacturing authorisation revocation	Donation centre	2	2	3	3	3	3	1	1
	Diagnostic laboratory	1	1	0	0	3	2	0	0
	Tissue centre	0	0	1	1	0	0	0	0
Application for authorisation to engage in the operation of:	Distribution of tissues and cells	0	1	2	2	1	1	0	0
	Donation centre	0	0	0	0	2	0	1	3
	Diagnostic laboratory	0	0	0	0	0	0	0	0
	Diagnostic laboratory	1	1	1	1	0	0	2	2
Application for variation to operation of:	Tissue centre	29	24	41	46	47	42	33	38
	Distribution of tissues and cells	0	0	0	0	0	0	1	1
	Donation centre	0	0	2	2	1	1	0	0
	Diagnostic laboratory	2	2	4	4	6	5	3	2
Application for revocation of operation of:	Tissue centre	0	0	0	0	1	1	0	0
	Distribution of tissues and cells	0	0	1	1	0	0	1	1
	Donation centre	0	0	0	0	0	0	0	0
	Diagnostic laboratory	0	0	1	1	0	0	0	0
Total		**156**	**135**	**133**	**168**	**145**	**157**	**188**	**190**

Table 17 Inspections carried out in 2024 and their results

	Number of inspections					Inspection rating			
	Total	**Initial**	**Follow-up**	**Targeted**	**Variation**	**Compli-ant[1]**	**Non-com-pliant**	**Breach of law**	**Proposed fine**
Manufacturers of medi-cinal products	**45**	3	34	1	7	45	0	1	0
Manufacturers of in-vestigational medicinal products	**16**	0	13	2	1	16	0	0	0
Manufacturers of active substances	**28**	6	16	0	6	27	1	0	0
Control laboratories	**14**	2	10	1	1	14	0	0	0
Control laboratories for investigational medicinal products	**2**	0	1	0	1	2	0	0	0
Active substance im-porters	**0**	0	0	0	0	0	0	0	0
Blood centres	**66**	0	63	0	3	66	0	0	0
Blood banks	**22**	0	22	0	0	22	0	0	0
GCP inspections	**27**	0	0	27	0	0	0	2	0
TC, DC, DL, DIS inspec-tions	**49**	4	41	2	2	48	1	0	0

Explanatory notes: TC – tissue centre; DC – donation centre; DL – diagnostic laboratory; DIS – distributor of tissues and cells
1 Rated only in case of initial and follow-up inspections.

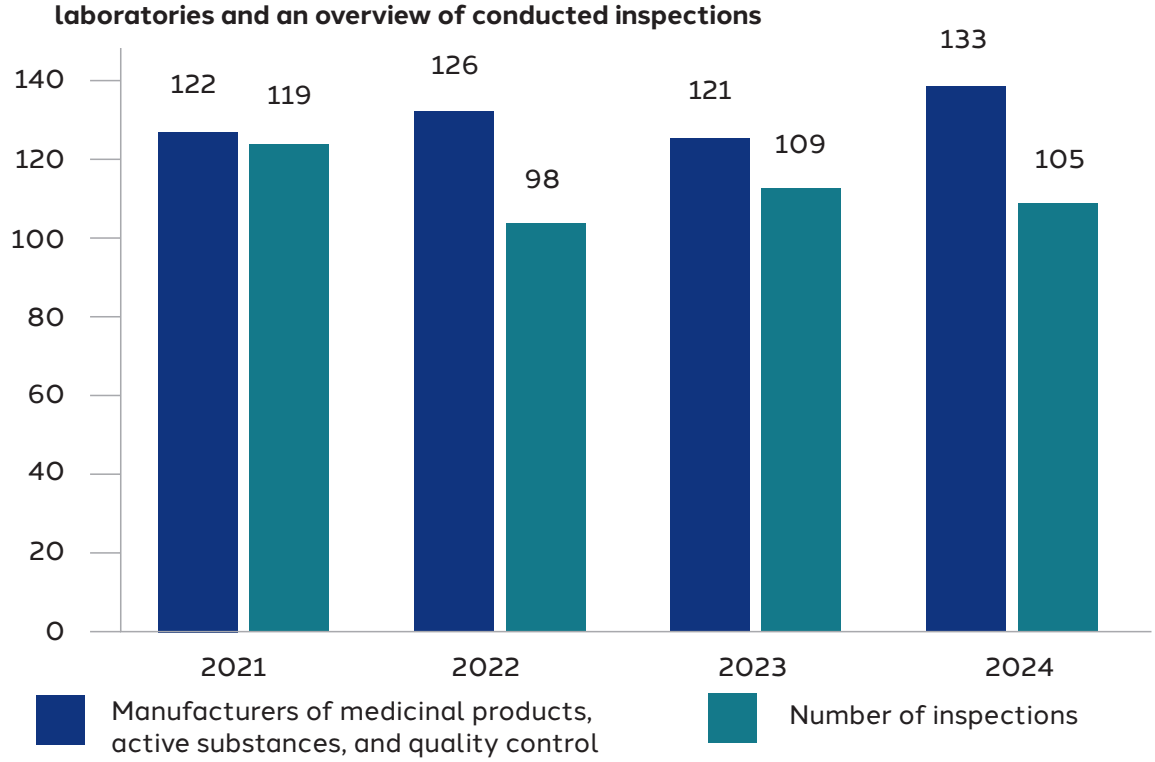
Human Tissues and Cells

This is an area regulated by the Institute pursuant to Act No 296/2008 Coll., on Human Tissues and Cells.

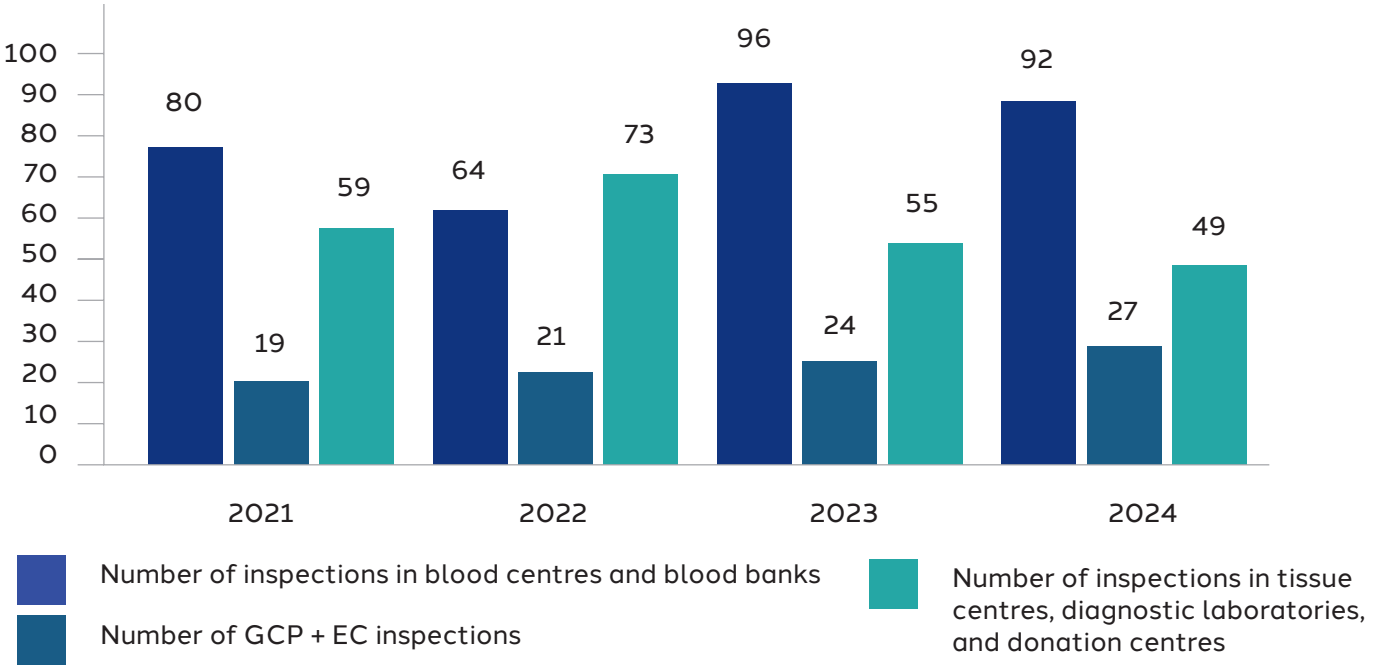
In 2024, 40 applications for authorisation to engage in an operation and applications for variations thereto were received.

In 2024, the total of 246 inspections were carried out, of which 49 inspections concerned the regulated area of tissues and cells. Their nature and resulting ratings can be found in Table 17. A comparison of the number of inspections and breaches of the Act on Pharmaceuticals, or of the Act on Human Tissues and Cells, where applicable, in the period of 2021-2024 is provided in Table 18 and in Graph 7 and 8.

Graph 7 Number of manufacturers of medicinal products and active substances, number of control laboratories and an overview of conducted inspections



Graph 8 Overview of inspections conducted in the area of blood centres + blood banks, GCP and HTC (tissue centres, diagnostic laboratories, donation centres) in the period of 2021–2024



Initial inspections were performed in relation to an application for operating authorisation as referred to under Section 63(4) of Act No. 378/2007 Coll. Follow-up inspections were carried out at sites of manufacturers of medicinal products and active substances or in control laboratories within intervals stipulated by Decree No. 229/2008 Coll., and those concerning blood centres pursuant to Decree No. 143/2008 Coll., or in abbreviated intervals on the basis of the previous inspection rating which, in addition to the evaluation of the standard of Good Manufacturing Practice (GMP) proper, covers also manufacture risk assessment and rating of other criteria. Inspections associated with variations are conducted where the conditions under which the operation was authorised have changed. Targeted inspections are conducted in order to review a certain section of activities (e.g., an inspection associated with a quality defect of a medicinal product).

Table 18 Inspections conducted in 2021–2024

	2021		2022		2023		2024	
	No. of inspections	Breaches of law	No. of inspections	Breaches of law	No. of inspections	Breaches of law	No. of in-spections	Breaches of law
Manufacturers of medicinal products	67	4	62	0	54	0	61	1
Manufacturers of active substances	33	1	17	0	29	0	28	0
Control laboratories	19	0	14	0	23	0	16	0
Active substance importers	4	0	5	0	3	0	0	0
Blood centres	77	0	52	0	74	0	66	0
Blood banks	3	0	12	0	22	0	22	0
GCP inspections	19	0	21	1	24	2	27	2
Tissue centres, donation centres, diagnostic laboratories	59	0	73	0	55	0	49	0
Total	**281**	**1**	**256**	**1**	**284**	**0**	**246**	**2**

Of the total number of 105 inspections at manufacturers' of medicinal products and active substances or in control laboratories, one breach of law was identified and one report on non-compliance with the requirements of Good Manufacturing Practice (GMP) was issued. The GMP standard in blood centres was rated mostly as good and no breach of law was identified. The plan of follow-up inspections was being fulfilled in respect of all regulated entities.

Inspections in tissue centres, donation centres and in diagnostic laboratories are performed 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.

Graph 9 Issued certificates

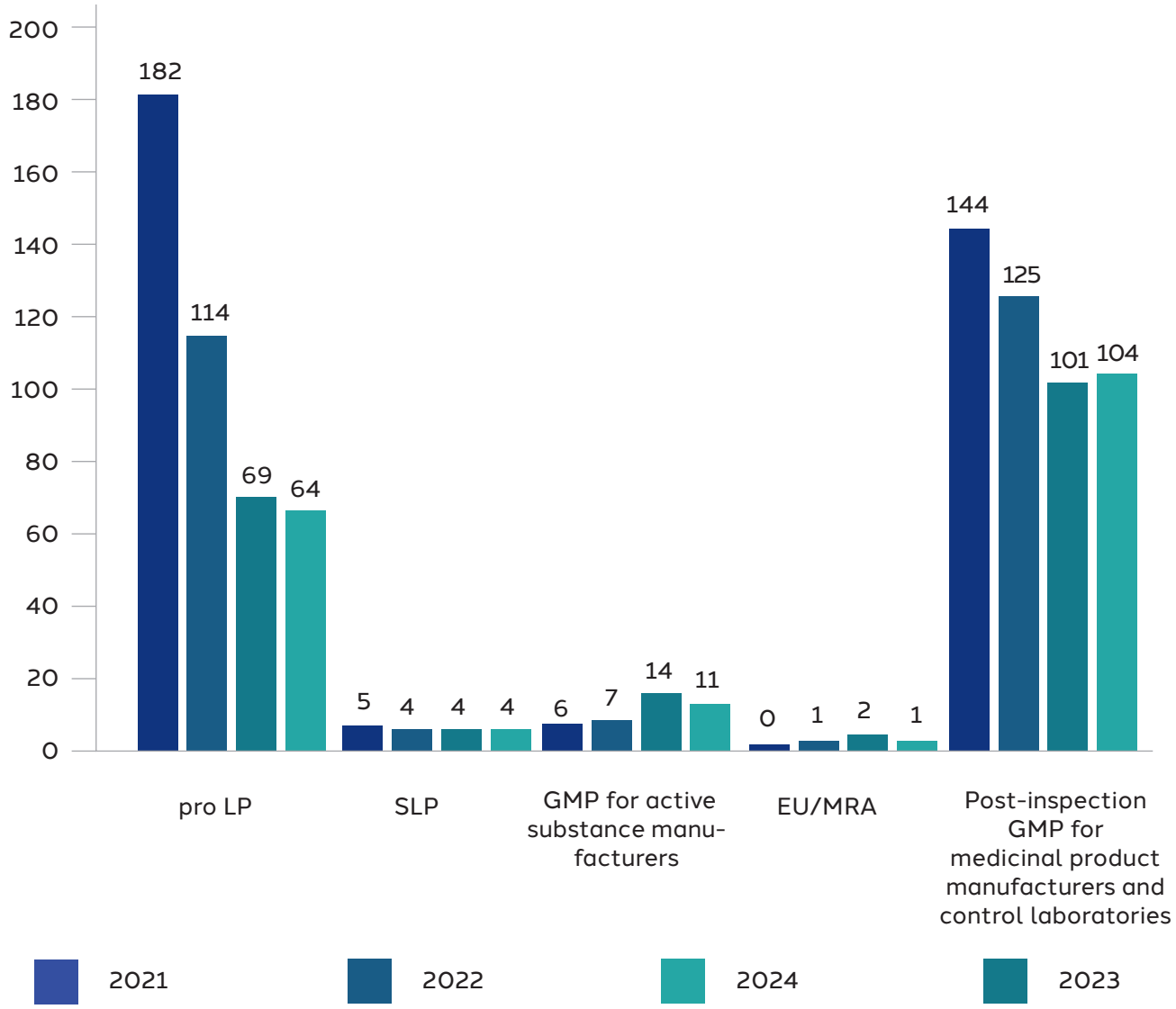


Table 19 Foreign GMP inspections

	2021	2022	2023	2024
Number of inspections	3	6	5	11
Certificate issuance	3	6	5	11
Issued non-compliance	0	0	0	0

Table 20 Number of reports received in 2024 (from 2015 to 2024)

Quality defects	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Reports received in total	333	420	443	496	497	496	559	840	841	832
Reports from the Czech Republic	181	243	277	286	284	304	301	431	439	425
Reports from abroad	152	177	166	210	213	192	258	409	402	407
Resulted in recall (in SÚKL codes)										
Administrative procedure (since 04/2017)	79	72	79	89	59	47	54	38	37	77
Rapid Alert										
(od 04/2017)	-	-	20	33	81	55	80	99	80	81
Rapid Alert	11	17	22	6	15	1	8	10	7	6

Explanatory notes: Rapid alert = a rapid alert notification sent by the Institute within the scope of the international Rapid Alert system

Haemovigilance

V In 2024, 51 reports of suspected serious adverse reactions (hereinafter referred to as "SAR") experienced by donors of blood and blood components or recipients of transfusion products were received, of which six reports are still pending and in 17 cases, the suspected SAR was not confirmed. Thirty SARs involved blood or blood component donors (five investigations are still pending, eleven suspected SARs were not confirmed) and 21 cases concerned post-transfusion reactions in transfusion product recipients (one investigation is still pending, seven suspected SARs were not confirmed) – the investigations concerned nine cases of anaphylaxis (one investigation is still pending); five cases of transfusion related acute lung injury (TRALI; of which, three suspected SARs were not confirmed); two cases of transfusion-associated circulatory overload (TACO; of which, one suspected SAR was not confirmed); two cases of immune haemolytic reactions caused by another alloantibody; one case of bacterial infection transmitted by transfusion (the suspected SAR was not confirmed); one sepsis and febrile reaction (the suspected SAR was not confirmed); and one case of suspected HBV transmission by transfusion (the suspected SAR was not confirmed). Of the concluded suspected SARs affecting transfusion product recipients, four cases resulted in death unrelated to the transfusion, other SARs completely resolved. Out of 30 suspected SARs in donors of blood or blood components, eleven were not confirmed, five investigations are still pending, and for 18 confirmed and concluded SARs affecting donors, donor recovery was confirmed; one case resulted in death of the donor unrelated to the donation.

Furthermore, 17 reports of suspected serious adverse events (SAE) associated with blood donation, testing, processing, storage, and distribution of transfusion products or raw materials for further manufacture, or transfusion product dispensing were reported; six cases concerned reports associated with donor infection (two cases of HBV infection, once case of HCV infection, once case of VHE infection, one case of syphilis, and one case of HIV; in five cases, the suspected infection transmission through transfusion was not confirmed, and one investigation is still pending); two reports concerned natural disaster consequences; three cases were reports of a human error during collection (two cases of confusion of saline and citrate during plasmapheresis, one confusion of labelled bags during whole blood collection); four cases concerned human error associated with transfusion product dispensing/administration (one case of transfusion product confusion during dispensing, one case of transfusion product confusion in the department, one case of patient confusion during sample collection, one case of dispensing of blood-group 0 plasma in vital indication); and one case concerned transfusion product haemolysis.

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 2024, the Institute received the total of 17 reports from eight countries. All of the cases concerned an epidemiological situation (14 were associated with the occurrence of the West Nile fever virus, two were associated with the occurrence of the dengue fever, and one with the occurrence of the chikungunya virus). One report (concerning the occurrence of the West Nile fever virus) was entered in the RAB system by the Czech Republic.

Good Laboratory Practice (GLP)

In 2024, 16 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. In the same year, three follow-up inspections took place.

Good Clinical Practice (GCP)

In the course of 2024, 27 Good Clinical Practice inspections were performed in total. Of the said number, 22 concerned a targeted inspection of a clinical trial site (a GCP inspection at the investigator's site); three were inspections of compliance with the obligations of the sponsor taken over by the Contract Research Organisation (CRO); two were inspections on the basis of an application for the issuance of a Good Clinical Practice Certificate conducted at a healthcare service provider where a first-in-human (FIH) clinical trial is conducted; and an inspection on the basis of an application for the issue of a Good Clinical Practice Certificate carried out at a healthcare service provider where a clinical trial without therapeutic or preventive effect for trial subjects is conducted, namely bioequivalence and pharmacokinetic clinical trials. In two cases, a potential breach of legislation was identified.

In 2024, one EMA GCP inspection associated with marketing authorisation of a medicinal product and two joint inspections upon SÚKL's request were conducted.

Certification

In total, 184 various certificates were issued. Post-inspection Good Manufacturing Practice Certificates are entered in the EudraGMDP database kept by EMA. All of the certificates for medicinal products were issued within the prescribed 30-day timeline and all post-inspection Good Manufacturing Practice Certificates within the 90-day timeline.

4. 9 Quality Defects of Pharmaceuticals and Counterfeit Products in Legal Distribution Chain

Since 2015, the number of reports in the area of quality defects of pharmaceuticals has been growing (Table 21 refers). A substantial increase in the number of received reports was seen in 2022; this included both reports received from the Czech Republic and from foreign countries (Graph 10 refers). This trend was seen also in 2023 and continued in 2024. The reason is, inter alia, the increased field awareness of the importance of reporting quality defects and the possibility to avail of electronic forms that make reporting easier. The growing number of reports from abroad is due to a higher involvement of non-European regulatory authorities in the information system via which quality defect reports are being received.

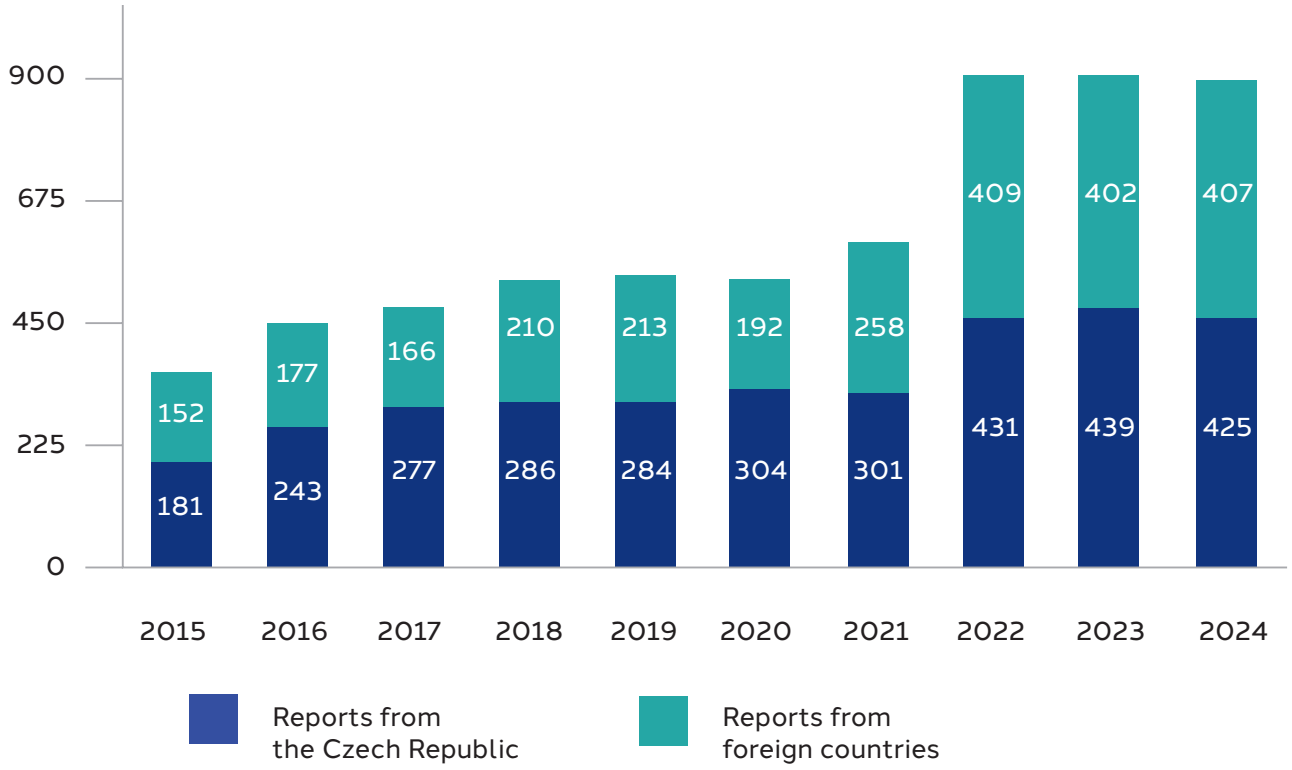
As part of addressing quality defects, effective actions have been taken to reduce the impact of quality defects of pharmaceuticals upon patient health. Similar to previous years, in 2024, the complaints concerned not only authorised medicinal products and individually prepared medicinal products, but also non-authorised or investigational medicinal products as well as substances intended for the manufacture of medicinal products and for the preparation of medicinal products in pharmacies. Through the international Rapid Alert System involving the EU, MRA, and PIC/S Member States, the Institute received and evaluated the total of 407 reports on quality defects. The percentage of received Czech and foreign reports has remained similar in recent years and it is illustrated by Graph 10.

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 2024, 81 administrative procedures in total were initiated and 79 final decisions were issued; these concerned 207 batches of medicinal products corresponding to 121 SÚKL codes of medicinal products. The issuance of two decisions was brought forward to the following year.

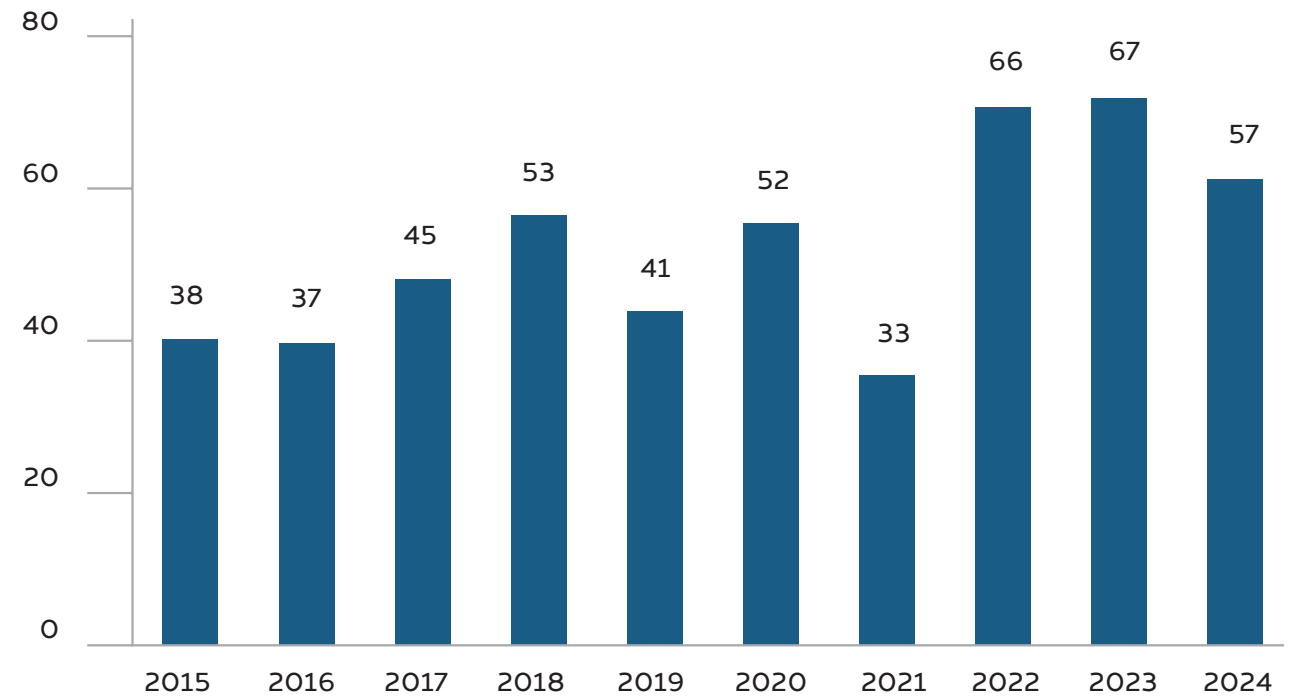
Since May 2022, the Quality Defects Unit has been publishing information letters for operators specifying the quality defect for which a decision on keeping the pharmaceutical on the market or a warning of a quality defect of a pharmaceutical or a condition that could be considered defective has been issued. In 2024, 37 information letters were published; some of them were updated, if the quality defect affected also another batch.

The Quality Defects Unit addresses also cases concerning the presence of counterfeit medicinal products in the legal distribution chain or theft of medicinal products. In 2024, the Quality Defects Unit addressed 57 such cases in total and there was no report of theft of medicinal products from the legal distribution chain. An overview of addressed cases concerning the presence of counterfeit products and theft of medicinal products is provided in Graph 11.

Graph 10 Number of reports received in the period from 2015 to 2024



Graph 11 Counterfeit medicinal products in the legal distribution chain and stolen medicinal products in the period from 2015 to 2024



Reports received from foreign countries include also reports on GMP non-compliance on the part of the manufacturer of a pharmaceutical. In 2024, the Quality Defects Unit received and evaluated 196 such reports in total.

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

An overview of measures adopted in 2024 for individual medicinal products (related to SÚKL codes) is provided in Table 21. All of these cases concerned measures taken by the marketing authorisation holders or operators themselves; the Institute was merely monitoring or adjusting these measures.

In the area of safety features, also in 2024, the Quality Defects Unit was involved in the implementation of Regulation 161/2016, supplementing Directive 2001/83/EC of the European Parliament and of the Council, in the Institute's procedures stipulating detailed rules for the entities concerned by the Regulation. The representatives of the Institute participated in the meetings of the expert group for safety features steered by the European Commission 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.

For 2024, the Institute recorded the total of 13,812 reports on unsuccessful safety feature verification (for the entire period from 09 February 2019 to 31 December 2024, this number amounted to 1,220,078 reports in total). In the course of 2024, the Unit issued favourable recommendations for the total of six medicinal products (six 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 of Health so as to safeguard the availability of medicinal products in the Czech Republic. The Quality Defects Unit also carried out investigations into 23 reports concerning suspected broken anti-tampering devices (ATDs), including other cases of non-compliances with Regulation No 2016/161.

4. 10 Enforcement

In 2024, active surveillance in the sphere of illegal handling of medicinal products focused particularly upon the identification, investigation, and penalisation of cases of illegal offers of medicinal product sale on the internet, namely through various advertising portals. In the sphere 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). Cooperation has been extended also to foreign partners, not only in the exchange of information, but also in the investigation of specific cases with potentially international impact.

In 2024, the total of 220 reports concerning illegal offers of medicinal product sale on the internet were investigated. The Institute conducted 33 internal investigations of illegal offers of medicinal product sale on the internet and executed twelve control purchases. In the sphere of enforcement, the Institute cooperates with the Czech Police. One hundred and forty-five cases of the illegal offers investigated by the Institute concerned a medicinal product containing a dependency-producing substance and the matter was forwarded to the Czech Police due to suspected criminal deed. In nine cases, the Czech Police forwarded the matter originally investigated as a suspected criminal deed to the Institute to be examined as an offence falling within the Institute's statutory powers.

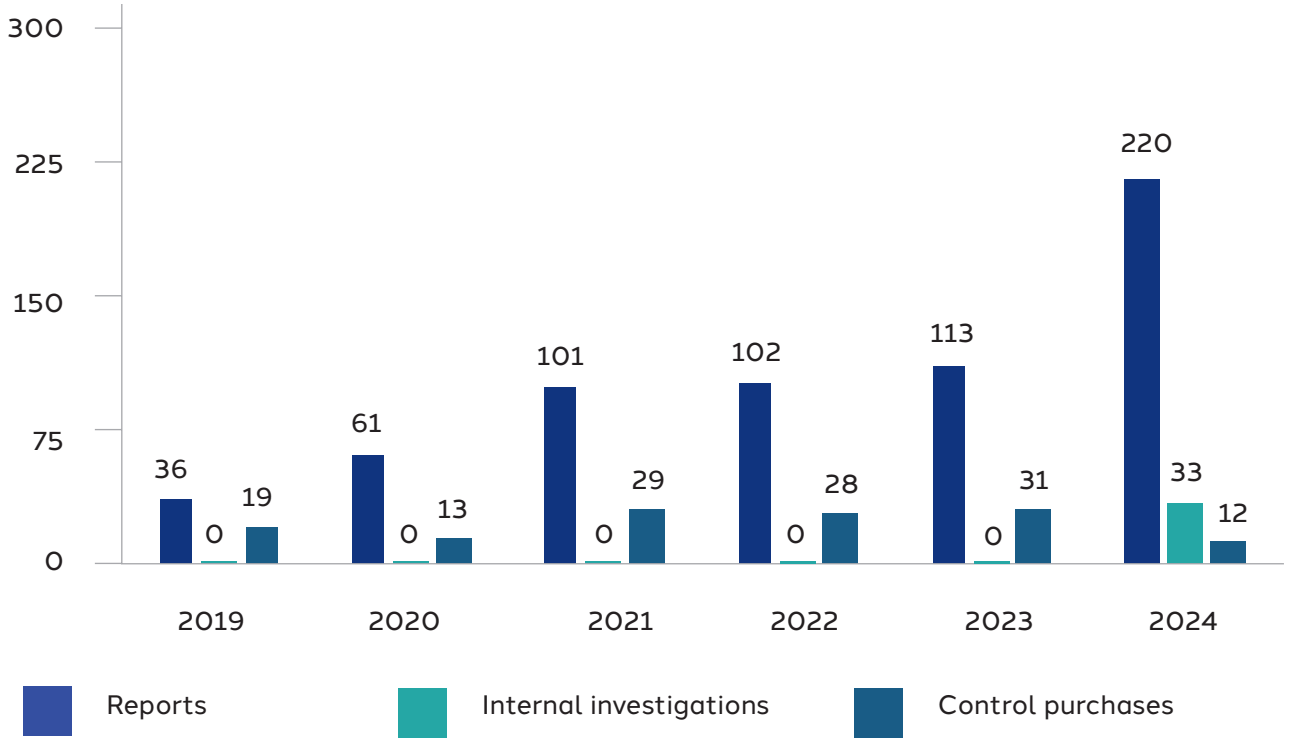
Table 21 Measures implemented in 2024 (related to SÚKL codes)

Implemented measures	Number
Recall from distributor level	0
Recall from healthcare facility level	74
Recall from patient level	3
Suspended distribution, dispensing and/or use	17
Released distribution, dispensing, and use	8
Permitted distribution, dispensing, marketing, and use in the provision of healthcare services through an administrative procedure	121 (number of batches: 207)

Table 22 Overview of investigated reports of suspected breaches of the Act on Advertising Regulation in 2024

Number of reports	Reports brought forward from 2023	New reports received in 2024	Total
Investigation completed	8	122	130
Forwarded for commencement of administrative procedure	8	120	128
Number of fines imposed with final effect	7	8	15
Number of fines imposed with final effect	15	3	18

Graph 12 Control activities in the period of 2019–2024



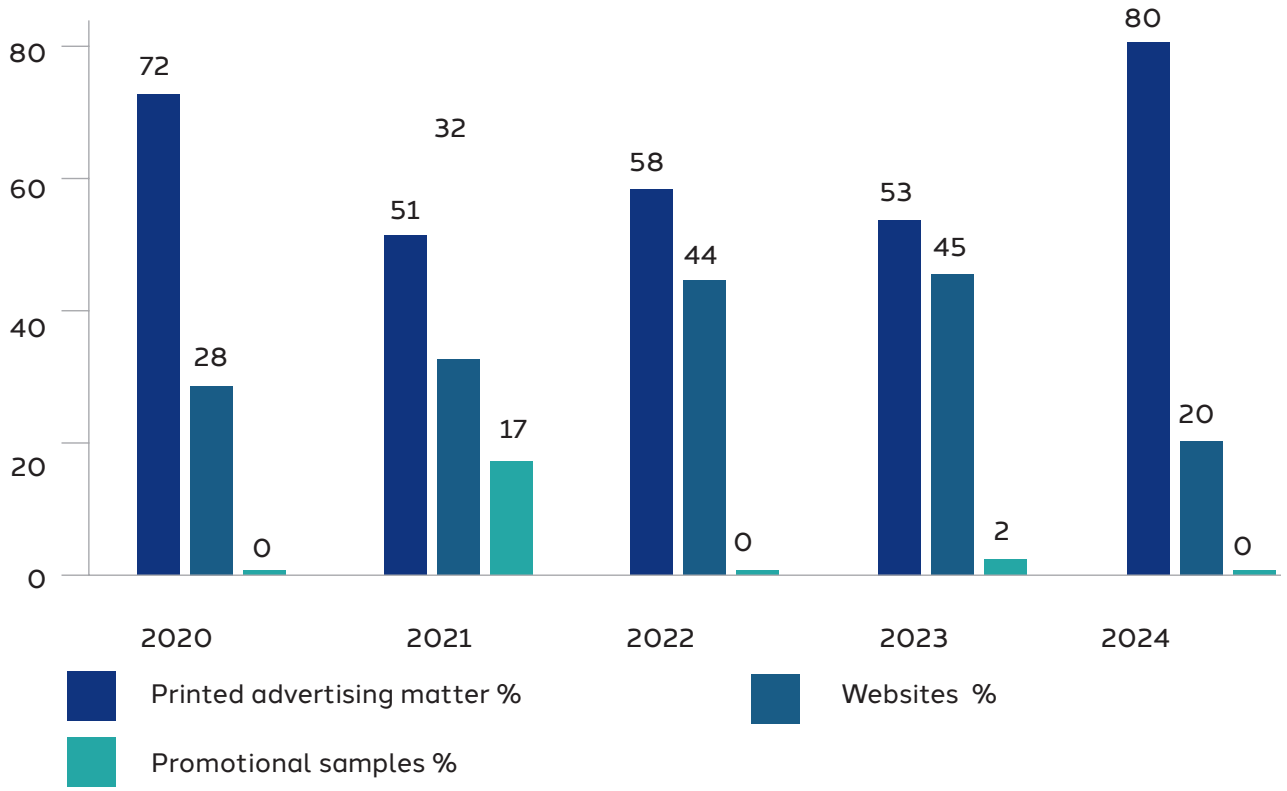
In 2024, the Institute prepared the total of 292 opinions on shipments from third countries for the customs authorities for the purposes of release or non-release of medicinal products imported from third countries. The Institute assessed whether products that were the object of non-commercial import in mail shipments, express shipments, and in other shipment channels, were medicinal products as defined by the provision of Section 2 of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals).

In compliance with its new power referred to under the provision of Section 13(3)(s) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (the Act on Pharmaceuticals), since 01 January 2022, the Institute has been keeping 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 2024, the Institute investigated 75 cases of websites with illegal medicinal product offer and included them in the list.

4. 11 Surveillance in the Area of Regulation of Advertising for Medicinal Products

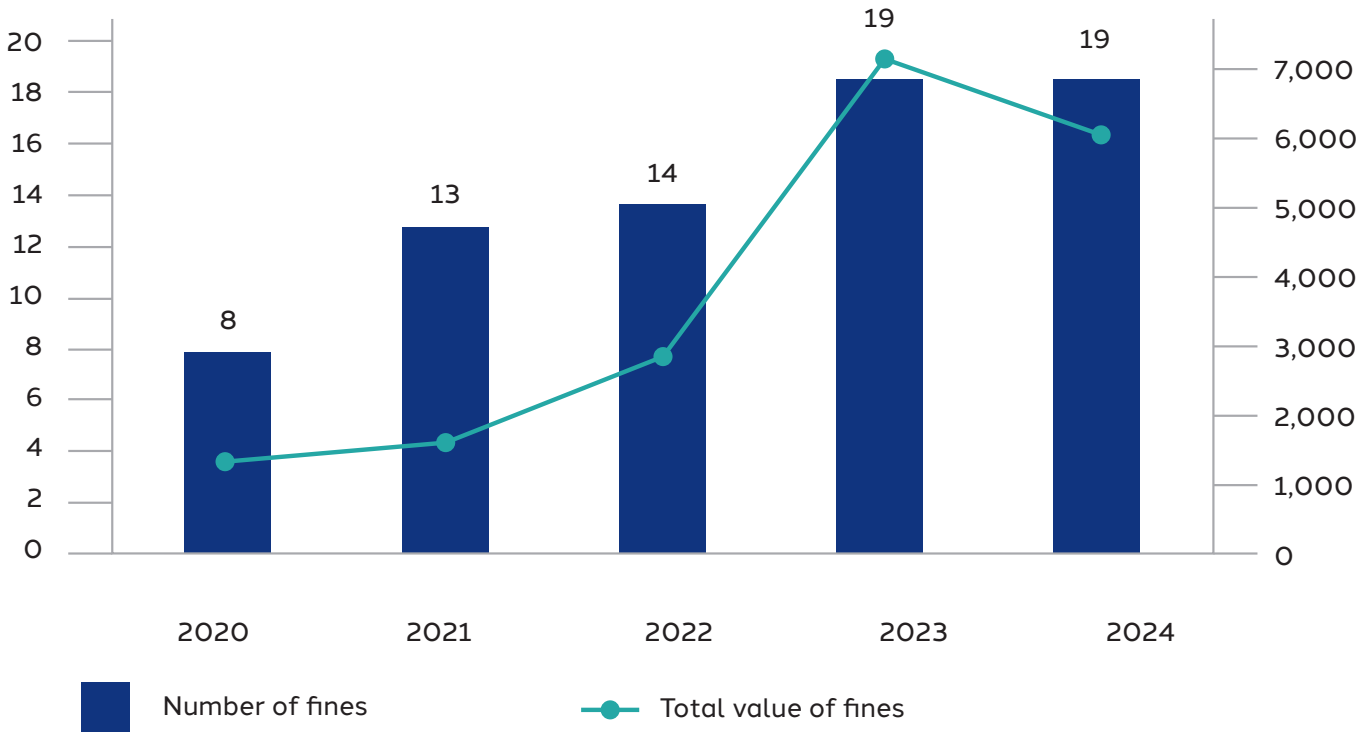
In 2024, the Institute investigated the total of 122 reports of suspected breaches of Act No. 40/1995 Coll., on Advertising Regulation, as amended (he-

Graph 13 Overview of investigated reports of suspected breaches of the Act on Advertising Regulation (2020–2024)



Graph 14 Overview of fines imposed for breaches of the Act on Advertising Regulation (2020–2024)

(thous. CZK)



reinafter referred to as the "Act on Advertising Regulation"); 19 administrative procedures were completed and these resulted in the imposition of 19 fines for breaches of the Act on Advertising Regulation in the aggregate amount of 5,040,000 CZK.

The subject of investigations into advertising was printed advertising matter (80 %) and websites (20 %).

Advertising for prescription-only medicines accounted for 45 % of the investigated cases; advertising for over-the-counter medicines represented 55 % of the cases.

Pharmaceutical companies or their legal representatives filed 2 % of reports on suspected breaches of the law, 11 % of reports were lodged by private individuals, 1 % by state administration authorities, and 84 % by SÚKL employees; anonymous reports accounted for 2 %.

Upon request, the Institute issued/provided 29 expert opinions/consultations on issues concerning proposed advertising for medicinal products for human use.

The inspectors of the Advertising Regulation Unit completed 25 inspections of compliance with the Act on Advertising Regulation and the Act on Pharmaceuticals and identified shortcomings in one controlled person.

Surveillance in the Area of Decision-making about Product Classification

In 2024, the Institute initiated investigation in respect of 86 various products, most often dietary supplements and cosmetic products, for suspected classification as a medicinal product. In one case, an ex officio/upon-request administrative procedure regarding product classification was initiated ex officio. In 2024, the Institute reclassified one product to the category of medicinal products.

Table 23 Number of texts in the European Part of Czech Pharmacopoeia 2023 – Supplement 2024

European Part	General Part	Special Part	Total
New	3	8	11
Revised	34	229	263
Total	37	237	274

Graph 15 Amount of finally imposed penalties in the area of pharmaceuticals and human tissues and cells in the period of 2020–2024

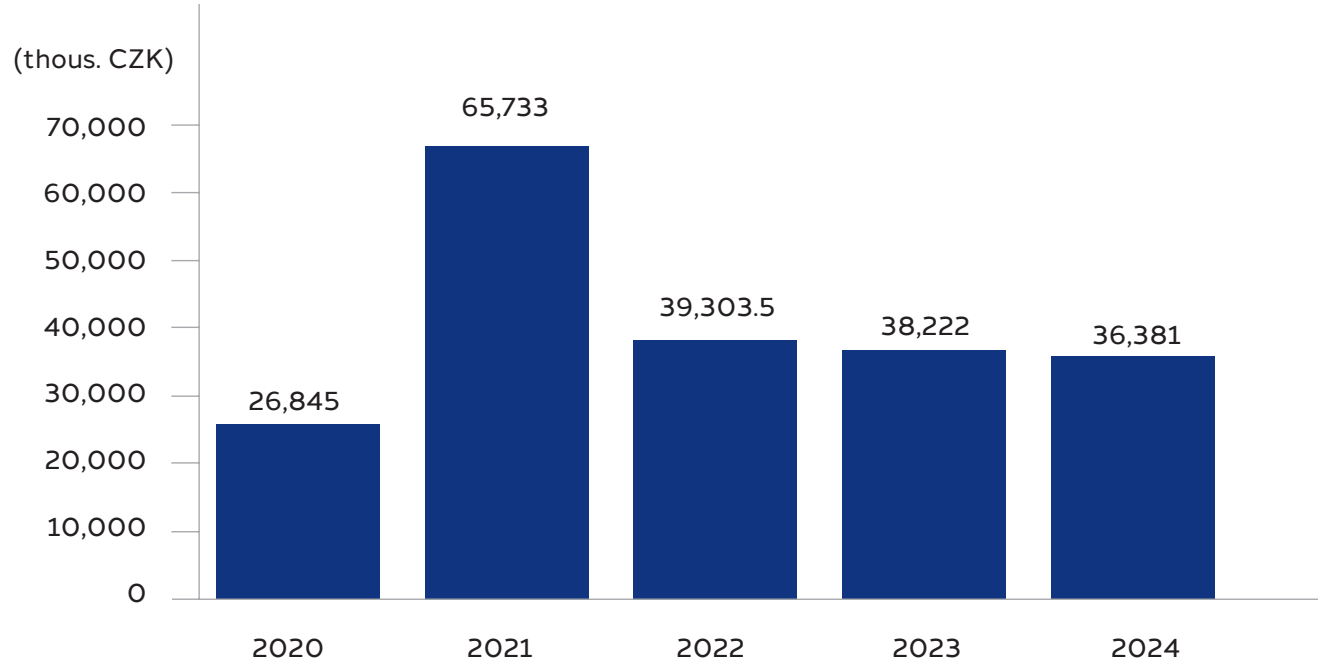


Table 24 Amounts of penalties in the area of pharmaceuticals and human tissues and cells in the period of 2020–2024

Act	2020	2021	2022	2023	2024
	26, 845	**65, 733**	**39, 303**	**38, 222**	**36, 381**
on Pharmaceuticals	24, 559	62, 237	26, 757	29, 674	29, 329
on Drug Precursors	0	0	45	0	0
on Dependency-Producing Substances	250	160	60	145	90
on Prices	54	872	9, 141	238	772
on Advertising Regulation	1, 090	1, 330	2, 370	5,970	5, 040
on Human Tissues and Cells	0	0	0	0	0
on Public Health Insurance	732	374	0	95	50
Code of Control Procedure	160	760	930	2,100	1, 100

4. 12 Standardisation and Pharmacopoeial Activities

During the first half of 2024, the first supplement to Czech Pharmacopoeia 2023 – Supplement 2024 (hereinafter referred to as Suppl. 2024) was prepared for print.

Suppl. 2024 was published in cooperation with the Grada Publishing house in two volumes as binding from 01 September 2024 and it is available also in electronic format (as a PDF file accessible via a paid link on Grada's website).

The special part of the European Pharmacopoeia is translated only selectively. The texts were selected by the Pharmacopoeia Commission in collaboration with healthcare professionals. The general part of the European Pharmacopoeia has been translated and published completely.

In total, this concerns 293 texts.

The European part contains 274 texts in total and it is updated to reflect four supplements of the European Pharmacopoeia – 11.1 to 11.4 (Suppl. 11.1, which is binding with effect from 01 April 2023; Suppl. 11.2 binding with effect from 01 July 2023; Suppl. 11.3 binding with effect from 01 January 2024; and Suppl. 11.4 binding with effect from 01 April 2024).

It contains translations of 133 new and amended general monographs, general chapters, and selected texts of the special part, and 141 selected non-amended texts from the previous editions of the European Pharmacopoeia.

Due to growing interest, a new monograph Cannabis flos (3028) was included as a priority in advance of the predefined content of Suppl. 2024 (in Ph. Eur., it was published in Suppl. 11.5 with binding effect as of 01 July 2024).

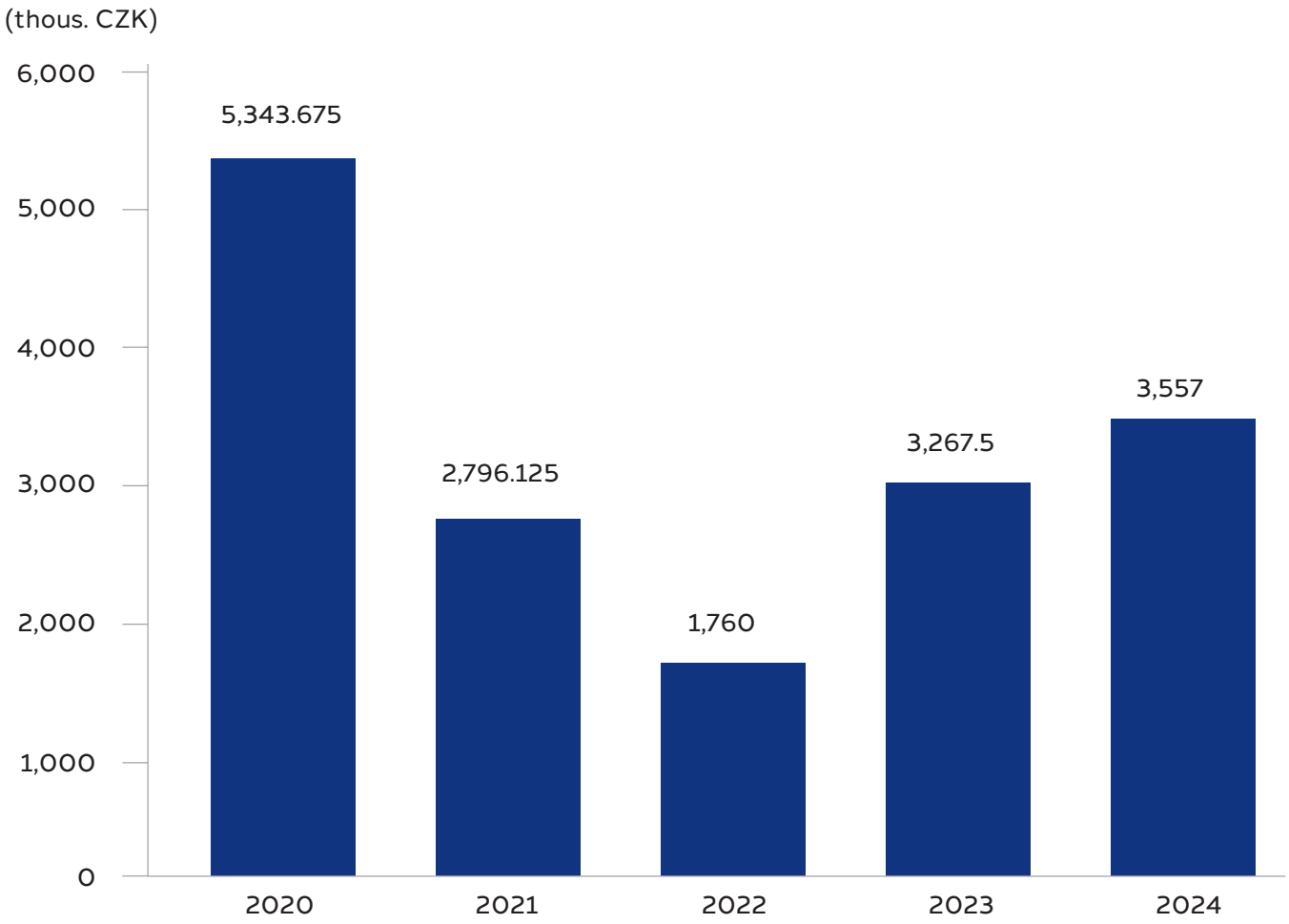
Other monographs from Supplements 11.1 to 11.4 of the European Pharmacopoeia are published in Suppl. 2024 only in tabular format and their translations have not been published.

In total, the national part of Suppl. 2024 contains 23 texts.

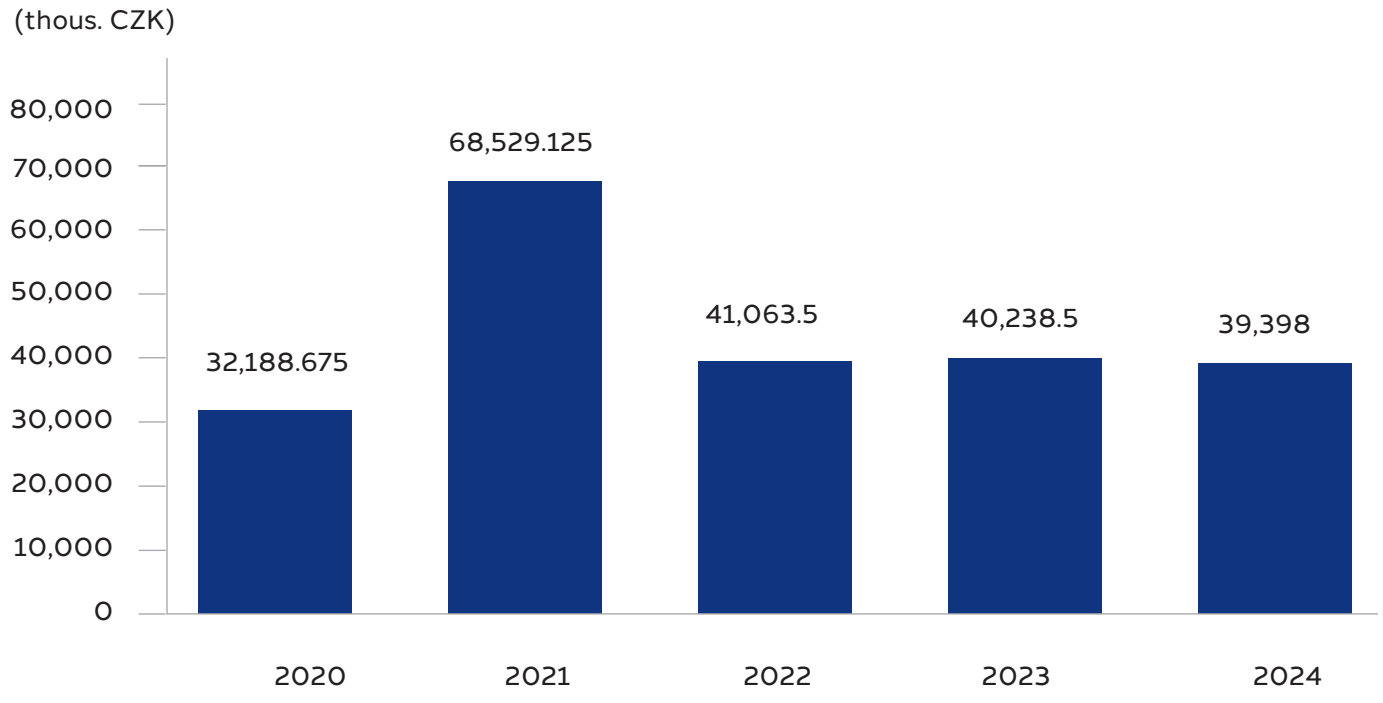
Part III of the Introductory texts contains an updated List of monographs of the Special part of European Pharmacopoeia, which contains an overview of all Ph. Eur. articles with basic information. The monographs shown in bold in this list are provided in full text in the Czech language in Ph. Cz. 2023 or in Suppl. 2024.

Along with the proof-reading and print preparation of Suppl. 2024, the preparation of the second supplement to Ph. Cz. 2023 – Supplement 2025 (hereinafter referred to as "Suppl. 2025") was under way. In its European Part, Suppl. 2025 will contain translations and revisions of monographs from Suppl. 11.5–11.8.

Graph 16 Overall comparison of fines in the area of medical devices in the period of 2017–2024



Graph 17 Total penalties imposed by the Institute (pharmaceuticals and medical devices)



The list of all monographs from the Special Part of European Pharmacopoeia, updated with Suppl. 11.5-11.8, was published on SÚKL's website (Czech Pharmacopoeia 2023 – Supplement 2025 – SÚKL).

For the European Part of Suppl. 2025, translations of 59 monographs from the General Part of Ph. Eur. (of which nine are new ones) have been prepared. To date, 87 European monographs have been included in the Special Part (incl. those which have no revision in Suppl. 11.5–11.8, but have been included upon request). In the European Part, this will amount to approx. 150 texts in total.

The preparation and distribution of national reference pharmacopoeial substances for national monographs Butamirati citras (five CRLNs in total) and Suxamethonium-dijodid CRLN was organised.

In September 2024, in cooperation with the laboratories and the pharmacy section of the Pharmacopoeial Commission, the "Shelf-Life of Individually Prepared Medicinal Products VI" project was completed. The project included the following products: Argenti nitratis unguentum compositum, Unguentum molle, Zinci oxidi suspensio, Zinci oxidi suspensio cum levomentholo. 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. 2025.

Cooperation with the European Pharmacopoeia Commission (hereinafter referred to as "EPC") 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.

The employees regularly attended the EPC meetings and meetings of secretariats of national pharmacopoeia commissions.

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

4. 13 Penalties Imposed in the Area of Pharmaceuticals and Medical Devices

Penalties in the Area of Pharmaceuticals and Human Tissues and Cells

Based on its ex-officio findings, particularly those identified during regular inspections of regulated entities or findings from reports received from the Czech Police and other administrative bodies of the Czech Republic or from private individuals or legal entities, the Institute initiates administrative procedures concerning offences within which penalties pursuant to the applicable laws are imposed according to the severity of the identified breach. In the sphere of penalisation, in 2024, the Institute continued to impose penalties in the form of so called aggregate fines for committed offences referred to under various acts under which the Institute is the body in charge of investigation into offences, particularly those arising in the area of medicinal product handling. As of 01 July 2017, the Institute has been applying Act No 250/2016 Coll., on Liability for Offences and Procedures Pertaining Thereto, as amended, in its practice of administrative penalisation. Pursuant to this Act, where less serious offences are concerned, the Institute has also the option to impose an admonition as an administrative penalty instead of a financial sanction. In 2024, the Institute imposed the total of 13 admonitions and 165 fines in the total amount of 36,381,000 CZK. Most frequently, the penalties were imposed for breaches of the Act on Pharmaceuticals (120 fines and three admonitions), for breaches of the Act on Prices (eleven fines and nine admonitions), for breaches of the Act on Advertising Regulation (19 fines), of the Code of Control Procedure (eight fines), and of the Act on Dependency-Producing Substances (six fines). For breaches of the Act on Public Health Insurance, one fine and one admonition were imposed. From 2021 until the end of 2024, the Institute imposed as many as 47 fines for systematic withdrawal of medicinal products from pharmacy stock, of which 14 fines in the total amount of 11,175,000 CZK became final in 2024. In two cases, penalties amounting to the total of 14,090,000 CZK were imposed for illegal distribution of medicinal products from the pharmacy stock.

Penalties in the Area of Medical Devices

On the basis of ex officio findings of the Institute arising, particularly those arising from inspection activities conducted at regulated entities, and on the basis of reports from private individuals, the Legal Support Unit of the Medical Device Regulation Section initiates administrative procedures concerning offences, within which penalties are imposed with a view to the severity of the identified breach as per the respective act. In the sphere of penalisation, in 2024, the Institute, furthermore, continued to impose penalties in the form of so-called aggregate fines for committed offences referred to by several acts according to which the Institute is the authority in charge of investigation into such offences. As of 01 July 2017, the Institute has been applying Act No 250/2016 Coll., on Liability for Offences and Procedures Pertaining Thereto, as amended, in its practice of administrative penalisation. Pursuant to this Act, the Institute has

also the option to impose an admonition as an administrative penalty instead of a financial sanction where less serious offences are concerned. The Institute has been availing of this possibility since 2018. With the coming into force of Act No 268/2014 Coll. (on 01 April 2015), since 2016, the Medical Device Legal Support Unit has observed an increase in proposals for initiation of administrative procedures for administrative offences as part of adverse incident investigation monitoring, particularly breaches of the obligation set forth by Section 75 of Act No 268/2014 Coll., i.e., to inform the Institute about established safety corrective actions and on their termination. In association with the new Act on Medical Devices and the Act on in Vitro Diagnostic Medical Devices that came into force on 26 May 2021, however, these merits of the case, however, have been kept only in the Act on in Vitro Diagnostic Medical Devices.

Summary of Penalties Imposed by the Institute in 2024 (Pharmaceuticals and Medical Devices)

In 2024, the Institute imposed penalties in the total amount of 39,938,000 CZK (Tables 25 and 26 refer). In compliance with Act No 250/2016 Coll., on Liability for Offences and Procedures Pertaining Thereto, as amended, in 2024, the Institute imposed the total of 13 admonitions instead of a financial penalty.

Table 25 Comparison of fines in the area of medical devices in the period of 2017–2024

Act	2017	2018	2019	2020	2021	2022	2023	2024
	659 500,00 CZK	**568 330,00 CZK**	**4 958 809,00 CZK**	**5 343 675,00 CZK**	**2 796 125,00 CZK**	**1 760 000 CZK**	**3 267 500 CZK**	**3 557 000 CZK**
Code of Control Procedure	0,00 CZK	0,00 CZK	0,00 CZK	0,00 CZK	50 000,00 CZK	250 000 CZK	200 000 CZK	380 000 CZK
on Medical Devices	559 500,00 CZK	568 330,00 CZK	3 210 058,00 CZK	3 723 125,00 CZK	1 320 000,00 CZK	1 095 000 CZK	2 945 000 CZK	3 167 000 CZK
on Technical Requirements for Products	100 000,00 CZK	0,00 CZK	1 748 751,00 CZK	1 620 550,00 CZK	1 426 125,00 CZK	415 000 CZK	120 000 CZK	0 CZK
On Prices	0 CZK	0 CZK	0 CZK	0 CZK	0 CZK	0 CZK	2 500 CZK	10 000 CZK

Table 26 Overview of administrative procedures in 2024

Applications for maximum ex-factory price determination	**Number of SÚKL codes**
Initiated	54
Decided	31
Appeal procedure pending	0
Became final	47
Applications for maximum ex-factory price change	
Initiated	172
Decided	167
Appeal procedure pending	0
Became final	124
Applications for maximum ex-factory price reduction – abbreviated procedure	
Initiated	1
Decided	1
Appeal procedure pending	0
Became final	1
Applications for maximum ex-factory price revocation	
Initiated	0
Decided	0
Appeal procedure pending	0
Became final	0

SECTION OF PRICING AND REIMBURSEMENT REGULATION

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. For proprietary medicinal products, this is done via administrative procedures that fully comply with the principles of procedure transparency stipulated by the European legislation. Administrative procedures are carried out in cases specified by law either ex officio (most often, so called in-depth and abbreviated revisions) or 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 filed by any person.

4. 14 Pricing and Reimbursements

In 2024, the primary legal regulation governing the sphere of pricing and reimbursement regulation of medicinal products and foods for special medical purposes continued to be the Act on Public Health Insurance. Compared to 2023, with effect as at 01 January 2024, the Act was amended in terms of including the possibility for the Institute to issue decisions through which it may temporarily determine or change the maximum price and the amount and conditions of reimbursement of a medicinal product important for the provision of healthcare services, in respect of which there is an imminent risk of or existing shortage of a medicinal product important in terms of public health protection, in order to maintain the availability of reimbursed services for the insureds. The aforementioned procedure is further detailed by the provision of Section 32d of the Act on Public Health Insurance. Administrative procedures referred to under the aforementioned provision shall be initiated ex officio or upon request of a person who is the holder of a distribution authorisation, a health insurance company, importer or domestic manufacturer or the marketing authorisation holder.

Maximum Ex-Factory Prices

For this year, 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, was issued with effect from 01 January 2024. Price regulation continues to govern producer prices, by determining the maximum price by the State Institute for Drug Control or by means of material price regulation as well as the profit margin by 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 continue to be regulated only in terms of profit margin.

Furthermore, with effect from 01 January 2024, Price Decision of the Ministry of Health no. 3/2024/CAU of 29 November 2023, laying down a list of ATC groups that are not subject to price regulation by setting the maximum price in the specified pharmaceutical form, was issued. 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.

In 2024, 33 administrative procedures regarding maximum price determination were initiated (cf. 24 administrative procedures in 2023). For maximum price change, 81 administrative procedures were commenced (cf. 164 administrative procedures in 2023); applications submitted by marketing authorisation holders prevailed (ten applications were submitted by health insurance companies and 71 by marketing authorisation holders).

In the last three years, the numbers of reimbursed medicinal products have been relatively similar. There has been a slight gradual decrease in the number of regulated medicinal products in the segment of medicinal products regulated by profit margin, while the number of products regulated by maximum price has been slightly growing (Graph 18 refers).

With a view to the structure of medicinal products (Table 29 refers), it may be said that in the individual months of 2024, the numbers of medicinal products in the aforementioned maximum price zones were decreasing in the lower price zo-

nes. The most significant decrease in the number of codes occurred in the zone of "More than 20 CZK up to 50 CZK incl." In the middle price zones where an increase in the number of codes occurred, the highest increase was seen in the zone of "More than 1,000 CZK up to 2,000 CZK incl."

Graph 18 Structure of reimbursed products by the type of price regulation (no. of codes of medicinal products/foods for special medical purposes)

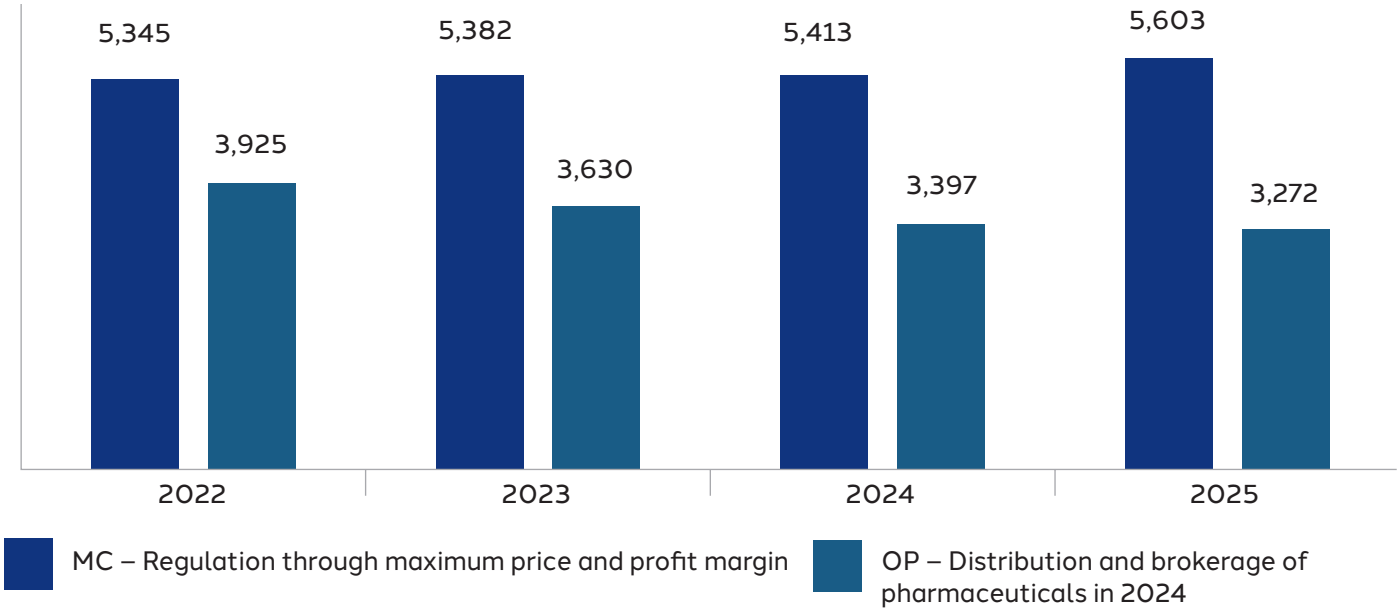


Table 27 Overview of the number of codes of medicinal products/foods for special medical purposes in the maximum price zones as per the List of Prices and Reimbursements (SCAU) by month

Price regulation zone	01	02	03	04	05	06	07	08	09	10	11	12
Up to 20 CZK incl.	6	7	7	7	7	7	7	7	7	7	7	5
More than 20 CZK up to 50 CZK incl.	216	215	220	221	223	223	219	213	210	209	205	179
More than 50 CZK up to 100 CZK incl.	588	589	608	606	610	607	606	601	592	588	579	575
More than 100 CZK up to 200 CZK incl.	854	852	869	863	865	868	865	858	855	838	818	819
More than 200 CZK up to 300 CZK incl.	492	489	496	496	498	503	502	504	505	512	511	508
More than 300 CZK up to 500 CZK incl.	503	505	506	516	522	513	508	521	509	512	501	498
More than 500 CZK up to 1,000 CZK incl.	703	701	700	707	714	720	725	727	727	729	727	726
More than 1,000 CZK up to 2,000 CZK incl.	531	530	534	558	563	559	563	570	576	581	582	583
More than 2,000 CZK up to 3,000 CZK incl.	240	245	245	249	253	256	257	259	257	259	261	262
More than 3,000 CZK up to 5,000 CZK incl.	270	272	269	283	289	290	289	290	289	292	289	291
More than 5,000 CZK up to 10,000 CZK incl.	250	253	251	252	254	256	262	266	266	270	272	292
More than 10,000 CZK up to 20,000 CZK incl.	233	235	237	242	242	240	239	243	246	253	256	256
More than 20,000 CZK up to 30,000 CZK incl.	113	113	115	116	117	117	121	123	128	129	131	130
More than 30,000 CZK up to 50,000 CZK incl.	114	114	117	120	119	119	123	127	127	132	132	136
More than 50,000 CZK up to 100,000 CZK incl.	193	194	193	193	195	197	197	204	207	207	207	211
More than 100,000 CZK	107	106	107	108	108	108	110	116	116	120	123	123
Number of codes	5 413	5 420	5 474	5 537	5 579	5 583	5 593	5 629	5 617	5 638	5 601	5 594

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

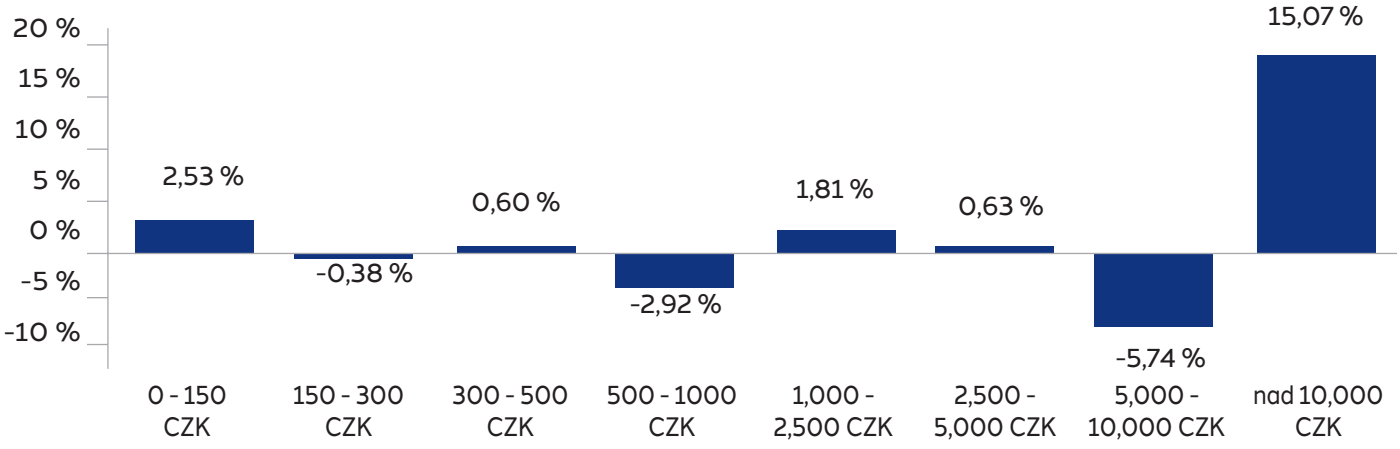
Code	ATC	Name	Name supplement	No. of packages	Original maximum price (CZK)	New maximum price (CZK)	Change to maximum price (%)
0243240	A11CC05	VIGANTOL	0,5MG/ML POR GTT SOL 1X10ML	1,679,188	71.35	78.50	10.0
0087076	R05CB15	ERDOMED	300MG CPS DUR 20	785,332	130.49	161.43	23.7
0231956	R03AC02	VENTOLIN INHALER N	100MCG/DÁV INH SUS PSS 200DÁV	644,088	39.80	84.56	112.5
0215956	J07BA01	FSME-IMMUN	0,5ML INJ SUS ISP 1X0,5ML+J	617,138	528.69	627.34	18.7
0176954	A03DA02	ALGIFEN NEO	500MG/ML+5MG/ML POR GTT SOL 1X50ML	604,840	101.98	108.82	6.7
0199466	N05AD03	BURONIL	25MG TBL FLM 50	367,580	100.28	129.00	28.6
0241078	J01XE01	FUROLIN	100MG CPS DUR 30	355,102	162.38	167.00	2.8
0225175	S01AA12	TOBREX	3MG/ML OPH GTT SOL 1X5ML	340,305	31.49	40.30	28.0
0225168	S01CA01	MAXITROL	OPH GTT SUS 1X5ML	339,270	57.76	62.63	8.4
0187427	H03AA01	LETROX	100MCG TBL NOB 100	286,358	50.17	71.09	41.7

Development of Average End-User Prices

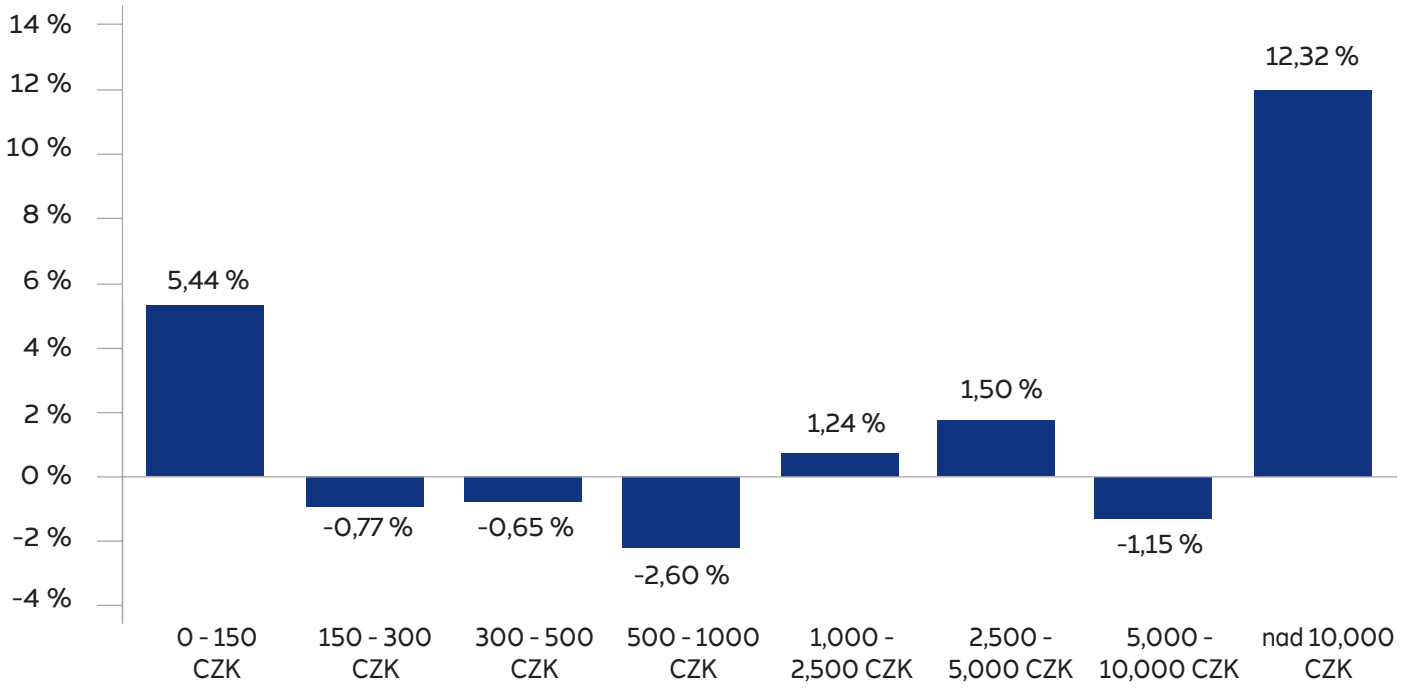
In 2024, there was no change to profit margins, but there was a change to the VAT, the rate of which was unified for medicinal products and foods for special medical purposes at 12 % as at 01 January 2024. In respect of medicinal products regulated by the maximum price (maximum price determined by an administrative procedure and profit margin as per the Price Regulation), the average end-user price increased by 8.3 %. The highest increase of average prices occurred in the "More than 10,000 CZK" price zone. 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 (as per the Price Regulation and Price Decision), the average end-user price increased by 2.3 %, 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 500 up to 1,000 CZK incl." price zone. The situation in ex-factory price levels (ex. profit margin and VAT) with focus upon a more detailed comparison of the last quarters of 2023 and 2024 is illustrated by Graph 19 and 20.

Graph 19 Prices of pharmaceuticals regulated by maximum price – comparison of average prices in Q4 2023 and Q4 2024 by price zone



Graph 20 Prices of pharmaceuticals regulated by profit margin – comparison of average prices in Q4 2023 and Q4 2024 by price zones



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 2024, 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 VENTOLIN INHALER N (Table 29 refers).

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 maximum price (CZK)	New maximum price (CZK)	Change to maximum price (%)
0223046	L01FF01	OPDIVO	10MG/ML INF CNC SOL 1X24ML	1,310,551,403	68,391.16	60,690.07	-11.3
0210636	J07BM03	GARDASIL 9	INJ SUS ISP 1X0,5ML+2J	678,549,092	2,393.12	2,513.30	5.0
0255591	C10AX16	LEQVIO	284MG INJ SOL ISP 1X1,5ML II	619,879,597	46,801.33	48,728.34	4.1
0215956	J07BA01	FSME-IMMUN	0,5ML INJ SUS ISP 1X0,5ML+J	534,170,927	528.69	627.34	18.7
0219166	L01XX52	VENCLYXTO	100MG TBL FLM 112(4X28)	520,497,192	125,684.02	101,247.76	-19.4
0209038	C09DX04	ENTRESTO	24MG/26MG TBL FLM 28 I	359,292,111	1,174.61	1,247.80	6.2
0238461	N02CD01	AIMOVIG	140MG INJ SOL PEP 1X1ML	316,373,041	10,208.65	5,792.09	-43.3
0209040	C09DX04	ENTRESTO	49MG/51MG TBL FLM 56 I	259,091,906	2,327.87	2,493.65	7.1
0210773	L01FF01	OPDIVO	10MG/ML INF CNC SOL 1X10ML	225,723,674	28,496.37	24,713.49	-13.3
0243240	A11CC05	VIGANTOL	0,5MG/ML POR GTT SOL 1X10ML	190,648,290	71.35	78.50	10.0

Medicinal products with the highest financial volume are found across all price zones, nevertheless, products from the highest price zone prevail (Table 30 refers)

Table 30 Overview of administrative procedures in 2024

Applications for determination or change of the amount and conditions of reimbursement	**Number of SÚKL codes**
Initiated	112
Decided	51
Appeal procedure pending	0
Became final	47
Applications for determination or change of maximum price and the amount and conditions of reimbursement	
Initiated	94
Decided	46
Appeal procedure pending	0
Became final	42
Applications for reimbursement revocation	
Initiated	468
Decided	336
Appeal procedure pending	0
Became final	312
Applications for maximum price and reimbursement revocation	
Initiated	74
Decided	63
Appeal procedure pending	0
Became final	63
Ex officio initiated procedures	
Initiated	1079
Decided	870
Appeal procedure pending	105
Became final	756
Procedures concerning similar products	
Initiated	872
Decided	793
Appeal procedure pending	1
Became final	733

Amounts and Conditions of Reimbursements from Health Insurance Funds

In 2024, 20 applications for determination of temporary reimbursement of highly innovative products were submitted as well as 20 applications for determination of the amount and conditions of reimbursement of orphan medicinal products.

In the course of 2024, the Section continued to initiate in-depth reimbursement revisions in line with the schedule. Twenty-two in-depth revisions were scheduled for 2024 and 18 of them (238 SÚKL codes) were initiated.

Pursuant to the provisions of Section 39 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 replaceable 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

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 health insurance funds
01/2024	109	7	213,732,514.00 CZK
02/2024	56	6	695,926,388.00 CZK
03/2024	61	3	121,208,860.00 CZK
04/2024	36	3	1,352,306,838.00,CZK
2024	0	0	0 CZK
06/2024	69	3	215,404,535.00 CZK
07/2024	59	3	149,591,545.00 CZK
08/2024	38	4	388,873,371.00 CZK
09/2024	76	2	125,128,172.00 CZK
10/2024	0	0	0 CZK
11/2024	97	6	322,211,078.00 CZK
12/2024	44	3	192,511,851.00 CZK

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

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

Reimbursement zone	01	02	03	04	05	06	07	08	09	10	11	12
Up to 20 CZK, incl.	146	147	148	148	148	148	148	147	147	147	147	147
More than 20 CZK up to 50 CZK, incl.	651	652	650	648	647	645	641	632	631	621	618	607
More than 50 CZK up to 100 CZK, incl.	1,150	1,150	1,150	1,150	1,151	1,155	1,174	1,172	1,163	1,158	1,153	1,142
More than 100 CZK up to 200 CZK, incl.	1,422	1,413	1,404	1,397	1,403	1,400	1,393	1,389	1,375	1,366	1,344	1,337
More than 200 CZK up to 300 CZK, incl.	862	862	855	845	854	857	868	877	892	888	882	872
More than 300 CZK up to 500 CZK, incl.	908	908	894	921	925	926	920	921	902	909	908	902
More than 500 CZK up to 1,000 CZK, incl.	949	953	946	979	996	1,007	996	1,005	1,000	1,009	991	1,001
More than 1,000 CZK up to 2,000 CZK, incl.	820	818	817	824	833	813	822	841	842	837	829	809
More than 2,000 CZK up to 3,000 CZK, incl.	319	318	313	318	322	317	313	313	325	329	331	347
More than 3,000 CZK up to 5,000 CZK, incl.	320	321	320	323	330	328	323	326	327	327	322	309
More than 5,000 CZK up to 10,000 CZK, incl.	471	473	471	473	478	480	485	480	479	477	484	500
More than 10,000 CZK up to 20,000 CZK, incl.	358	361	365	379	379	375	373	380	386	393	387	387
More than 20,000 CZK up to 30,000 CZK, incl.	134	136	136	135	135	133	139	148	151	151	155	158
More than 30,000 CZK up to 50,000 CZK, incl.	109	106	107	110	112	112	116	118	120	124	123	127
More than 50,000 CZK up to 100,000 CZK, incl.	110	111	113	114	115	117	117	121	121	124	123	126
More than 100,000 CZK	98	96	95	95	95	95	97	99	99	101	104	105
Number of codes	8,827	8,825	8,784	8,859	8,923	8,908	8,925	8969	8,960	8,961	8,901	8,876

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	3,855,862,779	64,391.30	66,210.12	2.8
0168904	B01AF01	XARELTO	20MG TBL FLM 98 II	843,242,583	3,915.08	2,426.62	-38.0
0268189	S01LA09	VABYSMO	120MG/ML INJ SOL 1X0,24ML+1FILTRJ	817,680,175	16,553.80	7,818.93	-52.8
0249566	L01FC01	DARZALEX	1800MG INJ SOL 1X15ML	780,511,773	107,479.88	105,557.96	-1.8
0193695	S01LA05	EYLEA	40MG/ML INJ SOL ISP 1X0,09ML	689,576,901	12,378.17	7,818.92	-36.8
0210636	J07BM03	GARDASIL 9	INJ SUS ISP 1X0,5ML+2J	678,549,092	3,228.90	3,385.94	4.9
0193747	B01AF02	ELIQUIS	5MG TBL FLM 168	667,927,820	3,355.79	2,079.96	-38.0
0215956	J07BA01	FSME-IMMUN	0,5ML INJ SUS ISP 1X0,5ML+J	534,170,927	769.92	902.50	17.2
0232990	L01FF03	IMFINZI	50MG/ML INF CNC SOL 1X10ML	511,266,953	67,474.92	47,272.44	-29.9
0210187	L01EL01	IMBRUVICA	140MG CPS DUR 90	434,501,410	137,861.17	120,652.10	-12.5

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 2024, 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 2024 are estimated at 2,086,179,095 CZK, and those arising from in-depth revisions at 1,690,716,057 CZK.

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 50–1,000 CZK (Table 33 refers). The value distribution in 2024 is quite similar to that of 2023.

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 a significant reduction in the reimbursement for individual packages of medicinal products. The highest reduction of reimbursement occurred for medicinal product VABYSMO. An increase in the reimbursement of these high-volume medicinal products occurred only in three cases, of which in two cases, the increase was by units of per cent only (Table 33 refers).

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 middle price zones. In 2024, reimbursements of the aforementioned products were being mainly reduced, except for medicinal product FSME-IMMUN, the reimbursement of which has rather increased. The response in distribution was not clear-cut, as both lower and higher levels of supplies were observed after the changes to the amounts of reimbursement of the said products (Table 35 refers).

Table 35 is a list of substantial changes in the reimbursement system in 2024 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.

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
0248801	M01AX25	CONDROSULF	800MG TBL NOB 30	320,862	224.76	134.86	324,442	
0215956	J07BA01	FSME-IMMUN	0,5ML INJ SUS ISP 1X0,5ML+J	178,737	769.92	902.50	436,567	
0166423	C02AC06	RILMENIDIN TEVA	1MG TBL NOB 90	152,774	322.09	272.48	225,174	
0168904	B01AF01	XARELTO	20MG TBL FLM 98 II	164,588	3,915.08	2,426.62	146,578	
0193747	B01AF02	ELIQUIS	5MG TBL FLM 168	132,234	3,355.79	2,079.96	145,462	
0168373	B01AE07	PRADAXA	150MG CPS DUR 60X1 I	146,105	1,198.49	742.84	130,300	
0180087	R03AK07	SYMBICORT TURBUHALER	160MCG/4,5MCG INH PLV 1X120DÁV	135,697	699.52	585.81	90,168	
0193741	B01AF02	ELIQUIS	2,5MG TBL FLM 168	104,957	1,677.89	1,039.99	113,818	
0169252	B01AC04	TROMBEX	75MG TBL FLM 90	110,103	305.79	252.15	115,328	
0210636	J07BM03	GARDASIL 9	INJ SUS ISP 1X0,5ML+2J	48,120	3,228.90	3,385.94	57,219	*/

* – the period of 1/4 of a year; x – the period of 1/6 of a year; n – not evaluable; a –number of packages distributed during six months prior to the change; B – number of packages distributed during six months after the change

Table 35 Overview of newly reimbursed original pharmaceuticals and significant reimbursement extensions with decisions issued in 2024

	Indication (clinical use)	Reimbursement effective from
OZURDEX (dexamethason)	Active non-infectious uveitis (affecting the posterior segment of the eye)	January 2024
IBRANCE (palbociklib)	Breast carcinoma in males	January 2024
XELJANZ (tofacitinib)	First as well as second/other line of biological therapy for psoriatic arthritis and ankylosing spondylitis	January 2024
ROACTEMRA (tocilizumab)	Systemic juvenile idiopathic arthritis with inadequate efficacy of current therapy	January 2024
LYNPARZA (olaparib)	Early triple-negative breast carcinoma with high risk of recurrence	January 2024
STELARA (ustekinumab)	Ulcerative colitis (UC): first and other lines of biological therapy	February 2024
tikagrelor 90 mg	Determination of reimbursement increase for ticagrelor 90 mg in the prevention of atherothrombotic events in new patient groups (e.g., age 75+ years; weight less than 60 kg; treatment through non-interventional access; acute ischaemic stroke or transitory ischaemic attack)	February 2024
tikagrelor 60 mg	Determination of reimbursement increase for ticagrelor 60 mg in the prevention of atherothrombotic events in new patient groups (patients with stable coronary artery disease and type 2 diabetes mellitus without previous myocardial infarction or stroke, who had a percutaneous coronary intervention)	February 2024
HYQVIA (SCIG)	Chronic inflammatory demyelinating polyradiculoneuropathy	February 2024
ZENON (rosuvastatin + ezetimib)	Primary hypercholesterolemia (heterozygous familial and non-familial) or homozygous familial hypercholesterolemia	March 2024
JAKAVI (ruxolitinib)	Treatment of acute graft-versus-host disease (in patients without adequate response to corticosteroid treatment or other systemic therapy)	April 2024
KEYTRUDA (pembrolizumab)	Malign melanoma (reimbursement extension to earlier stages of adjuvant treatment from the age of 12 years: stages IIB and IIC)	May 2024

ELFABRIO (pegunigalsidáza alfa)	Fabry disease in adults	May 2024
NUCALA (mepolizumab)	Severe refractory eosinophilic bronchial asthma, at least 2 severe asthma exacerbations, at least 150 or 300 eosinophils/microliter, resp.	April 2024
TYSABRI (natalizumab)	Reimbursement extension to patients with relapsing-remitting multiple sclerosis in 2nd-line treatment in escalation treatment strategy (patients with relapsing-remitting multiple sclerosis exhibiting signs of adverse prognosis of the disease, who developed at least one moderate or severe relapse despite treatment with at least one 1st-line medicinal product)	May 2024
SIGNIFOR (pasireotid)	Acromegaly in further treatment lines	May 2024
COMBAIR NEXTHALLER (beklometazon + formoterol)	Reimbursement extension to bronchial asthma relief treatment	June 2024
LUPKYNIS (voklosporin)	Active lupus nephritis	June 2024
GAPULSID (cinitaprid)	Treatment of dyspepsia	June 2024
JARDIANCE (empagliflozin)	Chronic kidney disease	June 2024
AQUIPTA (atogepant)	Prophylactic treatment of migraine	June 2024
ITULAZAX (standardizovaný extrakt alergenů z pylu břízy)	Birch pollen allergy	July 2024
FASENRA (benralizumab)	Severe refractory eosinophilic bronchial asthma (extension to patients with at least 2 severe asthma exacerbations and at least 150 or 300 eosinophils/microliter, resp.)	July 2024
BUDENOFALK suppositories (budesonid)	Treatment of ulcerative colitis affecting only rectum	July 2024
OPDIVO (nivolumab)	Neoadjuvant treatment of non-small cell lung carcinoma (in combination with platinum-based chemotherapy)	July 2024
BIMZELX (bimekizumab)	Moderate to severe psoriasis, psoriatic arthritis, and ankylosing spondylitis	August 2024
TOLVECAMO (telmisartan + amlodipin+hydrochlorothiazid)	Hypertension (a new combination of antihypertensives)	August 2024
OMVOH (mirikizumab)	Ulcerative colitis (second and other lines of biological therapy)	August 2024
OPDUALAG (nivolumab + relatlimab)	Metastatic malign melanoma	August 2024
ELIDEL (pimekrolimus)	Atopic dermatitis (reimbursement extension to children from 3 months to 2 years of age)	September 2024
TEZSPIRE (tezepelumab)	Severe refractory bronchial asthma	August 2024
LORVIQUA (lorlatinib)	Metastatic non-small cell lung cancer (first-line treatment)	August 2024
HUMIRA (adalimumab)	Psoriasis in patients with inadequate response to topical therapy and phototherapy	September 2024
LIVIZUX (lisdexamfetamin)	Treatment of ADHD in children/adolescents with inadequate methylphenidate efficacy.	September 2024
EMOXEN PLUS (esomeprazol + naproxen)	Treatment of osteoarthrosis, rheumatoid arthritis and ankylosing spondylitis in patients in risk of developing digestive tract ulcers	September 2024
PRADAXA (dabigatran)	Revocation of prescription restriction (the product may be prescribed as reimbursed for the prevention/treatment of thromboembolic conditions by doctors of any specialty)	September 2024
XELJANZ (tofacitinib)	Basic reimbursement of 2nd and further treatment lines for rheumatoid arthritis; further increased reimbursement: 1st-line treatment for RA	October 2024
SOTYKTU (deukravacitinib)	Treatment of moderate to severe psoriasis in 2nd-line therapy	October 2024
VUEWAY (gadopiklenol)	Contrast agent for magnetic resonance imaging (MRI)	October 2024
VEMLIDY (tenofovir alafenamid)	Chronic hepatitis B	October 2024
ALECENSA (alektinib)	Adjuvant treatment of adult patients with stage Ib to IIIA ALK-positive non-small cell lung carcinoma following complete resection	October 2024
KERENDIA (finerenon)	Chronic kidney disease (CKD) with albuminuria associated with type 2 diabetes mellitus in adult patients	October 2024

FRIMIG DUO (sumatriptan+naproxen)	Acute treatment of headache during migraine attacks with or without aura in adult patients in whom sumatriptan therapy is insufficient	November 2024
VYDURA (rimegepant)	Acute treatment of migraine in patients in whom previous treatment with at least 2 triptans exhibited inadequate efficacy, was contraindicated or was not tolerated	October 2024
BIKTARVY (biktegravir, emtricitabin, tenofovir alafenamid)	Reimbursement extension to treatment-naïve HIV patients (regardless of risk factor presence)	November 2024
DARZALEX (daratumumab)	Treatment of newly diagnosed multiple myeloma (in combination with lenalidomide and dexamethasone)	October 2024
LYNPARZA (olaparib)	Maintenance treatment of high-grade serous or endometroid epithelial tumour of the ovary, fallopian tube or primary peritoneal tumour with BRCA mutation	November 2024
ABILIFY MAINTENA (aripiprazol parenterální dvouměsíční)	Maintenance treatment of schizophrenia in patients stabilised by oral aripiprazole	November 2024
METALYSE (tenekteplaza)	Acute ischaemic stroke	November 2024
POMBILITI (cipaglukosidáza alfa)	Pompe disease	November 2024
JINARC (tolvaptan)	Autosomal dominant polycystic kidney disease (ADPKD) with chronic kidney disease (CKD 1–3 on treatment initiation)	November 2024
IMFINZI (durvalumab)	1st-line treatment of advanced-stage small-cell lung carcinoma	November 2024
LIBTAYO (cemiplimab)	Advanced spinocellular skin carcinoma	December 2024
INVOKANA (kanagliflozin)	DM2-associated diabetic kidney disease	December 2024
ORGOVYX (relugolix)	Prostate cancer, androgen deprivation therapy, p.o.	December 2024
	Highly innovative medicinal products	
ZEJULA (niraparib)	Advanced carcinoma of the ovary, fallopian tube or primary peritoneal carcinoma (in responders to first-line platinum-based chemotherapy)	March 2024
PADCEV (enfortumab vedotin)	Locally advanced or metastatic urothelial carcinoma in patients who underwent previous platinum-based chemotherapy and immunotherapy	March 2024
SARCLISA (isatuximab)	Relapsing/refractory multiple myeloma (combination isatuximab + carfilzomib + dexamethasone)	March 2024
KIMMTRAK (tebenafusp)	Non-resectable/metastatic uveal melanoma	April 2024
LORVIQUA (lorlatinib)	Non-small cell lung carcinoma (ALK positive) after progression on previous therapy	April 2024
TECVAYLI (teklistamab)	Relapsing/refractory multiple myeloma (in 4th-line and further treatment lines)	July 2024
OPDIVO (nivolumab)	Metastatic colorectal carcinoma (combination nivolumab + ipilimumab)	August 2024
TALZENNA (talazoparib)	HER2-negative locally advanced or metastatic breast carcinoma with positivity for BRCA1/2 mutation	October 2024
REBLOZYL (uspatercept)	Transfusion-dependent anaemia due to myelodysplastic syndrome and beta-thalassemia	October 2024
SYLVANT (siltuximab)	Treatment of idiopathic Castleman disease	October 2024
	Orphan medicinal products	
ADCETRIS (brentuximab vedotin)	Three indications: 1) Hodgkin's lymphoma with high risk of relapse after ASCT; 2) refractory/relapsing Hodgkin's lymphoma after two therapies where ASCT is not a treatment option; 3) refractory/relapsing sALCL (systemic anaplastic large-cell lymphoma)	January 2024
TAKHZYRO (lanadelumab)	Prevention of hereditary angioedema attacks	January 2024
KAFTRIO (ivakaftor+tezafaktor+elexafaktor)	Cystic fibrosis in patients from the age of 6 years with at least one F508del mutation in the CFTR gene	March 2024
EPIDYOLEX (kanabidiol)	Dravet syndrome, Lennox-Gastaut syndrome, tuberous sclerosis complex	April 2024
CABLIVI (kaplacizumab)	Acquired thrombocytopenic purpura	May 2024
COLUMVI (glofitamab)	DLBCL after at least two lines of systemic therapy	July 2024

REVESTIVE (teduglutid)	Treatment of short-bowel syndrome in patients from 4 months of gestational age	October 2024
LIVTENCITY (maribavir)	Treatment of cytomegalovirus infection and/or disease refractory (with or without resistance) to one or more previous therapies in adult patients who had HSCT or SOT, or in cases where first-choice treatment cannot be used	December 2024
	Systemic mastocytosis in pre-treated patients who are not suitable for transplantation	December 2024

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 since 2020. The Institute has been publishing these summaries for individual pharmaceuticals/procedures on its website in order to facilitate access to basic data and information on the assessed pharmaceuticals for the general public.

Validation of Applications

V n 2024, the total of 882 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.

The highest proportion (approx. 43 %) included applications for determination of the amount and conditions of reimbursement / 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, followed by submissions applying for revocation of the amount and conditions of reimbursement of medicinal products/foods for special medical purposes (approx. 26 %), and applications for change of the maximum price and the amount and conditions of reimbursement of medicinal products/foods for special medical purposes (approx. 15 %). In two cases, the decision on maximum price and reimbursement amount and condition determination was based upon applications submitted pursuant to Section 32d of the Act on Public Health Insurance in order to maintain availability of irreplaceable reimbursed pharmaceuticals. In respect of 28 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 (approx. 65 % of cases).

The total of six administrative procedures initiated upon request were suspended by resolution as early as during the check of the application in so-called validation phase, which represents a 75-% decrease compared to the previous year. In 2024, 73 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 2024, reimbursed costs of unperformed expert activities were returned in 24 cases; this was in association with an overpayment of the costs, non-submission of the application, or termination of the administrative procedure as early as in the validation phase.

In 2024, a label update in the database was performed for 45 SÚKL codes of foods for special medical purposes on the basis of an application submitted by the importer/domestic manufacturer of the food for special medical purposes. Upon request of the importer/domestic manufacturer of foods for special medical purposes, 335 SÚKL codes of non-reimbursed foods for special medical purposes were deleted from the database.

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

In 2024, several amendments to the data interface of the List of Prices and Reimbursements of Medicinal Products and Foods for Special Medical Purposes (hereinafter referred to also as the "List") were implemented:

As of 01 January 2024, the provision of Section 32d of the Act on Public Health Insurance was implemented to the List data interface through the introduction of new symbols in the items of the legal base of producer price and core reimbursement. Furthermore, in order to distinguish the types of pricing regulation of medicinal products reim-

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 – 2024

Period	Submitted applications	Suspended due to defective submission and application shortcomings	Discontinued in the validation phase
January	69	2	0
February	77	8	0
March	99	2	0
April	72	4	0
May	81	0	0
June	84	5	3
July	53	3	1
August	51	1	0
September	68	1	0
October	91	1	0
November	68	0	0
December	69	1	2
Total	882	28	6

bursed as referred to under the provision of Section 32c) of the Act on Public Health Insurance, a new symbol was added to this item and a new symbol in the NEZAP auxiliary index was introduced in order to define such medicinal products.

As of 01 August 2024, an amendment to the List data interface introduced new symbols in the items of core reimbursement legal base for medicinal products released from the reserve stock system pursuant to the provision of Section 77g) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts. Such tagging was subsequently complemented with another amendment of the data interface as of 01 January 2025. In order to facilitate the identification of so called identical products in compliance with the provision of Section 39b(9) of the Act on Public Health Insurance, as of 01 August 2024, an identifier of identical medicinal product parallel group was added to the List data interfaces.

With regard to the amendment to the Act on Public Health Insurance, which introduced new rules governing so called accreditable pay-ups with effect from 01 January 2025, the practice of publishing the regular List of Prices and Reimbursements of Medicinal Products and Foods for Special Medical Purposes, incl. the List of Pharmaceuticals Not Reimbursed from Health Insurance Funds, has changed and the Lists are now published as early as on the 27th day of the month (with effect from the 1st day of the following month). The purpose of publishing the Lists as early as on the 27th day is to allow for an earlier publication of the relevant indices of health insurance companies, timely set-up of pharmacy software, and hence real-time monitoring of the protective limits from the first day of the month. The first regular List of Prices and Reimbursements of Medicinal Products and Foods for Special Medical Purposes and the List of Pharmaceuticals Not Reimbursed from Health Insurance Funds were published on 27 December 2024 with effect from 01 January 2025.

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 2024). This regulation applies to the following groups of medicinal products: individually prepared radiopharmaceuticals (hereinafter referred to as "RF"), individually produced transfusion products and autologous transfusion products (hereinafter referred to as "TP"), parenteral nutrition products for home therapy (hereinafter referred to as "DPV"), medicinal products individually prepared in pharmaceutical care facilities – magistral formulas (hereinafter referred to as "MAG"), and advanced therapy products (hereinafter referred to as "ATP"), 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 then governed by the provisions of Sections 171-174 of Act No 500/2004 Coll., the Code of Administrative Procedure.

General Measures (OOP)

In the course of 2024, six OOP procedures in total were initiated and regularly completed.

For the DPV group, an OOP 01-24 Draft was issued in 2023; the procedure was regularly completed with effect from 01 March 2024. For the TP group, OOP 07-24 was issued in 2024, with effect from 01 January 2025, and for this reason, it has not been included in the assessed period of OOPs issued in 2024.

As of 01 March 2024, OOP 01-24 for the DPV group, OOP 02-24 for the RF group, and OOP 03-24 for the TP group were issued. As of 01 June, OOP 04-24 for the RF group was issued and, one month later, as at 01 July, OOP 05-24 for the TP group was issued; as at 01 November, complementary OOP 06-24 for the RF group was issued and subsequently, in the course of December, OOP 07-24 for the TP group was issued, but with effect from 01 January 2025. All of these OOPs were issued in compliance with effective legislation.

As of 01 March 2024, OOP 01-24 for the DPV group was issued; in this OOP, code 1401021 was included in the IPLP list and medicinal product Taurolidine was excluded. In the calculation, the OOP reflected the legislative change in VAT stipulated by Act No 349/2023 Coll., Amending Some Acts in Relation with Public Budget Consolidation, as amended, and a change to the minute rate for professionals performing procedures in the L3 category (specialists) pursuant to Decree No 320/2023 Coll., amending Decree No 134/1998 Coll., setting forth the list of healthcare procedures and their point values, as amended.

OOP 02-24 for the RF group and OOP 03-24 for the TP group reflected the change in the minute rate per procedure in compliance with Decree No 320/2023 Coll., amending Decree No 134/1998 Coll., setting forth the list of healthcare procedures and their point values, as amended, with effect from 01 January 2024. The overhead minute rate was increased from the original value of 3.51 points per minute of time performance to the new value of 4.04 points. In compliance with Decree No 319/2023 Coll., setting point values, reimbursement amounts for reimbursed services, and regulatory restrictions for 2024, the point value was decreased from the original amount of 1.11 CZK to the new amount of 1.04 CZK per point. Furthermore, in OOP 02-24 for the RF group, a new code of radiopharmaceutical 99mTc Mebrofenin inj. (product BROMO-BILIARON; code 0002024) within the scope of a specific therapeutic programme was included in the IPLP list. In OOP 01-24, OOP 02-24, and OOP 03-24, the Institute reflected an agreement concluded by the Ministry of Health of the Czech Republic and concerned entities on salary increase pursuant to previously agreed rules.

As of 01 June 2024, OOP 04-24 took effect; in this OOP, the Institute reflected new price source materials for radiopharmaceuticals (regular price reports) and the €/CZK exchange rate as per the materials published by the Czech National Bank for Q1 2024, on the basis of which it determined the amounts of reimbursement and, concurrently, in accordance with a suggestion, it amended the conditions of reimbursement for radiopharmaceuticals 18F Florbetaben inj. and 18F Flutemetamol inj.

With effect from 01 July, OOP 05-24 for the TP group was issued; this OOP reflected suggestions for a change to the amount and conditions of reimbursement and, at the same time, as of 01 January 2025, selected transfusion products (codes 0007901, 0007905, 0007917, 007956, 0007963, 0107930, 0107931, and 0107935) were deleted from the list.

As of 01 January 2024, complementary OOP 06-24 for the RF group came into effect; in this OOP, the Institute extended the IPLP list by newly included codes of radiopharmaceuticals 177Lu vipivotid tetraxetan inj. (product PLUVICTO; code 0002118) and 18F Fluordopa (product FLUORODOPA (18F); code 0002119) and concurrently excluded code 0002050 from the IPLP list on the basis of a change in the relocation of product IODOPOL 37-7400 MBq from code 0002050 to code 0002076.

In December 2024, the Institute issued OOP 07-24 for the TP group, which came into effect on 01 January 2025 and in which the Institute shortens the list of transfusion products mentioned in OOP 05-24. As the OOP did not come into effect in 2024, it will be reflected in the next Annual Report for 2025.

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, RF, and MAG subgroups, in 2024, the consumption decreased, while in respect of the DPV

subgroup, consumption slightly increased in comparison to the previous period. The values specified for the period of 2024 in the 2023 Annual Report were updated as of 22 January 2025. Data for the consumption of individually prepared medicinal products in 2024 are not complete due to the delay caused by the hand-over of statistical data by health insurance companies, and hence incompleteness of data from the Institute of Health Information and Statistics of the Czech Republic (hereinafter referred to as "ÚZIS"). For this reason, Q4 2024 is assessed as an estimate of the anticipated expenses and future cost prediction using the least squares method. An overview of the consumption of individually prepared medicinal products in DU for the period of 2022 to 2024 is shown in Graph 21.

In 2024, expenses incurred for individual IPLP groups were influenced by the change to the minute overhead rate per minute of time performance from the original value of 3.51 points to the value of 4.04 points in compliance with Decree No 320/2023 Coll., amending Decree No 134/1998 Coll., setting forth the list of healthcare procedures and their point values, as amended, with effect from 01 January 2024. In compliance with Decree No 319/2023 Coll., setting point values, reimbursement amounts for reimbursed services, and regulatory restrictions for 2024, the point value was decreased from the original amount of 1.11 CZK to the new amount of 1.04 CZK per point.

In 2024, new items from the RF group were placed on the IPLP List. The radiopharmaceutical 99mTc Mebrofenin inj. (product BROMO-BILIARON; code 0002024) was included with effect from 01 March 2024 until 31 December 2025 within a specific therapeutic programme, to be reported with procedures 47167, 47183, and 47187. With effect from 01 November, radiopharmaceuticals 177Lu vipivotid tetraxetan inj. (product PLUVICTO; code 0002118; reported with procedure code 09223) and 18F Fluordopa (product FLUORODOPA (18F); code 0002119; reported with procedures 47357 and 47355) were included in the IPLP list.

The distribution of expenses in the IPLP group in 2024 by individual subgroups is illustrated by Graph 22

Graph 23 illustrates also a comparison of expenses in the period of 2022-2024 for individual IPLP subgroups. A truly slight increase in the expenses incurred by the public health insurance funds was seen in the DPV, RF, and MAG subgroups; in 2024, only the TP subgroup exhibited a decrease compared to 2023, which corresponds also to the lower consumption in this subgroup.

Graph 21 Overview of consumption of individually prepared medicinal products in the period of 2022-2024 in thous. DU

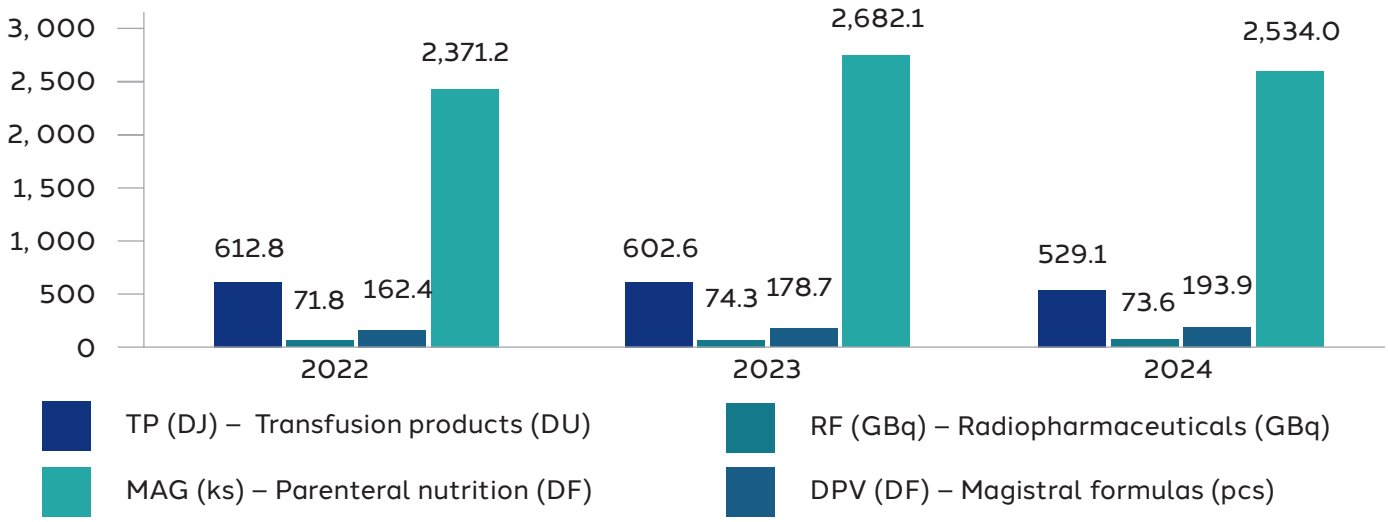
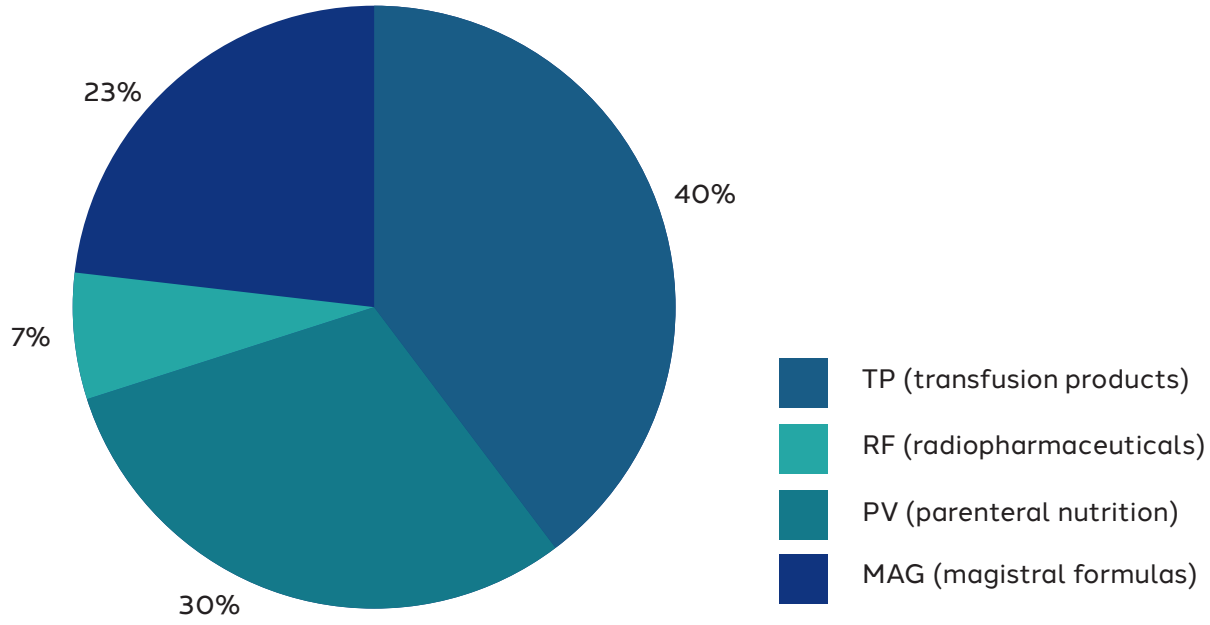


Table 37 Overview of inspections performed by the Control Unit

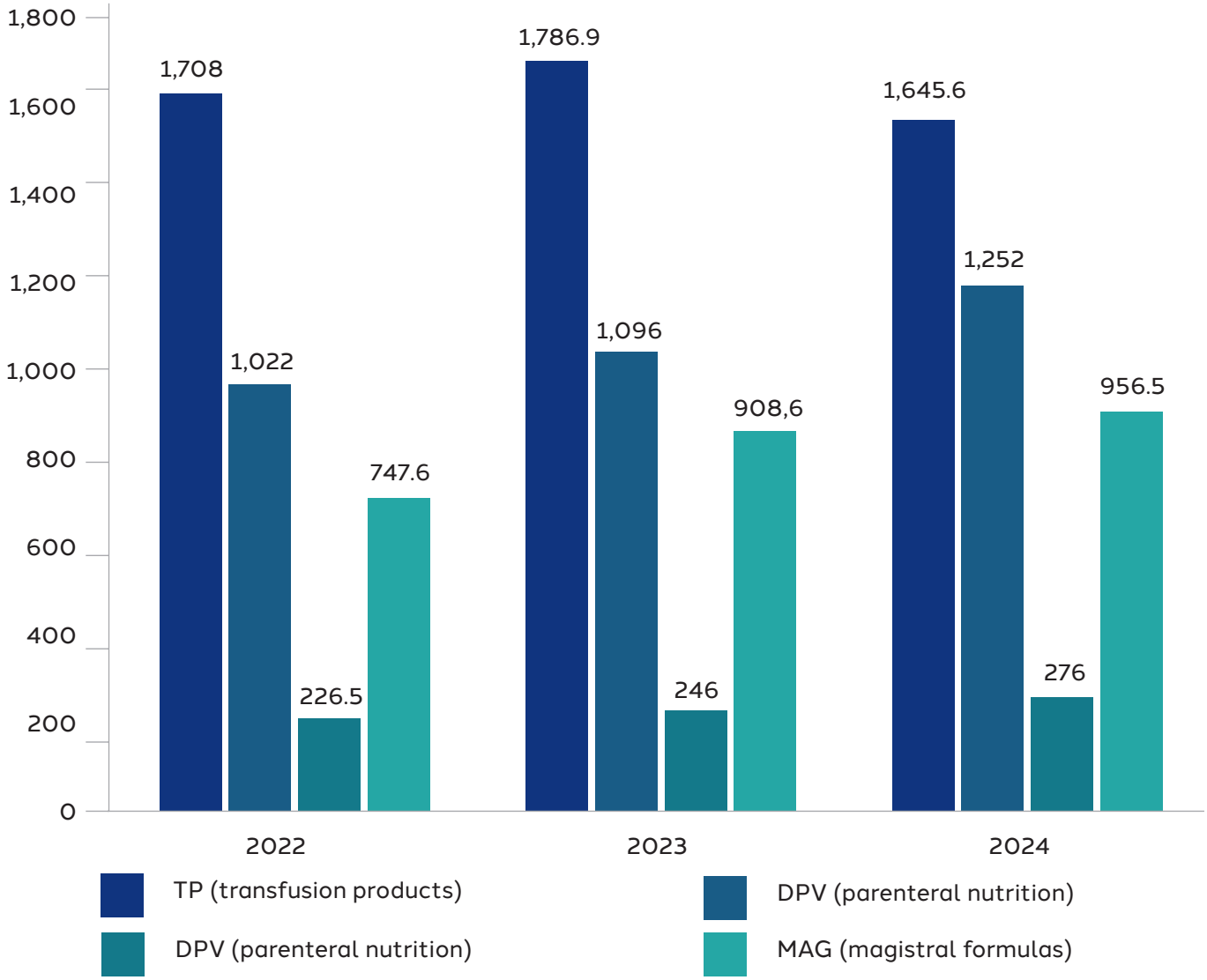
Number of inspections	**237**
Number of inspections instigated by a motion (of the total number of inspections)	31
Number of inspected medical devices	711*
Number of inspected legal measuring instruments (of the total number of inspected medical devices)	0
Number of motions forwarded to the Medical Device Legal Support Unit (proposals for administrative procedure initiation)	73

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

Graph 22 Distribution of total expenses in the IPLP group in 2024



Graph 23 Comparison of expenses by IPLP group in the period of 2022-2024 in mil. CZK



MEDICAL DEVICE REGULATION SECTION

The Medical Device Regulation Section constitutes of the Medical Device Market Surveillance Department, Expert Activity Department, and three separate units that report directly to the Section Director. Within the scope of systemisation, the agenda of registration of persons was moved from the Registration and Notification Unit to the Systems Unit as of 01 July 2024. Furthermore, the advertising surveillance agenda was moved under the Expert Activity Department and merged into one unit with the Expert Opinion Unit. In the course of the year, staffing capacities were allocated primarily to field education in specialised areas and familiarisation with the new set-up of processes implemented in the interface of the newly launched Medical Device Information System. At the same time, employees were involved in the implementation of the new European and national legislation that came into force in the sphere of medical devices and in activities concerning the impact of horizontal legislation upon the medical device regulation agenda. As part of their membership in working groups established by the European Commission, the Medical Device Regulation Section employees were actively involved in the preparation of new MDCG guidelines and the EUDAMED database. With regard to enhancing the specialised expertise of the Section, the employees of the Vigilance Unit and of the Control Unit have been involved in the EU4Health projects launched by the European Commission in order to safeguard the implementation of processes implied by European regulations in professional practice.

4. 15 MEDICAL DEVICE MARKET SURVEILLANCE DEPARTMENT

4. 15. 1 Control Unit (KON)

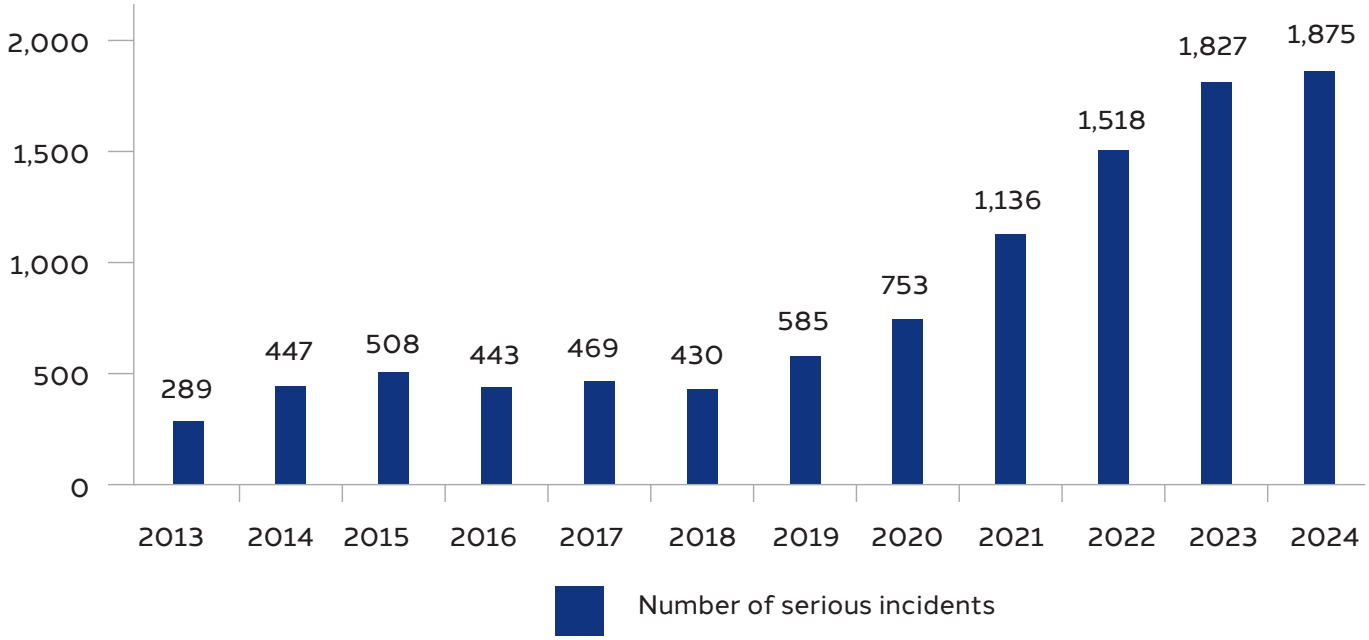
The Institute's surveillance activities over persons handling medical devices was in 2024 governed by Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (hereinafter referred to as the "MDR"), Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices (hereinafter referred to as the "IVDR"), and Act No 375/2022 Coll., which covers the area of medical devices on the national level (hereinafter referred to as "Act No 375/2022 Coll."). The inspected persons include healthcare service providers in the sphere of medical device use as well as medical device manufacturers, importers, distributors, persons servicing medical devices, and persons dispensing medical devices. This surveillance activity includes also the agenda of assessments of proper placement of medical devices on the market, surveillance pursuant to Act No 526/1990 Coll., on Prices, as amended, for medical devices with regulated price, and surveillance pursuant to Act No 634/1992 Coll., on Consumer Protection, as amended, in the area of medical device offers and sale to the consumer.

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 were safe and functional and that health care were provided using appropriate, safe, and effective medical devices in a manner preventing any damage to the health of users or patients in the proper use of the devices for their intended purposes. In 2024, the inspectors of the

Table 38 Inspections of individual entities

Entity	Number of inspections
POS – providers	55
CEN – price control	41
DIS/DOV – distributors and importers	75
SER – persons servicing medical devices	23
VYD – persons dispensing medical devices	22
VYR – manufacturers	15
OS – consumer protection	5

Graph 24 Overview of notified incidents/serious incidents in the period of 2013–2024



Control Unit completed the total of 237 inspections, of which 55 were inspections at providers of healthcare services (both state and non-state healthcare facilities) and 135 were inspections at medical device manufacturers, importers, distributors, persons dispensing medical devices, and persons servicing medical devices. The tables below provide more detailed statistical data on the total number of inspected persons.

As mentioned above, 55 inspections were carried out at providers of healthcare services, within the scope of which documents certifying compliance with the conditions for the medical device use in the provision of health care were checked. During 135 inspections completed as part of market surveillance, compliance with the requirements governing medical device supply to the market was checked.

The Control Unit forwarded the total of 73 motions for further procedure initiation to the Medical Device Legal Support Unit.

4. 15. 2 Medical Device Vigilance Unit (VIG)

On the basis of effective legislation of the Czech Republic, 1,875 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 these cases, monitoring was initiated. Investigations into 1,689 serious incidents are carried out separately, while the remaining 186 serious incidents are subject to aggregate investigations. The development of the number of serious incident reports in 2013-2024 is further illustrated in Graph 24.

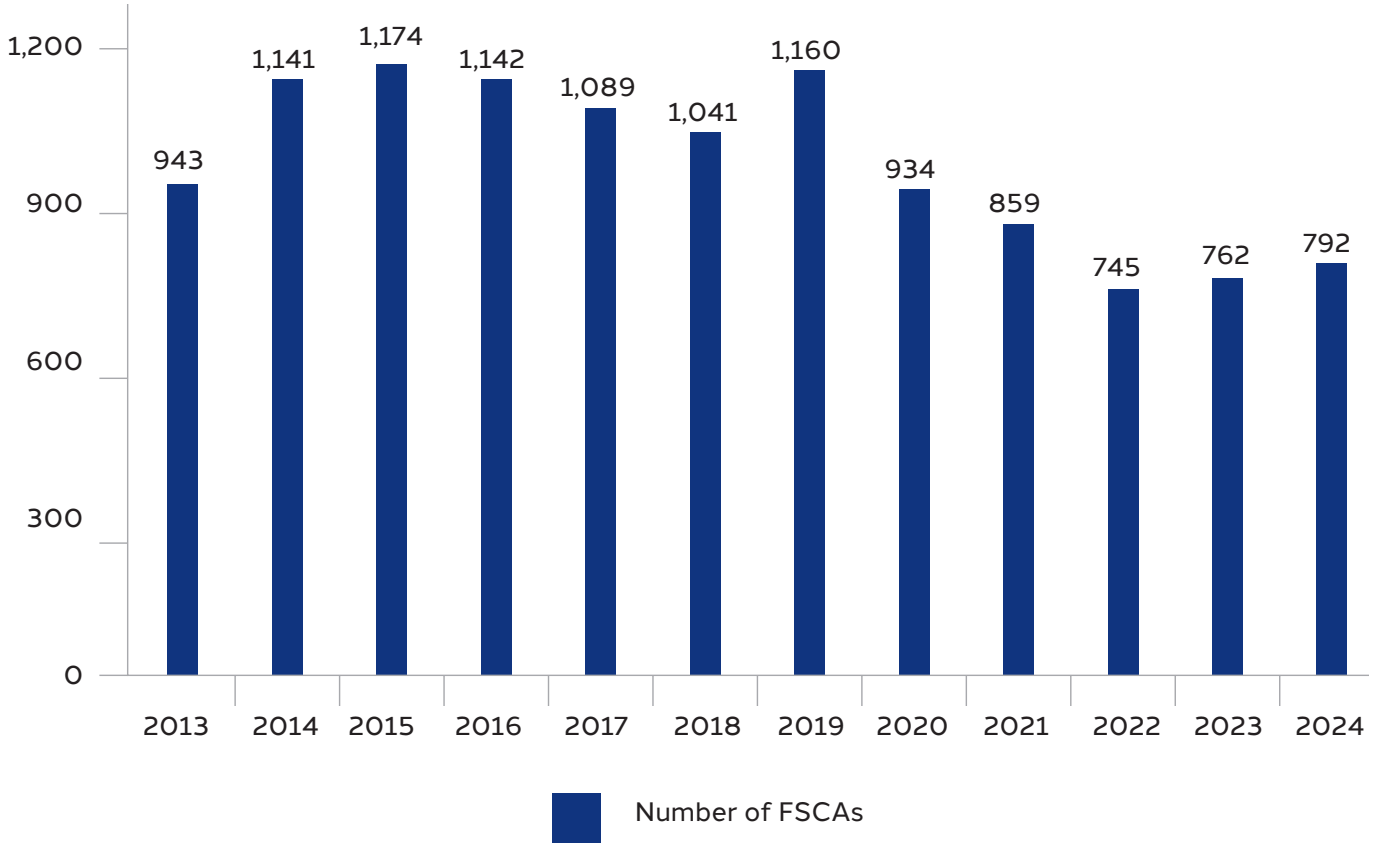
The total number of received reports on safety corrective actions regarding medical devices from competent national authorities, manufacturers or their authorised representatives, distributors or importers, as applicable, amounted to 792. Of the total number of received reports, 432 concerned medical devices made available on the Czech market. The development of the number of reports on safety corrective actions in 2013-2024 is illustrated by Graph 25.

In 2024, 413 communications to medical device users – Field Safety Notices (FSN) were published via the Registry of Medical Devices (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, ten 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. In association with the coming into force of a part of Regulation (EU) 2024/1860 of the European Parliament and of the Council, which imposes the obligation for medical device manufacturers to report, in predefined circumstances, information about suspended or terminated manufacture of medical devices to the State Institute for Drug Control, new processes covering the scope of such reporting were set up.

In 2024, the inspectors of the Medical Device Vigilance Unit regularly attended meetings of the

Graph 25 Overview of safety corrective actions for medical devices adopted in 2013–2024



Post Market Surveillance and Vigilance (PMSV) Working Group established by the Medical Device Coordination Group (MDCG) of the European Commission; a working group of the JAMS 2.0 project (signal detection and vigilance); and teleconferences focused upon exchange of information among Member States of the European Union concerning currently addressed vigilance cases and determination of further course of action to be taken in resolving them.

4. 16 EXPERT ACTIVITY DEPARTMENT (OEČ)

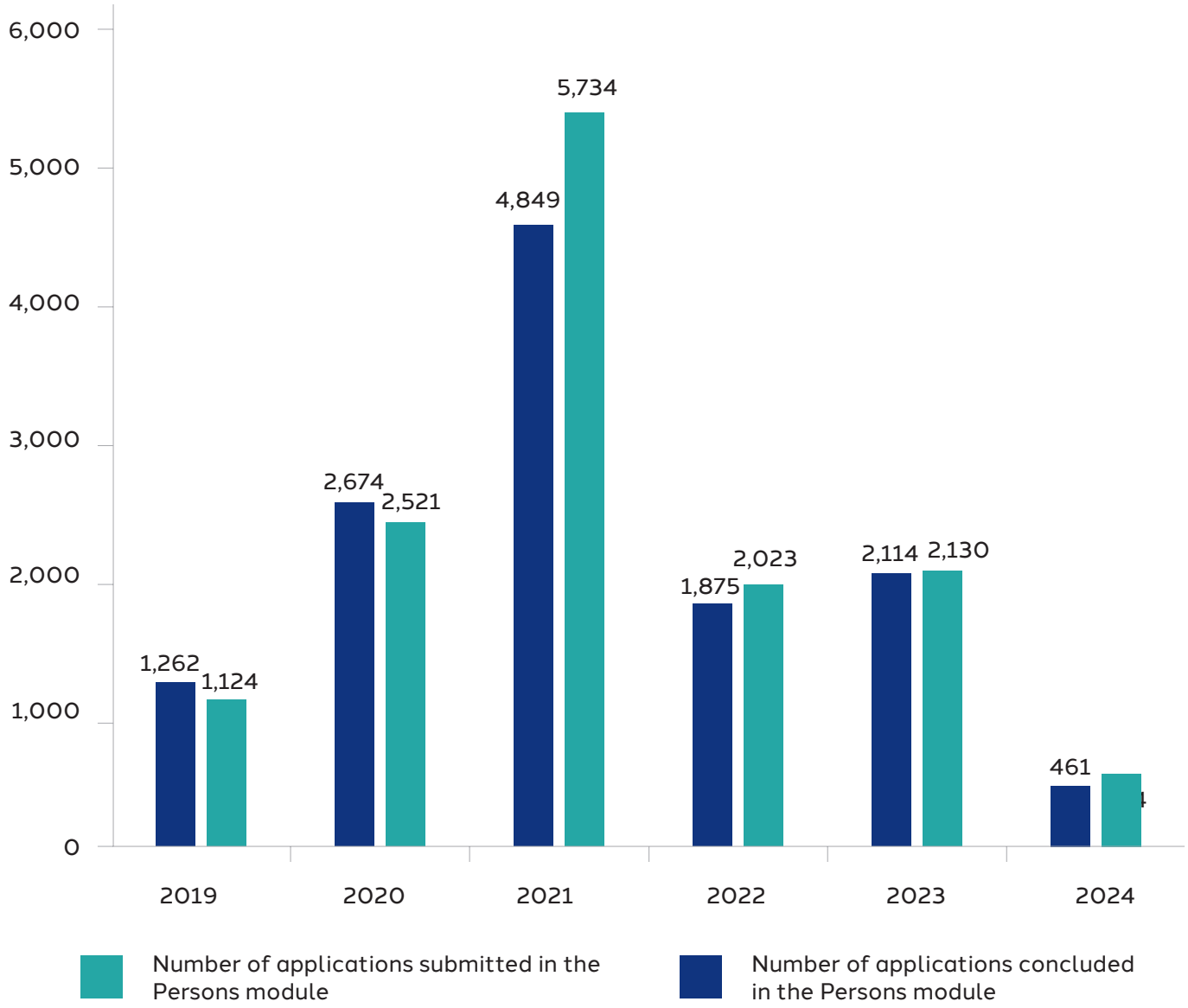
4. 16. 1 Registration and Notification Unit (RAN)

The Registration and Notification Unit (RAN) focuses upon registration of persons, medical device notifications, and activities associated therewith. Furthermore, the Unit issues certificates of free sale in compliance with Act No 375/2022 Coll. and with the MDR and IVDR.

Registration of Persons Handling Medical Devices

Since March 2024, the agenda of registration of persons has been split into two systems. Manufacturers, authorised representatives, and importers are still to be registered in the RZPRO registry, nevertheless, the notification duties of distributors, persons servicing medical devices, and manufacturers of custom-made devices have been, in compliance with Act No 375/2022 Coll., migrated to the Medical Device Information System (ISZP). Within the scope of systemisation effective from 01 July 2024, the entire agenda was moved to the Systems Unit. By 18 February 2024, the Registration and Notification Unit received 461 notifications in the RZPRO, and by 07 March 2024, it processed 544 notifications. Submissions of distributors, persons servicing medical devices, and manufacturers of custom-made devices filed by 18 February incl., were forthwith processed so as to allow for their migration together with others from the RZPRO to the ISZP system prior to

Graph 26 Ratio of submitted and concluded notifications in the Persons module



Note: In 2024, the Persons agenda was processed exclusively in the ISZP system from 07 March, and notifications were received in the RZPRO until 18 February.

the ISZP launch. A comparison of submitted and concluded notifications (completed procedures governed by the Code of Administrative Procedure – Act No 500/2004 Coll.) is illustrated by Graph 26.

From the ISZP launch until 30 June 2024, the Registration and Notification Unit received 594 notifications and processed 587 notifications in the ISZP.

Medical Device Notifications

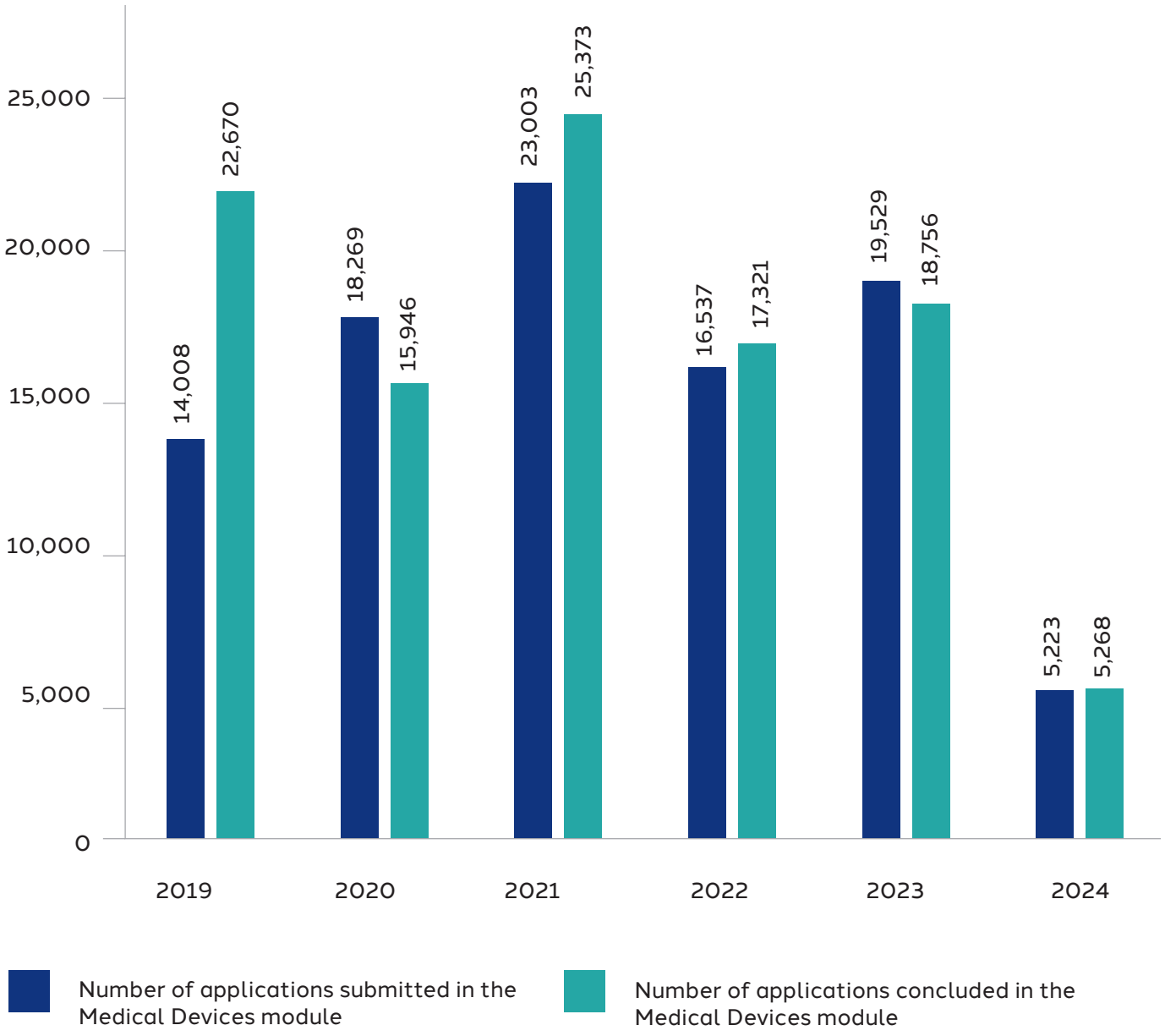
In total, the Registration and Notification Unit issued 8,133 documents, incl. invitations for amendment, in the Medical Devices module in the last year. In 2024, 5,223 applications were submitted in the Medical Devices module. A comparison of submitted and concluded applications (completed procedures governed by Act No 500/2004 Coll., the Code of Administrative Procedure) is illustrated by Graph 27. From 07 March 2024, the agenda of manufacturers, authorised representatives, and importers was processed in the Medical Devices module of the RZPRO.

Certificates of free sale

- Applications for certificate of free sale issuance

In 2024, 181 applications were submitted, of which 168 were concluded.

Graph 27 Ratio of submitted and concluded applications



Note: The chart does not illustrate data concerning certificates of free sale. In 2024, the distributor agenda was implemented solely in the ISZP system from 07 March and applications were received in the RZPRO until 18 February.

4. 16. 2 Expert Opinions and Advertising Surveillance Unit (OPDR)

On the basis of systemisation effective as of 01 July 2024, the Expert Opinion Unit (OPC) was merged with the Medical Device Advertising Surveillance Unit (DRZP), forming the Expert Opinions and Advertising Surveillance Unit (OPDR).

Expert opinions are issued on the basis of received requests for the issuance of an expert opinion 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. In 2024, the OPDR Unit issued 82 expert opinions concerning the nature of a product or medical device classification. In the conduct of the aforementioned activities, when processing opinions regarding product nature or medical device classification, the Unit cooperated also with the Pharmaceuticals Advertising Surveillance Unit. Of the aforementioned number, 71 opinions were issued on the basis of an external request and eleven opinions on the basis of requests from other units of the Institute.

The Institute's surveillance activities in the area of regulation of advertising for medical devices and in vitro diagnostic medical devices became part of the Institute's powers on 26 May 2021 as referred to under Section 7(b) of Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended (hereinafter referred to as the "Act on Advertising Regulation").

In the period from 01 January 2024 to 30 June 2024, the Medical Device Advertising Surveillance Unit (hereinafter referred to as "DRZP") was an independent unit carried out inspection activities based on received motions at entities defined by the Act on Advertising Regulation as well as controls of documentation of the investigated medical devices and investigations of persons as per Act No 375/2022 Coll., on Medical Devices and in Vitro Diagnostic Medical Devices. Furthermore, the DRZP unit was educating the general public, experts, and employees of healthcare service providers by means of information, recommendatory guidance published on the Institute's website, and lectures presented during seminars. As part of ongoing evaluation of the surveillance activities in this area, with regard to impact upon the market, the DRZP unit was involved in expert proposals on the drafted amendment to the Act on Advertising Regulation. In the period from 01 July 2024, on the basis of systemisation, the Expert Opinion Unit was merged with the Medical Device Advertising Surveillance Unit and personnel changes were implemented. A quantitative overview of the Unit's activities in the sphere of surveillance over advertising for medical devices is provided in the table below.

4. 16. 3 Medical Device Clinical Evaluation Unit (KHZP)

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 the MDR, 45 individual applications for authorisation of CIMD conduct and 24 individual applications for variations to CIMD conditions were submitted to the Institute in 2024 via the RZPRO Clinical Investigations module. The year-to--year increase in the number of applications for clinical investigations was 5 %.

In compliance with the IVDR, 15 applications for authorisation of the conduct of a performance study, 18 applications for authorisation of a modification of a performance study, and three notifications of the conduct of a performance study were submitted.

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

Thirty-one decisions authorising modifications to clinical investigations were issued; two procedures were stopped.

Fourteen authorisations of the conduct of a performance study were issued, one procedure was stopped and, at the same time, four notifications of the conduct of a performance study were assessed.

Table 39 Overview of the Unit's activities in 2024

Number of motions external/internal	16/7
Number of investigated communication media	83
Number of investigated entities	57
Number of investigated medical devices	61
Number of opinions	0
Number of consultations	1
Number of motions forwarded to other authorities	8
Number of motions forwarded to the Medical Device Legal Support Unit for administrative procedure initiation	12
Number of recommendatory guidelines and information published on the website – updates arising from legislative amendments	7 in English version
Number of seminars	4

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

In respect of ongoing clinical investigations, 370 individual serious adverse event (SAE) reports were filed in total.

Within the scope of international cooperation in the sphere of clinical evaluations, in 2024, a representative of the Medical Device Clinical Evaluation Unit attended regular (face-to-face as well as virtual) meetings of the IVDR implementation working group as well as of the medical device expert WG on Clinical Investigation and Evaluation of the European Commission (hereinafter referred to as the CIE group). A representative of the Unit is actively involved in the activities of two working groups under the CIE group. The meetings focus upon the development, implementation, and uniform interpretation of implementing regulations and the EUDAMED database in association with the MDR and, furthermore, upon exchange of information among the EU Member States. At the same time, intensive international cooperation in the implementation of the IVDR has been ongoing. The Unit has been also involved in the COMBINE project, which focuses upon clinical trials on pharmaceuticals and clinical investigations or performance studies run in parallel, and concurrently, in an essential project of coordinated assessment of applications for clinical investigations and performance studies.

Table 40 Number of applications in the sphere of clinical investigations and performance studies

	2022	2023	2024
Number of submitted applications for clinical investigation authorisation in RZPRO	32	43	45
Number of authorised clinical investigations	23	30	39
Number of suspended clinical investigations	8	8	9
Number of declined clinical investigations	1	1	1

	2022	2023	2024
Number of submitted applications for authorisation of modification to clinical investigation in RZPRO	40	39	24
Number of authorised modifications to clinical investigations	39	36	31
Number of suspended modifications to clinical investigations	2	1	2
Number of declined modifications to clinical investigations	0	0	0

	2022	2023	2024
Number of submitted applications for performance study authorisation in RZPRO	4	18	15
Number of authorised performance studies	4	9	14
Number of suspended performance studies	0	5	1
Number of declined performance studies	0	0	0
Number of notifications of performance study conduct	1	3	4

	2022	2023	2024
Number of submitted applications for authorisation of modification to performance study in RZPRO	0	8	18
Number of authorised modifications to performance study	0	8	13
Number of suspended modifications to performance study	0	0	3
Number of declined modifications to performance study	0	0	0

14. 17 Legal Support Unit of the Medical Device Regulation Section (PPZ)

Decision-Making on Whether a Product is Governed by MDR/IVDR

In compliance with Act No 375/2022 Coll., the Institute has the power to commence procedures to determine whether a product is governed by MDR or IVDR.

In 2024, three proposals for the commencement of an administrative procedure on whether a product was governed by MDR/IVDR, were forwarded to the Medical Device Legal Support Unit.

In 2024, the Institute commenced three ex-officio administrative procedures on whether a product was governed by MDR/IVDR.

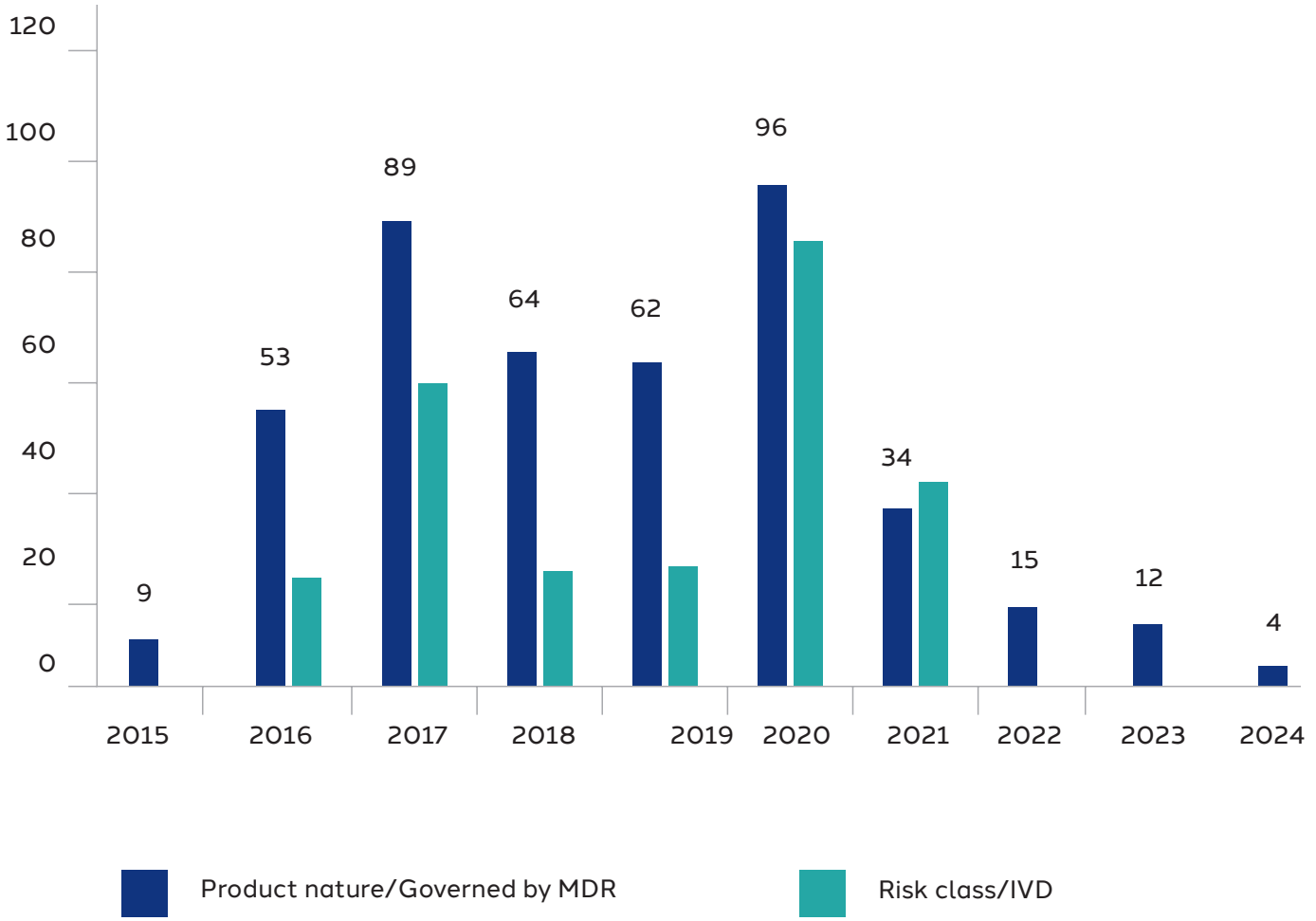
In 2024, the Institute received four applications for a decision on whether a product was governed by MDR/IVDR.

In 2024, four decisions stating that a product was governed by MDR/IVDR were issued.

Offences

The Institute, as the first-instance administrative authority, commences administrative procedures regarding offences in case a breach of Act No 375/2022 Coll., particularly with reference to the inspection activities carried out at manufacturers, providers of healthcare services, distributors, authorised representatives, persons servicing, dispensing or prescribing medical devices, importers, clinical investigation sponsors and investigators, both for medical devices and for IVD devices.

Graph 28 Overview of forwarded proposals for the commencement of ex-officio administrative procedures in the period of 2015–2024



In 2024, the Institute imposed fines for breaches of the Act on Medical Devices amounting to the total of 3,557,000 CZK. The highest proportion of fines imposed in 2024 for breaches of the Act on Medical Devices were fines imposed upon medical device distributors and healthcare service providers. In 2024, 33 orders and two decisions were issued. In recent years, the Medical Device Legal Support Unit has observed the highest increase of offences in the area of distribution, specifically in the area of Good Storage and Transportation Practices, where breaches of Article 14 of MDR/IVDR occur, and hence offences referred to under Section 58(g) of Act No 375/2022 Coll. are committed; with the coming into force of this Act, the area of offences was extended compared to the previous legislation, and, moreover, with the coming into force of MDR and IVDR, the maximum amounts of fines were increased.

Graph 29 Overview of decisions issued in 2024

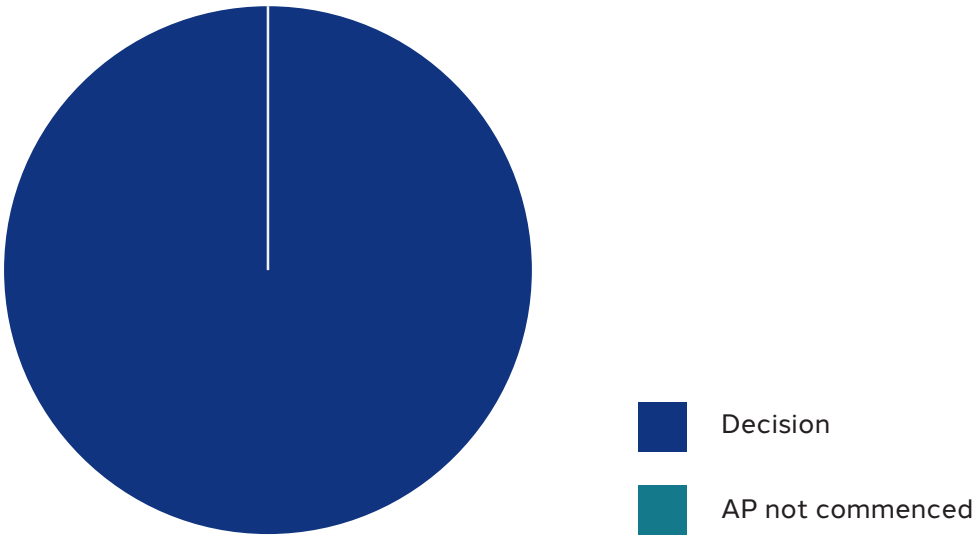


Table 41 Overview of forwarded motions for administrative procedure commencement in the period of 2015–2024

Overview for year:	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Clinical Evaluation Unit	-	3	1	-	-	-	4	-	-	1
Vigilance Unit	2	47	79	88	185	65	21	4	5	-
Control Unit	22	69	64	20*	-*	116	71	58	60	73
Medical Device Notification Unit	-	-	-	-	6	-	1	1	-	-
Medical Device Advertising Surveillance Unit	-	-	-	-	-	-	-	-	-	12
Total	**24**	**119**	**144**	**108**	**191**	**181**	**97**	**63**	**65**	**86**

** In the period from 01 August 2018 to 31 December 2019, surveillance over the medical device market was the responsibility of SÚKL's Surveillance Section..*

Table 42 Overview of appeals forwarded to the Ministry of Health of the Czech Republic in 2024

Unit	No. of appeals	Returned for re-consideration	Granted	Declined	Withdrawn by applicant	Terminated administrative procedures
Legal Support Unit	12	-	2*	-	-	2 *

** Number of decisions of the Ministry of Health of the Czech Republic that were sent back to the Institute.*

Table 43 Overview of submitted applications for exemption per Section 65(2) of the Act on Medical Devices in the period of 2021–2024

Overview for year:	2021	2022	2023	2024
Applications	6	17	11	12
Not commenced	1	2	0	1
AP suspended	3	4	8	1
Decision	0	10	6	8

Explanatory note: AP – administrative procedure

Appeals

In 2024, the Medical Device Legal Support Unit received the total of twelve appeals to be addressed. In compliance with Section 88 of Act No 500/2004 Coll., the Code of Administrative Procedure, as amended, these appeals were forwarded via the Institute to the Ministry of Health of the Czech Republic as the appellate authority

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Exemptions

Pursuant to Act No 375/2022 Coll., the Institute decides on granting exemptions referred to under Section 64(2) of the aforementioned Act, which may be granted on the basis of an application 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 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. With regard to the stable trend in received applications, it may be summarised that such procedure is used rather commonly, with positive feed-back and without any appeals filed.

14. 18 Medical Device Reimbursement Unit (UZP)

Reimbursement regulation has been based on a notification principle. Decisions on the inclusion of a specific medical device into a particular reimbursement group are primarily not taken via administrative procedures. Manufacturers themselves notify the Institute of the inclusion of their medical device in a reimbursement group. It is possible to notify of a new inclusion, change or removal of a medical device from the reimbursement group, which influences its reimbursement from the public health insurance funds and out-of-pocket payment for the patient. 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 or removal from the reimbursement group. Notifications of medical device reimbursements may be filed at any time, without any time limitations. Reimbursement limits for individual reimbursement groups are set forth by the Act on Public Health Insurance.

An important part of the Medical Device Reimbursement Unit's operation is the agenda of the year-to--year producer price increase, which is implemen-

ted 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 an *in vitro* diagnostic medical devices, amending Price Regulation 1/2023/OLZP of 30 November 2022, on the regulation of prices of medical devices an *in vitro* diagnostic medical devices.

The main output from the Medical Device Reimbursement Unit's operation is, in particular, the process of issuing the list of all medical devices reimbursed on prescription order (hereinafter referred to as the "Medical Device List"), which is the main index for the realisation of reimbursements for medical devices reimbursed on order from the public health insurance funds. As at 31 December 2024, the Medical Device Price List contained 13,350 items in total.

Table 44 Medical device reimbursement notifications in 2024

Reimbursement notifications	Number
Total submissions	7,088
New notifications	1321
Change notifications	1,002
Removal notifications	1571
Year-to-year producer price increases	3,194

Table 45 Overview of administrative procedures

Administrative procedures	Number
Commenced	0
Concluded	12

Table 46 Medical Device List as at 31 December 2024

Medical Device List	Number
Total	**13,350**
Included	1,102
Excluded	855

Table 47 Overview of the number of submissions from 01 July 2024, when part of the agenda was transferred from the RAN Unit to the SYS Unit

	Notification of activity	Notification of change of activity	Application for activity deletion	Confirmation of correctness	Invitations for rectification
Number of submitted notifications	150	1,250	2	0	0
Number of concluded procedures	153	1,255	3	0	0
Number of issued decisions, incl. invitations	190	1,432	3	0	0

4. 19 Systems Unit (SYS)

In the course of 2024, the Systems Unit focused upon the launch of the new Medical Device Information System (ISZP), established on the basis of the currently effective legislation governing medical devices. Concurrently, modifications to the Registry of Medical Devices (RZPRO) arising from the partial transfer of some agendas to the ISZP system were being implemented. Analytical work associated with the connection of the ISZP to the European EUDAMED database, which is to be launched in the course of 2025, begun during 2024. With regard to systemisation effective from 01 July 2024, the agenda of person registration was transferred from the Registration and Notification (RAN) Unit to the Systems Unit. In association with the transfer of the agenda, optimisation of processes related to the person notification agenda was carried out. The Systems Unit was involved in the organisation of 18 seminars of the Medical Device Regulation Section in order to safeguard proactive education for professionals and it participated in meetings of working groups established by the Medical Device Coordination Group (MDCG).

MEDICINE SHORTAGE AND AVAILABILITY

4. 20 Medicine Shortage and Availability Unit

On 01 January 2024, an amendment to the Act on Pharmaceuticals No 456/2023 Coll. (hereinafter referred to as the "Amended Act on Pharmaceuticals") took effect; the Amendment describes new rights and obligations of individual entities (such as marketing authorisation holders, distributors of pharmaceuticals, entities authorised to dispense pharmaceuticals, and public authorities) with regard to ensuring the availability of pharmaceuticals for patients in the Czech Republic. For the purposes of fulfilment of new goals implied by this Amendment, the Medicine Shortage and Availability Unit (hereinafter referred to as the "DAN Unit") was established within the scope of systemisation. The DAN Unit takes over and extends the agenda of the Expert Activity Coordination Unit which had been in charge of similar tasks in the period from 2019 until the end of 2023.

Due to extended new obligations of the Institute, the number of positions in the Unit was increased via systemisation as necessary from the original five employees to double the count. Within the scope of these changes, *inter alia,* two new inspector positions were created. DAN inspectors specialise in the control of agenda associated with ensuring the availability of medicinal products at all levels of the distribution chain (i.e., from the placement of the medicinal product on the market, that is from the marketing authorisation holder level, via the distributor up to persons authorised to dispense medicinal products, i.e., pharmacies).

The DAN Unit thus represents the Institute in activities stipulated by Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (hereinafter referred to as the "Act on Pharmaceuticals") in areas safeguarding the availability of medicinal products, and in this sphere, it provides maximum cooperation to the Ministry of Health (hereinafter referred to also as the "Ministry"), which plays the main role in safeguarding the availability of medicinal products within the territory of the Czech Republic.

Activities of the DAN Unit in Respect of Safeguarding the Availability of Medicinal Products

4. 20. 1. Market Report Administration – mandatory reports from marketing authorisation holders (hereinafter referred to as "MAHs") 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, within timelines and by ways stipulated by the Act and Decree. Reporting is performed via an electronic application on the Institute's portal. Data from these reports are copied to the "Database of Medicinal Products" and presented in overviews available at: https://prehledy.sukl.cz/mr.html#/.

- The task of DAN assessors is to evaluate the reported suspensions or terminations of supplies with a view to safeguarding the availability of medicinal products important for the provision of healthcare services and to assess replaceability of such medicinal products. The Institute always assesses the replaceability of each medicinal product individually (with regard to the characteristic properties of the medicinal product, its current consumption and duration of supply disruption). The DAN employee always allocates the replacement medicinal product or evaluation of its replaceability with another therapy to the individual reports.

- Furthermore, DAN employees answer questions on medicinal products availability and check for availability with the MAHs where reporting discrepancies arise.

- In late 2024, a new application for shortage reporting was established, the goal of which is to facilitate the fulfilment of the MAH's obligations, to unify varying habits of MAH's in the submission of the reports, to enhance the accuracy of report evaluation by the Institute, and to streamline shortage reporting both for healthcare professionals and for the general public. As a new feature, the application allows the MAH to edit/invalidate previously submitted reports. Change history is newly available also in the public overview.

Reporting Statistics for the Mandatory Market Reports in 2024:

- suspended supplies: 3,808 reports (in 75 % of which supplies have already been renewed);

- terminated supplies: 930 reports;
- renewed supplies: 2 396 reports;
- initiated supplies: 809 reports;
- rreplaceable medicinal products: 167 (suspended supplies) and 28 (terminated supplies).

In 2024, for the first time over the past few years, a decrease in the previously growing trend of the number of submitted reports of suspended/terminated supplies of medicinal products onto the market was seen. The number of submitted reports of suspended/terminated supplies in 2024 was approx. 10 % less than in the previous year.

Letters to healthcare professionals concerning medicinal product availability

- Together with MAHs, the Institute strives to provide timely and maximum information on jeopardised medicinal product availability to healthcare professionals. One of the instruments for the dissemination of information provided in the Market Report and in cases where the MAH or the Institute consider it appropriate, are letters to healthcare professionals, through which it is possible to provide substantial information on the availability of medicinal products.

In 2024, the Institute, with MAH involvement, assessed and published on its website the total of eleven letters concerning medicinal product availability.

4. 20. 2. 2. Addressing Medicinal Product Unavailability

Addressing Medicinal Product Shortages within the Institute

- Checking/addressing the current situation for each medicinal product individually.

Calls for stock level reporting in Case of Suspected Jeopardy to Availability

- This new power given to the Institute by the Amended Act on Pharmaceuticals, has been exercised by the Institute in relation to MAHs, distributors, and persons authorised to dispense medicinal products since January 2024.

- During 2024, the Institute issued 32 calls, of which eleven were addressed to MAHs (20 medicinal products in total), eleven to distributors (85 medicinal products in total), and ten to persons authorised to dispense medicinal products (particularly pharmacies; 83 medicinal products in total).

General Measures – Limited Availability

- As of 01 June 2024, the Amended Act on Pharmaceuticals has given the Institute the power to flag a medicinal product with the "limited availability" tag under conditions stipulated by Section 33b of the Act on Pharmaceuticals; Section 33c of the Act on Pharmaceuticals then stipulates that the Institute is to issue a general measure in order to flag the medicinal product with the "limited availability" tag and in order to delete such tag.
- The application of the "limited availability" tag implies a number of obligations for distributors and persons authorised to dispense medicinal products, particularly daily stock level reporting. Other obligations concerning the safeguarding of medicinal product availability then arise for the Institute and MAHs.
- As early as prior to the effect of the Amended Act on Pharmaceuticals, the Institute had prepared IT systems for stock level reporting and its subsequent analyses necessary for the evaluation of medicinal product availability. At the same time, the Institute organised several seminars and the employees of the Institute gave lectures at seminars/conferences organised by other entities, in order to educate healthcare professionals. Furthermore, the Institute answered numerous questions concerning these new obligations.
- **From June to December 2024, the Institute issued 109 general measures (concerning the total of 346 medicinal products labelled with the "limited availability" tag)** and, at the same time, revoked 35 general measures (the "limited availability" tag was deleted from 103 medicinal products in total).

Provision of information about medicinal product availability to the Ministry of Health

- The Amended Act on Pharmaceuticals allowed the Ministry of Health to temporarily adjust the

conditions of distribution, prescribing, and dispensing of medicinal products the availability of which was jeopardised; this power is implied by Section 112c of the Act on Pharmaceuticals.
- In 2024, the Institute provided the Ministry of Health with information about the availability of several medicinal products (inhalation salbutamol, oral levofloxacin, and phenobarbital) and with information on possible adjustment of conditions of their distribution, prescribing, and dispensing, including the duration of such restriction, on the basis of three requests raised by the Ministry.

Allowing for the Placement of a Foreign-Language Batch of a Medicinal Product on the Market

- Pursuant to Section 38 of the Act on Pharmaceuticals, the Institute, having regard to public health protection, may allow for the omission of certain particulars 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 applications for the placement of individual batches of a medicinal product the labelling of which is in a language other than Czech on the market, the DAN employee abides 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 2024, no such request was submitted to the Institute.

- **In 2024, the Institute issued the total of 230 decisions allowing for the placement of a foreign-language batch on the market, which copies the 2023 trend in terms of the number of submitted applications and decisions issued by the Institute.**

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.

- DAN Unit employees check the database in compliance with Article 57 (EMA database, Regulation [EC] no. 726/2004 of the European Parliament and of the Council) to see whether medicinal products which could be used as a replacement for the medicinal products unavailable in the Czech Republic have been authorised in the EU. 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 the application of Section 77(1)(i) of Act No 378/2007 Coll., on Pharmaceuticals, and Section 46 of Decree No 229/2008 Coll., on manufacture and distribution, the DAN Unit assesses and issues approvals of submitted applications for import of non-authorised medicinal products from third countries.

In 2024, 229 approvals of import of non-authorised medicinal products from third countries were issued in total, which is 17 % more 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 of Health, having regard to the anticipated duration of supply disruption, authorises the Institute within the meaning of the provision of Section 2a(b) of Minister's Order No 20/2011, "Coordination of the activities of the Ministry and SÚKL in addressing certain specific processes to safeguard the availability of medicinal products important for the provision of health care", to publish a communication about the emergency need and call for proposals of specific therapeutic programmes (hereinafter referred to as "SpTP") using non-authorised medicinal products for human use.

- Furthermore, in compliance with Section 49 of Act No 378/2007 Coll., on Pharmaceuticals, and Section 2 of Decree No 228/2008 Coll., on marketing authorisation of medicinal products, the DAN Unit safeguards the preparation of opinions on the submitted applications for 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 of Health, the Institute drafts also opinions on special therapeutic programmes.

- **In 2024, the Institute drafted opinions on 62 submitted applications for opinion on a thera-**

peutic programme (of which four were opinions on proposed special therapeutic programmes).

Processing of Expert Opinions on Emergency Measures Issued by the Ministry of Health

- On the basis of requests of the Ministry of Health, in 2024, the Institute processed two expert opinions on medicinal products for the purposes of issuance of emergency measures by the Ministry of Health, the issuance of which is governed by 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 (Hereinafter Referred to as "Individually Prepared Medicinal Products" or "IPLPs") in Pharmacies

- 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. DAN Unit employees consult such alternative options with pharmaceutical specialists.

4. 20. 3. Communication with the Public

- Within the scope of their activities, DAN Unit employees also address questions from healthcare professionals as well as from the general public concerning medicinal product availability and replaceability.

- In 2024, 425 questions were answered, mostly in writing.

4. 20. 4. Assessment of Medicinal Product Replaceability in Relation to the Activities of Other Organisational Units

- DAN employees also assess medicinal product replaceability for the Quality Defects Unit (hereinafter referred to as "ZJ") and the Marketing Authorisation Section (hereinafter referred to as "REG"). In 2024, this concerned 29 replaceability assessments for the Quality Defects Unit and 47 assessments of exemptions from the sunset clause for the Marketing Authorisation Section.

4. 20. 5. Preventive Measures Related to Restricted Re-export of Medicinal Products

In compliance with Section 77c of Act No 378/2007 Coll., on Pharmaceuticals, the Institute collects information on the volume of medicinal products on the market in the Czech Republic and on the volume of medicinal products dispensed and used in the provision of healthcare services from marketing authorisation holders, distributors, and pharmacies. The Institute processes this information and assesses whether the quantities of a medicinal product irreplaceable with another medicinal product of adequate therapeutic properties or of medicinal products mutually replaceable in terms of their therapeutic properties sufficiently covers the current needs of patients in the Czech Republic. Where the Institute, having regard to the evaluation of the stated facts, arrives at a conclusion that the current stock level of the concerned medicinal product or medicinal products no longer adequately covers the current needs of patients in the Czech Republic and shortage of this medicinal product would jeopardise the availability and efficacy of treatment of patients in the Czech Republic with a direct impact upon the protection of the people's health and a significant impact upon the provision of healthcare services, it notifies the Ministry of Health to this effect, providing also background materials and information on the basis of which the Institute drew this conclusion.

In 2024, the DAN Unit submitted the total of 27 motions on jeopardised availability for 55 medicinal products (SÚKL codes) in total; furthermore, two proposals for deletion from the list were submitted to the Ministry of Health.

In case the Institute receives a report from a distributor as referred to under Section 77(1)(q) of Act No 378/2007 Coll., 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, DAN Unit employees assess whether such distribution abroad would, in the coming period, cause a shortage of the medicinal product that is not replaceable with another medicinal product of adequate therapeutic properties or of medicinal products that are mutually replaceable in terms of their therapeutic properties, for the current needs of patients in the Czech Republic. In 2024, the Institute validated 2,364 applications from distributors intending to distribute listed products abroad, which is 5 % more than in the previous year. In case the availability of treatment for patients in the Czech Republic is jeopardised, with a direct impact upon the protection of the people's health and a significant impact upon the provision of healthcare services, the Institute submits a motion to the Ministry of Health for the issuance of a general measure as referred to under Section 77d of Act No 378/2007 Coll., on Pharmaceuticals, by means of which the Ministry of Health would prohibit the distribution of the concerned medicinal product(s) abroad.

In 2024, the DAN Unit submitted 39 motions suggesting prohibition of distribution abroad for the total of 46 medicinal products (SÚKL codes) and in respect of 35 codes, SÚKL suggested revocation of the ban on distribution abroad, namely in those cases, where the situation jeopardising availability of treatment for patients in the Czech Republic ceased to exist.

4. 20. 6. Inspection Activities of the DAN Unit

With regard to the fact that following the adoption of the Amended Act on Pharmaceuticals, inspection activities were new for the DAN Unit, new employees were recruited for these positions during Q1 and Q2 2024. After initial training in the first half of the year, the DAN inspectors developed and set up processes for inspections within the Unit. The inspection activities proper were commenced in Q3 2024. The completed inspections focused primarily upon the implementation of new obligations of pharmacies. Furthermore, the Institute checked compliance with MAH obligations and continues to carry out such controls, e.g., whether medicinal products are supplied to czech market in compliance with legislative requirements, or whether reports associated with suspended or terminated supplies are submitted in a timely and appropriate manner, so as to be able to forthwith adopt measures safeguarding medicinal product replacements where necessary. Furthermore, DAN inspectors check obligations imposed upon entities performing distribution activities in the area of medicinal product availability. The inspectors also closely examine any received motion drawing attention to potential breach of law. **In 2024, DAN inspectors checked eleven regulated entities and addressed six received motions in total.**

4. 20. 7. Preparation, Sharing, Communication, and Addressing of Availability on the European Level

In 2024, 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 pharmaceuticals and discuss adequate solutions. The Institute has been playing a significant role in negotiations concerning the supplies of medicinal products with limited availability at the European level, and, moreover, has substantially contributed to the development of methodology; on a continuous basis, moreover, it has been involved in the compilation of the EU list of critical medicines.

5. PROCESSING AND PROVISION OF INFORMATION

5. 1 Information Technologies

In the area of information technologies, 2024 was marked by the preparation of new key systems. These are, in particular, the following ones:

- new information portal SUKL.cz and migration to the new domain sukl.gov.cz;
- Medical Device Information System (ISZP);
- information system for administrative procedures in the area of pricing and reimbursements (ASTERx);
- back-up datacentre reconstruction;
- relocation of the regional unit in České Budějovice.

In 2024, the new portal was successfully launched and migration to the new sukl.gov.cz domain begun, which represents a major step toward enhanced safety, modernisation, and uniformity of online presentation of the Institute. In the course of the year, web portals and e-mail addresses were migrated to the new domain, which resulted in greater efficiency in communication and development of uniform identity of the organisation, including harmonisation of design with other state administration websites. Migration of other systems to the new domain will continue also in 2025. Along with the new portal, the electronic notice board was also modernised.

In March 2024, a new medical device information system intended for healthcare professionals was launched in production environment. Its roll-out brought enhanced process simplicity and effectiveness and ensured compliance with legal regulations.

In 2023, the development of a new information system for administrative procedures in the area of pricing and reimbursements was initiated. This system is to fully replace the existing one which is no longer suitable for the current needs both in terms of its technical and user aspects. This new, full-process system has been designed in manner allowing it to significantly contribute to a higher efficiency in the processing of the pricing and reimbursement agenda. Due to ongoing development, the originally anticipated launch of the system in late 2024 has been postponed to the second half of 2025.

Also in 2024, the work of the Information Technology Department was much influenced by new legislation requiring also amendments to the ope-

rated information systems. One of the substantial changes was the introduction of accreditable pay-up protection limit monitoring in the ePrescription system. It was necessary to design, develop and launch the entire system in production environment during a very short period of time to observe the timeline required by the legislation.

In association with the ePrescription system operation, hardware infrastructure was substantially enhanced. This step was implemented within the scope of the National Recovery Plan project.

The reconstruction of a back-up datacentre, for which project documentation had been prepared, was initiated and coordinated with the SÚKL building no. 24 roof reconstruction project as scheduled. The back-up datacentre reconstruction was successfully completed in 2024, including performance enhancement of this component of the infrastructure. With the implemented back-up datacentre reconstruction, back-up infrastructure was substantially enhanced. This modernisation included also physical separation of the back-up infrastructure from other components of the datacentre. Overall, this reconstruction contributed to a major improvement in the efficiency and safety of the back-up datacentre. In late 2024, the existing OKL regional unit in České Budějovice was relocated to new, modern premises. The new premises provide better working conditions and allow for greater operational effectiveness of the OKL regional unit, thus contributing to an overall improvement of the working environment.

Home-office style of work became part of normal routine in the Institute's operation. The employees availed of mobile technologies and remote access to the Institute to a great extent. On the basis of a successful tender, in 2024, the Institute transferred to a new internet connection provider for all workplaces and the back-up line. This step contributed to the modernisation of the technical infrastructure and improved digital communication.

As part of internal IT processes, certain administrator activities in the IT Unit became automated.
In 2024, the Information Technology Department continued to fulfil its key role in the implementation of measures aimed at enhanced performance, availability, and security standard of the systems operated in the Institute. Such measures were consistent with the current trends in the area of information technologies and responded to the growing risks of cyber-attacks, which are associated with the operation of modern systems. Also, the efforts to enhance electronisation of processing of expert agendas have been successful, thanks to modern information systems that contribute to a more effective management and better quality of data processing. This continuous modernisation demonstrates the Institute's commitment towards technological development and safeguarding of key processes.

ePrescription System

Electronic prescription and the establishment of the ePrescription information system are legislatively based on Act No 378/2007 Coll., on Pharmaceuticals, as amended. By means of the ePrescription system, the doctor issues an electronic prescription (ePrescription) for the patient; on the basis of this prescription, the pharmacy dispenses the medicinal product. The Central Repository of Electronic Prescriptions, as one of the components of the ePrescription system, collects and stores all ePrescriptions under conditions stipulated by effective legislation. The established ePrescription system is one of the eHealth services and, since 01 January 2018, its operation in the Czech Republic has been mandatory. Pursuant to Section 81f of Act No 378/2007 Coll., on Pharmaceuticals, exceptional situations when it is possible to continue to issue paper-based prescriptions are still permissible.

In association with the requirement for mandatory electronic prescription, the process of modernisation of the entire system, also with regard to its inclusion in the eHealth National Strategy of Electronic Healthcare and Strategic eGovernment Development Framework 2014+, was initiated as early as in 2015. The implementation of the ePrescription project was carried out according to the effective schedule and the project was completed in December 2017. The ePrescription system has been included in the critical infrastructure of the state, and hence has been governed by the tightest security measures as referred to by the Act on Cyber-Security and related legal regulations.

An ongoing system support has been established and on the basis of suggestions submitted by professional as well as the general public, the system is being continuously improved, which is consistent with the performance of the service agreement on the provision of service support. In an open tender held in 2020, the currently effective service agreement was awarded; it provides support and development of all of the ePrescription system components, which, pursuant to Section 81 of the Act on Pharmaceuticals, includes the Central Repository of Electronic Prescriptions (CÚER), the Central Repository of Electronic Orders (CÚEP), the Central Repository of Vaccination Records (CÚEO), the Registry of Restricted Medicinal Products ("RLPO"), the medication record, consent administration, and other specified components.

Since 01 January 2018, the system has been opera-

ted in the mode of mandatory electronic prescription. Throughout 2024, 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 their application, doctors have the possibility to prescribe an ePrescription and an eVoucher or make a record of applied vaccination also outside their offices. The eVoucher prescription module is available in the application also to other healthcare professionals who are authorised to carry out this activity. Pharmacists and other persons dispensing medical devices may use the application to record the dispensing of a medical device on eVoucher. In the application, doctors and pharmacists may also view the patient's medication record, i.e., information on prescribed medicinal products or recorded vaccinations, if they are authorised to access such data. For pharmacists, moreover, there is a special application allowing them to obtain information about an ePrescription in case functional standard communication with the ePrescription system is not available.

The patient application allows patients to view the list of ePrescriptions and eVouchers prescribed for them or applied vaccinations, in respect of which the individual patient was unequivocally identified in the Registry of Inhabitants (ROB). Furthermore, parents have the option to view the ePrescriptions, eVouchers and vaccination records for their underage children. In the application, the patient may set up his/her consent or disagreement with the viewing of his/her medication record (list of ePrescriptions and vaccination records) or the medication record of his/her underage children. Furthermore, the complete history of accesses to his/her data, i.e., when a particular doctor or pharmacist viewed the lists of the patient's data, is available to the patient. Since November 2023, the patient may also grant or accept a mandate for viewing of ePrescriptions or eVouchers in the patient application.

The ePrescription system offers a wealth of benefits, particularly for the patient. **Electronic delivery of the ePrescription identifier – via SMS or e-mail messages – has been gaining an ever-growing popularity. The final volume for 2018 amounted to three million SMS messages and 492 thousand e-mail messages; in 2019, these Graphs increased to more than 10.5 million SMS messages and 702.5 thousand e-mail messages; in 2020, it was 28.5 million SMS messages and 840 thousand e-mail messages; in 2021, almost 34 million SMS messages and 688 thousand e-mail messages; in 2022, the Graphs exceeded 41 million SMS messages and 700 thousand e-mail messages; in 2023 they amounted to as many as 47.8 million SMS messages and 800 thousand e-mail messages; and, in 2024, the Graph grew to almost 55.8 million SMS messages and more than 913 thousand e-mail messages.**

Since the launch of the electronic prescription, the https://epreskripce.gov.cz/ website is being continuously updated. In 2024, the website was completely redesigned and the uniform gov.cz domain was applied. This website is the publication point for any information concerning the ePrescription, medication record, vaccination record, the electronic medical device order, and other news from the area of eHealth.

As part of the electronic prescription system operation, the Institute provides also support for the users of the given system. A free hotline has been made available to professional as well as lay users during working days from 7:00 a.m. to 5:00 p.m. (Monday through Thursday), and from 7:00 a.m. to 4:00 p.m. (Fridays).

The Institute, as the administrator and operator of the ePrescription system, safeguards continuous access also to data maintained in the RLPO registry for prescribing doctors and dispensing pharmacists, the purpose of which is to ensure the limitation of prescription and dispensing of the medicinal product to the quantity stipulated by the marketing authorisation pursuant to Section 39(4)(c) or Section 39(5) of Act No 378/2007 Coll., and the restriction stipulated by Decree No 236/2015 Coll. To fulfil the provision of Section 43a(2)(b) of Act No 167/1998 Coll., on Dependency-Producing Substances, as amended, which establishes the authority of the Czech Police to retrieve data from the RLPO registry via a defined point of contact, electronic access to this Registry via the ePrescription system has been made available for the Czech Police.

In 2018, the total of 58.5 million ePrescriptions were issued; 56 million ePrescriptions were dispensed; the total value of reimbursements of the dispensed reimbursed medicinal products prescribed via the ePrescription system exceeded 26,118,000 thous. CZK.

In 2019, more than 73.5 million ePrescriptions in total were issued; 71.5 million ePrescriptions were dispensed; the total value of reimbursements of the dispensed reimbursed medicinal products prescribed via the ePrescription system exceeded 33,154,301 thous. CZK, which represents more than a 25-% increase.

In 2020, more than 79 million ePrescriptions were issued; almost 77 million ePrescriptions were dispensed (Graph 30 refers) and the total value of reimbursements of the dispensed reimbursed medicinal products prescribed via the ePrescription system exceeded 32,981,849 thous. CZK.

In 2021, more than 76 million ePrescriptions were issued and almost 75 million ePrescriptions were dispensed, which was a clear proof of the well-established routine operation and utility of the system.

In 2022, more than 81 million ePrescriptions were issued and almost 80 million ePrescriptions were dispensed, which, to date, were the highest Graphs since 2018. In February 2022, the borderline of 300 million ePrescriptions issued since the start of mandatory electronic prescription was overcome.

In 2023, more than 83 million ePrescriptions were issued and more than 82 million were dispensed, which, to date, were the highest Graphs since 2018. In May 2023, the borderline of 400 million ePrescriptions issued since the start of mandatory electronic prescription was overcome.

In 2024, almost 86 million ePrescriptions were issued and more than 85 million were dispensed, which were the highest Graphs since 2018 to date. In July 2024, the borderline of 500 million ePrescriptions issued since the start of mandatory electronic prescription was overcome. The ePrescription system has hence become an essential instrument in the area of healthcare service provision.

Almost 50 thousand doctors and dentists, i.e., their vast majority, have access data generated by SÚKL for them. In 2024, application verifications with all professional chambers was flawlessly carried out on a continuous basis. Dispensing of prescribed medicinal products may be carried out practically in all pharmacies in the Czech Republic. **As of 31 December 2024, 49,702 doctors, 18,426 healthcare facilities, 8,653 pharmacists, and 2,743 pharmacies were actively involved.** At the moment, the numbers of active entities and healthcare professionals reflect only common changes in the sector, i.e., retiring individuals, arrivals of new graduates, establishment or dissolution of healthcare service providers.

In 2022, almost 158 thous. eVouchers were issued and approx. 133 thous. were dispensed.

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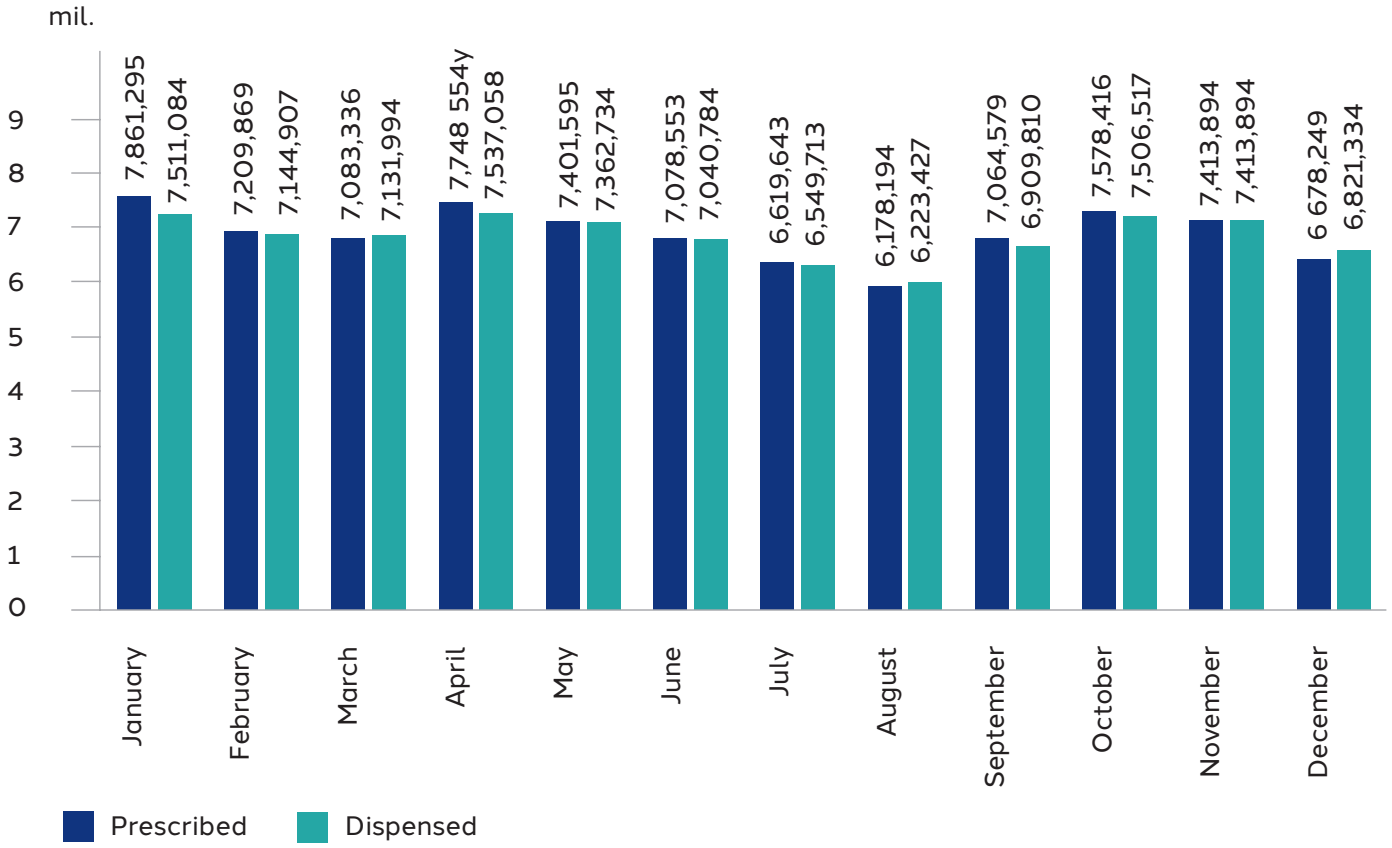
In 2024, almost 1,286 thous. eVouchers were issued and the number of prescribers and dispensing persons has reached approx. 10 thousand.

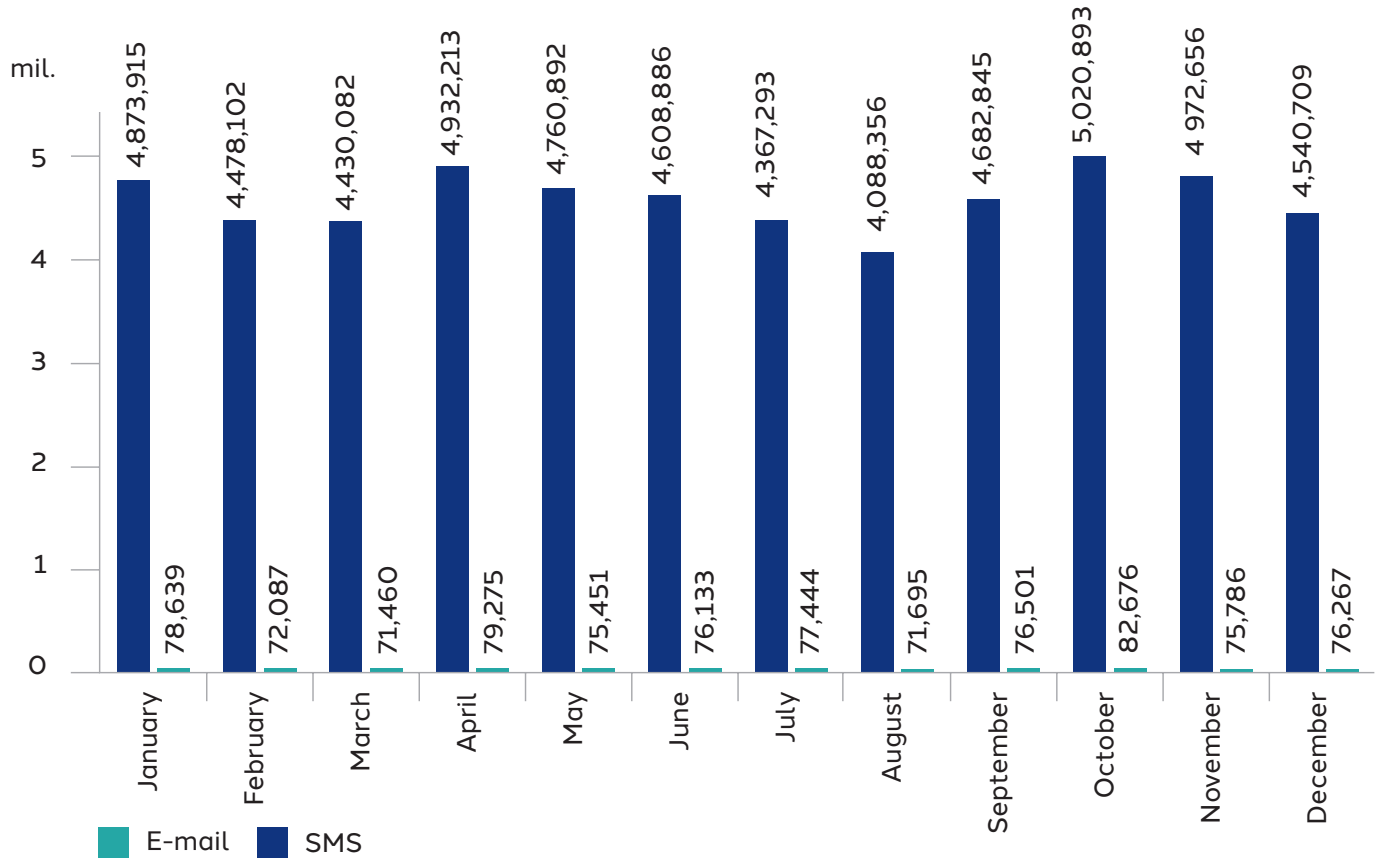
The https://epreskripce.gov.cz/ website publishes current information about active dispensaries where eVouchers may be used for dispensing. Their number is now more than 3.500.

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

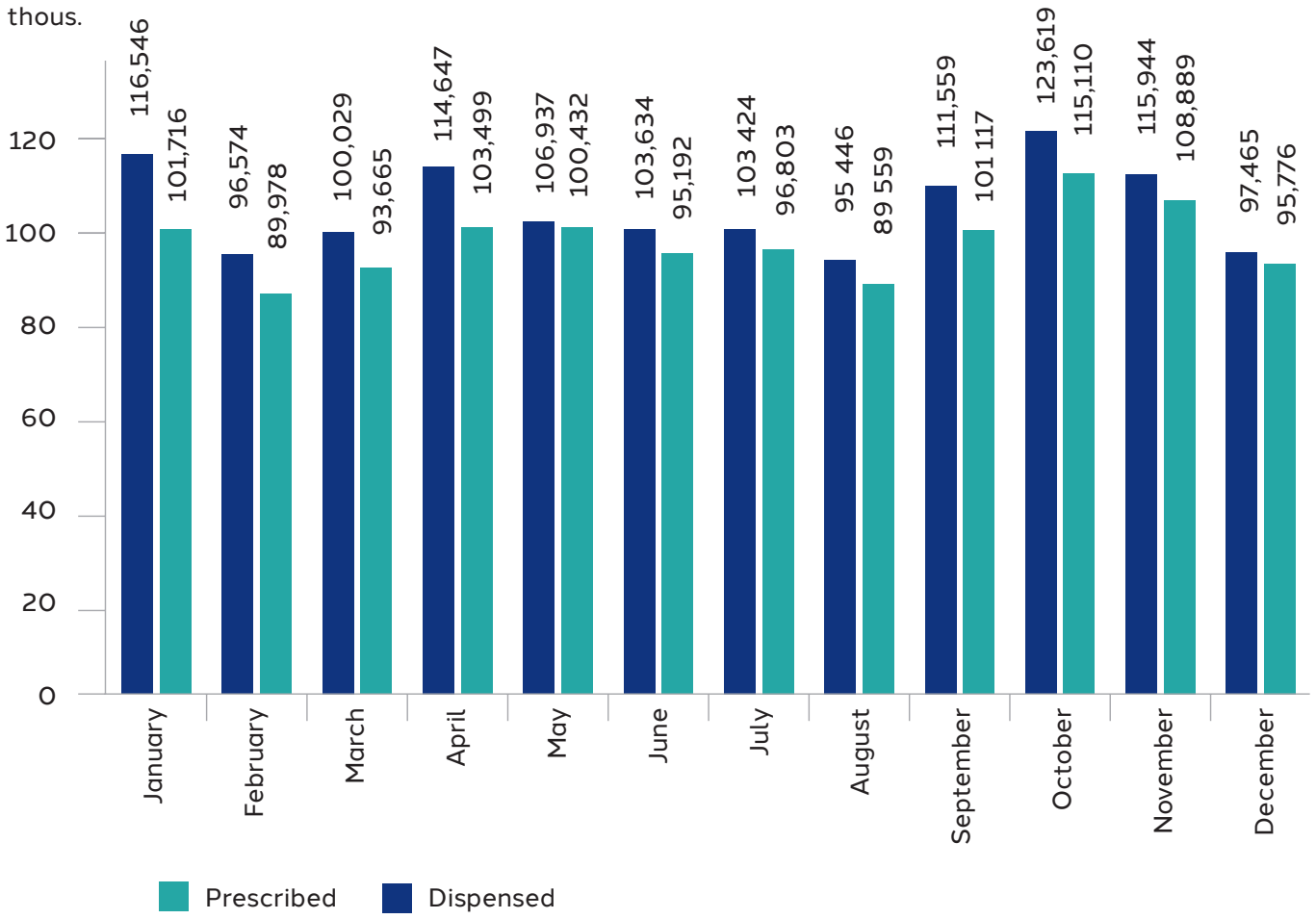
Graph 30 Number of prescribed and dispensed ePrescriptions in individual months of 2024 (mil.)



Graph 31 Number of e-mail and SMS messages sent out in individual months of 2024



Graph 32 Number of prescribed and dispensed eVouchers in individual months of 2024



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.

Cross-border exchange of electronic prescriptions will provide access to the ePrescription to a pharmacist in another participating EU Member State than the state where the ePrescription was issued. The Czech patient will be able to collect his/her medicine in any other EU Member State involved in the production operation of this cross-border exchange of electronic prescriptions. And, on the other hand, patients from those European countries that operate in the production environment, will be able to collect their medicines in Czech pharmacies.

In 2022, final steps towards launching the cross-border ePrescription system were taken. Following successful European testing, the final audit conducted by the European Commission was also successfully completed.

In 2023, production operation with Croatia, Poland, Estonia, Spain, and Portugal was launched. In the aforementioned countries, almost 800 Czech ePrescriptions were dispensed in the course of 2023. Step-by-step extension to other EU countries is planned in the coming years.

In 2024, production operation with Estonia, Finland, Croatia, Latvia, Poland, Portugal, Greece, and Spain was carried out. In these countries, 1,450 Czech ePrescriptions were dispensed in the course of 2024. Step-by-step extension to other EU countries is planned in the coming years.

In November 2023, another module of the ePrescription system – the Mandate Registry – was launched. Via this module, the patient can grant a power of attorney to be represented in negotiations concerning access to data entered in the ePrescription system established pursuant to Section 81(1) of Act No 378/2007 Coll., on Pharmaceuticals. The patient (principal) can appoint an agent to represent him/her in individual areas – ePrescription, eVaccination, eVoucher or consent administration.

The authorisation may be set up via a web or mobile application for patients, by submitting a completed form via the principal's data mailbox or by

sending a paper-based submission with an officially authenticated signature of the principal to SÚKL's registered office address. The Mandate Registry serves also for the purposes of setting up access to the ePrescription system for guardians of persons who have been legally incapacitated by a court decision.

In 2024, intensive preparations of the new module for accreditable pay-up administration took place; this is an agenda that must be, pursuant to amended legislation, covered by the ePrescription system as of 01 January 2025.

The ePrescription system has proven to be much valuable particularly at the time of the COVID-19 epidemic in the Czech Republic. During this difficult period, the electronic prescription rather effectively supported the desirable social distancing, significantly reducing the need for patients to come to doctors' offices, which substantially contributed to safeguarding the protection of health of all citizens of the Czech Republic. The importance of the ePrescription system may be evidenced also by numerous awards gained thereby since 2018. In 2022, ePrescription was awarded 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.

5. 2 Database of Medicinal Products and Monitoring of Supplies to Pharmacies

On the basis of the obligation stipulated 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 published information from DLP is displayed in the database of medicinal products available on SÚKL's website.

Registry of Active Substances

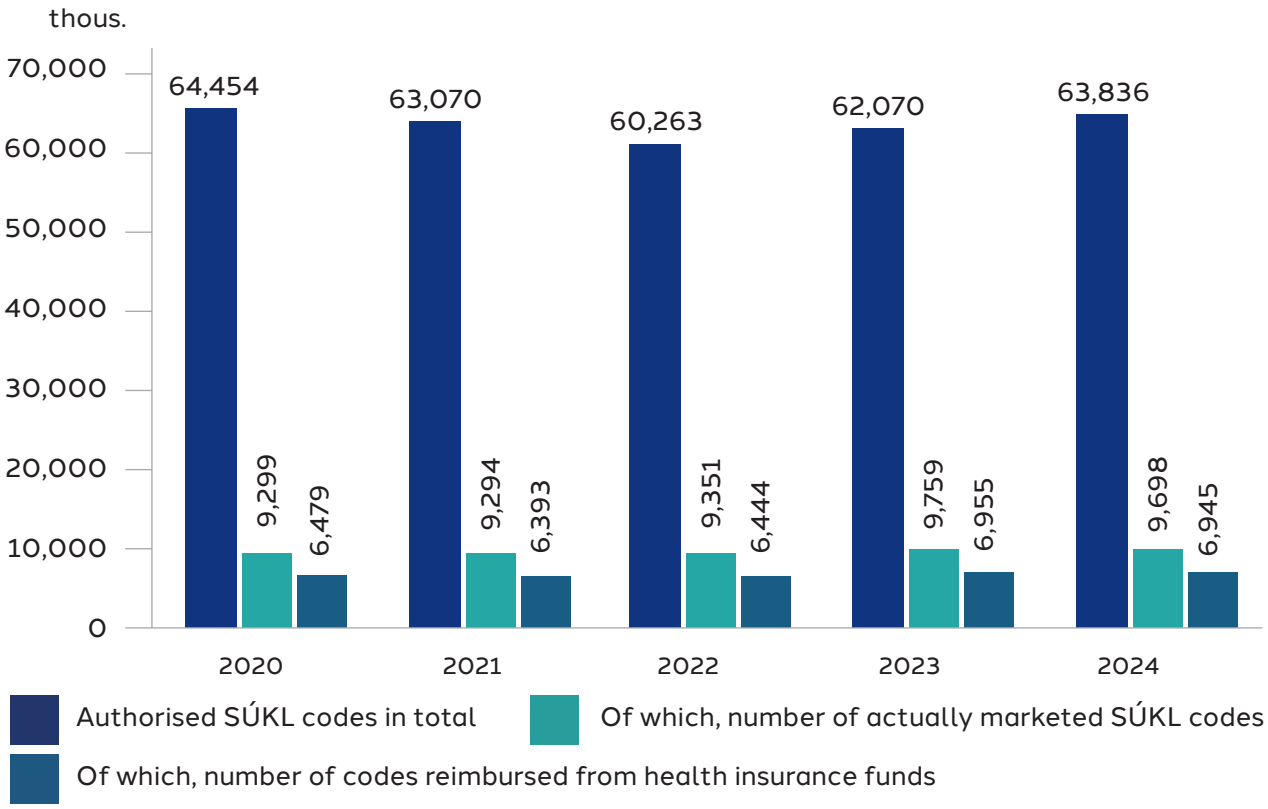
At present, the DLP Component Library contains 20,996 components (incl. combined components). In 2024, 499 new components were entered.

- In 2024, the flagging of components as prohibited substances in terms of doping and flagging of products containing such substances was updated in compliance with "The 2024 Prohibited List – The World Anti-Doping Code", effective as of 01 January 2024. Thereafter, flagging was performed on a weekly basis and a list of all authorised medicinal products with doping components was sent to the Czech Antidoping Committee on a monthly basis.

Table 48 Selected subgroups of authorised medicinal products entered in SÚKL's database as of 31 December 2024

	Total no. of MA numbers / marketed MA numbers	Total no. of SÚKL codes / marketed SÚKL codes
Medicinal products in total (excl. homeopathic preparations)	19,489/6 524	63,836/9,698
Of which by MA numbers:		
MA numbers granted by the Institute	6,585/4 791	50,864/7,475
MA numbers of products authorised via Community Centralised Procedure	12,904/1 732	12,953/1,746
Of which by content:		
Single-component	15,837	52,174
Multi-component	3,653	11,654
Of which by type of dispensing:		
Prescription-only medicinal products	18,687/5 885	60,146/8 188
OTC medicinal products	867/660	3,647/1 042
Restricted OTC medicinal products	4/3	16/3
Restricted prescription-only medicinal products	4/3	25/3
Homeopathic preparations	268/266	783/335

Graph 33 Authorised medicinal products in the period of 2020–2024



- New components were entered and components were amended as per Czech Pharmacopoeia 2023 – Supplement 2024 and European Pharmacopoeia – Supplements 11.4, 11.5, and 11.6.

- Components from the Proposed and Recommended INN WHO lists issued in 2024 were entered or amended.

Registry of Medicinal Products

In 2024, the Institute granted 504 marketing authorisations (3,582 SÚKL codes). Authorisation was revoked for 376 marketing authorisation numbers, which corresponds to 3,925 codes. The authorisation was revoked either upon request of the marketing authorisation (MA) holder (310 marketing authorisation numbers), due to the sunset clause (53 marketing authorisation numbers), or due to the fact that the MA holder did not apply for marketing authorisation renewal (13 marketing authorisation numbers). The validity of 4,321 codes in total expired (the period of the code final sale expired or marketing authorisation was revoked).

Authorised medicinal products contain 2,694 various active substances in total.

In the course of 2024, no distribution was reported for 54,138 codes (84.8 %) of medicinal products, excluding homeopathic preparations. Hence despite having a valid marketing authorisation, these products were not being placed on the market.

Regular Outputs from the Database of Medicinal Products

For professional 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 all details in the database of authorised medicinal products.

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

Graph 34 Deliveries of medicinal products in the period of 2020–2024

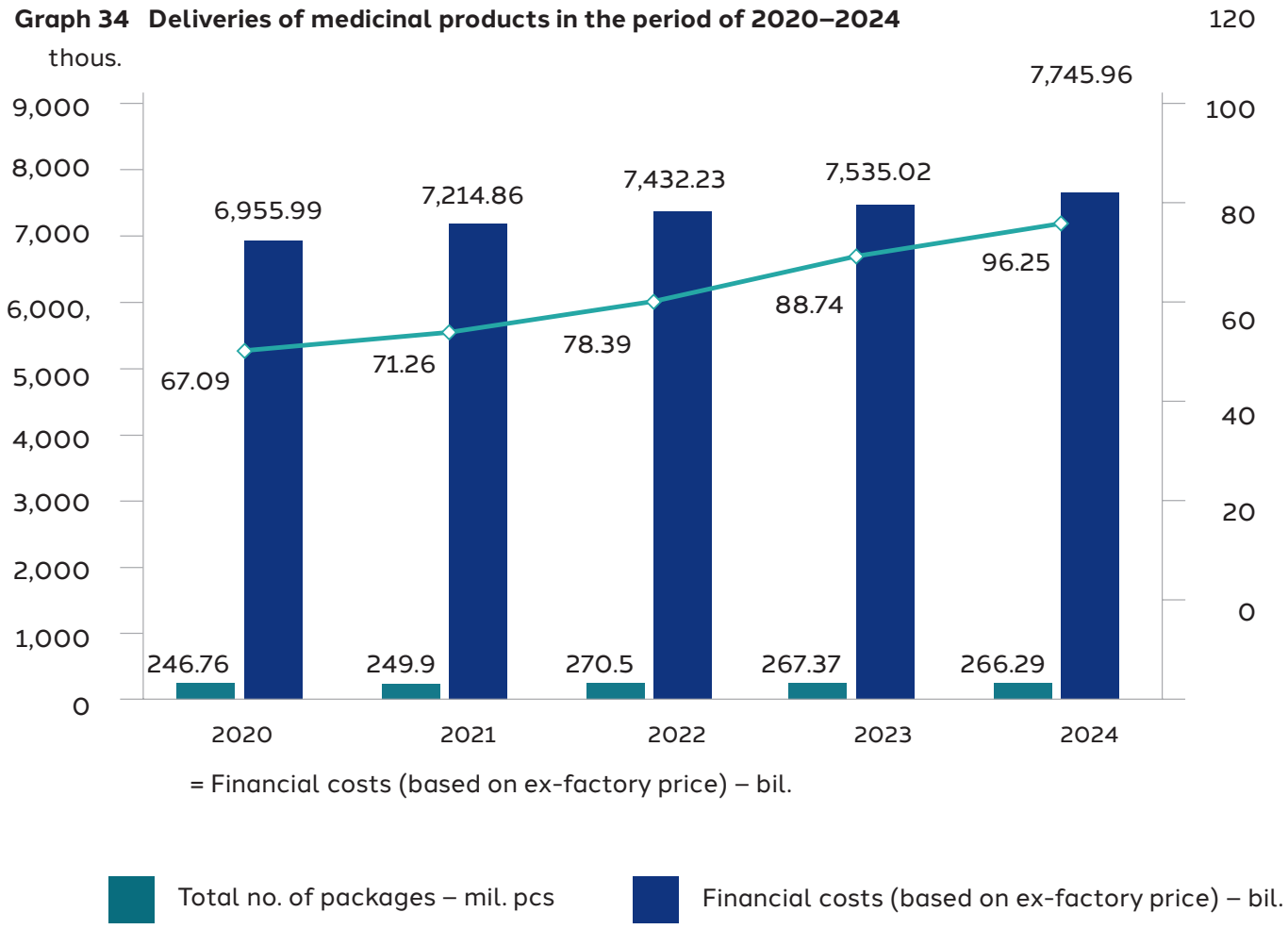


Table 49 Deliveries of distributed medicinal products in 2024

Medicinal products in total	**Number**
Deliveries to pharmacies and healthcare facilities (mil. packages)	266.294
Deliveries to pharmacies and healthcare facilities (mil. CZK based on ex-factory price)	96,252.489
Deliveries to pharmacies and healthcare facilities (mil. DDD)	7,745.961
DDD/1,000 inhabitants/day	1,946.955
Prescription-only medicinal products	**Number**
Deliveries to pharmacies and healthcare facilities (mil. packages)	185.015
Deliveries to pharmacies and healthcare facilities (mil. CZK based on ex-factory price)	96,024.093
Deliveries to pharmacies and healthcare facilities (mil. DDD)	7,118.335
DDD/1,000 inhabitants/day	1,789.200
OTCs and selected pharmaceuticals	**Number**
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuticals (mil. packages)	80.974
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuticals (mil. CZK based on ex-factory price)	228.395
Deliveries to pharmacies, healthcare facilities and vendors of selected pharmaceuticals (mil. DDD)	627.625
DDD/1,000 inhabitants/day	157.754
Restricted OTCs	**Number**
Deliveries to pharmacies and healthcare facilities (mil. packages)	0.281
Homeopathic preparations	**Number**
Deliveries to pharmacies (mil. packages)	1.887

termination of supplies of medicinal products onto the market) as well as for the overview of variations to marketing authorisations or for the overview of non-interventional post-marketing studies.

Evaluation of Deliveries of Distributed Medicinal Products

In 2024, 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 concerned deliveries of medicinal products to pharmacies and 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 summary information from monthly reports of entities authorised to distribute medicinal products in the Czech Republic on its website.

In 2024, 266.29 million packages of medicinal products were distributed, which corresponds to approx. 7,745.96 million DDDs. The value of these deliveries amounted to 96 billion CZK (based on ex-factory prices).

5. 3 Information Activities

As part of systemisation, the Director's Support Unit (PŘO) and Press and Information Unit (TIO) were merged in the course of 2024. After the merger, the unit is called Communications and Director Support Unit (PŘO). All activities of both units continue to be carried out.

Websites

The main task of the Communications and Director Support Unit is to provide information about SÚKL's operation and data both for professionals and the general public. The primary and most commonly employed communication channel is the Institute's website. The Institute administered several portals – sukl.cz, sakl.cz, olecich.cz, niszp.cz, and nebezpecneleky.cz. All of these portals were merged under the new website sukl.gov.cz, which was launched in mid-October 2024.

The website of the Institute was substantially redesigned so as to better comply with the needs of various user groups, such as patients, healthcare professionals or representatives of pharmaceutical companies. This new structure provides visitors with easy access to relevant information adapted to their specific requirements.

In the development of its new website, the Institute implemented the gov.cz system design, which ensures a uniform graphic design of and navigation through the websites of state authorities. Such implementation is mandatory for information systems subjected to Request for Opinion of the Chief eGovernment Architect on the planned project as referred to under Act No 365/2000 Coll., on Public Administration Information Systems, and under Resolution of the Government of the Czech Republic No 86 of 27 January 2020.

Social Media

In the provision of information for the public, the Communications and Director Support Unit also regularly avails of social media (Facebook, X [formerly Twitter], Instagram, and LinkedIn), through which it communicates news, information as well as the current topics covered by SÚKL. For example, social media were used also for the presentation of the MedSafety Week international campaign or the campaign for reducing overuse of antibiotics.

Specialised Library

The Communications and Director Support Unit is also in charge of administering the specialised library and organising of publication activities, specifically the preparation and publication of the monthly "Bulletin" ("Věstník") as well as the drug bulletin "Pharmacotherapeutic Information" ("Farmakoterapeutické informace") published eleven times per year (SÚKL is a member of the International Society of Drug Bulletins – ISDB) and the "Adverse Drug Reactions Bulletin" ("Zpravodaj nežádoucích účinků léčiv") published on a quarterly basis. All of the aforementioned publications are available from sukl.gov.cz.

An interesting publication, which is available from SÚKL's website, is a brochure on the 100-year history of the Institute.

Coordination of Expert Lectures

Expert lectures represent yet another important form of information provision. This agenda is coordinated by the Communications and Director Support Unit. In 2024, 35 requested lectures for commercial entities and healthcare facilities took place.

Inquiries

Another part of the Unit's agenda includes responding to inquiries from media and from the public. In 2024, the Communications and Director

Table 50 State budget income (thous. CZK)

Item	Approved budget	Actual amount
Administrative fees	24,800	18,927
Received penalty payments	4,000	6,848
Income from lease	0	341
Income from service provision	0	3
Received non-capital contributions and compensation	0	386
Transfers from other own funds	0	878
Transfers from the reserve fund	0	605,767
Payment to the state budget	250,000	250,000
Investment transfers received from the EU	0	17,941
TOTAL	**278,800**	**901,091**

Table 51 Expenditures (thous. CZK)

Indicator	Approved budget	Final budget	Actual amount
Regular employee salaries	24,590	53,468	53,468
Civil servant salaries	93,437	329,710	329,710
Other payments for completed work, severance pay, surrenders	3,604	16,310	16,310
Mandatory insurance premium	41,111	132,791	132,788
Fund of Social and Cultural Needs contribution	1,180	3,840	3,820
Operating acquisitions and related expenditure	967	194,748	194,415
Acquisition of long-term tangible and intangible fixed assets	0	38,569	38,560
TOTAL	**164,890**	**769,436**	**769,070**
of which: operating expenditure	164,890	730,867	730,511
capital expenditure	0	38,569	38,560

Support Unit addressed 2,575 questions both from the general public and from professionals, submitted either by e-mail or by post. Further 2,184 inquiries were handled by the infoline. Via e-mail, the total of 357 questions from media were answered and tens of questions were handled by phone.

Furthermore, the Unit was issuing press releases, organised or co-organised press conferences, and the representatives of the Institute also provided statements for radio or television broadcasting. On its website, the Institute published 16 press releases, notifications or reactions, and one press conference attended by the representatives of SÚKL took place.

Other activities of the Unit focused upon the preparation of the ePrescription campaign, with anticipated implementation in early 2025.

Table 52 Overview of selected types of assets and liabilities of the organisation (thous. CZK)

Item	Past period 2023	Current period 2024
ASSETS	**1,395,995**	**1,196,957**
A. Total fixed assets	**398,996**	**408,287**
of which:		
I. Long-term intangible fixed assets – total	106,052	109,898
II. Long-term tangible fixed assets – total	292,944	298,388
of which:		
Lots	4,530	4,530
Buildings	244,260	257,586
Separate tangible movables and sets of tangible movables	38,555	31,644
Unfinished long-term tangible fixed assets	5,599	4,628
B. Total current assets	**996,998**	**788,670**
of which:		
I. Inventory - total	157	158
II. Short-term receivables - total	15,971	26,221
III. Short-term financial assets - total	980,870	762,292
LIABILITIES	**1,395,995**	**1,196,957**
C. Equity	**1,343,900**	**1,144,709**
of which:		
I. Assets of the accounting entity and adjustments	226,552	226,552
II. Funds of the accounting entity	936,517	720,658
Fund for Cultural and Social Needs	2,864	1,191
Reserve Fund	933,653	719,467
III. Economic result	–1,253,977	–1,105,288
Economic result for the current accounting period	–111,380	148,689
Economic result for the previous accounting periods	–1,142,598	–1,253,977
IV. Income and expenditure account of the budget management	1,434,808	1,302,787
D. Total borrowed capital	**52,095**	**52,248**
of which:		
I. Total long-term liabilities	0	0
II. Total short-term liabilities	52,095	52,248

6. FINANCIAL AND MATERIAL RESOURCES OF THE INSTITUTE

6. 1 The 2024 Income and Expenditure Account

Income

In 2024, extra-budgetary income amounted to the total volume of 639,781 thous. CZK. The major part of this income was generated by the reimbursement of costs of expert activities that were carried out by SÚKL upon requests raised by 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 annual fees. The income from completed expert activities was used piecemeal by the Institute in compliance with Act No 378/2007 Coll., on Pharmaceuticals, as amended, Act No 296/2008 Coll., on Human Tissues and Cells, as amended, Act No 48/1997 Coll., on Public Health Insurance, as amended, Act No 167/1998 Coll., on Dependency-Producing Substances, as amended, and Act No 375/2022 Coll., on Medical Devices and on in Vitro Diagnostic Medical Devices, as amended, for the funding of payroll, operating, and investment expenditures not covered by financial resources allocated from the state budget. In 2024, the total amount of 605,767 thous. CZK was used in this manner through permissible excess expenditure. Of this amount, 568,810 thous. CZK was used for non-investment expenditure and 36,957 thous. CZK for the financing 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 18,927 thous. CZK, income from imposed fines amounting to 6,848 thous. CZK, income from lease in the amount of 341 thous. CZK, compensations of administrative procedure costs and refunds of excess advance payments made, related fully to the previous budgetary years, in the amount of 386 thous CZK, etc. The Transfers from the reserve fund line shows the volume of extra-budgetary income used for the funding of expenditures in 2024. State budget income includes also the payment of extra-budgetary resources of SÚKL in the amount of 250,000 thous. CZK. Investment transfers received from EU amounted to 17,941 thous. CZK in 2024. An overview of the budget income as of 31 December 2024 is provided in Table 50.

Expenditure

Data on expenditures incurred in 2024 broken down by individual categories are provided in Table 51.
The total investment expenditure incurred in 2024 amounted to 38,560 thous. CZK; 36,948 thous. CZK came from extra-budgetary resources. The funds were used, in particular, to finance the digital transformation of SÚKL operations, IT technology modernisation, office space reconstruction as well as the renewal of laboratory equipment. The expenditures incurred by the "Shared medication record – extended service in the sphere of consent management and access log" project, implemented as part of the National Recovery Plan, amounted to 1,611 thous. CZK and came from the state budget and EU resources.

Non-investment expenditures were utilised in the total amount of 730,511 thous. CZK, of which 156,257 thous. CZK came from the state budget and 574,254 thous. CZK were taken from extra-budgetary resources, incl. claimed unspent expenditure. Extra-budgetary resources included resources from abroad provided for international projects within the EU.

Assets

The total assets as of 31 December 2024 amounted to 1,196,957 thous. CZK, of which fixed assets were in the volume of 408,287 thous. CZK and current assets in the volume of 788,670 thous. CZK. Of the total liabilities of 1,196,957 thous. CZK, equity amounted to 1,144,709 thous. CZK and borrowed capital to 52,248 thous. CZK. Selected types of assets and liabilities are provided in Table 52.

Auditing

In 2024, public administration audits conducted by the Ministry of Health and by the Ministry of Interior pursuant to the Act on Financial Audits took place.

SÚKL's INVOLVEMENT IN INTERNATIONAL PROJECTS WITHIN THE EU

JAMS 2.0.

Reinforced market surveillance of medical devices and in-vitro devices

The purpose of this project is to deepen cooperation in the sphere of market surveillance, vigilance, and harmonisation of approaches across EU Member States.

Table 53 Numbers of employees at regional workplaces as of 31 December 2024

Brno	**36**
České Budějovice	**3**
Hradec Králové	**6**
Olomouc	**4**
Ostrava	**5**
Pilsen	**2**
Prague	**493**

Table 54 Age structure of employees as of 31 December 2024

Year	% of employees under 35 years	% of employees aged 36-55 years	% employees older than 55 years
2020	28.9	53	18.1
2021	27.1	53.3	19.6
2022	22.4	57.6	20.0
2023	23.3	57.5	19.2
2024	**20.1**	**58.8**	**21.1**

Table 55 Qualification structure of employees by achieved level of education as of 31 December 2024

Highest achieved education	Primary	Secondary	Technical colleges	University – bachelor's degree	University – master's degree	Postgraduate
Number of employees*	1	96	6	30	412	56
% of the total number of employees	0.16	16.1	1	5	68.52	9.2

** The data include employees taking their compensatory leave, maternity leave, and parental leave.*

The objective of the project is to share information, well-established procedures, know-how and resources, to support exchange of information about market surveillance among the competent authorities via data collected from the entire EU market, to develop standard control procedures, and to support the development of inspection methods. Furthermore, joint procedures for the implementation of campaigns in the area of market surveillance will be introduced, and, eventually, training tools for uniform skill development and enhanced technical know-how in the sphere of vigilance and surveillance over the medical device and in vitro diagnostic medical device market will be created.

The total project budget is 80,303 EUR.

In 2024, the working group organised two joint workshops in total; one was held as part of the working group focusing upon device vigilance in Malta and the other as part of a group specialised in market surveillance in Brussels. SÚKL's inspectors organised two joint inspections of Czech manufacturers and were invited to participate in another two joint inspections carried out in Belgium and in Slovenia.

EU4H 11

Joint Action on quality of medicines and implementation of the pharmaceutical legislation/ strategy

The joint action on quality of medicines and implementation of the pharmaceutical legislation/ strategy is part of the EU4Health programme funded by the European Commission. The total budget of this joint action is more than 3 million EUR; 80 % of the costs is to be co-financed by the European Commission. The project will support enhancement of capacity of Good Manu-

facturing Practice (GMP) and Good Distribution Practice (GDP) inspectorates in EU/EEA countries, with the objective of global mutual reliance on inspection data in order to better safeguard the quality of medicinal products and public health protection.

The project has been undertaken by 39 EU/EEA medicines inspectorates from the total of 29 EU/EEA countries. The inspectorates oversee regulatory compliance by pharmaceutical manufacturers of medicines for human and veterinary use from all over the EU/EEA. The joint action is led by Austria (AGES/BASG) as the coordinator together with the national competent authorities of France (ANSM), Croatia (HALMED), and Hungary (NCPHP) as work package leaders. The three main objectives of EU4H 11 are as follows:

- enhancement of the Joint Audit Programme (JAP) for good manufacturing practice inspectorates in the EU/EEA;
- drafting of proposals for the inclusion of good distribution practice in the current Joint Audit Programme;
- introduction of harmonised training and qualification processes for GMP inspectors in cooperation with the PIC/S Inspectorates Academy (PIA).

Co-financing of the costs associated with the JAP activities supports participation of Member States in the JAP and initial as well as ongoing training of GMP inspectors to enhance the competences of GMP inspectors in the entire EU/EEA.

The total project budget is 34,989 EUR.

CHESSMEN

Coordination and Harmonization of the Existing Systems against Shortage of Medicine – European Network

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.

Sharing of approaches of EU Member States to the evaluation of causes, prevention, monitoring, evaluation, IT solutions, and medicinal product shortage solutions. In individual technical work packages (WP), best practices will be shared and recommendations on a harmonised approach will be created. The aim of the project is, moreover, to complement and support activities in the sphere of medicine shortages with the tasks of other working groups and newly adopted legislation, such as the implementation of Regulation (EU) 123/2022.

The total project budget is 384,986 EUR.

CT-CURE

Clinical Trial Competitive multinational assessment timelines in the European Union ensuring Regulatory Excellence (CT-CURE)

Support of coordinated and accelerated assessments of clinical trials on anti-COVID-19 therapeutic agents and accelerated fight against the COVID-19 pandemic.

The CT-CURE project associates 15 EU Member States responsible for the assessment of clinical trials in the EU with a common, specific, and strategic task: 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 aims to improve access to, availability, and affordability of medicinal products intended for the treatment of COVID-19, to support innovations concerning such products, and hence accelerate the fight against the COVID-19 pandemic. Another task of the project is to inform both commercial sponsors and the academia about this project – and for this purpose, the https://ctcure.eu/ website has been developed.

The total project budget is 56,905 EUR.

Table 56 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
Total	**108**	**36**	**36**	**25**

Table 57 Overview of employment and civil service terminations in 2024 by reason of employment/civil service termination

	Cancellation of employment/civil service in probationary period	Agreed time expiry	Termination by agreement (Section 49 of the Labour Code)	Notices given by employees/ termination of civil service upon request of the civil servant	Notices given due to organisational reasons/by decision of the civil service authority	Termination of civil service performance in SÚKL due to transfer of the civil servant to another civil service authority	Retirement	TOTAL
Employment	6	9	14	8	1	-	0	38
Civil service	**5**	**0**	**0**	**15**	**2**	**2**	**1**	**25**

Graph 35 Civil-service examinations in 2024

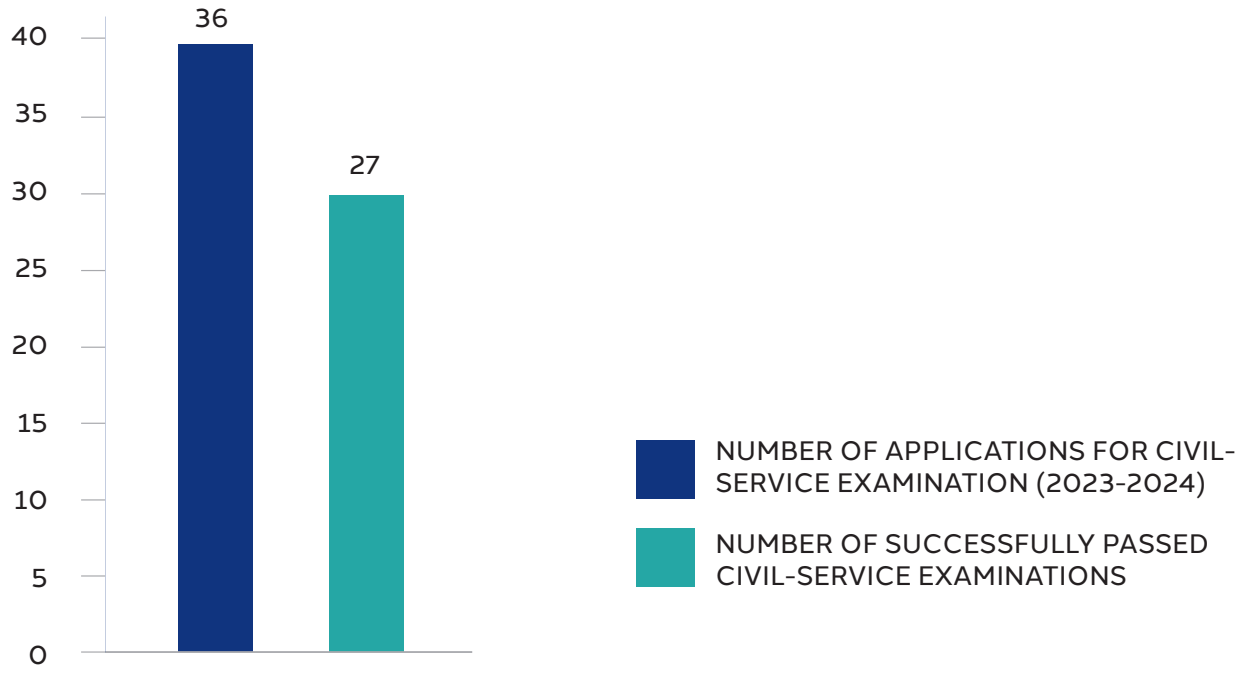


Table 58 Overview of educational activities in 2024 – continuous education

Type of event	Number of events	Number of hours	Number of attendees
Specialised courses & training; language courses	1,550	5560	2,784
Mandatory training	152	1,450	1200
Foreign specialised training	19	366	22

IncreaseNET (Supporting the increased capacity and competence building of the EU medicines regulatory network)

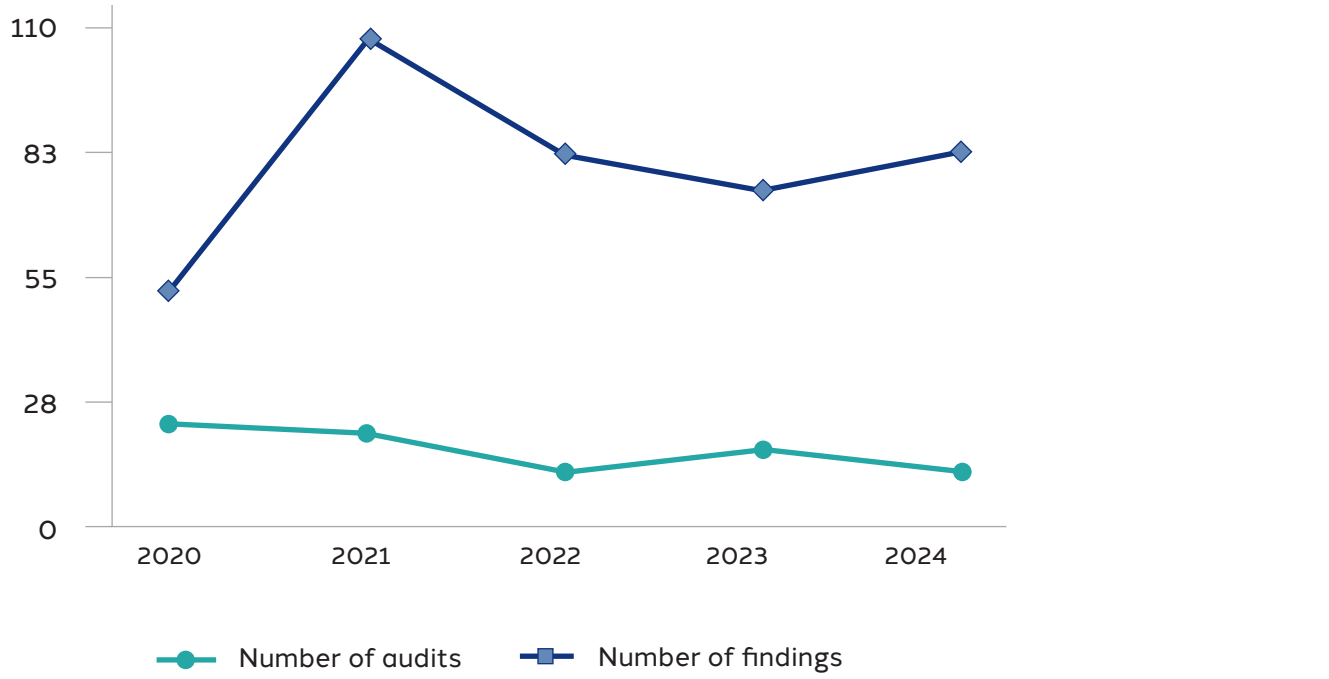
The project is coordinated by the Slovenian medicine and medical device agency (JAZMP) and it associates 29 partner organisations, mostly national medicines regulatory authorities from 27 EU/EEA countries and Ukraine. This joint action/project will be conducted for the period of three years, from 01 January 2024 to 31 December 2026. The purpose of the joint action/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). Exchange of knowledge, ideas, well-established practices, and the new training programme both for new and experienced assessors will enhance the quality of work of the entire group of regulatory authorities. Empowering national regulators in the area of medicines, and hence also strengthening of the European network will result in enhanced public health protection with benefits particularly for the patient. All activities will be coordinated in cooperation with the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) network, the EU Network Training Centre (EU NTC), the "Accelerating Clinical Trials in the EU" (ACT EU) initiative, Committee for Human Medicinal Products (CHMP), Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), Committee for Advanced Therapies (CAT), The Biologics Working Party (BWP), and the EU Innovation Network (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 10,000,059.72 EUR.

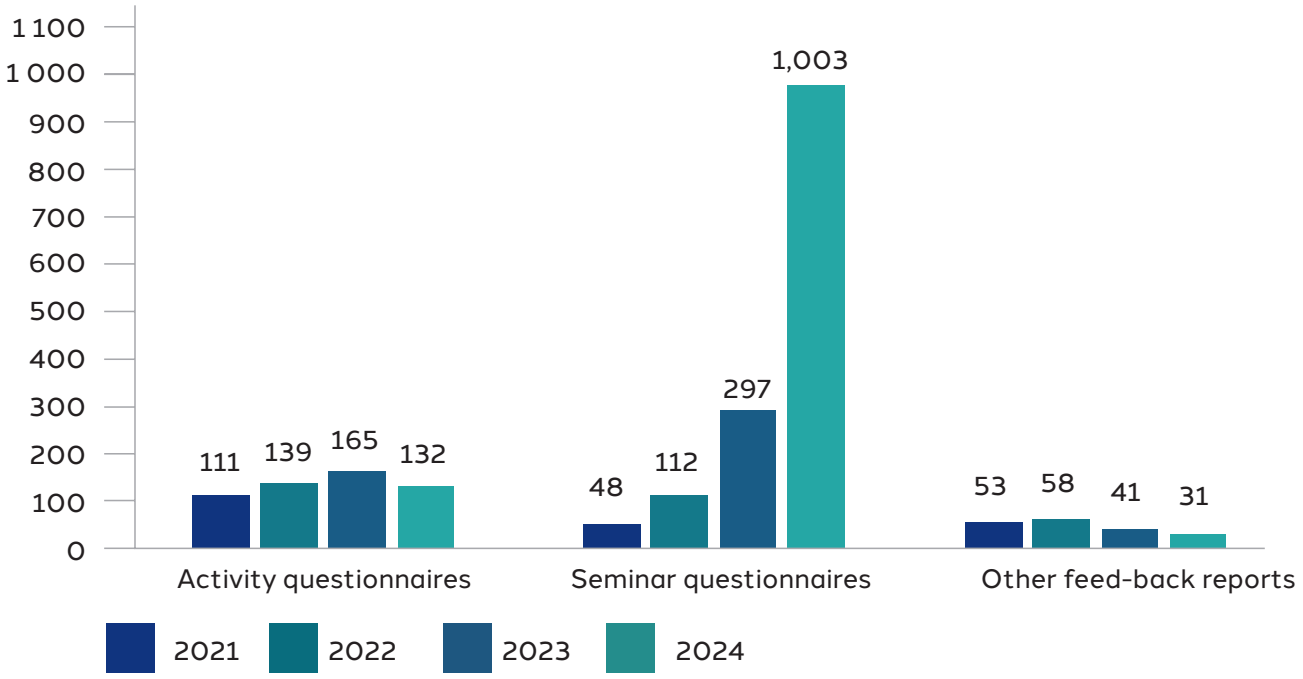
Table 59 Development of QMS internal audits in the period of 2021–2024

Year	2020	2021	2022	2023	2024
Number of completed QMS audits	23	21	12	17	12
Number of identified nonconformities	0	4	15	6	0
Number of identified shortcomings	1	14	9	2	4
Number of recommendations for improvement	45	69	46	46	66
Number of new risks	7	23	14	21	15

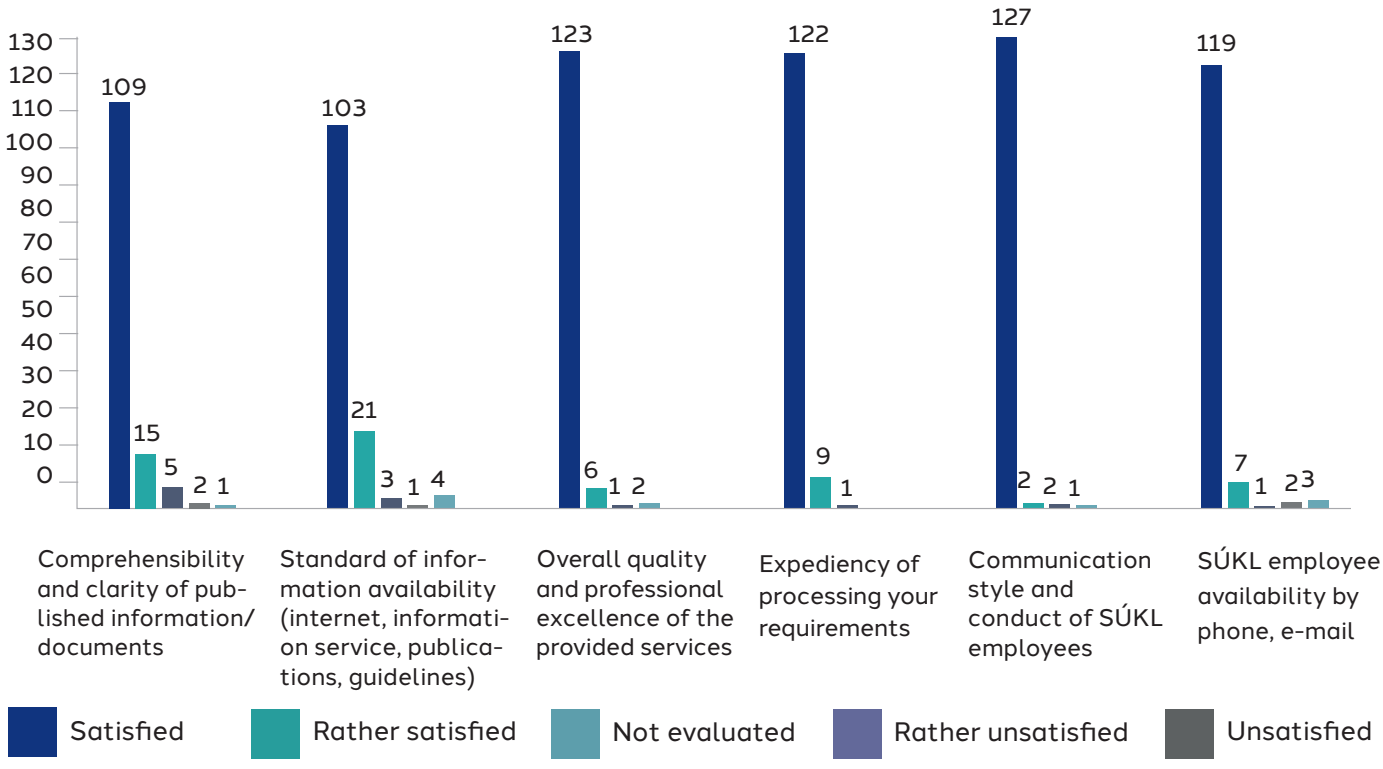
Graph 36 QMS internal audit development in the period of 2021–2024



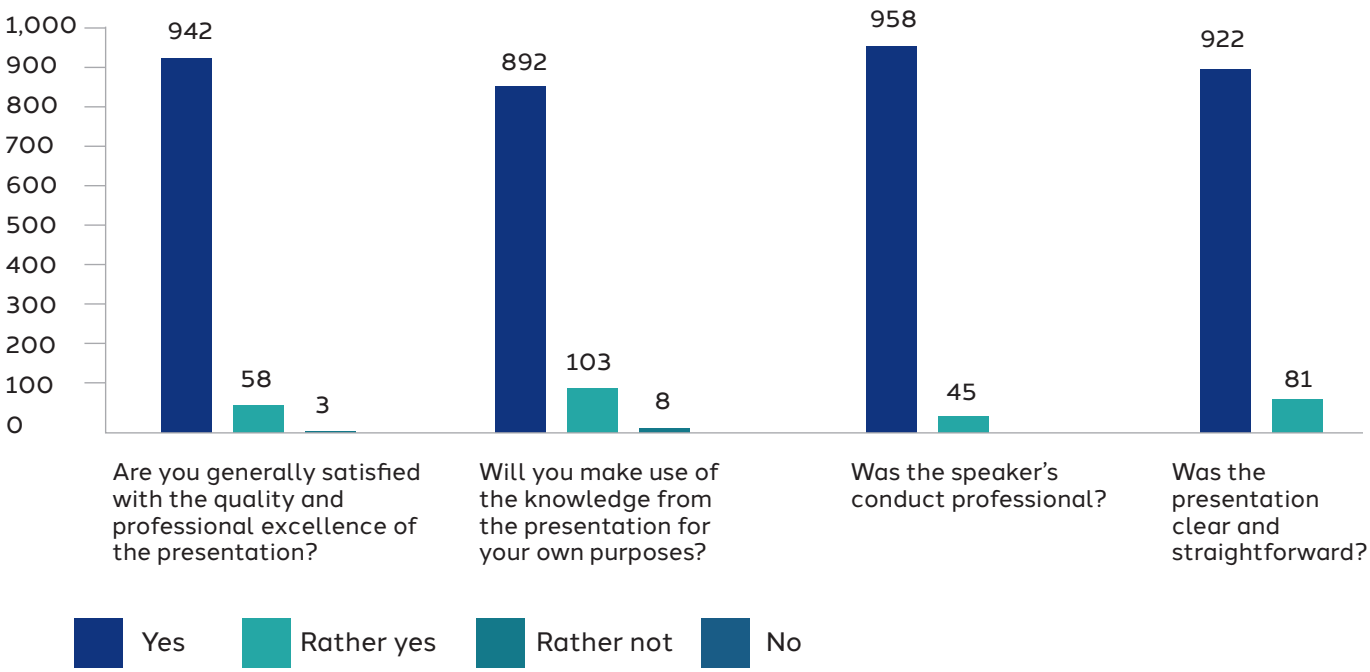
Graph 37 Feed-back obtained in the period of 2021–2024



Graph 38 Outcomes of questionnaires focusing upon SÚKL's activities



Graph 39 Outcomes of questionnaires focused upon SÚKL's seminars or presentations



7. FOCUS UPON EMPLOYEES

7. 1 Personnel Issues

Organisational Structure

In accordance with the Institute's systemisation approved for 2024 pursuant to Act No 234/2014 Coll., on Civil Service, as of 01 January 2024, the total number of systemised positions in the Institute was 584, of which 478 were civil service positions and 106 were employment positions.

As part of the organisational changes associated with the Institute's systemisation effective as of 01 January 2024, compared to the situation on 01 January 2023, the number of civil-service and employment positions decreased by three systemised positions (four systemised positions were transferred to the central civil service authority and one position was created from unused FTEs).

In the course of 2024, several other amendments to systemisation were implemented with effect as of 01 March 2024, 01 July 2024, and 01 October 2024; these amendments concerned changes to the subordination of civil service positions, changes to other attributes of civil service positions, and modifications to civil-service activity codes pursuant to effective legislation.

As of 01 July 2024, the number of civil-service positions changed to 474 and the number of employment positions to 106, i.e., four positions were transferred to the central civil service authority. The total number of positions hence decreased to 580.

The number of physical employees on the Institute's payroll as of 31 December 2024 was 549 persons, of which 439 were women (i.e., 80 %) and 110 were men (i.e., 20 %).

As part of the Work-Life Balance Policy support, as of 31 December 2024, the total of 84 employees of the Institute (of which 82 were women), i.e., 15.5 % of the total number of employees, worked part-time.

Age Structure of Employees

Average age: females 44.5 years; males 43.3 years. The over all average age of all employees is 43.9 years.

Qualification Structure of Employees Staff Turnover

The overall staff turnover taking into account all entries into and terminations of employment/civil service amounted to 11.62 %, which was a slight decrease compared to 2023.

In the course of 2024, the total of 144 tenders for vacancies were opened, of which 61 job openings were filled (see Table 56).

In 2024, the total of 63 employees/civil servants terminated their jobs, of which 38 were employment terminations and 25 were civil-service terminations.

Civil-Service Examination

Pursuant to Section 35 of Act No 234/2014 Coll., on Civil Service, a civil servant is obliged to successfully complete a civil-service examination comprising of two parts – the general part and a specialised part (depending on the field of service of the civil-service position).

Eight applications were brought forward from 2023 to the next calendar year and in the course of 2024, 28 new applications submitted by the employees of the Institute were registered, which amounts to 36 applications in total. Of the total number of submitted applications, 27 employees successfully passed both parts of the civil-service examination in 2024. The remaining nine employees will take the examination in 2025 (within twelve months of their recruitment as civil servants, as stipulated by the Act on Civil Service). In the following year, the rules governing civil-service examinations will be changed due to amendment to the Act on Civil Service (such as changes to timelines and implementation of the general and specialised parts of the civil-service examination).

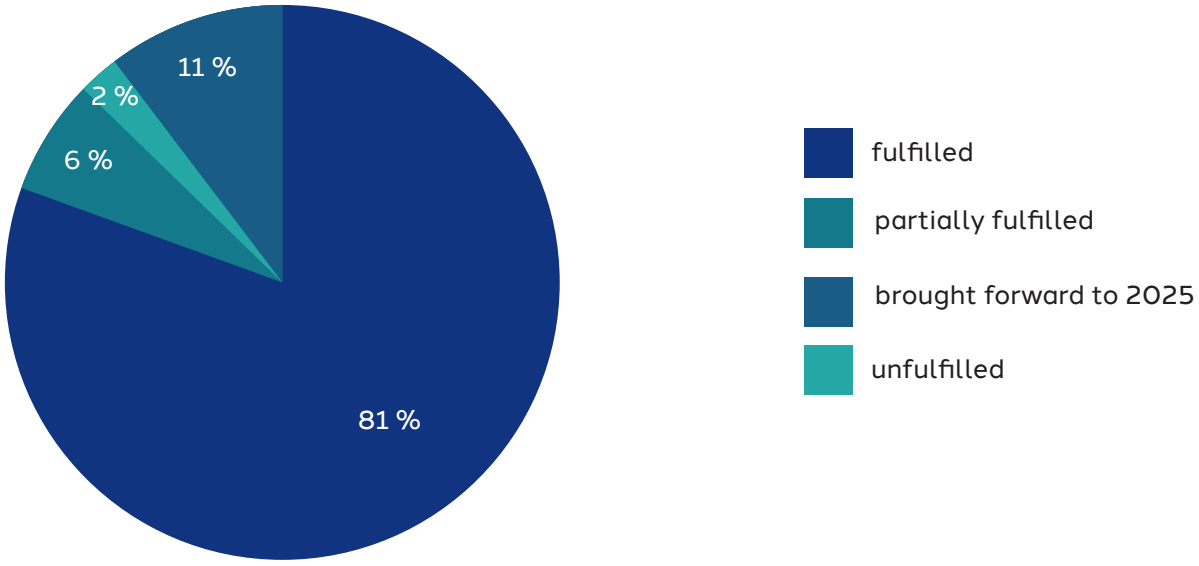
Of the total number of civil-service examinations taken, all of the employees successfully passed the concerned civil-service examination on the first attempt.

7. 2 Employee Education

In 2024, education of SÚKL employees assumed mostly the form of face-to-face courses, complemented with on-line education.

As part of initial education, all new employees were trained in all topics stipulated by the currently effective legislation: *basic information about the Institute and its internal regulations, employee performance evaluation, information security incl. personal data protection, quality management, the Code of Ethics, internal regulation of conflict of interest, human rights protection, equality of men and women and prohibited discrimination, environmental responsibility, and whistle-blower protection*. In the course of the year, initial education was being updated and complemented to comply with legislative requirements.

Graph 40 Fulfilment of specific objectives in the period of 2021–2024



Other, follow-up employee education focused primarily upon expert education, due to the high demands on staff expertise, implementation of legislative changes, and the need for continuous deepening and increasing of qualification and knowledge of our staff in individual fields.

In the course of the year, internal training in the Athena documentary service took place, particularly with focus upon new users. In 2024, employees were trained in the sphere of cyber-security. As part of training organised by the National and Cyber Security Agency (NUKIB), the employees completed the "Run cyber!" and "Handle cyber!" courses.

The employees also deepened their knowledge via business trips abroad, as required by their professional specialisation.

Management training focused primarily upon the development of personal talents and management skills, particularly for managerial staff. The content of management training reflected the requirements of the Management of the Institute. This type of education employed discussions, case studies, model situations, and role-playing.

In-house language courses continued also in 2024. Employees were split into groups; some of the employees completed individual language courses. The knowledge gained through language courses was applied in studying of documents and during participation in international and global organisations, institutions, audits, congresses.

The total volume of financial costs incurred for all types of educational activities amounted to **2,506,000 CZK.**

8. INFORMATION DISCLOSURE PURSUANT TO ACT NO 106/1999 COLL.

2024

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 2024, the State Institute for Drug Control received 181 requests for information lodged in compliance with the Act on Free Access to Information. In six 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)
No court procedures regarding information disclosure pursuant to the Act on Free Access to Information were held.

Paragraph 1(d)
The State Institute for Drug Control 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, three complaints concerning the course of action taken when addressing the request for information were filed.

9. FOCUS UPON QUALITY

SÚKL has an established and certified quality management system compliant with the requirements set forth by the ČSN EN ISO 9001 standard and the Methodological Guideline for Quality Management in Civil-Service Authorities.

The Laboratory Control Department has developed a management system compliant with requirements set forth by the ČSN EN ISO/IEC 17025 standard.

Safeguarding the necessary standard of quality management forms an integral part of all key and auxiliary processes in SÚKL.

In January 2024, SÚKL conducted a review of compliance with improvement criteria defined by the Methodological Guideline for Quality Management in Civil-Service Authorities in order to identify opportunities for improvement.
Furthermore, in 2024, a BEMA Improvement Plan was issued on the basis of suggested opportunities for improvement arising from the fifth cycle of "Benchmarking of European Medicines Agencies – BEMA V" that took place in SÚKL in late 2023.

In November 2024, the LL-C (Certification) Czech Republic, s.r.o., certification body carried out the first surveillance audit of SÚKL's processes and confirmed that the Institute's quality management system continues to meet the requirements set forth by the aforementioned standard.

Internal Audits

The functionality of the quality management system and process effectiveness were being conti-

nuously verified also within the scope of internal audits; in 2024, twelve such internal audits were completed.

The internal audit plan is based upon the 2021–

2025 Audit Strategy and upon risk analysis.

Feed-back

SÚKL continuously strives to carry out activities at a high standard, predictably, using transparent documentation, at 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 creating a positive image of SÚKL, and at achieving international recognition.

In 2024, SÚKL received 1,166 feed-back reports from external entities which were provided in the form of answers to questions in satisfaction surveys or as opinions submitted in other forms.

The answers to questions from questionnaires focusing upon SÚKL's activities suggest that the stakeholders were the least satisfied with the "comprehensibility and clarity of published information/documents", where two respondents were unsatisfied and five respondents rather unsatisfied; with the "standard of information availability", where one respondent was unsatisfied and three respondents rather unsatisfied; and with "employee availability", where two respondents were unsatisfied and one respondent rather unsatisfied.

The answers provided in questionnaires focusing upon SÚKL's seminars or presentations suggest that the lowest satisfaction level was for the item "Will you make use of the knowledge from the presentation for your own purposes?", where eight respondents answered "Rather not". Furthermore, three respondents were rather unsatisfied with the "Quality and professional excellence of the presentation".

SÚKL much appreciates any suggestions and comments from the obtained feed-back, as these are a step towards ensuring a higher effectiveness and improvement of our activities. Most of the suggestions for improvement received in 2024 concerned the organisation of seminars. Also in the coming year, our employees will organise numerous seminars for external entities to provide education on good practice or to inform about new regulations or changes.

10. STRATEGY

Mission

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

Vision

SÚKL 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, governed by high standards of quality of work.

Strategy

For the fulfilment of its mission and achievement of its vision, SÚKL 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 SÚKL Management.

In total, 11 % of unfulfilled or partially fulfilled specific objectives are brought forward to the next period.

Eight 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 SÚKL, workload or shortcomings on the part of the vendor, and external factors.

11. INFORMATION SECURITY MANAGEMENT POLICY AND CYBERSECURITY

Every year, the demands for safeguarding adequate level of cybersecurity keep growing and this trend continued also in 2024.

The number of detected cybersecurity attacks targeting SÚKL's information systems was high also in

2024; nevertheless, none of the attacks was successful.

With regard to increasing amount of socially engineered cybersecurity attacks, in 2024, much emphasis was placed upon enhancing the security awareness of the employees.

In October 2024, the Institute successfully passed a recertification audit of the information security management system (ISMS) pursuant to the ČSN ISO/IEC 27001 standard, which means that it has been the holder of the relevant certificate for as long as 17 years.

In mid-year, the role of the Cybersecurity Manager was re-staffed and from the end of June, this role has been staffed internally.

12. OUTLOOK FOR 2025

Traditionally, the Czech Republic has been one of the most frequently used Reference Member States in Europe, not only for the purposes of decentralised procedures and mutual recognition procedures, (both in terms of launched procedures and completed procedures), but also for the purposes of variations assessment, so called worksharing procedures (WS). In 2025, SÚKL will prepare for the implementation of the amended Classification Guideline, associated with Regulation 1234/2008 (the Variations Regulation), which means that it will be necessary to adjust the processes of submission and assessment of variations to marketing authorisations. In association therewith, it is assumed that the number of WS procedures with the Czech Republic as the reference authority will continue to increase significantly in 2025.

Also in 2025, SÚKL continues its involvement in the assessment of centralised procedures, particularly with focus upon biosimilar medicinal products (whose proportion in the number of submitted applications for marketing authorisation continues to grow), be it in the position of a Multinational Assessment Team (MNAT) member, or in the role of a rapporteur for re-examination ad hoc procedures. SÚKL has been involved also in the Scientific Advice Working Party (SAWP) quality assessment work, where the Institute typically evaluates questions not only on ATMPs, but also on products containing biological and chemical substances. SÚKL intends to enhance its active involvement in EMA committees and working groups, particularly the CHMP, PRAC or the renowned SAWP. Along with the aforementioned, the Institute will continue its active involvement in and assessment of procedures also in other EMA committees, specifically the PDCO. SÚKL has been also actively contributing to the IncreaseNET initiative and providing expert leadership to other EU Member States.

SÚKL plans to further develop its position of a transparent, forthcoming regulatory authority sought by regulated entities on the global level also in the coming years. SÚKL believes that in the coming years, it will again be able to increase its involvement in centralised procedures both through the role of the CHMP rapporteur/co-rapporteur and PRAC rapporteur, and, last but not least, its participation in quality assessment in the SAWP. We will continue to support and develop the provision of important safety information on medicinal products via the ePrescription functionalities, the medication record, or through direct communication with healthcare professionals. For the coming period, SÚKL intends to intensify its communication with professionals and improve dissemination of information about medicinal product safety.

SÚKL will continue its proactive work in the area of clinical trial application submission via the new Clinical Trials Information System (CTIS). The transition period, after which it is possible to submit applications for clinical trial authorisation only via CTIS, ended in January 2025. In the area of clinical trials, in the coming year, SÚKL will also focus upon enhancing support for academic clinical trials, it will actively participate in the preparation of the strategy of the Ministry of Health aimed at encouraging the sponsors' interest in conducting clinical trials in the Czech Republic, and it will engage in international cooperation in the sphere of improved harmonisation of clinical trial assessment.

In the course of 2025, SÚKL will focus upon full application of the amending provisions of the Act on Pharmaceuticals in practice. It will look at the effectiveness of established processes and the implications of the adopted measures to safeguard medicinal product availability. Furthermore, the Institute intends to further develop data analyses of sources to detect and address shortages, and, last but not least, it will concentrate on controls of compliance with the obligations of MAHs, distributors, and pharmacies in the area of medicinal product availability.

In 2025, SÚKL will focus upon the integration of the Medical Device Information System (ISZP) and the European EUDAMED database, which the Commission plans to launch as mandatory as of 01 January 2026. Within the scope of this integration, related processes will be adjusted so as to comply with effective legislation. With the coming into force of part of Regulation (EU) 2024/1860 concerning the manufacturer's obligation to inform about suspended or terminated supplies of

medical devices, this obligation will be adopted on the national legislation level and implemented in processes of the Medical Device Regulation Section. Setting up processes for the new agenda of medical device and in vitro diagnostic medical device evaluation pursuant to Regulation (EU) 2021/2282 on healthcare technology assessment (HTA), the exercise of which has been conferred on the Institute by the Minister of Health with effect from 01 January 2025, will be an important task. Surveillance activities will include preparations for extending the powers to medical devices with integrated AI, brought by the coming into force of Regulation EU 2024/1689, laying down harmonised rules on artificial intelligence. The provisions of this Regulation governing medical device regulation will come into force during 2026.

In the agendas falling within SÚKL's powers, the employees of the Institute represent the Czech Republic in negotiations concerning new legislative proposals and non-legislative documents on the EU Council working level and they provide expert support for all levels of negotiations, including the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) of ministers. Furthermore, the Institute has been involved in the preparation of implementing regulations and guidance associated with adopted legislative acts, specifically through the participation of its representatives in expert groups of the European Commission, European Medicines Agency, and other authorities. SÚKL expects that in 2025, in the area of the Institute's competences, attention will focus primarily on finalisation of the general pharmaceutic legislation revision, i.e., Regulation (EU) 726/2004 and Directive 2001/83/EC, so called pharmaceutical package. The aim of the Council is to adopt so called general approach and, in the second half of 2025, initiate the phase of trialogues with the European Parliament and the European Commission, so as to progress the negotiations as far as practicable by the end of 2025. SÚKL will be also involved in negotiations concerning the Critical Medicines Act, which is to be published in March 2025, and in the preparation of legislation implementing the Regulation on standards of quality and safety for substances of human origin.

In compliance with SÚKL's approved strategy for the period of 2020–2025, the objective of the Institute is to sustain a consistent and transparent control system which has been built for many years, and keep the team of qualified experts and inspectors capable of ad hoc interventions anywhere in the Czech Republic without affecting the efficiency of the performed surveillance activities. Our constant aim is to enhance the quality of the conducted activities, to fully avail of all information resources of the Institute, and to improve the established processes of controls, their professional conduct, synchronisation of individual actions, and optimisation and adequacy of control duration. SÚKL plans to continue its successful work in the field of consultations and education intended for professionals and to enhance control efficiency in the area of price regulation, including active cooperation in processes associated with ensuring the availability of sufficient quantities of medicinal products for the needs of Czech patients.

In the coming years, SÚKL will focus upon implementation of the requirements set forth by the approved European Regulation on standards of quality and safety for substances of human origin (the SoHO Regulation). In terms of laboratory control, it is important to get ready for the upcoming periodic international audit, the purpose of which is to confirm the competence of the laboratories to work in compliance with the ISO/IEC 17025 standard governing control and calibration laboratories, and to further enhance the potential for analyses, specifically to move towards large molecule analyses, which reflects the current situation in the sphere of analyses of peptide-based pharmaceuticals. Furthermore, the Institute plans to introduce a new method which will allow to perform monoclonal antibody analyses.

In 2025, SÚKL will continue to carry out activities in the pivotal area of administrative procedures concerning maximum prices and reimbursements of medicinal products and foods for special medical purposes, striving to optimise processes in order to safeguard maximum practicable effectiveness in key output delivery.

One of the primary objectives will be successful involvement in the joint clinical assessment (EU HTA) project and preparations for new legislation, specifically the amended Act on Public Health Insurance with potential effect from 01 January 2026. Last but not least, SÚKL will continue to closely cooperate with relevant stakeholders in the area of the agenda covered thereby.
In 2025, SÚKL plans to carry on the established trend of internal process digitalisation, with the objective to achieve complex digitalisation of economic and operational processes, resulting in enhanced efficiency of financial management and reporting, routine task automation, better insight into the economic operation of individual centres, and easier and quicker processing of economic data. Interconnecting the new economic system with existing IT solutions will safeguard smooth data flows. In accordance with the trend of digitalisation, SÚKL will implement advanced IT tools, including the use of artificial intelligence (AI) for big data analyses and for automation of the Institute's processes. Furthermore, a Business Intelligence (BI) solution will be implemented, which includes advanced analytical

tools for improved management decision-making and the creation of interactive dashboards allowing for key indicator monitoring. Digitalisation of the agendas of regulatory sections of the Institute will result in reduced administrative burden, acceleration of processes, and positive impact upon the public. With a view to the growing digitalisation, emphasis will be placed on enhancing cyber-security by means of advanced security solution implementations, sensitive and personal data protection, regular security audits and penetration tests. Enhanced cyber-security awareness among all employees will be achieved by means of employee training.

SÚKL will continue to modernise its working environment, which includes reconstruction of common areas in the building and development of contemporary and ergonomic working environment utilising smart technologies to achieve energy savings. Extending the fleet with electric cars and the installation of charging stations on SÚKL's grounds will support ecological vehicles.

The implementation of all amendments to the Act on Civil Service and of the planned amendments to the Labour Code in personnel agendas, with the effort to achieve maximum electronisation, is a challenge for the next year. We will further pursue our focus upon corporate culture enhancement, reinforcing the education and development of employees, and personnel process optimisation. Through the aforementioned, we wish to increase not only employee satisfaction, but also the image of the Institute as an attractive employer on the labour market. Last but not least, it should be mentioned that as part of the effort for enhanced quality of internal and external communication with professionals as well as with the general public, SÚKL intends to improve its website in 2025 so as to fulfil its long-term aim to provide a comprehensive source of expert, clear, and verified information about authorised medicinal products, notified medical devices, and reimbursements of such medicinal products or medical devices both for professionals and for the general public.
All of the aforementioned objectives for 2025 represent an important step towards modernisation of the Institute. Their implementation will contribute to greater efficiency, transparency, and sustainability of our activities, which will eventually support the primary mission of SÚKL – to protect the health of the inhabitants of the Czech Republic.

13. LIST OF ABBREVIATIONS

ACT EU	The Accelerating Clinical Trials in the European Union
ACRO	Association of Clinical Research Organizations of Czech Republic
AD	Alzheimer's disease
AGES	Austrian Medicines and Medical Devices Agency
AIFP	Association of Innovative Pharmaceutical Industry (Asociace inovativního farmaceutického průmyslu)
AM	Addition of the Czech Republic as a new Member State to a previously authorised clinical trial
AMR	Antimicrobial resistance
ANSM	National Agency for the Safety of Medicines and Health Products
ASTERx	Information system for administrative procedures in the sphere of pricing and reimbursement
ATC	Anatomical Therapeutic Chemical
ATD	Anti-tampering device
BASG	The Federal Office for Safety in Health Care
BEMA	Benchmarking of European Medicines Agencies
CAT	Committee for Advanced Therapies
CAU	Pricing and Reimbursement Regulation Section
CDNÚ	Central Database of Adverse Drug Reactions
CEN	Price control
CHMP	Committee for Medicinal Products for Human Use
CKS	End-user price
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMS	Concerned Member State
CP	Price zone
CRLN	National chemical reference substances
CRO	Contract Research Organization
CRS	Chemical Reference Substance
CTAG	Clinical Trials Advisory Group
CTCG	Clinical Trials Coordination Group
CT-CURE	European Union ensuring Regulatory Excellence
CTEG	Clinical Trial Expert Group
CTIS	Clinical Trial Information System
CTR	Clinical Trial Regulation
CÚEO	Central Repository of Vaccination Records (Centrální úložiště záznamů o očkování)
CÚEP	Central Repository of Electronic Orders (Centrální úložiště elektronických poukazů)
CÚER	Central Repository of Electronic Prescriptions (Centrální úložiště elektronických receptů)
CZECRIN	Czech Clinical Research Infrastructure Network
ČAFF	Czech Association of Pharmaceutical Companies (Česká asociace farmaceutických firem)
Cz.Ph.	Czech Pharmacopoeia
ČR	Czech Republic
ČSN	Czech technical standard
ČSN EN ISO	Czech version of an international standard (adopted by the European Committee for Standardization)
ČSN EN ISO/IEC	Czech version of a standard published by the International Organization for Standardization and by the International Electrotechnical Commission (adopted by CEN)
ČSSZ	Czech Social Security Administration (Česká správa sociálního zabezpečení)
DCP	Decentralised Procedure for marketing authorisations
DDD	Daily defined dose
DIS	Distributor of tissues and cells
DIS-13	Distributed human medicinal product supply and stock report
DOV	Importers
DU (DJ)	Defined unit
DL	Diagnostic laboratory
DLL	Importers of active substances
DLP	Database of medicinal products (Databáze léčivých přípravků)
DPV	Parenteral nutrition products for home therapy
DRZP	Medical Device Advertising Surveillance Unit
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
EC	European Communities
EU	European Union
EUDAMED	European database of medical devices
EudraGMP	European Community of Manufacturing Authorisations and of Certificates of Good Manufacturing Practice
EV EWG	EudraVigilance Expert Working Group
FF	Pharmaceutical Faculty
FIH	First-in-human
FKSP	Fund of social and cultural needs
FN	University Hospital
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
PV	Pharmacovigilance

GMO	Genetically modified organisms
HALMED	Medicines and Medical Products Agency
HARP	Harmonisation of risk management plans
HAV	Human autogenous vaccines
HLP	Medicinal products for human use
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
HVLP	Proprietary medicinal products
IKEM	Institute for Clinical and Experimental Medicine
IMPD	Investigational Medicinal Product Dossier
INIT	Initial applications
INN WHO	International Non-proprietary 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	In Vitro Diagnostic Medical Device Regulation
JAP	Joint Audit Programme
KB	Blood bank
CT	Clinical trial
KHZP	Medical Devices Clinical Evaluation Unit
QC	Quality control
KLP	Cannabis for medical use
KOČ	Expert Activity Coordination Unit
KON	Control Unit
KOP	Medical Device Control and Expert Opinion Unit
KZZP	Clinical investigation of medical devices
LER	Low Endotoxin Recovery
LK	Pharmacopoeia Commission
AS (LL)	Active substance
LMS	Lead Member State
MP (LP)	Medicinal product
ATMP	Advanced therapy medicinal products
HTC	Human tissues and cells
MAG	Magistral formula
MAH	Marketing Authorisation Folder
MC	Maximum price
MDCG	Medical Devices Coordination Group
MDR	Medical Device Regulation
MRA	Medicine Regulatory Authority
MRP	Mutual Recognition Procedure
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MZ ČR	Ministry of Health of the Czech Republic
MŽP	Ministry of Environment of the Czech Republic
NCAR	National Competent Authority Report (medical devices)
NCPHP	The North Carolina Professionals Health Program
NCR	Non-Compliance Report
NOOL	Organisation for Medicines Verification (Národní organizace pro ověřování pravosti léčiv, z. s.)
AE	Adverse events
NPC	National Antidrug Centre (Národní protidrogová centrála)
ADR	Adverse drug reaction
NÚKIB	National Cyber and Information Security Agency
OCABR	Official Control Authority Batch Release
OECD	Organisation for Economic Co-operation and Development
OEČ	Expert Activity Department
OFN	SÚKL's Pharmacovigilance Department
OFV	Pharmacovigilance Department
OLZP	Pharmaceuticals and Medical Devices Department
OMCL	Official Medicines Control Laboratories
ONM	Nuclear Medicine Department
OOP	General Measure
OOVL	Detached pharmaceuticals dispensing unit
OP	Profit margin
OS	Consumer protection
OZ	Donation centre
PČR	Czech Police
PhV	Pharmacovigilance
PhV IWG	Pharmacovigilance Inspectors Working Group
PIA	PIC/S Inspectorates' Academy

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
RA	Rapid Alert
RAB	Rapid Alert System for Blood and Blood Components
RAN	Rapid Alert Network
RAN	Registration and Notification Unit
RATC	Rapid Alert System for Human Tissues and Cells
RF	Radiopharmaceuticals
RLPO	Registry of Restricted Active Substances (Registr pro léčivé látky s omezením)
RMS	Reference Member State
ROB	Registry of Inhabitants (Registr obyvatel)
RZPRO	Registry of Medical Devices (Registr zdravotnických prostředků)
SAE	Serious Adverse Event
SAFE CT	Safety assessment cooperation and facilitated conduct of clinical trials
SAKL	State Agency for Medical Cannabis
SCAU	Foods for special medical purposes reimbursed from health insurance funds
GDP	Good Distribution Practice
SER	Persons servicing medical devices
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
SM	Submitted applications for substantial modification
QMS	Quality Management System
SPI	Specific performance indicator
SpTP	Specific therapeutic programme
SPOC	Single point of contact
SPOC WP	Single Point of Contact Working Party
AP	Administrative procedure
SSL	Secure Socket Layer
SŠ	Secondary school
SÚKL	State Institute for Drug Control
SUP	Suspected unknown product
SUSAR	Suspected Unexpected Serious Adverse Reaction
GMP	Good Manufacturing Practice
SYS	Systems, Education, and European Affairs Unit
CAFIA	Czech Agriculture and Food Inspection Authority
ŠÚKL	Slovak State Institute for Drug Control (Štátny ústav pre kontrolu liečiv)
TB	Tissues and Cells Group
TP	Transfusion products
TTR	Transition trials
TZ	Tissue centre
UHR	Reimbursement
ÚZIS	Institute of Health Information and Statistics of the Czech Republic (Ústav zdravotnických informací a statistiky)
UZP	Medical Device Reimbursement Unit
VIG	Medical Device Vigilance Unit
VOŠ	Technical college
VŘ	Tender
VŠ	University
VŠCHT	University of Chemistry and Technology Prague
VUC	Materially regulated price
VYD	Persons dispensing medical devices
VYR	Manufacturers
WHO	World Health Organisation
WP	Work packages
ZJ	Quality Defects Unit
ZNP	Serious incident
ZNR	Serious adverse reaction
ZNU	Serious adverse event
ZoRR	Act on Advertising Regulation
ZP	Health insurance
ZP	Medical device
ZTS	Blood centre
ZZ	Healthcare facility

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SÚKL