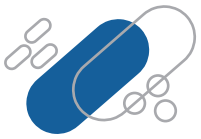
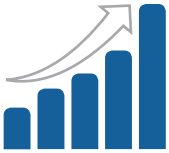












2024

ANNUAL REPORT

OF THE PRESIDENT OF THE OFFICE
FOR REGISTRATION OF MEDICINAL PRODUCTS,
MEDICAL DEVICES AND BIOCIDAL PRODUCTS

Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products

Mission

of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Acting in the areas of medicinal products,
medical devices and biocidal products
we protect the health and take care of the safety of the society.

Management of the Office

Marcin Kołakowski
Vice-President of the Office for Medicinal Products

Aleksandra Wilczyńska
Vice-President of the Office for Biocidal Products

Grzegorz Cessak
President of the Office

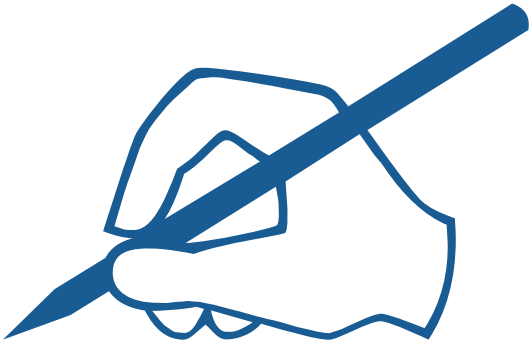
Sebastian Migdalski
Vice-President of the Office for Medical Devices

Agata Andrzejewska
Vice-President of the Office for Veterinary Medicinal Products

Magdalena Wojciechowicz
Director General

Chapter 1

FOREWORD BY THE PRESIDENT OF THE OFFICE



Grzegorz Cessak
President of the Office

We present to you the Annual Report of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products for the year 2024.

The publication, in a changed graphic formula, introduces a modern and clear design, which we hope will facilitate the reception of the information it contains. The use of graphic elements and infographics will allow for a better understanding of the data and results of the Office's activities. In addition, the Report takes into account modern trends in visual communication, which makes it more attractive to different audiences.

The year 2024 was a period of intensive activities for the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLMiPB), aimed at strengthening Poland's position as a key player in European and international cooperation in the regulation of medicinal products and medical devices.

In 2024, there were a number of meetings, both national and international, which strengthened cooperation with other regulatory agencies and institutions from the world of health care. Of particular importance were meetings with our partners from Ukraine, Canada, the USA and Moldova to share experiences, implement best practices and align regulations with European Union standards for countries aspiring to join the community.

In February 2024, we had the opportunity to host a delegation from the State Expert Centre of the Ministry of Health of Ukraine. This meeting, with the participation of the top management of the Authority, addressed key issues such as the Clinical Trials Information System and the principles of Good Clinical Practice. This event opened up new opportunities for cooperation, which has become increasingly important in view of the challenges facing Ukraine in the context of health system reform.

The following months brought a number of important meetings under the Belgian Presidency of the Council of the EU, where, as President of the URPLWMiPB, I actively participated in meetings of such bodies of the European Medicines Regulatory

Network as EMACOLEX and the Heads of Medicines Agencies Group. The topics of these meetings focused on current challenges of the regulatory system for medicinal products and medical devices, systemic solutions in problematic areas as well as the use of modern technologies, including big data and artificial intelligence, in regulatory processes, responding to the growing need for innovation in healthcare.

In April 2024, the Office hosted Dr. Richard Pazdur, Director of the Oncology Centre of Excellence from the US Food and Drug Administration (FDA), which provided an opportunity to share experiences in the evaluation and marketing of oncology medicines. The meeting highlighted the importance of international cooperation in the context of ensuring patient access to modern therapies.

The first half of 2024 has also seen events to expand and strengthen our existing collaboration with our Canadian partners – where we signed an agreement with Health Canada to collaborate on clinical trial inspections during a dedicated visit to Ottawa – and with Moldova. In the case of the Moldovan partner, after several years of twinning, we are now focusing on supporting the Moldovan Medicines Agency's drive to achieve regulatory maturity in the area of medical devices.

In the second half of the year, the URPLWMiPB continued its intensive efforts to strengthen cooperation with partner countries, including Ukraine and Moldova. This cooperation aims not only to improve patient safety, but also to facilitate access to innovative therapies.

On 2 July 2024, in the presence of Minister Katarzyna Kacperczyk, as President of the Office, I signed a cooperation agreement with Minister Maryna Slobodnichenko of the Ministry of Health of Ukraine. The agreement paves the way to support Ukraine in aligning its regulatory processes for medicinal products and medical devices with EU law and best practices.

The year 2024 was also a time when the URPLWMiPB actively engaged in debates on the future of the healthcare system in Poland, participating in events such as the European Forum for New Ideas and organising meetings with representatives of the pharmaceutical and medical industries. During these discussions, key topics such as the use of artificial intelligence in pharmacy and the need for appropriate legislation were addressed.

In summary, 2024 was a period of dynamic change and intensive cooperation on many levels. The URPLWMiPB successfully implemented a number of initiatives that not only strengthened its role as a regulatory institution, but also contributed to improving the quality of the healthcare system in Poland and the EU. Further development of international cooperation and implementation of innovative solutions will be crucial for the future of regulation of medicinal products and medical devices. The goal of the URPLWMiPB, for the coming years, is to continue its activities for the benefit of patients and all stakeholders in the area of broadly defined health care.

A detailed calendar of the most important events of 2024 can be found in a separate section of the Report.

In the pages of the 2024 Annual Report, you will also find extensive information on all fields of the operation of the Office in the past year, including data on the divisions of medicinal products for human use, medical devices, biocidal products and veterinary medicinal products.

Have an enjoyable read!

Dr. Grzegorz Cessak
President of the Office


URZĄD REJESTRACJI PRODUKTÓW LECZNICZYCH WYROBÓW MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH

Chapter 2

KEY ACTIVITIES AND EVENTS IN 2024

JANUARY 2024

24 January
online meeting

115th Meeting of the Group of Heads of Medicines Agencies (HMA) under the Belgian Presidency of the Council of the European Union (EU).
Among the topics discussed at the meeting was the role of the European Medicines Regulatory Network in the context of the Critical Medicines Alliance initiative, which aims to increase the availability and security of supply of critical medicines in Europe. Participants at the meeting also focused on the Pharmaceutical Review, addressing issues related to medicine shortages and possible solutions to strengthen the supply system and improve patients' access to essential therapies.

30 January
URPLWMiPB
Poland
hybrid meeting

The first meeting of the President of the URPLWMiPB with Representatives of Bioethics Committees acting in the territory of the Republic of Poland. The aim of the meeting was to raise awareness among members of bioethics committees of the dynamically changing legislation on clinical trials of medical devices and *in vitro* diagnostic devices, as well as to exchange experiences and identify future challenges in this field.

30 January

Publication of the Human Medicinal Products Bulletin and the Veterinary Medicinal Products Bulletin for 2023.

FEBRUARY 2024

2 February
online meeting

An online meeting was held between the URPLWMiPB and the Health Sciences Authority (HSA), Singapore's national regulatory authority, to exchange experience in the area of clinical trial inspections

21 February
URPLWMiPB,
Warsaw, Poland

Visit of the State Expert Centre of the Ministry of Health of Ukraine (SECMOH) to URPLWMiPB. The Ukrainian delegation was led by the director of SECMOH, Mykhaylo Babenko.
During the meeting, Poland's support for Ukraine's accession to the European Union (EU) within the framework of the Memorandum of Cooperation (MoU) was highlighted. Discussions focused on technical aspects such as the eCTD system, clinical trials (CTIS) and GMP inspections in third countries.

21 February
URPLWMiPB,
Warsaw, Poland

Continuing and developing the tradition of joint debate with representatives of notified bodies for the certification of medical devices, as well as with representatives of bodies that are yet to apply for such notification, initiated in 2022. The aim of the meeting was to develop a common position on a number of issues concerning the interpretation of regulations and guidelines provided by notified bodies in the European Union (EU) and other competent authorities.

26 February

Publication of Guidance to Applicants – Veterinary Medicinal Products in the Official Journal of the EC – the published Guidance is a harmonised recommendation to help stakeholders fulfil their obligations under Regulation 2019/6.

29 February
Helsinki, Finland

Meeting of Heads of Chemicals Authorities at the headquarters of the European Chemicals Agency in Helsinki (ECHA).
Priorities for action in the field of chemicals, including biocides, were prioritised and emerging challenges and opportunities for cooperation were discussed, which will, inter alia, further the aim of the Biocidal Products Regulation (BPR), i.e. to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and use of biocidal products, while ensuring a high level of protection of human and animal health and the environment.

MARCH 2024

7 March
online meeting

Pharmacovigilance Forum conducted by the State Expert Centre of the Ministry of Health of Ukraine (SECMOH) in cooperation with UkrComExpo. Organised by Ukraine's Pharmacovigilance, the event provided a forum for the exchange of experience and support for further harmonisation with the best European and global standards in pharmacovigilance. URPLWMiPB presented a strategy for conducting pharmacovigilance. Representatives from the World Health Organisation (WHO), the European Medicines Agency (EMA) and the Uppsala Monitoring Center (UMC), among others, attended the event.

21 March

Publication in the Official Journal of the EC of European Commission Implementing Regulation (EU) 2024/875 establishing a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation 2019/6, which will reduce the amount of text on the packaging of veterinary medicinal products, improve the legibility of product information, and reduce the administrative burden of the workload involved in the assessment and approval of product information.

21 March
Amsterdam,
the Netherlands

123rd Meeting of the Management Board of the European Medicines Agency (EMA).
The meeting covered the ongoing work of the Management Board and topics related to the implementation of the Health Technology Assessment Regulation (HTAR), improving monitoring of medicine shortages and the development of clinical trials through state-of-the-art platforms (e.g. CTIS), planning and budgeting the work of the EMA, further developing global regulatory partnerships with agencies such as the FDA.

APRIL 2024

4 April
Brussels, Belgium

European Medicines Agencies Co-operation of Legal and Legislative Issues (EMACOLEX) meeting under the Belgian Presidency of the Council of the European Union (EU).
The President of URPLWMiPB – Grzegorz Cessak, in his capacity as Mentor of the EU Medicines Agencies Co-operation of Legal and Legislative Issues (EMACOLEX) Legal Working Group, attended and co-chaired its meeting under the Belgian Presidency of the Council of the EU.
EMACOLEX supports the exchange of knowledge and experience between the legal services of the registration agencies, improving cooperation on EU pharmaceutical law.

17 April
Łódź, Poland

Meeting with Sharon McGuinness, Executive Director of the European Chemicals Agency in Helsinki at the Bureau of Chemicals in Łódź.
The visit of ECHA's Executive Director was an opportunity to present the chemicals management system in Poland, present ECHA's objectives and mission, and discuss mutual needs and expectations. In the field of biocidal products, the Office's cooperation with ECHA within the framework of its membership in the Biocidal Products Committee, the working groups of this Committee, the Coordination Group, the Helpnet and the current activities of the Biocidal Products Division were presented.

19 April
URPLWMiPB,
Warsaw, Poland

Visit of Dr. Richard Pazdur, Director of the Oncology Centre of Excellence at the Food and Drug Administration (FDA) at URPLWMiPB.
The meeting was an opportunity to identify and compare the points of convergence of the two administrations, present the European Union (EU) regulatory system and discuss experiences in the evaluation and authorisation of oncology medicines.

19 April
Brussels, Belgium

The 116th meeting of the Group of Heads of Medicines Agencies (HMA) under the Belgian Presidency of the Council of the European Union (EU).
The meeting discussed issues including Big Data and AI, the CMD-h update, the ACT EU platform and the revision of pharmaceutical legislation. The HMA/HTA HAG/NCAPR meeting discussed unmet medical needs and their impact on healthcare.

19 April

Publication in the Official Journal of the EU of Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of authorised veterinary medicinal products intended for oral administration by routes other than medicated feed and administered by the animal keeper to food-producing animals. The regulation shall apply from 9 November 2025.

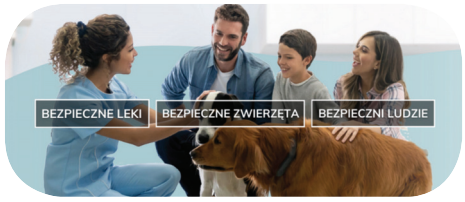
MAY 2024

10 May
Warsaw, Poland

Meeting with the American Chamber of Commerce in Poland.
A delegation of URPLWMiPB led by the President Grzegorz Cessak attended a meeting with the American Chamber of Commerce in Poland at the invitation of the US Ambassador to Poland. The discussions focused on improving access to innovation in healthcare in our country.

15 May
online meeting

Webinar as part of the 'Safe medicines – safe animals – safe people' awareness campaign.
The aim of the campaign is to raise public awareness of the responsible use of veterinary medicines and to present the role of veterinarians and responsible parties in ensuring the safety of the aforementioned products.



15 May
Chișinău, Moldova

Polish and Moldovan Regulatory Agency Leaders Roundtable.
At the invitation of Dragoş Guțu – Director General of the Medicines and Medical Devices Agency of Moldova, Grzegorz Cessak – President of URPLWMiPB participated in the Regulatory Agency Leaders Roundtable. The aim of the meeting was to promote cooperation and improve the regulatory system in health care. Topics discussed included the approximation of Moldovan legislation to the acquis communautaire, the role of medical devices and pharmacovigilance.

JUNE 2024

5 June
Ottawa, Canada

Signing of cooperation agreement with Health Canada.
Minister Linsey Hollett of Health Canada and Grzegorz Cessak, the President of URPLWMiPB, signed an agreement to strengthen cooperation in the inspection of clinical trials. This partnership aims to strengthen regulation, improve patient safety and facilitate access to new therapies.

25 June

Publication of the Annual Report of the President of URPLWMiPB for 2023.

12-13 June
Amsterdam,
the Netherlands

124th Meeting of the Management Board of the European Medicines Agency (EMA).
The EMA Management Board meeting discussed the new opportunities that clinical trials, CTIS and ACT EU open up for European regulators, as well as future challenges and opportunities related to artificial intelligence and Big Data. Summing up 2023, several reports were also adopted, of which the EMA report was key.

JULY 2024

2 July

Amendment to the Statute of URPLWMiPB, introduced by Order No. 63 of the President of the Council of Ministers of 11 June 2024 amending the Order on granting the Statutes of URPLWMiPB (M.P. of 2024, item 466).

2-3 July
URPLWMiPB,
Warsaw, Poland

Trilateral regulatory meeting between Poland, Sweden and Ukraine on harmonising regulations. During the meeting, representatives of URPLWMiPB, the Deputy Minister of the Ministry of Health of Ukraine, Maryna Slobodnichenko, and Björn Eriksson, Director General of the Swedish Medical Products Agency, discussed prospects for trilateral cooperation. The aim was to support Ukraine in bringing the regulation of medicinal products and medical devices in line with European Union (EU) standards.

2 July
Ministry of Health,
Warsaw, Poland

Signing of a cooperation agreement with the Ministry of Health of Ukraine with the participation of Deputy Minister Katarzyna Kacperczyk.
Grzegorz Cessak, President of URPLWMiPB, in the presence of Deputy Minister Katarzyna Kacperczyk, signed a cooperation agreement with Deputy Minister Maryna Slobodnichenko from the Ministry of Health of Ukraine. The agreement paves the way to support Ukraine in aligning its regulatory processes for medicinal products and medical devices with European Union (EU) law and best practices.

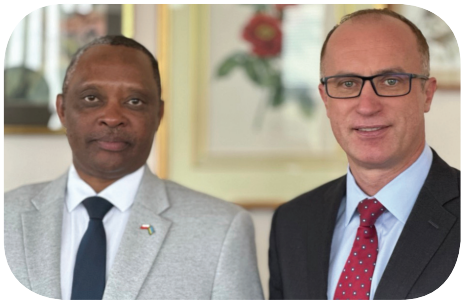
18 July

Publication in the Official Journal of the European Union of Commission Implementing Regulation (EU) 2024/1973 establishing a list of antimicrobial agents that cannot be used in accordance with Articles 112 and 113 of Regulation 2019/6 or which may be used in accordance with those Articles only under certain conditions.
The Regulation contains a list of antimicrobial agents or groups of antimicrobial agents, together with the conditions specifying when and under what circumstances they may be used in animals.

AUGUST 2024

1 August
URPLWMiPB,
Warsaw, Poland

Meeting with the Ambassador of Rwanda.
URPLWMiPB hosted a meeting between Grzegorz Cessak, President of URPLWMiPB and H.E. Professor Anastase Shyaka, Ambassador of Rwanda. Future cooperation between Poland and Rwanda and the role of the African Medicines Agency (AMA), headquartered in Rwanda since 2022, were discussed. The discussions were part of the European Medicines Agency's (EMA) initiative to share knowledge and experience with African regulators.



6-8 August
URPLWMiPB,
Warsaw, Poland

Visit of a delegation from the Moldovan Agency for Medicines and Medical Devices together with representatives of the National Chamber of Commerce of Medical Devices POLMED SA. Discussions focused on regulatory systems and challenges related to medical devices in Moldova, Poland and the European Union. Key topics included the role of AI in the medical device lifecycle, strengthening international regulatory cooperation, and POLMED's involvement in supporting the development of a regulatory framework in Moldova.

13 August
The Supreme
Medical Chamber,
Warsaw, Poland

Signing of a cooperation agreement with the Supreme Medical Chamber (NIL).
The President of URPLWMiPB – Grzegorz Cessak signed a cooperation agreement between URPLWMiPB and the Supreme Medical Chamber (NIL). The aim of the agreement is to promote high standards of education in health care. The cooperation includes the organisation of training, conducting research, educational and editorial activities and monitoring the safety of therapy.

30 August
URPLWMiPB,
Warsaw, Poland

Meeting with a delegation from the Uzbek Centre for Pharmaceutical Product Safety and signing of the Memorandum of Understanding (MoU) with Uzbekistan.
The meeting was an opportunity to sign a cooperation agreement to strengthen collaboration on the regulation of medicinal products and improving public health. The agreement lays the foundations for active dialogue, periodic progress assessments and a shared commitment to address global health challenges such as medicine shortages and pandemic preparedness.

SEPTEMBER 2024

5 September
URPLWMiPB,
Warsaw, Poland

Meeting with the Chief Pharmaceutical Inspector and Chief Sanitary Inspector.
A meeting was held at URPLWMiPB between the President of the Office, Grzegorz Cessak, Head of the Chief Pharmaceutical Inspectorate, Łukasz Pietrzak, and Head of the Chief Sanitary Inspectorate, Paweł Grzesiowski. The participants discussed closer cooperation in the area of public health safety supervision.

10 September
Warsaw, Poland

Debate 'Fast Track for e-innovation in Health'.
A panel discussion organised by Rynek Zdrowia, a leading Polish health policy portal, was held at Kozminski University, with the participation of Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB). The discussion addressed the use of AI in European regulatory institutions, the importance of education in this area, and the challenges of public-legal partnerships. The participants also discussed the necessary amendments to Polish legislation in connection with the implementation of the AI Act.

12 September
online meeting

117th Meeting of the Group of Heads of Medicines Agencies (HMA) under the Hungarian Presidency of the Council of the European Union (EU).
Topics discussed during the meeting included progress in artificial intelligence (#AI) innovation and strategic cooperation mechanisms for the regulation of medicinal products at the European Union level. Participants also heard the latest information from the European Medicines Agency (EMA) and the European Commission on the functioning of the European Medicines Regulatory Network (EMRN).

18 September

Communication of the President of the URPLWMiPB regarding the use of biocidal products in flood recovery.
Due to the state of natural disaster caused by flooding in parts of the Lower Silesian, Opole and Silesian Voivodeships, URPLWMiPB has developed and published basic information on biocidal products of public health importance in the context of flood recovery.

19-20 September
Tashkent, Uzbekistan

Visit to Tashkent at the invitation of the leadership of the Uzbek Ministry of Health and the Centre for Pharmaceutical Product Safety.
The visit included scheduled meetings, participation in the 16th International Healthcare Exhibition (UZMEDEXPO) and a tour of the Tashkent Pharma Park pharmaceutical cluster.
A joint action plan was signed to implement the MoU in specific areas of cooperation, indicating a commitment to harmonising regulations and improving public health.

OCTOBER 2024

3 October
Amsterdam,
the Netherlands

125th meeting of the Management Board of the European Medicines Agency (EMA).
The meeting was attended by the President of URPLWMiPB – Grzegorz Cessak. During the meeting, the European Medicines Agencies Network Strategy (EMANS) until 2028 was approved, the increase in the number of applications for the registration of medicines was discussed and a Data Steering Group for information management and AI integration was established.

17 October
Sopot, Poland

EFNI – European Forum for New Ideas.
During a panel at the European Forum for New Ideas, Grzegorz Cessak, President of URPLWMiPB, discussed Poland's drug safety, highlighting the role of the Shortage and Safety of Medicines Group at the European Medicines Agency (EMA), and touched on Poland's upcoming Presidency of the Council of the European Union (EU), noting URPLWMiPB's intensive work during this period.

22 October
Warsaw, Poland

National Pharmacist Day Celebration
During the ceremony, Grzegorz Cessak, President of the URPLWMiPB, highlighted the crucial role of pharmacists in the healthcare system. He discussed the growing importance of AI in pharmacy, its impact on diagnostics and therapy, and the need for the responsible implementation of technology in the service of patients.

23-25 October
Budapest, Hungary

Meeting of delegates of the Committee for Veterinary Medicinal Products and the Coordination Group for the Mutual Recognition Procedure and the Decentralised Procedure for Veterinary Medicinal Products under the Hungarian Presidency of the Council of the European Union.
Discussed topics included the results of the first round of harmonisation of reference characteristics for veterinary medicinal products. Legal regulations concerning the registration of veterinary paramedical products and animal health products in Hungary were discussed. URPLWMiPB was represented by officials from the Veterinary Medicinal Products Division, including Agata Andrzejewska, Vice-President of URPLWMiPB.

29 October
Warsaw, Poland

Medical Reason of State.
As part of the *Medical Reason of State event*, Grzegorz Cessak, President of the URPLWMiPB, discussed the Office's activities in the area of health crisis management. He highlighted the role of the Office and the European Medicines Agency (EMA) within the EU/EFTA regulatory network, as well as the importance of rapid authorisation of innovative therapies and vaccines in response to health threats such as the COVID-19 pandemic.

NOVEMBER 2024

5 November
URPLWMiPB,
Warsaw, Poland

Continuation and expansion of the tradition, initiated in 2022, of a joint dialogue with representatives of notified bodies involved in the certification of medical devices, as well as those currently seeking notification.
The aim of the meeting was to develop a common position on numerous issues related to the interpretation of regulations and guidelines raised by notified bodies within the European Union and other competent authorities.

5 November
Warsaw, Poland

Signing of a Cooperation Agreement with the Polish Academy of Sciences.
Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB), and Professor Marek Krawczyk, MD, PhD, Dean of the Division V: Medical Sciences of the Polish Academy of Sciences (PAS), signed a cooperation agreement to support the development of clinical research on advanced therapy medicinal products (ATMPs) and stem cells.
The collaboration includes the organisation of trainings, conferences, and the exchange of expertise to enhance the quality of healthcare.

12-13 November
Brazil

Summit of the International Coalition of Medicines Regulatory Medicines ICMRA.
Poland was represented by Grzegorz Cessak, President of URPLWMiPB. The COVID-19 pandemic, antimicrobial resistance and medicines availability were discussed. The importance of global cooperation and regulatory harmonisation for the safety of therapies was emphasised.

18-22 November
URPLWMiPB,
Warsaw, Poland

Study Visit of Caribbean Representatives to URPLWMiPB.
The event was organised within the framework of the European Commission project TAIEX INTPA Study Visit Guyana and Barbados – Regulatory Systems for Medicines.
The beneficiaries of the project were representatives of the regulatory agencies of Guyana and Barbados, and its objective is to support Caribbean countries in reforming their regulatory systems and to create the foundations for establishing mutual support mechanisms with European regulatory authorities.

25 November

Publication of the 2024 Annual Supplement to FP XIII with a cumulative electronic version of FP XIII.
The supplement includes the Polish versions of texts published in Supplements 11.3, 11.4, and 11.5 of the European Pharmacopoeia (Ph. Eur.), as well as national requirements whose effective date was announced in the Official Journal of the URPLWMiPB on 25 November 2024.

26-27 November
URPLWMiPB,
Warsaw, Poland

Meeting of Medicinal Products and Medical Devices Regulators of the Baltic States – Pribaltica. During the meeting of regulators responsible for medicinal products and medical devices from the Baltic States, participants discussed challenges related to the availability of medicines and prospects for future cooperation.
The need to strengthen collaboration in the face of shared challenges was emphasised, in order to respond more effectively to patients' needs and ensure the safety of therapies.

DECEMBER 2024

5-6 December
Budapest, Hungary

118th meeting of the Heads of Medicines Agencies (HMA). Organised as a joint session with EMACOLEX (European Union and European Economic Area Agency Lawyers' Working Group for Medicines) in Budapest, organised under the Hungarian Presidency of the Council of the European Union. This was the last HMA meeting before the Polish Presidency.

11-12 December
Amsterdam,
the Netherlands

126th meeting of the Management Board of the European Medicines Agency (EMA).
The Management Board meeting focused on setting the budget of the European Medicines Agency, approving the annual action plan and ensuring the effective functioning of the Agency and its cooperation with partners inside and outside the European Union (EU). They also discussed issues related to clinical trials – ACT EU and CTIS, the problem of medicine shortages and the implementation of EU Regulation 2024/568 on fees. The President of URPLWMiPB, Grzegorz Cessak, presented the EMA's multi-annual work programme for 2025-2028.

12 December

Publication of the Communication by the President of URPLWMiPB regarding the content of Supplement 11.6 to the 11th edition of the European Pharmacopoeia. The supplement introduces additions and amendments to the Ph. Eur., which become legally binding in the countries applying the European Pharmacopoeia, including the Republic of Poland, as of 1 January 2025, pursuant to Resolution AP-CPH (23) 3 of the Council of Europe, adopted by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH).

Chapter 3

THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS

General information about the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products was established in 2002. Since then, the scope of tasks and competences of the President of the Office has evolved. A key change was the entry into force of the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws 2023, item 1223), as a consequence of which the President of the Office, as of 1 May 2011, acquired the status of a government administration body. Currently, the President of the Office is responsible for issues connected with:

- marketing authorisation of medicinal products, exclusive of medicinal products authorised without the need to obtain a relevant authorisation – within the scope specified in the Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws of 2024, item 686, as amended);
- marketing authorisation of veterinary medicinal products – within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Official Journal of the EU L 4 of 07.01.2019, p. 43, as amended), hereinafter referred to as "Regulation 2019/6";
- placing on the market and use of biocidal products – within the scope defined by the Act of 9 October 2015 on biocidal products (Journal of Laws of 2021, item 24);
- clinical trials, inclusive of clinical veterinary trials – within the scope specified in the Act of 6 September 2001 – Pharmaceutical Law, regulations on medical devices, the Act of 9 March 2023 on clinical trials of medicinal products for human use (Official Journal of Laws of 2023, item 605) and the Regulation of the European Parliament and of the Council (EU) No 536/2014 of 16 April 2014 on clinical trials of medicinal products for human use and repealing Directive 2001/20/ EC (Official Journal of the EU L 158 of 27.05.2014, p. 1, as amended);
- medical devices, medical device accessories, procedure packs and systems, non-medicinal products, including their clinical trials, safety and placing on the market and putting into use, and supervision of them in the scope of Regulation of the European Parliament and of the Council (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC (Official Journal of the EU L 117, 05.05.2017, p. 1 as amended), hereinafter referred to as "Regulation 2017/745";
- in vitro diagnostic medical devices and in vitro diagnostic medical device equipment, including their performance testing, safety and placing on the market and putting into use, as well as their supervision, in the scope of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/ EC and Commission Decision 2010/227/EU (OJ L 117, 05.05.2017, p. 176 as amended), hereinafter referred to as "Regulation 2017/746";
- notification in accordance with Art. 42 sections 2, 5 and 8 of Regulation 2017/745 and in accordance with Art. 38 sections 2, 5 and 8 of Regulation 2017/746;
- within the scope defined by the relevant laws for the aforementioned areas[1].

The adoption of the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also led a change in the organisational structure of the unit introduced by a new statute granted by Ordinance No. 37 of the President of the Council of Ministers of 14 June 2011 on granting the statute of the Office for Registration of Medicinal

[1] Act of 6 September 2001 - Pharmaceutical Law (Journal of Laws of 2024, item 686 as amended), Act of 9 October 2015 on biocidal products (Journal of Laws of 2021, item 24), Act of 7 April 2022 on medical devices (Journal of Laws of 2024, item 1620), Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws of 2023, item 605).

Products, Medical Devices and Biocidal Products (M. P./ Monitor Polski – Polish Monitor of 2019, item 681, as amended)[2].

The statute of the Office was amended again in 2024, introducing changes to its organisational structure through the reorganisation of the Division of the President and the Division of the Director General. Within the Division of the President, the Cabinet of the President was transformed into the Office of the President, and the Department of International Cooperation was separated from its structure. Within the Division of the Director General, the Organization and Quality Office was separated from the Office of the Director General, and the IT Office was separated from the Administrative and Economic Office. The amendment to the statute was driven by the need to adapt the Office's operations to the conditions under which the institution currently functions. The new statute entered into force on 2 July 2024[3].

Description of the core activity of the Office

Pursuant to the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the statutory activities of the Office cover three main areas:

Carrying out proceedings and activities related to medicinal products for human use and veterinary medicinal products, in particular:

- issuing marketing authorisations for medicinal products by means of decision;
- issuing marketing authorisations for veterinary medicinal products by means of decision;
- issuing notifications about the acceptance/ rejection of post-registration variations;
- issuing decisions regarding post-registration variations, regarding the extension/shortening of the validity of authorisations for the placing of such products on the market;
- providing information on documents and actions required in the medicinal product and veterinary medicinal product marketing authorisation process;
- granting parallel import licenses for medicinal products by means of decisions;
- granting parallel trade permits for veterinary medicinal products by means of decision;
- issuing registration certificates for homeopathic veterinary medicinal products;
- keeping the Official Register of Medicinal Products Authorised for Marketing in the territory of the Republic of Poland and issuing decisions to refuse access to this register;
- granting authorisations for clinical trials or veterinary clinical trials by means of decisions;
- keeping the Central Register of Clinical Trials;
- conducting inspections of clinical trials to verify compliance of such trials with the requirements of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC and, in the case of clinical trials on veterinary medicinal products or investigational veterinary medicinal products – with the requirements of Good Veterinary Clinical Practice;
- collecting and evaluating periodic reports on the safety of medicinal products and collecting information on adverse reactions to an investigational medicinal product;
- pharmacovigilance and safety monitoring of medicinal products;
- carrying out inspections of the pharmacovigilance system for medicinal products;

[2] The Statute were amended by Ordinance No. 62 of the President of the Council of Ministers of 15 September 2014 amending the Order on granting the Statutes of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P./Monitor Polski – Polish Monitor/ of 2014, item 833), Ordinance No. 172 of the President of the Council of Ministers of 16 November 2017. amending the Ordinance on granting the Statute of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P./Monitor Polski – Polish Monitor/ of 2017, item 1064) and Ordinance No. 63 of the President of the Council of Ministers of 11 June 2024 amending the Ordinance on granting the Statute of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P./Monitor Polski – Polish Monitor/ of 2024, item 466).

[3] Ordinance No. 63 of the President of the Council of Ministers of 11 June 2024 amending the Ordinance on granting statutes to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P./Monitor Polski – Polish Monitor of 2024, item 466).

- pharmacovigilance of veterinary medicinal products and monitoring of the pharmacovigilance system;
- collecting reports of suspected adverse events for veterinary medicinal products and submitting these reports to the EU pharmacovigilance database;
- annual analysis of pharmacovigilance data for veterinary medicinal products;
- publishing in the Official Journal of the minister responsible for health, at least once a year, the Official List of Medicinal Products Authorised for Marketing on the territory of the Republic of Poland with a separate list of veterinary medicinal products;
- publishing once a month in the Public Information Bulletin a list of medicinal products which have been granted a marketing authorisation by the President of the Office;
- participating in the harmonisation of the characteristics of veterinary medicinal products in accordance with the principles set out in Section 4 of Chapter IV of Regulation 2019/6;
- enabling the reporting of information on adverse reactions to medicinal products and the collection and processing of the information obtained in such a manner that, given due diligence, can be considered medically reliable;
- implementation and maintenance a dedicated website providing information on aspects relating to the safe use of medicinal products for medicinal products, excluding veterinary medicinal products.

Conducting proceedings and supervising devices, device safety, marketing and use of devices, in particular:

- issuing decisions in respect of medical devices;
- collecting data from reports and notifications concerning medical devices;
- verifying applications in accordance with Art. 31 sec. 2 of Regulation 2017/745 and Art. 28 sec. 2 of Regulation 2017/746 and issuing unique registration numbers;
- maintaining a list of distributors referred to in Art. 21 sec. 1 of the Medical Devices Act of 7 April 2022 (Journal of Laws, item 974, as amended), collecting information on devices, systems and procedure packs referred to in Art. 22 sec. 1 of that Act, and registering manufacturers of custom-made medical devices, their authorised representatives, and importers referred to in Art. 23 section 1 of that act;
- supervising medical devices manufactured, being placed and placed on the market or forwarded for performance evaluation in the territory of the Republic of Poland;
- issuing, by means of decision, authorisations for placing on the market or use in the territory of the Republic of Poland individual devices necessary to achieve the required preventive, diagnostic or therapeutic objectives, and for which no conformity assessment procedures confirming that these devices meet the relevant requirements have been carried out;
- monitoring serious incidents within the meaning of Regulation 2017/745 or Regulation 2017/746, as well as activities related to device safety;
- publishing safety notices and administrative decisions related to device safety;
- issuing Certificates of Free Sale referred to in Art. 60 of Regulation 2017/745 and Art. 55 of Regulation 2017/746;
- issuing opinions on whether a device meets the relevant requirements at the request of the customs authorities;
- granting authorisations for a clinical trial or a performance study of a device, as well as issuing authorisations for changes to such a trial;
- listing clinical trials in the Central Register of Clinical Trials;
- collecting and analysing information on serious adverse events that have occurred in connection with the conduct of a clinical trial of a medical device or active implantable medical device and the final reports on the performance of such a clinical trial;
- conducting inspections of clinical trials and performance studies;
- issuing opinions, at the request of notified bodies, on the quality and safety of a substance constituting an integral part of a device and which, if used separately, would constitute a medicinal product;
- issuing opinions, upon request of notified bodies, referred to in Section 5.4 of Annex IX to Regulation 2017/745;
- issuing opinions on request of notified bodies regarding the suitability of a product for diagnosis

in targeted therapy with respect to a specific medicinal product;
– performing tasks related to supervision, designation, notification, and control of notified bodies.

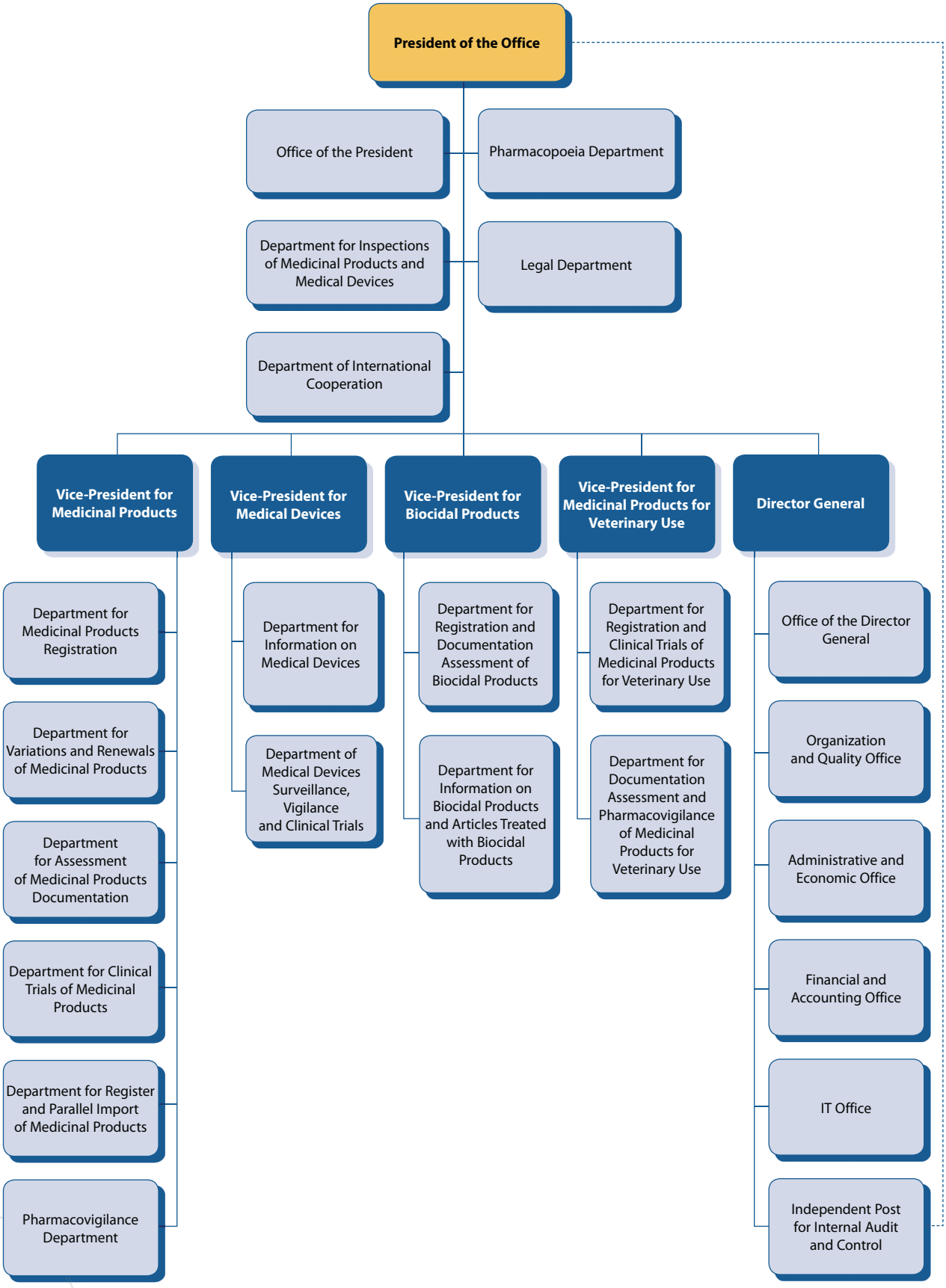
Carrying out proceedings and activities related to biocidal products, in particular:

– granting, by means of decision, national authorisations;
– issuing, by means of decision, authorisations pursuant to Art. 26 of Regulation 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (Official Journal of the EU Law 167 of 27.06.2012, p.1, as amended), referred to as "Regulation 528/2012";
– granting, by means of decision, parallel trade permits;
– granting, by means of decisions, marketing authorisations for biocidal products;
– keeping the List of Biocidal Products;
– conducting the evaluation of the dossier on complex active substances for their approval pursuant to the provisions of Regulation 528/2012;
– conducting the evaluation of the dossier submitted for the Union authorisation referred to in Art. 3 sec. 1 (n) of Regulation 528/2012;
– referring objections to the Coordination Group in accordance with Art. 35 of Regulation 528/2012;
– issuing opinions regarding scientific and development research that may involve or result in the release of a biocidal product into the environment;
– keeping the records of reports of poisoning incidents caused by biocidal products;
– providing information on documents and actions required in the process of issuing authorisations for biocidal products;
– forwarding the report referred to in Art. 65 sec. 3 of Regulation 528/2012.

The tasks of the President of the Office also include:

– appointing experts referred to in Art. 40 of Regulation 2017/745 and in Art. 36 of Regulation 2017/746;
– issuing opinions on the non-compliance of a food product with the requirements of a medicinal product referred to in Art. 31 sec. 2 of the Act of 25 August 2006 on Food and Nutrition Safety (Journal of Laws of 2023, item 1448);
– developing and publishing the Polish Pharmacopoeia and announcing the date from which the requirements set out in it shall apply in the form of an announcement in the Public Information Bulletin;
– cooperation with public administration bodies and research institutes;
– cooperation with relevant institutions of the European Union, the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), the European Directorate for the Quality of Medicines (EDQM), competent authorities of the Member States of the European Union, the Swiss Confederation and the Member States of the European Free Trade Association (EFTA), which are parties to the Agreement on the European Economic Area;
– providing scientific advice on the conduct of tests and studies necessary to demonstrate the quality, safety or efficacy of medicinal products for human use concerning qualitative, clinical, non-clinical aspects, pharmacovigilance or methodological issues concerning ongoing or planned studies.

Organisational structure of the Office[4]



[4] As of 31 December 2024.

Chapter 4

AREA SUPERVISED BY THE PRESIDENT OF THE OFFICE

Advisory Commissions of the President of the Office

Pursuant to the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of 18 March 2011. (Journal of Laws of 2023, item 1223), there are 6 advisory commissions which operate under the President:

- Commission on Medicinal Products;
- Commission on Veterinary Medicinal Products;
- Commission on Medical Devices;
- Commission on Biocidal Products;
- Commission on Borderline Products;
- Pharmacopoeia Commission.

The Commissions operate on the basis of the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws of 2023, item 1223, as amended), the Regulation of the Minister of Health of 29 June 2011 on the Commissions operating at the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws of 2011, No. 159, item 953) and the Internal Regulations of the individual Commissions.

A total of 22 meetings of the above commissions were held in 2024.

Commission on Medicinal Products

The tasks of the Commission on Medicinal Products include, in particular:

- making a substantive assessment of the dossier on medicinal products submitted by the President of the Office, mainly with regard to efficacy, safety of use, reported in the application for marketing authorisation;
- giving an opinion on assessment reports on authorised medicinal products submitted by the President of the Office;
- making a substantive assessment of the dossier concerning compliance with the relevant requirements set out in the Act of 6 September 2001 – Pharmaceutical Law for devices that are systemically absorbed or whose metabolic products are systemically absorbed by the human body in order to achieve the intended use.

In 2024, there were 5 meetings of the Commission on Medicinal Products (13.02.2024, 13.03.2024, 22.05.2024, 9.10.2024, 3.12.2024), at which 9 cases on registration of medicinal products, post-registration variations and parallel imports were considered. Summaries of the most important current publications and guidelines (including safety messages from the PRAC) were also presented at the meetings. In 2024, 9 resolutions were adopted during the meetings of the Commission on Medicinal Products.

Commission on Veterinary Medicinal Products

The tasks of the Commission on Veterinary Medicinal Products include, in particular:

- making a substantive assessment of the dossier on veterinary medicinal products submitted by the President of the Office, in particular as regards efficacy, safety of use and suitability for use of the veterinary medicinal product submitted in the application for marketing authorisation;
- analysis of veterinary medicinal products in terms of their suitability for treatment and availability of the latest generation of veterinary medicinal products;
- making proposals to the President of the Authority to ensure appropriate standards for the assessment of the characteristics of veterinary medicinal products;
- giving an opinion on assessment reports on authorised veterinary medicinal products submitted by the President of the Office;
- to express an opinion on the risk assessment of residues of veterinary medicinal products in food of animal origin;
- carrying out other tasks assigned by the President of the Office with regard to veterinary medicinal products.

There were no meetings of the Veterinary Medicinal Products Commission in 2024.

Commission on Medical Devices

The tasks of the Medical Devices Commission include, in particular, giving opinions:

- regarding the quality, effectiveness and safety of products;
- concerning conformity assessment, clinical evaluation and performance evaluation of devices; the need to perform the necessary tests and evaluations of devices;
- on labelling, instructions for use, advertising and promotional material for the products;
- on the appropriateness of authorising the placing on the market or putting into service in the territory of the Republic of Poland of products for which the conformity assessment procedures have not been carried out confirming that these products meet the requirements relating to them;
- whether the product is a device, system or treatment kit;
- on product classification;
- whether the product is a product with a measuring function;
- on product safety actions taken or required, including external safety corrective actions;
- on serious incidents within the meaning of Article 2(65) of Regulation 2017/745 and Article 2(68) of Regulation 2017/746;
- on serious adverse events within the meaning of Article 2(58) of Regulation 2017/745 and Article 2(61) of Regulation 2017/746;
- on the quality and safety of the substance, including the clinical benefit-risk balance, in the case of a device containing, as an integral part, a substance which would be a medicinal product if used separately;
- on a clinical trial or device performance study;
- on the suitability of a diagnostic device for targeted therapy in relation to a given medicinal product.

There were no meetings of the Medical Devices Commission in 2024.

Commission on Biocidal Products

The tasks of the Biocidal Products Commission include, in particular:

- providing opinions on biocidal product efficacy test methodologies;
- giving an opinion on the safe range and use and on the impact on human health and the environment of biocidal products;
- making a methodological assessment of the studies contained in the dossiers for registration of biocidal products.

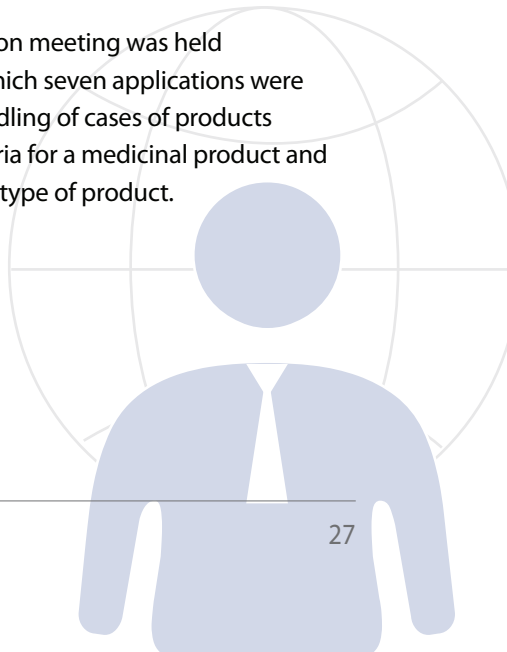
There were 13 meetings of the Biocidal Products Commission in 2024 (31.01.2024; 28.02.2024; 27.03.2024; 24.04.2024.; 22.05.2024; 26.06.2024; 30.07.2024; 04.09.2024; 25.09.2024; 30.10.2024; 13.11.2024; 26.11.2024; 18.12.2024). The meetings were held remotely by videoconference. A total of 176 applications for approval of non-standardised biocidal product efficacy test methods were submitted to the Commission for deliberation.

Borderline Products Commission

The tasks of the Borderline Products Commission include, in particular:

- giving an opinion on the classification of a product as a medicinal product, a device or a biocidal product;
- to give an opinion on whether a substance which is an integral part of a medical device or an active implantable medical device used separately would be a blood product or another medicinal product and whether it is likely to act upon the human body with action ancillary to that of the medical device or active implantable medical device.

In 2024, one Commission meeting was held (20.03.2024), during which seven applications were considered for the handling of cases of products meeting both the criteria for a medicinal product and the criteria for another type of product.



Composition of the Borderline Products Commission

Pharmacopoeia Commission

The tasks of the Pharmacopoeia Commission are, in particular:

- to propose test methods to be used for determining the quality of medicinal products and their packaging and pharmaceutical raw materials, including methods laid down by the European Pharmacopoeia, which should be included in the Polish Pharmacopoeia, and to update it in this respect;
- to propose a list of pharmaceutical raw materials, medicinal products and their packaging, including those published in the European Pharmacopoeia, for which the essential requirements as regards testing methods, composition and quality should be published in the Polish Pharmacopoeia, and to update it in this respect;
- to initiate the experimental work needed to establish appropriate test methods, and the basic requirements for test methods, composition and quality for individual pharmaceutical raw materials, medicinal products and their packaging, and to prepare pharmacopoeial monographs containing the established methods or requirements on the basis of these materials and the results of the experimental work;
- preparing sets of pharmacopoeial monographs and other materials referred to above in the form of a draft of a new edition of the Polish Pharmacopoeia as a whole or of individual volumes or supplements to the current edition of that Pharmacopoeia;
- participation in the work of the European Pharmacopoeia Commission and cooperation with the pharmacopoeia committees of other countries with a view to international harmonisation of the above test methods.

In 2024, there were 3 meetings of the Pharmacopoeia Commission on 08.04.2024, 27.06.2024 and 03.12.2024 and 13 meetings of the Pharmacopoeia Commission's expert groups. The work of the Pharmacopoeia Commission and its expert groups in 2024 was related to the preparation of materials for Supplement 2024 FP XIII, published in November 2024, and the commencement of work on materials for Supplement 2025 FP XIII, scheduled for publication in November 2025, and the development of further national monographs for the Polish Pharmacopoeia. The meetings also consider issues related to the application of the Pharmacopoeia.

Composition of the Pharmacopoeia Commission

Polish Pharmacopoeia

The elaboration and publication of the Polish Pharmacopoeia is a task carried out by the Office in the Pharmacopoeia Department (hereinafter ″PhDep″) in cooperation with the Pharmacopoeia Commission (hereinafter ″PhCom″) and its expert groups. The Pharmacopoeia defines the basic quality requirements and testing methods for medicinal products (including veterinary medicinal products) and their packaging and pharmaceutical raw materials; it also contains formulations for the preparation of medicines made in pharmacies. Since 2006, the Polish Pharmacopoeia has been the Polish version of the European Pharmacopoeia (hereinafter ″Ph. Eur.″), supreme in Europe, developed by the European Pharmacopoeia Commission at the Council of Europe. PhDep participates in the work of this Commission and coordinates the participation of Polish specialists in the work of its expert groups. The Polish Pharmacopoeia also includes national requirements, i.e. those which do not have their equivalents in the Ph. Eur.

In 2024, work was carried out on Supplement 2024 Ph. Pol. XIII supplementing the main part of the 13th edition of the Polish Pharmacopoeia (Ph. Pol. XIII 2023). Supplement 2024 Ph. Pol. XIII was published in print in November 2024 together with a cumulative electronic version of Ph. Pol. XIII on a pen drive.

The publication system of the European Pharmacopoeia (triennial editions consisting of a basic part and eight supplements) results in the necessity of systematic updating of the Polish Pharmacopoeia, hence materials for Supplement 2025 to Ph. Pol. XIII have been prepared, which will contain changes and additions published in Ph. Eur. 11.6 – 11.8. Preliminary work was also commenced on a new 14th edition of the Polish Pharmacopoeia, within the scope of available materials of Ph. Eur. 12.

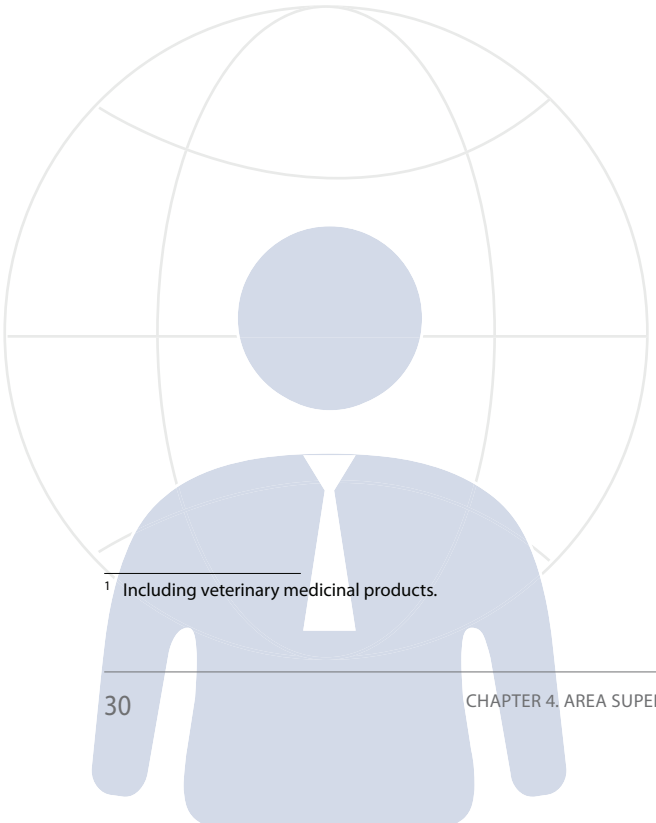
Supplement 2024 Ph. Pol. XIII contains the Polish version of the texts published in Supplements 11.3, 11.4 and 11.5 of the European Pharmacopoeia, as well as national requirements. The ″National Monographs″ section contains the monograph *Drugs prepared in the pharmacy* with an addendum (Part 6) on the preparation of such drugs with antibiotics. The section ″List of doses″ and ″List of very potent substances, potent substances and narcotic drugs″ includes the active substances described in the new individual monographs of Ph. Pol. XIII Supplement 2024 , hence this list is complementary to the data published in Ph. Pol. XIII 2023. Ph. Pol. XIII Supplement 2024 includes 30 general chapters, 2 general monographs and 224 individual monographs.

The date from which the requirements of Supplement 2024 Ph. Pol. XIII are applicable, in terms of national requirements, is announced in the Official Journal of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, available on the website of the Registration Office (Public Information Bulletin) and is 1 June 2025. In the case of the requirements of Supplement 2024 of Ph. Pol. XIII, which are in line with Supplements 11.3 – 11.5 of the European Pharmacopoeia, they apply respectively from the dates specified in the Resolutions of the Council of Europe.

As part of the process of preparation for publication of Ph. Pol. XIII materials, elaborated in the PhDep and by external specialists, drafts of new and revised texts were discussed at meetings of expert groups of the PhCom. In the case of Supplement 2024 of Ph. Pol. XIII, the PhDep prepared and submitted for review to the PhCom the Draft of this Supplement (in terms of chapters and monographs new and revised to a major extent), and then participated in the process of printing composition of the materials, including technical verifications.

Activities related to the inspections of clinical trials on medicinal products[1] and medical devices and the control of the pharmacovigilance system for medicinal products[1]

The inspection is carried out in relation to clinical trials on medicinal products for human use, veterinary medicinal products and medical devices as well as pharmacovigilance systems for medicinal products, including veterinary medicinal products. The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is responsible for carrying out inspections of conducted trials.



Conducting Inspections of Clinical Trials relating to medicinal products, veterinary medicinal products and medical devices

The President of the Office conducts inspections of clinical trials to medicinal products, inspections of clinical trials to veterinary medicinal products and clinical trials to medical devices. In 2024, a total of 30 inspections of clinical trials of medicinal products were conducted, including 11 on behalf of the European Medicines Agency (EMA), 1 inspection of clinical trials of veterinary medicinal products and 2 inspections of medical devices (Graph. 4.1).

As part of the inspections carried out on behalf of the EMA, Polish inspectors acted as Reporting Inspectors on four occasions.

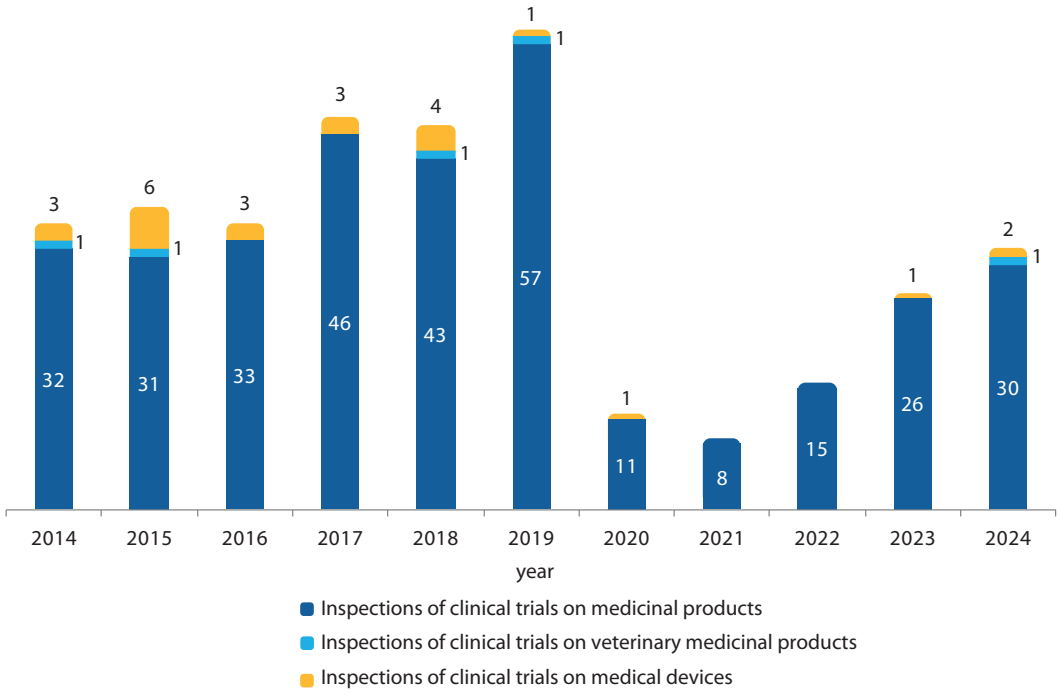
The employees of the Office worked within the GCP Inspectors Working Group and the Pharmacovigilance Inspectors Working Group at the European Medicines Agency. As part of strengthening international contacts, cooperation with the Inspectorate of Canada was continued.

[1] Including veterinary medicinal products.

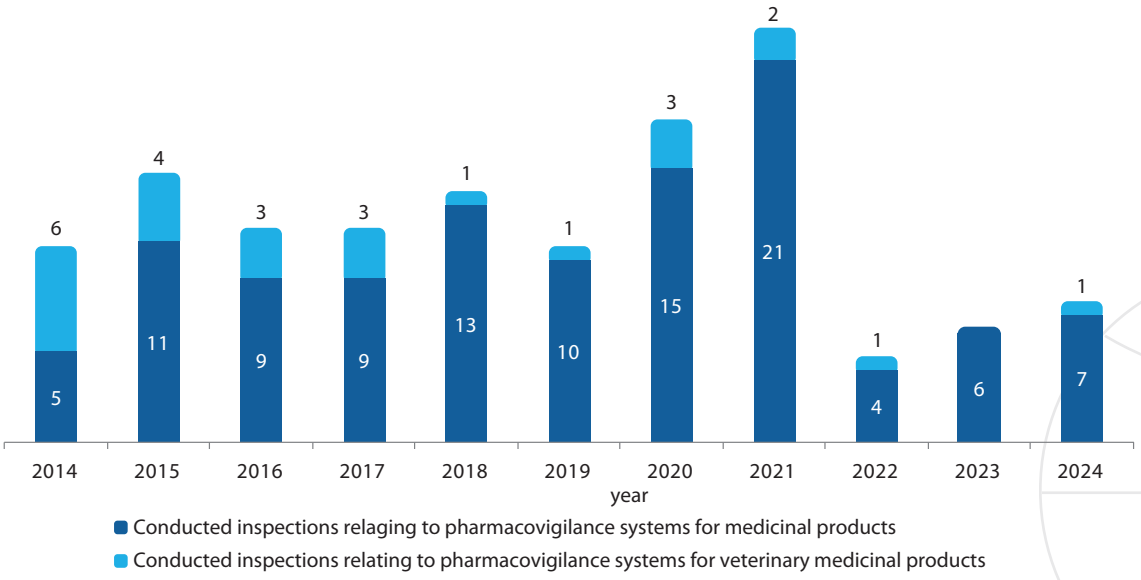
Conducting inspections to the pharmacovigilance system for medicinal products and veterinary medicinal products

In terms of the pharmacovigilance, 7 inspections regarding the pharmacovigilance system for medicinal products were carried out in 2024 of which 1 was commissioned by the European Medicines Agency, and 1 inspection of the pharmacovigilance system for veterinary medicinal products (Graph. 4.2).

Graph. 4.1: Conducted inspections of clinical trials on medicinal products, veterinary medicinal products as well as medical devices and active implantable medical devices in 2014–2024



Graph 4.2: Conducted inspections relating to pharmacovigilance systems for medicinal products and veterinary medicinal products in 2014-2024



Legislative work

In 2024, the President of the Office participated in legislative work on the bill amending the Act on biocidal products, the bill on veterinary medicinal products and the bill amending the Act – Pharmaceutical Law as regards compassionate use.

Bill amending the Act on biocidal products

The bill amending the Act of 9 October 2015 on Biocidal Products (Journal of Laws 2021, item 24) – aims to enforce the judgment of the Court of Justice of the European Union of 23 November 2016 C-442/14 Bayer CropScience SA-NV, Stichting De Bijenstichting v. College voor de toelating van gewasbeschermingsmiddelen en biociden (access to environmental information – information on environmental emissions of plant protection products and biocidal products – protection of commercial information). In addition, this bill clarifies the existing provisions for the proper application of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 on the making available on the market and use of biocidal products (Official Journal of the European Union L 167of 27 June 2012, p. 1, as amended).

In 2024, work on the law was re-initiated and the bill was subjected to consultation, public consultation and opinion. In 2025, legislative work will be continued by the Minister of Health.

Bill on veterinary medicinal products

The purpose of the proposed law is to create national provisions for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Official Journal of the European Union L 4 of 7 January 2019, p. 43,as amended). The aforementioned regulation introduces a fundamental change in the area of veterinary medicinal products, thus replacing the currently applicable Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Official Journal of the European Union L 311 of 28 November 2001, p. 67, as amended; Official Journal of the European Union, Polish Special Edition, Chapter 13, vol. 27, p. 69). Hence, it became necessary to develop a regulation-related bill which, while serving the application of the above-mentioned EU regulation will replace the previous national regulation in this area, i.e. the provisions of the Act of 6 September 2001. – Pharmaceutical Law. In 2024, legislative work was restarted. In 2025, further work is planned to draft the aforementioned Act and continue the legislative process.

Bill amending the Pharmaceutical Law

In 2024, the President of the Office was also authorised by the Minister of Health to draft a bill to amend the Pharmaceutical Law Act with regard to the introduction into this Act of provisions concerning the institution of so-called compassionate use, i.e. the procedure for compassionate use of a medicinal product referred to in Art. 83 of Regulation (EU)No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down EU procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (Official Journal of the European Union L 136 of 30 April 2004, p. 1, as amended; Official Journal of the European Union Polish Special Edition, Chapter 13, Vol. 34, p. 229). In 2024, work was underway to draft the aforementioned legislation. Work on the bill is to continue in 2025.

In 2024, intensive legislative work was also underway at European level on the so-called revision of pharmaceutical legislation, which consists of:

- draft Directive of the European Parliament and of the Council on the EU code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM/2023/192 final) and
- draft Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and laying down the rules governing the European Medicines Agency,

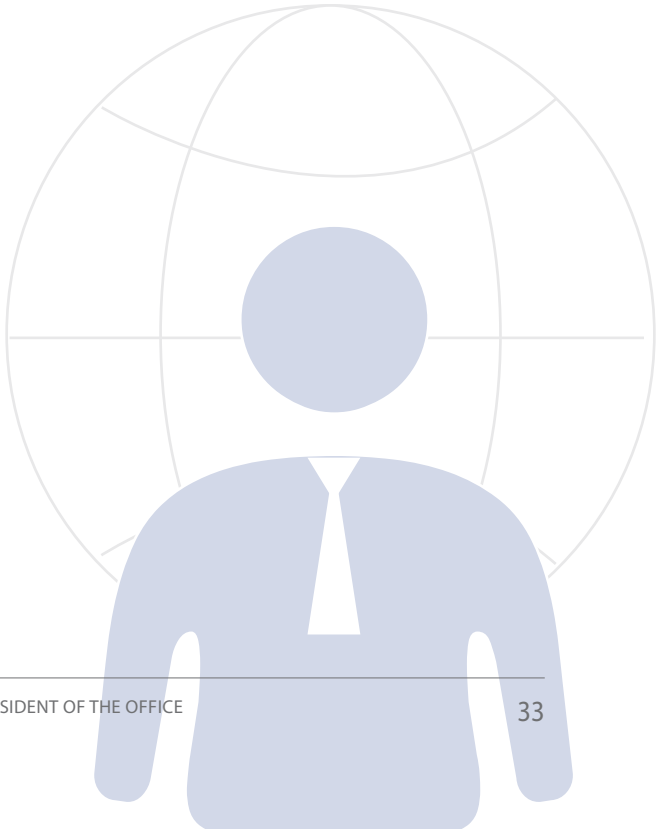
amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM/2023/193 final).

The legislative work in the above-mentioned scope was coordinated by the Ministry of Health, while representatives of the Office participated in the above-mentioned work as experts delegated to work in the Working Party (WP) on Pharmaceuticals and Medical Devices of the Council of the EU, in particular with regard to the preparation of the position of the Government of the Republic of Poland to be presented at the sessions of the group with regard to the discussed parts of the draft legislation prepared as material for discussion by the given Presidency (in 2024 BE and HU). The Hungarian Presidency organised fifteen meetings devoted to the package, spread over 21 negotiation days. The progress achieved under the BE and HU presidencies was presented in a progress report that was submitted to the EPSCO Council on 3 December 2024. Detailed discussions referred to provisions on regulatory data and modulation of market protection, incentives for orphan and paediatric medicinal products, adapted frameworks and incentives for the development of priority measures antimicrobials, national and centralised marketing authorisations, the structure of the European Medicines Agency, as well as the management of shortages and security of supply of medicinal products.

The legislative work on the revision of pharmaceutical legislation will continue in 2025. The work of the Working Party (WP) on Pharmaceuticals and Medical Devices will be conducted under the chairmanship of the Permanent Representation of the Republic of Poland in Brussels as part of the Polish Presidency in the first half of 2025.

In view of the ongoing legislative work in 2024 on the creation of the provisions of the new Medicines Directive, which provide for the possibility of introducing an electronic version of the leaflet (ePIL) for all types of medicinal products, the President of the Office has also taken the necessary steps to implement an ePIL pilot programme in the territory of the Republic of Poland for medicinal products intended for use in a hospital setting. The aim of the ePIL pilot would be to assess the impact on the safety of medicinal products in the event of a switch from a paper leaflet to an electronic version for the medicinal products covered by the pilot before adopting future target solutions for all medicinal products. 2024 was a year of intensive dialogue with the public on this issue, with the participation of the Ministry of Health. In 2024, approval was also sought from the European Commission for the ePIL pilot. The above-mentioned work is expected to be finalised in 2025, bearing in mind that digitisation in health care is an ongoing topic of many discussions, one of the priorities for changes in EU legislation, and taking action on the implementation of the ePIL pilot programme is in line with the objectives of the Polish Presidency of the EU Council in the first half of 2025.

In addition to the legislative work carried out in the aforementioned scope, the President of the Office also provides opinions on the drafts of legal acts submitted to it as part of their opinion in the course of the governmental legislative procedure and participates in the sittings of parliamentary and senate committees, including those dealing with the consideration of parliamentary drafts concerning the scope of the Office's activities. In addition, it should be pointed out that experts from individual substantive departments of the Office participate in the work of specific working groups and provide substantive opinions on draft legal acts issued by EU institutions.



International cooperation

The President of the Office actively participated in the international meetings of the Group of Heads of Medicines Agencies (HMA), the International Coalition of Medicines Regulatory Authorities (ICMRA) and the Management Board of the European Medicines Agency (EMA). In addition, as part of multilateral cooperation, regular meetings with the European partners of the Steering Board of the European Commission and the European Medicines Regulators Network (EMRN) continued, with a view to strengthening global cooperation and communication.

In the multilateral cooperation dimension, representatives of the Office have cooperated with or participated in the work of a numerous platforms operating under the auspices of the following bodies:

European Medicines Agency (EMA)

The European Medicines Agency (EMA) is an autonomous European Union institution responsible for the central coordination and supervision of the scientific evaluation, registration, monitoring and pharmacovigilance of medicines used in the EU Member States and the European Economic Area (EEA). In addition, the EMA also prepares recommendations for the European Commission as part of the central authorisation procedure for medicinal products. The presence of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products on the Agency's Management Board and on its key Budget and Work Programme Group provides even more opportunities for real, effective cooperation with the EMA.

In order to maintain our ability to co-decide on strategic issues relating to the cycle of assessment and authorisation of medicinal products for both human and animal use, and to comply with the provisions of, inter alia, Regulation No 726/2004 of the European Parliament and of the Council (EU) of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, we have ensured appropriate representation on seven Scientific Committees of the Agency:

- the Committee for Medicinal Products for Human Use (CHMP);
- the Committee for Veterinary Medicinal Products (CVMP);
- the Pharmacovigilance Risk Assessment Committee (PRAC);
- the Committee for Orphan Medicinal Products (COMP);
- Paediatric Committee (PDCO);
- the Committee on Herbal Medicinal Products (HMPC);
- the Committee for Advanced Therapies (CAT).

The Office was also represented on the following key working groups and task forces of the European Medicines Agency:

- Clinical Trials Information System Member State Group (CTIS MS Group);
- Name Review Group (NRG);
- Working Group on Quality Review of Documents (QRD);
- GCP Inspectors Working Group;
- Pharmacovigilance Inspectors Working Group (PhV IWG);
- Biologics Working Party (BWP);
- CMDh Working Party on Variation Regulations;
- Joint CHMP/CVMP Quality Working Party;
- Medicinal Product Quality Working Party (QWP);
- Pharmacokinetics Working Party (PWP);
- Central Nervous System Working Party (CNSWP);
- Coordination Group for Mutual Recognition and Decentralised Procedures for Medicinal Products for Human Use (CMDh);
- Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv);
- Pharmacovigilance Working Party (PhVWP-V);
- IT Directors Group;
- Scientific Advice Working Party (SAWP);
- The Pilot Signal Management Expert Group (P-SMEG);
- Harmonisation of RMP Project (HaRP);
- Executive Steering Group on Shortages of Medical Devices;
- Drafting Group Article 34 Regulation (EU) 2019/6);
- Emergency Task Force (ETF);
- Non-Clinical Working Group (NcWP);

– The Patients' and Consumers' Working Party (PCWP).

The Management Board of the European Medicines Agency (EMA) held four traditional meetings in 2024. Discussions during the meetings addressed urgent priorities such as the implementation of the Health Technology Assessment Regulation (HTAR), improved monitoring of drug shortages and the development of clinical trials through state-of-the-art platforms such as CTIS. Strategic decisions included increasing the budget to more than €600 million (a 24% increase), adopting the European Medicines Agency Network Strategy to 2028 and fostering global regulatory partnerships with agencies such as the FDA.

Board members discussed access to innovative therapies, the fight against antimicrobial resistance and, in particular, significant progress was made in the use of patient experience data and artificial intelligence to improve regulatory processes. The joint actions confirmed the EMA's leading role in innovation and public health, while setting a new benchmark for international cooperation and regulatory excellence.

European Chemicals Agency (ECHA)

The European Chemicals Agency (ECHA) is a decentralised agency of the European Commission established on 1 June 2007 by Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). In 2012, ECHA's mandate was extended by Regulation (EU) No 528/2012 of the European Parliament and of the Council (EU) on the making available on the market and use of biocidal products. Member States are involved in the work of the Agency, inter alia through membership of a number of working groups.

The forums for cooperation within the European Chemicals Agency are the Biocidal Products Committee (BPC) and the following working groups:
– Working Group of Biocidal Products Committee: Analytical Methods and Physico-chemical Properties;
– Working Group of Biocidal Products Committee: Environment;
– Working Group of Biocidal Products Committee – Efficacy;
– Working Group of Biocidal Products Committee: Human Health;
– Ad Hoc Working Group – Environmental Exposure;
– Ad hoc Working Group – Human Exposure;
– Ad hoc Working Group – Assessment of Residue Transfer to Food;
– Coordination Group;
– HelpNet Steering Group;
– Member State Communicators' Network.

European Commission, Council of the European Union

Fulfilling the tasks of a Member State, the delegates of the Office represented Poland in the work of European Union bodies and participated in the meetings of the following groups:
– Notified Bodies Oversight (NBO);
– In vitro diagnostic medical devices (IVD);
– Clinical Investigation and Evaluation (CIE);
– European Database on Medical Devices (EUDAMED);
– Medical Device Coordination Group (MDCG);
– Pharmaceutical Committee;
– New Technologies;
– Post-Market Surveillance and Vigilance (PMSV);
– Borderline and Classification (B&C);
– Market Surveillance (MSOG);
– Coordination Group on the In vitro Diagnostic Medical Devices Regulation (IVDR);
– Standards;
– Unique Device Identification (UDI);
– International Matters;
– Nomenclature;
– Annex XVI products;
– Committee on the approximation of the laws of the Member States relating to medical devices – Standing Committee on medical devices.

European Medicines Regulatory Network (EMRN)

The marketing of medicines in Europe is subject to a rigorous process and the European Medicines Regulatory Network (EMRN) has a key role in this area. Its task is not only to ensure, but also to maintain, the

highest standards of safety, efficacy and quality of medicines in the European Union (EU).

The benefits of the EMRN for EU citizens centre, among other things, on enabling Member States to pool resources and coordinate their work in order to deal efficiently and effectively with the regulation of medicines, as well as ensuring that patients, healthcare professionals, industry and governments have consistent standards and benefit from the best available expertise. Furthermore, the functioning of the EMRN is also guided by reducing the administrative burden through the use of a centralised procedure, speeding up the availability of medicines for patients, and accelerating the exchange of information on important issues such as the safety of medicines.

As part of international cooperation, URPLWMiPB staff actively participate in the Borderline Products Network (EDQM) working group. This group deals with borderline products issues, helping to develop common regulatory approaches and supporting the harmonisation of regulatory interpretations on the classification of medicinal products and other categories of devices.

Group of Heads of Medicines Agencies of the European Union and the European Economic Area (HMA)

The Heads of Medicines Agencies (HMAs) is a comprehensive, informal but extremely important forum for cooperation. The HMA meetings, which traditionally take place four times a year, two per Presidency, discuss the most important current issues of the regulatory authorities with jurisdiction over human and animal medicinal products. A common approach to controversial or difficult issues is also developed in this forum. The President of the Office is an official member of the HMA and a Mentor of its EMACOLEX Working Group. Staff members according to their expert profile participate in the following HMA working groups:

- Homeopathic Medicinal Products Working Group (HMPWG);
- Clinical Trials Coordination Group (CTCG);
- Working Group of Quality Managers (WGQM);
- European Innovation Network (EU-IN);
- European Medicines Agencies Co-operation of Legal and Legislative Issues EMACOLEX;
- EU Network Training Centre (EU – NTC).

The 2024 meetings discussed key regulatory challenges, legislative initiatives and efforts to strengthen cooperation in the European Medicines Regulatory Network (EMRN). Key findings included the fight against drug shortages, EU pharmaceutical law reform, the development of digital tools and artificial intelligence (AI), as well as advanced therapies. The HMA meetings in 2024 highlighted the importance of working together internationally, adapting to technological and environmental challenges and ensuring that patients in the EU have access to safe and effective medicinal products.

Medical Devices Competent Authorities Group (CAMD)

The CAMD is a forum for cooperation between the National Competent Authorities of the European Economic Area and the European Commission to strengthen and harmonise the supervision of medical devices and to ensure consistent and effective implementation of medical device legislation within the EU.

Council of Europe

In 2024, the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products continued its cooperation with the European Pharmacopoeia Commission under the EDQM (European Directorate for the Quality of Medicines and Healthcare) in the Council of Europe.

The Office has been actively involved in the work of the Commission and its expert/working groups. This work is related to the development of materials for the overarching European Pharmacopoeia. The European Pharmacopoeia (Ph. Eur.) is being prepared in accordance with the Convention on the laboration of a European Pharmacopoeia, to which Poland acceded in 2006.

World Health Organisation (WHO)

In 2024, representatives of the Office participated in the WHO meetings of the International Regulatory Cooperation on Herbal Medicinal Products (IRCH).

International Coalition of Medicines Regulatory Authorities (ICMRA)

On 12–13 November 2024, President of URPLWMiPB Grzegorz Cessak took part in the International Coalition of Medicines Regulatory Authorities (ICMRA) Summit.

ICMRA is a strategic organisation established to assist regulators in addressing existing and coping with and preventing emerging new challenges related to public health safety in the context of medicinal products and medical devices. ICMRA strategically, continuously, transparently and institutionally targets areas and activities common to the many missions of regulatory authorities worldwide. The coalition provides opportunities for improved communication, information sharing, crisis response and resolution of regulatory science issues. ICMRA is also involved in initiating changes to guidelines and recommendations for the registration of medicinal products, including collaboration on the development of recommendations for the formulation of COVID-19 adapted vaccines. The most frequently discussed topics at ICMRA meetings and summits are antibiotic resistance, communication, drug shortages, innovation, drug safety monitoring, reliance on and recognition of regulatory outcomes, big data, adverse reaction reporting, building public confidence in vaccines, the 3Rs of reducing the use of research animals, supply chain integrity and responding to emerging public health threats.

ICMRA's membership includes the major authorities responsible for the registration and pharmacovigilance of medicinal products from around the world (currently 38), including institutions such as the European Commission, the European Medicines Agency (EMA) and the World Health Organisation (WHO).

Bilateral cooperation

Cooperation with Canada

In June 2024, the official signing of the Cooperation Agreement for the Inspection of Clinical Trials of Medicinal Products and Medical Devices for Human Use with the existing partner of the Office – Health Canada took place.

The purpose of the aforementioned document is to establish a cooperation mechanism between URPLWMiPB and Health Canada that will facilitate the exchange of information and cooperation in the inspection of clinical trials for human medicinal products and medical devices.

International Coalition of Medicines Regulatory Authorities Summit, 12-13 November 2024, Brazil

Signing of cooperation agreement with Health Canada, 5 June 2024 Ottawa, Canada

Among the most important areas of cooperation are the establishment of stable channels of communication between the competent inspectorates of both countries responsible for the supervision of the clinical trial in order to exchange information or jointly establish positions.

Cooperation with Barbados and Guyana

A study visit by regulators from Barbados and Guyana to the Office took place in November. It was organised as part of the European Commission's TAIEX INTPA Study Visit Guyana and Barbados – Regulatory Systems for Medicines project. The beneficiaries of the project were representatives of the regulatory agencies of Guyana and Barbados.

The visit was one element of a European initiative that aims to globally build regulatory maturity by supporting Caribbean countries in reforming their regulatory systems and creating the conditions for establishing mutual support systems with European regulators.

The role of the Office in this project was to conduct a series of training sessions related to presenting the functioning of the European regulatory authority on the example of URPLWMiPB and the specifics of its

Visit of representatives of Caribbean countries to URPLWMiPB, 18-22 November 2024, Poland

competences, tasks and activities in the field of clinical trial registration. The partner of the Office in the project was its Lithuanian counterpart, the State Medicines Control Agency.

Cooperation with Ukraine

On 21 February 2024, a delegation led by the Director of the State Expert Centre of the Ministry of Health of Ukraine (SECMOH) Mykhaylo Babenko visited the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. During the meeting, the Director of SECMOH expressed his gratitude for Poland's support in Ukraine's EU accession process. Discussions focused on technical aspects related to the functioning of the

Visit of the State Expert Centre of the Ministry of Health of Ukraine (SECMOH) to URPLWMiPB, 21 February 2024, Poland

eCTD systems, as well as CTIS and GMP inspections in third countries. Grzegorz Cessak, President of URPLWMiPB, reaffirmed Poland's leadership in the twinning project to harmonise Ukrainian regulations with EU standards, emphasising unwavering support for Ukraine's European integration.

On 2-3 July 2024, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products hosted a meeting with representatives of the Ministry of Health of Ukraine. The main element of the visit was the signing of a Memorandum of Understanding (MoU) aimed at strengthening cooperation in the regulation of medicinal products and medical devices between Poland and Ukraine.

The agreement is a milestone in deepening bilateral relations between Poland and Ukraine, focusing on improving the quality, safety and efficacy of medicinal products and medical devices in both countries and emphasising the harmonisation of regulatory practices in line with EU legislation, addressing drug shortages and strengthening the reliability of clinical data.

Areas of cooperation highlighted in the MoU include: exchange of knowledge and experience on marketing authorisations, monitoring of the safety and efficacy of medicinal products as well as clinical trials; mutual support for access to the legal framework and technical requirements related to medicinal products; exchange of information on medicinal products, medical devices and clinical trials; joint efforts to monitor and analyse adverse drug reactions, especially serious ones; conducting inspections and audits of clinical trials of medicinal products and medical devices.

Poland-Sweden-Ukraine trilateral regulatory meeting for regulatory harmonisation, 2-3 July 2024, Poland

The MoU also aims to promote consistent standards across the regulatory landscape of both countries and promote stronger alignment with EU regulations. This cooperation will enable both countries to deal more effectively with current and future healthcare challenges, especially as Ukraine moves closer to EU membership.

The discussion also touched on the possibilities of trilateral cooperation, including the creation of a Polish-Swedish consortium to support the development of the Ukrainian regulatory authority. Representatives of Ukraine are actively working to bring their regulatory framework in line with EU standards, while using proven Polish and Swedish models.

Cooperation with Uzbekistan

On 30 August 2024, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products hosted a delegation from the Uzbek Centre for Pharmaceutical Product Safety. The meeting, attended by His Excellency Amirsaid Agzamkhodjaev, Ambassador of Uzbekistan, and Alisher Temirov, Director of the Centre, was an opportunity to sign a Memorandum of Understanding (MoU) to strengthen cooperation in regulating medicinal products and improving public health.

Within the framework of the signed MoU, the aforementioned institutions undertake, among other things, to exchange information on the regulatory framework and the safety of medicinal products, as well as to cooperate on pharmaceutical innovation and technology transfer.

The agreement further lays the foundations for active dialogue, periodic assessments of progress and a shared commitment to address global health challenges such as drug shortages and pandemic preparedness.

On 19-20 September 2024, at the invitation of the Centre for Pharmaceutical Product Safety of the Ministry of Health of Uzbekistan, a visit to Tashkent by representatives of URPLWMiPB took place.

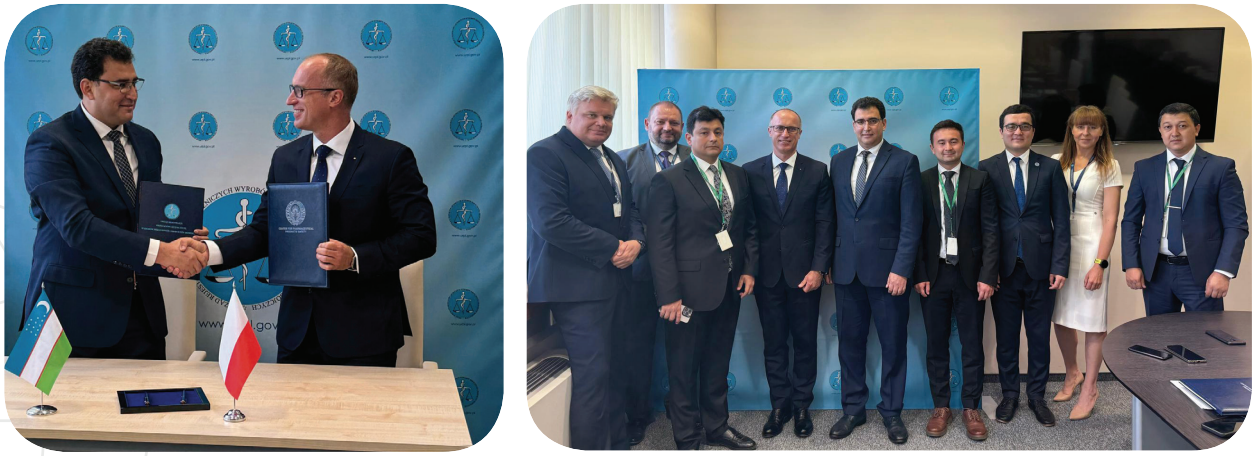
Highlights of the visit were meetings with the leadership of the Ministry of Health and the ˝Centre for Pharmaceutical Product Safety˝. Discussions focused on the regulation of medicinal products and how the two countries can work together to strengthen the regulatory framework.

In addition, the delegation attended the 16th International Healthcare Exhibition (UZMEDEXPO), which showcased the achievements of both national and international manufacturers in the healthcare and pharmaceutical sectors.

The outcome of the meetings and discussions is the signing of a joint Action Plan, which details specific actions to implement the terms of the Memorandum of Understanding signed on 30 August 2024 in Warsaw.

This plan laid the foundations for practical cooperation between the two countries in several key areas:

– Registration of medicines: establishment of a working group to facilitate the exchange of regulatory information and the organisation of



Signing of Memorandum of Understanding (MoU) with Uzbekistan, 30 August 2024, Poland


Visit of URPLWMiPB representatives to Tashkent, 19-20 September 2024, Uzbekistan

internships for professionals in Poland in order to streamline drug registration processes.
- Pharmacopoeia cooperation: agreement to share experience in the development of state pharmacopoeias, with joint visits, working groups and scientific publications.
- Registration of medical devices: development of training and apprenticeship programmes related to the registration of medical devices based on the EU Medical Device Regulation (MDR).
- Technology transfer: exchange of experience to support the development of national technology transfer legislation in Uzbekistan, involving European expertise.
- Pharmacovigilance: commitment to strengthen pharmacovigilance systems, including the development of the National Electronic Information System in Uzbekistan, with technical support from Polish experts.
- Clinical trials: exchange of expertise in clinical trials and bioequivalence studies, with plans for reciprocal visits by specialists from both countries.

The visit concluded with confirmation of the strong bilateral cooperation between Uzbekistan and Poland in the field of pharmaceutical regulation. The action plan sets the stage for further cooperation, with specific steps in regulatory exchange, training and joint development of critical pharmaceutical standards.

Cooperation with Moldova

On 15 May 2024, the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMiPB) participated in the Regulatory Agency Leaders Roundtable: ″Strategic Insights and Cooperation″ at the Medicines and Medical Devices Agency of Moldova, at the invitation of Director General Dragoş Guțu.


Participation in the Regulatory Agency Leaders Roundtable, 15 May 2024, Moldova

Visit of a Moldovan delegation to URPLWMiPB, 7 August 2024, Poland

The roundtable discussions were very fruitful, offering strategic insights into the map of future cooperation. The exchange of experiences highlighted the importance of knowledge sharing and underlined Poland's commitment to supporting Moldova in its quest for European Union membership. Recognising the common goals of regulatory harmonisation, Poland invited Moldovan representatives for another visit to URPLWMiPB to deepen discussions and enhance cooperation.

On 7 August 2024, URPLWMiPB President Grzegorz Cessak hosted a delegation from the Moldovan Medicines and Medical Devices Agency, led by Director Dragos Guțu.

The discussion focused on regulatory regimes and challenges for medical devices in Moldova, Poland and the EU. Topics discussed included the role of artificial intelligence in the life cycle of medical devices, strengthening international regulatory cooperation, as well as the involvement of the POLMED Chamber in supporting the development of cooperation with Moldova.

The meeting confirmed the importance of working together to enhance the safety and efficacy of medical devices, improve public health and address emerging challenges. Both meetings demonstrate a strong commitment to supporting knowledge sharing and regulatory alignment as Moldova progresses towards European Union integration.

Visit of the Director of the Centre of Excellence for Oncology, FDA to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

On 19 April 2024, the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products had the honour of hosting Dr. Richard Pazdur, Director of the FDA's Centre of Oncology Excellence.

The meeting provided an opportunity to discuss the key role of the Office in ensuring the safety and efficacy of medicinal products, medical devices and biocidal products through effective registration processes. Discussions highlighted the importance of streamlined regulatory systems for improving public health, particularly in the field of oncology, where timely access to innovative therapies is crucial.

The exchange reinforced a shared commitment to improving patient outcomes through regulatory excellence and highlighted the importance of

Visit of Dr. Richard Pazdur, Director of the Centre of Excellence in Oncology, FDA to URPLWMiPB, 19 April 2024, Poland

international collaboration in addressing global health challenges.

Meeting of the Baltic States at the headquarters of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

On 26-27 November 2024, the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products hosted the annual Baltic countries meeting in Warsaw, uniting regulatory agencies from Lithuania, Latvia, Estonia and Poland with experts from the HTA and OMCL bodies.

The discussion at the meeting covered key topics at the moment, including pharmaceutical regulatory updates, drug shortages, digital safety, as well as the safety of advanced therapy medicinal products (ATMPs), while promoting regional cooperation and regulatory harmonisation.

The meeting highlighted the importance of ensuring safety, combating illegal practices and improving patient care for ATMPs, as well as strategies to strengthen supply chains and resilience. This highly valuable meeting strengthened the partnership and prepared the groundwork for a unified approach to

Baltic States Meeting at URPLWMiPB, 26-27 November 2024, Poland

improving the public health and regulatory framework in the Baltic Sea Region.

Participation in international projects in 2024

Project Horizon 2020 – CORE-MD

The Office has been actively involved in the CORE-MD (Coordinating Research and Evidence for Medical Devices) project, which aims to advise on optimal statistical methods, the utility of patient-reported outcomes, the conduct of registry studies, clinical criteria for evaluating AI as a medical device, and how to evaluate medical devices used in children. The links between CORE-MD partners are a catalyst for sustainable research networks. The consortium is led by the European Society of Cardiology and the European Federation of National Associations of Orthopaedics and Traumatology, and includes 33 specialist medical societies that are members of the Biomedical Alliance in Europe.

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products is involved in these tasks:

- recommending alternative clinical trial projects that can be used to provide high-quality clinical evidence for new high-risk medical devices;
- examining existing guidelines and recommending criteria for the clinical evaluation and compliance assessment of artificial intelligence and machine learning as high-risk medical devices;
- recommending a method for assessing high-risk medical devices used in children;
- dissemination of publications, educational resources and CORE-MD results in the clinical community and with all stakeholders through newsletters, webinars and social media;
- ensuring effective and efficient project coordination, both administratively and technically;
- managing and coordinating communication between the Consortium, external contacts and the European Commission.

The final recommendations developed in the CORE-MD will be submitted to the European Commission's Clinical Trials and Evaluation Working Group for consideration in the development of EU guidelines or common specifications.

CORE-MD will translate scientific and clinical expertise on research projects for the evaluation of high-risk medical devices into advice for EU regulators to strike the right balance between innovation, safety and efficacy.

Project Simultaneous National Scientific Advice (SNSA)

The Office is involved in the Simultaneous National Scientific Advice (SNSA). The purpose of SNSA is:

- providing international scientific and regulatory advice, enriching the offer of regulatory bodies to support developers of innovative medicinal products and related technologies,
- increase the consistency and effectiveness of the national scientific advice provided by the various national competent authorities in order to maximise the potential of the SNSA pilot concept.

The Simultaneous National Scientific Advice seeks to develop procedures designed for applicants who will be interested in obtaining scientific advice in two countries at the same time.

Project JAMS 2

Participation of staff from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in the Joint Action for Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices (JAMS 2.0) project set up under the EU for Health – EU4Health programme, which aims to strengthen market surveillance of medical devices (MDs) and in vitro diagnostic (IVD) devices between Member States and harmonise approaches across the European Union.

The JAMS 2.0 project aims to strengthen market surveillance of medical devices between Member States and harmonise approaches across the European Union.
The project is divided into 4 technical work packages (WPs) covering different aspects of market surveillance. Each WP provides opportunities for the exchange of best practice, knowledge and resources between competent authorities.

WP5. Signal detection will work to promote the exchange of market surveillance information between competent authorities.
WP6. The inspection aims to establish current practices and promote the development of inspection methods through the experience of joint inspections carried out by a team of inspectors from different Member States. Activities will promote cooperation between inspectors and enforce harmonisation of inspections at EU level.
WP7. It aims to establish common procedures for conducting market surveillance campaigns, encouraging cooperation between competent authorities.
WP8. It will create training tools to uniformly develop skills and increase technical knowledge on regulations, including for in vitro diagnostic devices.

In parallel to the ongoing implementation of the regulations, the activities carried out will lay the foundations for increased dialogue and facilitate future coordination and cooperation between competent authorities through the adoption of adapted and consistent working methods. The project will thus help to enhance the safety of medical devices and thereby effectively contribute to the protection of public health by ensuring that medical devices on the market are safe, function as intended and remain in compliance with the applicable regulations.

Project – ACTION PLAN KOREA AND JAPAN

In 2024, representatives of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products took an active part in inter-ministerial consultations, where the Action Plan for the Implementation of the Strategic Partnership between the Government of the Republic of Poland and the Government of the Republic of Korea for 2025-2028 and the Action Plan for the Implementation of the Strategic Partnership between the Government of the Republic of Poland and the Government of Japan for 2025-2029 were established.

In addition, representatives of the Office took part in the Sixth Economic Consultation between Poland and the Republic of Korea, held at the headquarters of the Ministry of Development and Technology (MRiT) in September 2024.

Project EMA/GRANT/2024/02/IA – Medicines regulatory systems strengthening in Sub-Saharan Africa

The project is organised by the European Medicines Agency (EMA) and its aim is to support the development of regulatory systems on the African continent and to operationalise the African Medicines Agency (AMA). The role of the Registration Office for Medicinal Products, Medical Devices and Biocidal Products in this project is to provide a series of training courses for Botswana drug agency representatives on clinical trial registration as well as marketing authorisation. The project is scheduled to be implemented in 2025 and 2026.

In August 2024, the President of the Office Grzegorz Cessak had the pleasure of hosting H.E. Prof. Anastase Shyaka Ambassador of the Republic of Rwanda.
The conversation concerned the potential for future cooperation between Poland and Rwanda in the area of medicinal products and medical devices. However, the main topic of conversation was the functioning of the African Medicines Agency AMA, which has been based in Kigali, Rwanda since 2022.

Study of the potential use of AI in the performance of the tasks of the office

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products is actively exploring the use of artificial intelligence (AI) in the life cycle of medicinal products. In 2024, particular attention is being paid to AI in precision medicine, clinical data analysis, research support and drug registration and manufacturing processes.

AI can support individualisation of therapy, risk analysis, replacement of animal testing and pharmacovigilance. However, it is important to ensure data quality, regulatory compliance and risk control.

The Office is involved in initiatives of the European Medicines Regulatory Network and the Big Data Steering Group (BDSG), focusing on AI guidelines, international cooperation and pilot programmes. The use of AI has great potential, but requires continuous monitoring, testing and adaptation to changing regulations.

Coordination of the centralised procedure

In 2024, the experts of the Office worked intensively with all the Scientific Committees of the European Medicines Agency (EMA), evaluating medicinal products for both humans and animals.

Ms. Ewa Bałkowiec-Iskra, MD, PhD, DSc, Polish delegate to the Committee for Medicinal Products for Human Use (CHMP) put forward expert teams from URPLWMiPB for 21 new centralised procedures in the role of Co-Rapporteur and for 2 procedures as Rapporteur (Graph 4.3). As a result, the CHMP appointed Poland to lead 19 new marketing authorisation procedures. In addition, Poland was assigned 26 post-authorisation variation procedures.

For 130 medicinal products, the experts of the Office prepared scientific comments on the assessments prepared by the Rapporteurs and Co-Rapporteurs in each procedure. In 2024, the experts of the Office performed assessments in 32 post-registration variation procedures.

In addition, the experts of the Office also contributed to the pre-registration development of new human medicinal products. In the SAWP's Scientific Advice Working Group, Ms. Ewa Bałkowiec-Iskra, MD, PhD, DSc, and her collaborating experts produced 66 scientific advices, and the preparation of 14 qualifications for PRIME status (PRIority Medicines scheme).

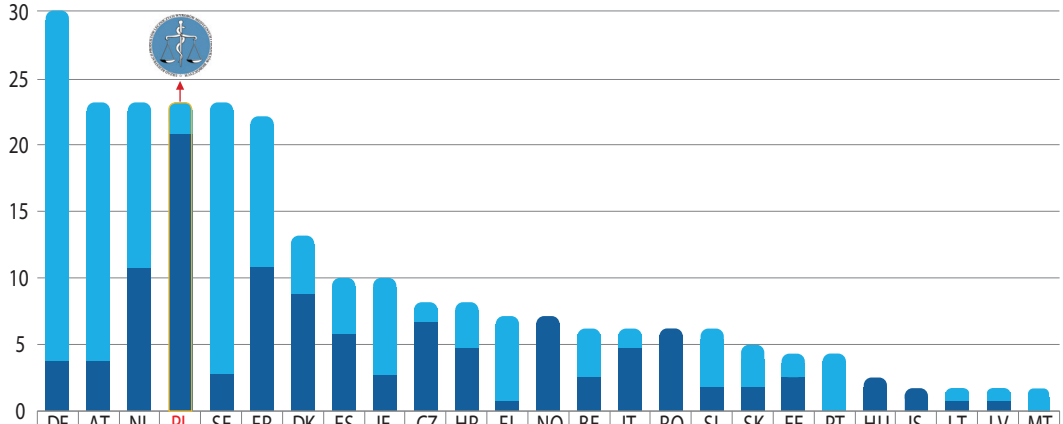
The experts of the Office also participated in the evaluation of 7 registration procedures for veterinary medicinal products. In the case of one of these procedures, the Polish representative on the Committee for Veterinary Medicinal Products (CVMP) acted as Rapporteurs for the first time during the registration of a new veterinary medicinal product and led an international expert team (MNAT). Polish specialists also participated in 2 post-registration variation procedures for veterinary medicinal products.

In cooperation with the Pharmacovigilance Risk Assessment Committee (PRAC), the experts of the Office assessed 2 new medicinal products submitted for registration in the central procedure in 2024 and also assessed 6 products in the re-registration procedure. In addition, 46 periodic safety report assessments (PSUSAs) were carried out for products registered in the central procedure. Post-registration variation procedures were also assessed and 22 comments on periodic safety reports were prepared.

Polish specialists also carried out the verification of 738 central information templates for medicinal products for human use and 89 for veterinary medicinal products.

The Polish delegate to the Committee on Herbal Medicinal Products has prepared in 2024: 7 new monographs, 16 monograph reviews, 15 monograph updates and 4 monograph reviews.

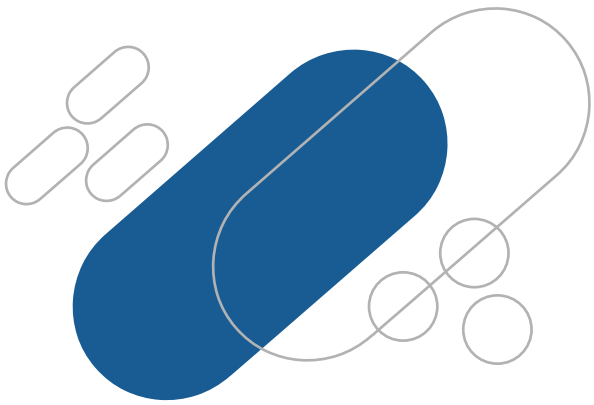
Graph 4.3: CHMP (Co-)Rapporteurships in pre-authorisation for Human Medicinal Products in 2024



	DE	AT	NL	PL	SE	FR	DK	ES	IE	CZ	HR	FI	NO	BE	IT	RO	SI	SK	EE	PT	HU	IS	LT	LV	MT
Total Rapporteurs	26	19	12	2	20	11	4	4	7	1	3	6	0	3	1	0	4	3	1	4	0	0	1	1	2
Total Co-Rapporteurs	4	4	11	21	3	11	9	6	3	7	5	1	7	3	5	6	2	2	3	0	3	2	1	1	0

Chapter 5

AREA OF COMPETENCE OF THE VICE-PRESIDENT OF THE OFFICE FOR MEDICINAL PRODUCTS



Marcin Kołakowski
Vice-President of the Office for Medicinal Products

For several years, Poland has been successively strengthening its position on the European arena as the Reference Member State (RMS) responsible for leading and coordinating the registration process in European procedures. In 2024, almost 32% of all applications submitted in the mutual recognition procedure (MRP) were applications where Poland played a leading and coordinating role in the procedure, while applications with Poland designated as the RMS in the decentralised procedure (DCP) accounted for 17.5% of all applications submitted in this procedure in 2024. This is once again the highest result achieved since the beginning of Poland's accession to the European Union.

URPLWMiPB, in collaboration with the eHealth Centre, carried out continuous work on the further development of the Hazard Monitoring System (HMS). The result of this work was the creation of a new version of the CMS. The work on the new system took into account the comments and experiences of the Staff of the Office and representatives of the medical profession and patients.

In 2024, work continued on the expansion of the Register of Medicinal Products. In this regard, the Office, in cooperation with the eHealth Centre, introduced in the second half of 2024 a new functionality for the public search engine of the Register of Medicinal Products for products authorised through the European central procedure by the European Commission. It provides that each medicinal product authorised through this procedure and available within the search engine has a direct link to the EU Register of Medicinal Products website, where decisions, leaflets and product characteristics are available. In addition, an instructional video is available on the same site, showing how the user can reach the document they are looking for.

In the previous year, URPLWMiPB has participated very actively in meetings, groups and teams at the European Medicines Agency (EMA). Representatives of the Medicinal Products Division are members of working groups at the EMA that develop common positions for all regulatory agencies dealing with medicinal products in the European Union.

In addition, representatives of the Medicinal Products Division have joined educational activities at the Faculty of Pharmacy of the Warsaw Medical University. Classes are conducted for students of the fifth year, during which issues of medicine registration, post-registration variations, evaluation of documentation of medicinal products, inspection of clinical trials,

participation of URPLWMiPB representatives in the work of EMA working groups and committees, as well as the principles of marketing under parallel import are discussed. Issues concerning the Polish Pharmacopoeia and the use of sources of information on medicine are also discussed.

In addition, the Office supported the activities of candidate countries for accession to the European Union, such as Moldova and Ukraine. At working meetings, we shared knowledge and experience so that the new countries would benefit as much as possible during their preparations for accession to EU structures.

In summarising the achievements of the past year, it is important to emphasise the enormous commitment, from both staff and management, put into the Division's tasks and responsibilities, for which I thank everyone.

Marcin Kołakowski
Vice-President of the Office for Medicinal Products

Performance of tasks in the area of medicinal products

In the area of medicinal products, a total of 46,424 applications were accepted in 2024, and 59,856[1] proceedings were completed.

Marketing authorisation for medicinal products, post-authorisation variations and renewals of medicinal products

In Poland, decisions on marketing authorisations for medicinal products are issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Each medicinal product undergoes a verification and evaluation procedure where, on the basis of the documentation received, the fulfilment of the formal requirements and the requirements concerning the quality, efficacy and safety of the medicinal product is verified.

Marketing authorisation procedures for medicinal products are conducted through the national procedure (NP) and the European procedures: mutual recognition procedure (MRP) or decentralised procedure (DCP).

If a medicinal product has not yet been authorised in any Member State of the European Economic Area, the marketing authorisation decision may be sought by the marketing authorisation holder in a national procedure or in a decentralised procedure.

Under the decentralised procedure, the marketing authorisation is based on the assessment report prepared by the competent authority of the Member States, which evaluates the dossier. Most applicants choose this procedure as it allows a new medicinal product to be authorised simultaneously in several countries of the European Economic Area.

A medicinal product that has already been registered in one Member State is subject to a mutual recognition procedure whereby it can obtain a marketing authorisation on the basis of recognition of an assessment report on an authorisation issued in another Member State.

In 2024, 15,788 applications were registered for marketing authorisations, extensions, shortenings, and post-authorisation variations of medicinal products**.** Detailed data are presented in Table 5.1 and Graph. 5.1.

In 2024, the Office received 99 applications for marketing authorisation for a medicinal product/ pharmaceutical raw material, of which 169[2] in the national procedure, 114 in the mutual recognition procedure and 711 in the decentralised procedure (Graph. 5.2).

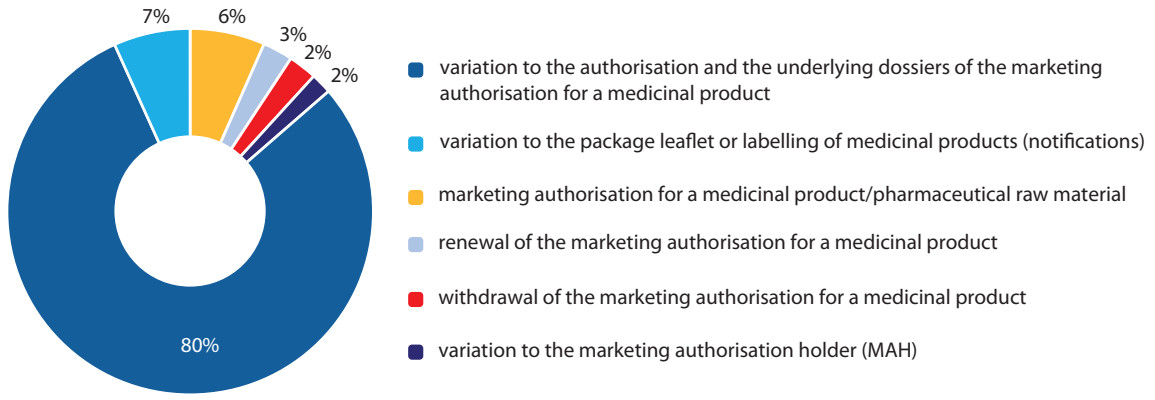
[1] The number of proceedings includes the number of variations.

[2] The figure takes into account 4 applications made at second instance.

Table 5.1: Number of applications submitted, by procedure, for marketing authorisation, renewal, shortening of the authorisation period, and for post-authorisation variations to of medicinal products from 1 January 2024 to 31 December 2024

Type of application	Type of procedure			Number of applications received
	NP	MRP	DCP	
marketing authorisation for a medicinal product/pharmaceutical raw material	181	120	743	**1,044**
renewal of the marketing authorisation for a medicinal product	417			**417**
withdrawal of the marketing authorisation for a medicinal product	397			**397**
variation to the marketing authorisation holder (MAH)	288			**288**
variation to the authorisation and the underlying dossiers of the marketing authorisation for a medicinal product	3,318	9,247		**12,565**
variation to the package leaflet or labelling of medicinal products (notifications)	964	103		**1,067**
Total	**15,778**			

Graph. 5.1: Number of applications submitted, as a percentage, concerning medicinal products received by the Office from 1 January 2024 to 31 December 2024

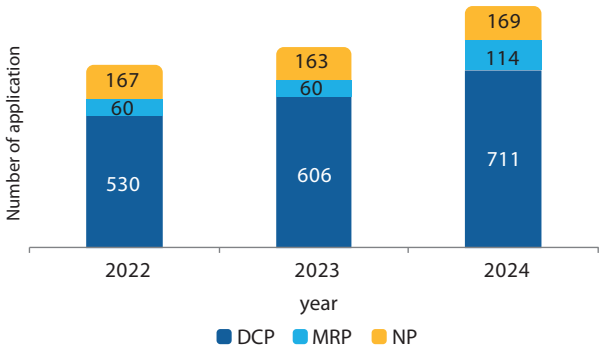


For both permits issued in the national procedure and in the European procedures, it is possible to submit grouped variations. Under this procedure, it is possible to submit more than one variation per application.

In 2024, a total of 30,136 variations were submitted as part of 13,920 applications to make variations to the authorisation and underlying documentation for a medicinal product, to make variations to the package leaflet or labelling of medicinal products and to change the Marketing Authorisation Holder.

80% of all submitted applications concern post-authorization variations to the marketing authorisation and its underlying dossier (Graph. 5.1).

Graph. 5.2: Number of submitted applications concerning medicinal product/pharmaceutical raw material[3] authorisations, by procedure, in 2022–2024



[3] Applications submitted at the second instance are included.

In addition, with regard to the non-expiry of the marketing authorisation of the medicinal product sunset clause, 457 applications were submitted and 457 proceedings were completed, of which 452 proceedings were concluded with a positive decision.

In 2024, a total of 15,435 proceedings concerning medicinal product authorisation were completed (Table 5.2). The largest group consisted of proceedings concerning variation to the authorisation and the dossier underlying the marketing authorisation of a medicinal product – 79% (Graph. 5.4).

A total of 28,945 variations were completed as part of proceedings to make variations to the authorisation and the dossier on which the marketing authorisation for the medicinal product is based, to make variations to the package leaflet or labelling of medicinal products and to make variations to the Marketing Authorisation Holder.

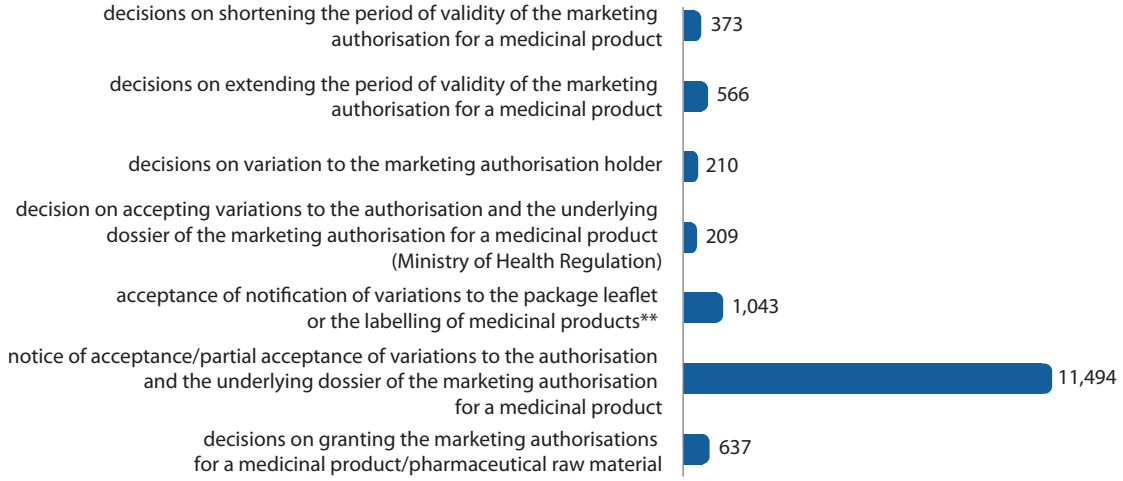
Most cases handled by the Office concerning variations to the data covered by the authorisation and the underlying dossier of the marketing authorisation for a medicinal product result in issuing a notice of acceptance/partial acceptance of the variation. In 2024, 11,494 proceedings were completed this way.

Table 5.2: Number of completed proceedings for medicinal products from 1 January 2024 to 31 December 2024

Type of proceedings	Number of completed proceedings
granting the marketing authorisation for a medicinal product/pharmaceutical raw material	875
renewal of the marketing authorisation for a medicinal product	677
withdrawal of the marketing authorisation for a medicinal product	393
variation to the authorisation and the underlying dossier of the marketing authorisation for a medicinal product	12,192
variation to the package leaflet or the labelling of medicinal products	1,062
variation to the marketing authorisation holder	236
Total	**15,435**

Graph. 5.3: Number of completed proceedings, as a percentage, concerning medicinal products from 1 January 2024 to 31 December 2024

Graph. 5.4: Number of favourable decisions/notices concerning medicinal products from 1 January 2024 to 31 December 2024



**notification of acceptance of notification - 987 and acceptance of notification without issuance of notification (including CMS) – 56

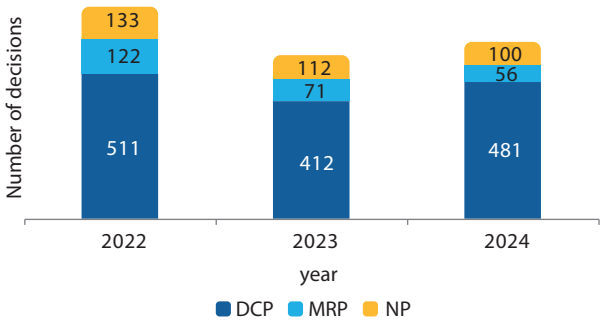
In addition, as regards variations to the authorisation and the underlying dossier on which the marketing authorisation for the medicinal product, 2,528 decisions were issued to amend the data covered by the marketing authorisation for the medicinal product on the basis of Regulation 1234/2008 – the decision is issued for specific proceedings on completed variations.

In 2024, 611 medicinal product marketing authorisation decisions and 26 pharmaceutical raw material marketing authorisations were issued.

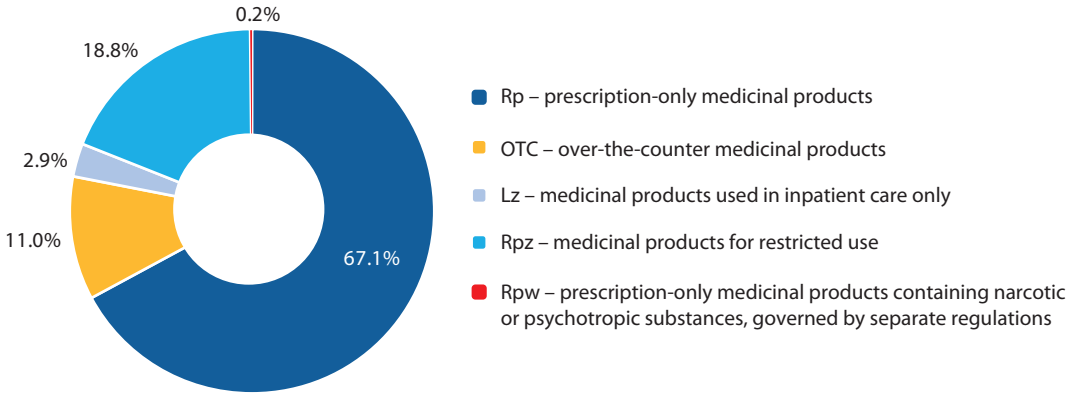
Of the medicinal products authorised for marketing in 2024, the majority (more than 67%) were products with the Rx legal status, i.e. products dispensed under medical prescription. Products with a prescription for restricted use, i.e. with an Rpz legal status, accounted for nearly 19% of the authorisations granted, while OTC medicinal products, i.e. those not subject to prescription, accounted for 11% (Graph. 5.6).

Among the marketing authorisations granted in 2024, the largest number was granted for medicinal products for the treatment of the central nervous system (19.1%), blood and haematopoietic diseases (17.8%), and the anticancer and immunomodulatory medicine group (17.7%) (Graph. 5.7).

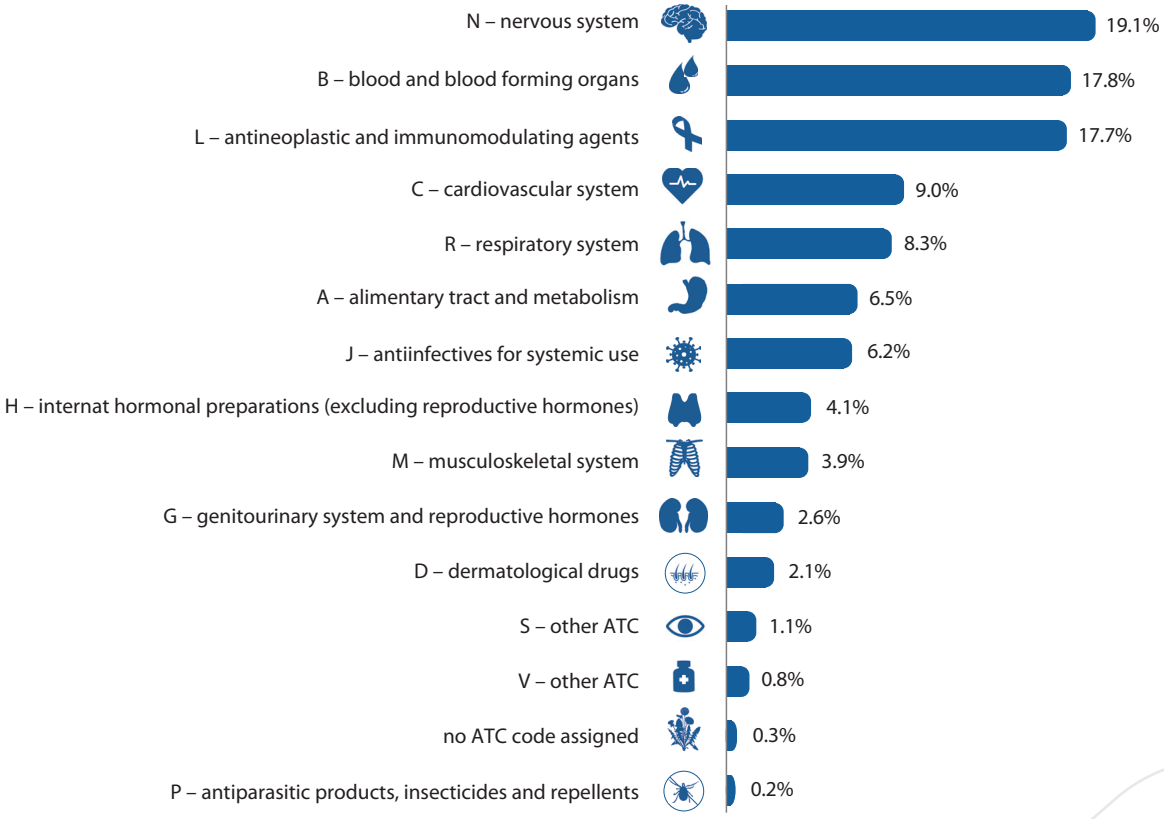
Graph. 5.5: Number of decisions on granting the marketing authorisation for a medicinal product/ pharmaceutical raw material by procedure in 2022–2024



Graph. 5.6: Number of authorised medicinal products, as a percentage, by availability category in the period from 1 January 2024 to 31 December 2024



Graph. 5.7: Number of decisions on granting the marketing authorisation for a medicinal product by ATC[4] code from 1 January 2024 to 31 December 2024



[4] The Anatomical Therapeutic Chemical (ATC) Classification – a system for organising medications and other agents and products used in medicine.

Provision of scientific advice

The President of the Office shall provide scientific advice on the conduct of tests and studies necessary to demonstrate the quality, safety or efficacy of medicinal products for human use on qualitative, clinical, non-clinical aspects, pharmacovigilance or methodological issues of ongoing or planned studies.

In addition, in 2024 URPLWMiPB was included in Phase 2b of the Simultaneous National Scientific Advice (SNSA) pilot project. The SNSA procedure is designed for applicants who wish to receive scientific advice in more than one country at the same time.

Maintenance of the Register of Medicinal Products and publication of the Official List of Medicinal Products Authorised in the Republic of Poland

Under Article 28 (2) of the Pharmaceutical Law (Dz. U. of 2024, item 686), the Register of Medicinal Products Authorised on the territory of the Republic of Poland is maintained by the President of URPLWMiPB. The Register includes medicinal products authorised by the President of the Office under the national (NP), mutual recognition (MRP) and decentralised (DCP) procedures. The Register also includes medicinal products with authorisation issued by the European Commission in the centralised procedure (CP) and medicinal products with a parallel import licence (PI). Information on newly authorised medicinal products is published on the website of the Public Information Bulletin (BIP) in the form of monthly bulletins.

The Register is a source of information on authorised medicinal products for doctors, pharmacists, central authorities competent for pharmaceutical market surveillance and patients. Information from the Register, in terms of data of a non-confidential nature, is available in electronic form on the website: https://rejestry.ezdrowie.gov.pl/rpl/search/public.

The Register of Medicinal Products is the basis for developing an official list of Medicinal Products authorised in the territory of the Republic of Poland, published in the form of the announcement of the President of the Office in the Official Journal of the Minister of Health. In the part concerning medicinal products for humans, the document contains: a list of medicinal products authorised in the territory of the Republic of Poland, the total number of which is 10,490 products, a list of medicinal products authorised on the basis of permits issued by the European Commission in the number of 3,160 permits and a list of medicinal products which obtained parallel import permits in the number of 3,019.

Information on the list of veterinary medicinal products is provided later in the report.

Granting of parallel import licences for medicinal products

Parallel import of medicinal products consists in importing to Poland medicinal products that have been granted a marketing authorisation issued in a Member State of the European Union or a Member State of the European Free Trade Association (EFTA) – a party to the Agreement on the European Economic Area and which have been granted a parallel import licence. Provisions concerning parallel import of medicinal products were included in the Act of 6 September 2001. Pharmaceutical Law (Dz. U. of 2024, item 686). In Poland, the parallel import licence is issued by the President of the Office.

In 2024, the Office received 1,573 applications for parallel imports of medicinal products, including 496 applications for parallel import licences.

Within the filed applications, a total of 1,574 proceedings were completed, including 449 decisions on the authorisation of parallel import of a medicinal product, i.e. a 43% increase compared to 2023.

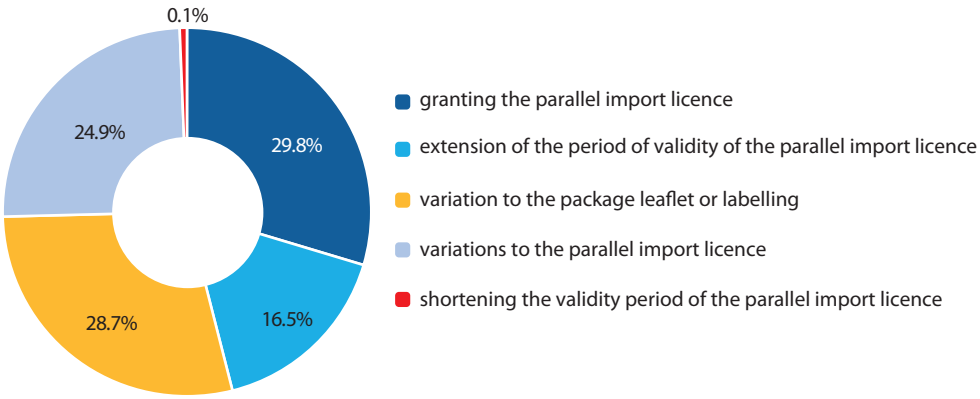
Detailed data on completed proceedings is presented in Table 5.3 and Graph. 5.8.

As in the previous years, the largest number of parallel import licences were prescription-only medicinal products (Rp) – 80% of all the licences. Over-the-counter (OTC) products accounted for 16% of licences issued (Graph. 5.10).

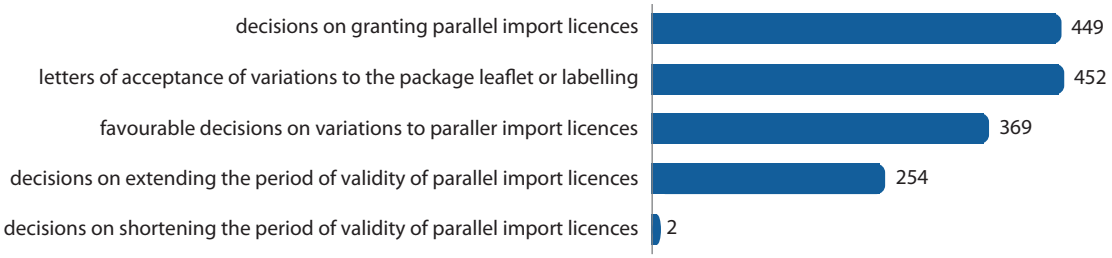
Table 5.3: Number of completed proceedings concerning parallel import from 1 January 2024 to 31 December 2024

Process name	Number of completed proceedings
granting the parallel import licence	469
extension of the period of validity of the parallel import licence	259
shortening the validity period of the parallel import licence	2
variation to the package leaflet or labelling	452
variations to the parallel import licence	392
Total	**1,574**

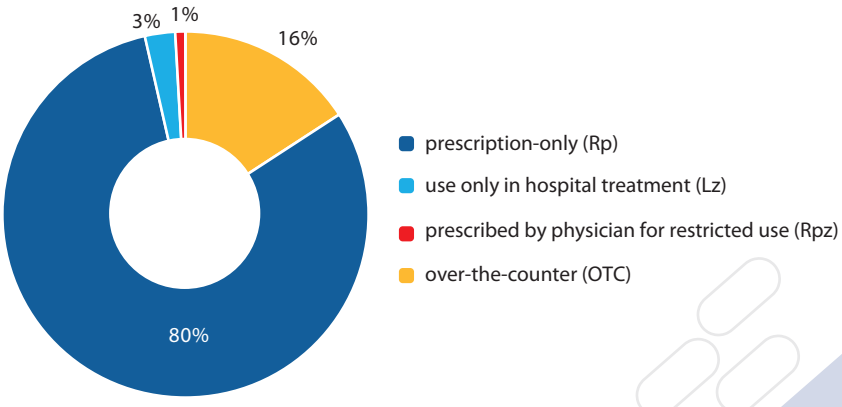
Graph. 5.8: Number of completed proceedings, as a percentage, concerning parallel import from 1 January 2024 to 31 December 2024



Graph. 5.9: Number of favourable decisions/letters issued by the Office concerning parallel import from 1 January 2024 to 31 December 2024

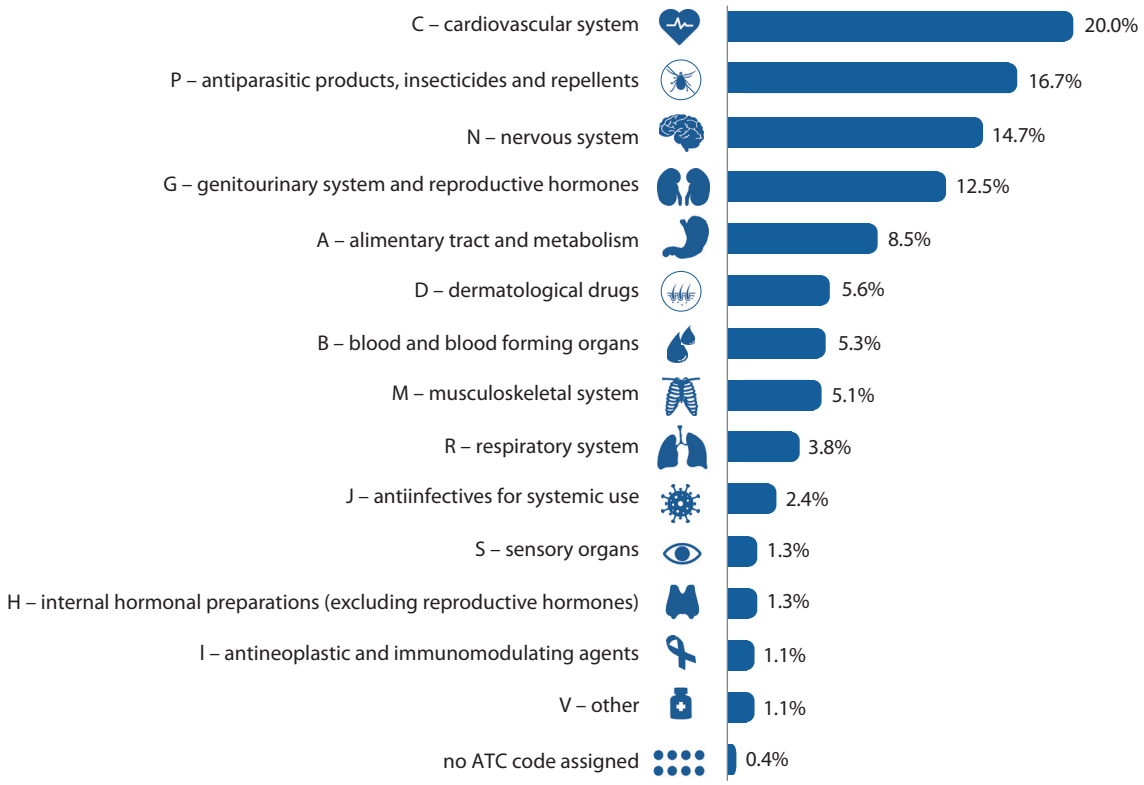


Graph. 5.10: Number of parallel import licences, as a percentage, issued by availability category from 1 January 2024 to 31 December 2024



Graph. 5.11: Number of parallel import licences issued by country of export from 1 January 2024 to 31 December 2024

Graph. 5.12: Number of parallel import licences issued, by ATC code, in the period from 1 January 2024 to 31 December 2024



In 2024, the largest number of parallel import licences were issued for medicinal products from Greece, Romania and Bulgaria (Graph. 5.11).

Considering the classification of medicinal products in terms of ATC code, the predominant number of parallel import licences in 2024 was for medicinal products for cardiovascular diseases – 20% (Graph. 5.12).

Issuance of approvals by the President of the Office for importing medicines from abroad for private medicinal use and approvals of the President of the Office under Article 4b[5] and 4c of the Pharmaceutical Law

In 2024, the Office received 683 applications for the President of the Office's approval to import medicines from abroad for private medicinal use and approvals under Articles 4b and 4c of the Pharmaceutical Law. The President of the Office issued 454 approvals for importing medicines from abroad for private medicinal use, 56 approvals under Article 4b and 171 approvals under Article 4c of the Pharmaceutical Law.

Collection of notifications of temporary or permanent suspension of marketing of a medicinal product

At least two months before the date on which the medicinal product ceases to be placed on the market unless there are exceptional circumstances, the marketing authorisation holders submit a notification of the temporary or permanent suspension of marketing of a given medicinal product. In 2023, the Office received 5,231 such notifications, which were then forwarded to the Ministry of Health, the Chief Pharmaceutical Inspectorate, the National Health Fund and the Polish Pharmaceutical Chamber.

[5] Article 4b of the Pharmaceutical Law: „ The President of URPLWMiPB may authorise foreign-language content of packaging labelling for a certain number of packages of orphan medicines as defined in Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ EC L 18, 22.01.2000, p. 1; OJ EU Official Journal Polish Special Edition, Chapter 15, Vol. 5, p. 21)."

Proceedings for the authorisation of clinical trials on medicinal product

In accordance with Article 9 paragraph 2 of the Act of 9 March 2023 on clinical trials on medicinal products for human use, the President of the Office is the competent authority, inter alia, to conduct proceedings for the authorisation of a clinical trial and the authorisation of a substantial modification of a clinical trial.

The year 2024 was the culmination of the transition period set by the provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC. In accordance with the provisions of the aforementioned Regulation, as of 31 January 2025, trials approved under Directive 2001/20/EC on clinical trials that are still ongoing must be brought into line with the requirements of the Clinical Trials Regulation and entered into CITS.

In 2024, the Office received 1,411[6] applications to initiate clinical trials of a medicinal product and completed 1,511[7] proceedings.

In addition, 2,600[8] requests for material variations to the clinical trial dossier based on the provisions arising from Directive 2001/20/EC and on the provisions of Regulation 536/2014 were submitted to ongoing clinical trials, while 2,247 proceedings were completed in this regard.

In terms of monitoring the safety of medicinal products during clinical trials, the Office received 2,590 cases.

In accordance with the applicable legislation, i.e. Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards establishing rules and procedures for cooperation between Member States in assessing the safety of clinical trials, 118 new active substances requiring safety assessment Member State (saMS) monitoring were allocated to Poland during 2024, bringing the total number of substances monitored by Poland to 166 at the end of 2024. The impact included the preparation of 1,548 data sets for the review of suspected unexpected serious adverse reactions (SUSARscreening) with the resulting assessments.

In addition, 1,363 Annual Safety Reports and 1,057 Final Reports from clinical trials were received in 2024.

Pharmacovigilance and safety monitoring of medicinal products

Adverse reactions to a medicinal product are both the adverse and unintended effect of using the medicine as described in the information leaflet and the effect of misuse, use outside the terms of the marketing authorisation, including misuse resulting from an overdose of the medicinal product or a medical error in the use of the medicinal product.

Adverse reactions to medicinal products can be reported by professionals in the healthcare system, pharmaceutical companies as well as by patients themselves and their carers. URPLWMiPB makes it possible to report adverse reactions by traditional mail, fax, e-mail or telephone. In addition, the Office provides the possibility to report adverse reactions to medicinal products via electronic forms, located in the Hazard Monitoring System (HMS), at: https://smz2.ezdrowie.gov.pl/.

The reporting of adverse reactions via HMS electronic forms and the Office's compilation of reports of adverse reactions to medicinal products collected in the HMS is the result of the Office's cooperation with the eHealth Centre (CeZ) as part of its patient-centred activities, including enhancing the safety of medicinal products by implementing solutions leading to greater accessibility and electronicisation.

The Office is active in promoting the reporting of adverse reactions. A number of information campaigns are carried out as part of the ˝Safe Drug˝ campaign, e.g. short educational films are produced to promote safe pharmacotherapy. All these activities are aimed

[6] The figure of 1,411 includes 579 applications to start clinical trials (new applications), 824 applications (Transitional Trials applications) and 8 applications submitted at second instance.

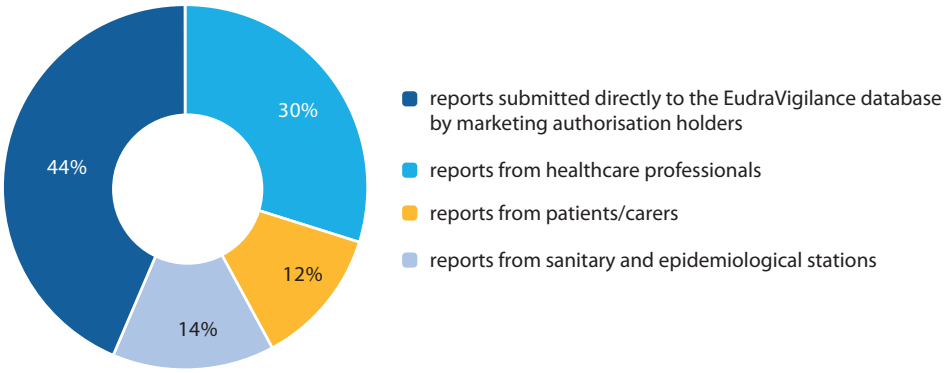
[7] The total number of 1,511 includes: 1,487 positive decisions, comprising: 786 approvals for new clinical trials (excluding Transitional Trials), 686 positive decisions for Transitional Trials, 13 conditional approvals, and 2 presumed consents.

[8] The figure of 2,600 includes applications made under the provisions arising from Directive 2001/20/EC and applications made under the provisions of Regulation 536/2014, as well as 1 application made at second instance.

Table 5.4: Summary of reports of individual cases of adverse reactions to medicinal products in Poland, by severe and non-severe cases, from 1 January 2024 to 31 December 2024

Type of report	Number of severe cases reported	Number of non-severe cases reported	Total
reports from healthcare professionals	1,927	4,417	6,344
reports from patients/carers	1,008	1,588	2,596
reports from sanitary and epidemiological stations	446	2,600	3,046
Total			**11,986**

Graph. 5.13: Number of reports of individual cases of adverse reactions to medicinal products, as a percentage, in Poland from 1 January 2024 to 31 December 2024



at creating a system to ensure that the information received contributes to improving patient safety. The Office has been running a website dedicated to the safety of pharmacotherapy at www.urpl.gov.pl/pl/produkty-lecznicze/monitorowanie-bezpieczenstwa-lekow, providing key information and guidance on reporting adverse reactions.

In addition, the Office's website publishes communications on the safety of medicines, including, inter alia, recommendations developed by the Pharmacovigilance Risk Assessment Committee.

In 2024, 11,986 reports of adverse reactions to medicinal products were submitted directly to the Office, including 6,344 from healthcare professionals, 2,596 from patients or their carers and 3,046 from the State Sanitary Inspectorate, concerning vaccine adverse events (Table 5.4).

In addition, 9,253 reports of adverse reactions to medicinal products were collected by the marketing authorisation holders and submitted directly to the EudraVigilance database, including 4,001 reports on severe adverse reactions.

The percentage of reports of individual cases of adverse reactions to medicinal products in Poland in 2024 is presented in Graph. 5.13.

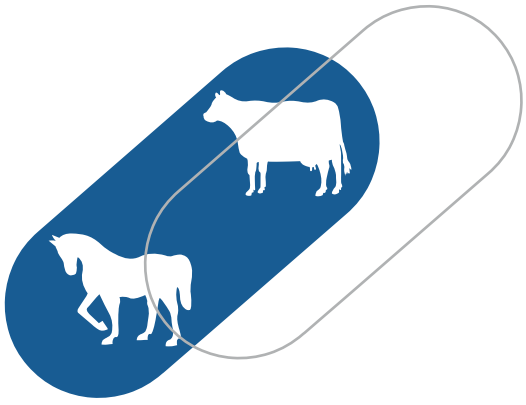
A total of 16,157 assessed adverse reaction reports were sent to the EudraVigilance database.

As regards the evaluation of potential signals, the Office received 230 eRMR reports prepared by the EMA concerning substances allocated to Poland under the division of labour (a double increase compared to 2023). These reports contained 3,203 adverse reactions requiring assessment by the Office. All potential signals contained in the EMA reports were analysed. The data analysed by the Office did not confirm any new signals.

Furthermore, pharmacovigilance activities included reviewing and evaluating 30 safety communications and 207 educational materials prepared by by marketing authorisation holders.

Chapter 6

AREA OF COMPETENCE OF THE VICE-PRESIDENT OF THE OFFICE FOR VETERINARY MEDICINAL PRODUCTS



Agata Andrzejewska
Vice-President of the Office for Veterinary Medicinal Products

The year 2024 was another period of implementation of Regulation (EU) No 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ EU L 4, 07.01.2019, p. 43, as amended), hereinafter referred to as 'Regulation 2019/6'. The Division's work mainly focused on streamlining existing procedures and creating new ones to meet the requirements of Regulation 2019/6.

As part of the cooperation with the eHealth Centre (CeZ), particular emphasis was placed on the development and maintenance of the Register of Medicinal Products Authorised for Marketing in the territory of the Republic of Poland (RPL) for veterinary medicinal products, in order to maintain consistency of the RPL with the EU database on veterinary medicinal products (UPD).

In 2024, we have intensively continued, in cooperation with the Coordination Group on Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv), the work related to the procedure for harmonisation of the characteristics of reference veterinary medicinal products. This substantive undertaking entails the next stage of harmonisation of characteristics – harmonisation of generic and hybrid veterinary medicinal products, carried out as part of post-registration variations requiring assessment. We have entered the implementation phase of this project in 2024.

We have also continued our work on the adaptation of product information to the requirements of Articles 10-16 of Regulation 2019/6. In Poland, amendments under a single post-registration variation requiring assessment concern approximately 2,200 marketing authorisations for veterinary medicinal products. The entire process for all marketing authorisations should be completed by 29 January 2027. With each passing year, work under this procedure is gaining momentum and more applications are submitted.

As part of educational activities, representatives of the division participated as speakers at numerous scientific conferences on issues related to the registration and use of medicinal products in animals. In addition, in 2024 we took an active part in the educational campaign, ″Safe drugs – safe animals – safe people″, to draw attention to the issues of

adverse events related to the use of veterinary medicinal products.

The second half of 2024 was marked by preparations, for the Polish Presidency of the Council of the European Union. In May 2025 Veterinary Medicinal Products Division will host the meeting of ´The Committee for Veterinary Medicinal Products and the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products˝. The organisation of the aforementioned meeting will be a major challenge for the Division.

Agata Andrzejewska
Vice-President of the Office for Veterinary Medicinal Products

Performance of tasks in the area of veterinary medicinal products

In the field of veterinary medicinal products, a total of 4,712 applications were accepted in 2024 and 3,420 proceedings were completed (number of proceedings taking into account the number of variations).

Marketing authorisation for veterinary medicinal products, post-registration variations and re-registration of veterinary medicinal products

The current provisions of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC place a strong emphasis on ensuring a high level of public health protection and safety through the implementation of a number of measures in line with the 'One Health' approach, most notably: supervision of the reduction of uncontrolled use of antibiotics in animals, the creation of a list of antibiotics reserved for use only in humans and, consequently, the reduction of the development of drug resistance.

A veterinary medicinal product is placed on the market after obtaining a marketing authorisation issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in the course of the national procedure (NP), decentralised procedure (DCP), mutual recognition of marketing authorisations issued in the national procedure (MRP) and in the procedure of subsequent recognition procedure for marketing authorisations by additional Member States concerned (SRP) or in the centralised procedure.

In 2024, a total of 2,353 applications were registered for veterinary medicinal product authorisations, variations requiring evaluation and re-registration and notifications for variations not requiring assessment.

As in previous years, the largest category of applications – 91.9% concerned variations to the marketing authorisation for a medicinal product or variations to the dossier on which the marketing authorisation of a veterinary medicinal product was granted (Graph 6.1).

In both the national procedure and the European procedures, it is possible to group post-registration variations. It is, therefore, possible to submit more than one post-registration variation in a single application.

In 2024, 3,221 post-registration variations were submitted as part of the 2,163 applications for variations to the authorisation and underlying dossier for a veterinary medicinal product and notifications for variations not requiring assessment.

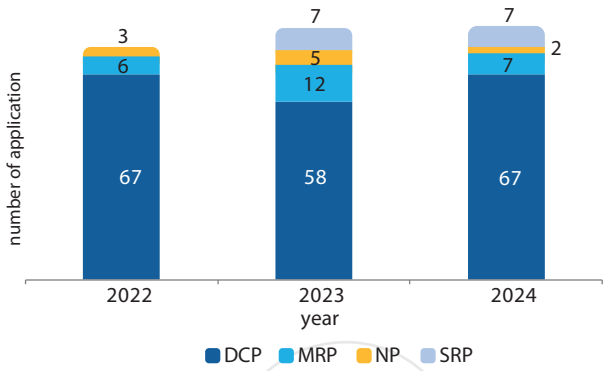
Applications for marketing authorisation of a veterinary medicinal product accounted for 3.5% of all applications for veterinary medicinal products. In 2024, the Office received 78 applications for marketing authorisation of a veterinary medicinal product. The largest number of applications in this area are submitted under the decentralised procedure (DCP) (Graph. 6.2), which allows a marketing authorisation to be obtained in several EU countries simultaneously.

Graph. 6.1: Percentage of submitted applications concerning veterinary medicinal products received by the Office from 1 January 2024 to 31 December 2024

Table 6.1: Number of applications submitted for marketing authorisations, renewals, shortenings of authorisations and post-authorisation variations of veterinary medicinal products from 1 January 2024 to 31 December 2024

Type of application	Number of applications
granting a marketing authorisation for a veterinary medicinal product	83
variations to the marketing authorisation and to the documentation based on which the marketing authorisation for the veterinary medicinal product was granted	2,163
change of the marketing authorisation holder (MAH) for veterinary medicinal products	18
renewal of the marketing authorisation for a veterinary medicinal product (NP, MRP, DCP)	37
shortening of the validity period of the marketing authorisation for a veterinary medicinal product	52
Total	**2,353**

Graph. 6.2: Number of submitted applications for the marketing authorisation for veterinary medicinal products, by procedure, from 2022 to 2024



In 2024, a total of 2,689[1] proceedings for marketing authorisation, post-registration and re-registration of veterinary medicinal product were completed, of which as many as 89% were proceedings of variations to marketing authorisation and to the dossier on which the veterinary medicinal product authorisation was based. Detailed data on completed proceedings are presented in Table 6.2 and Graph. 6.3.

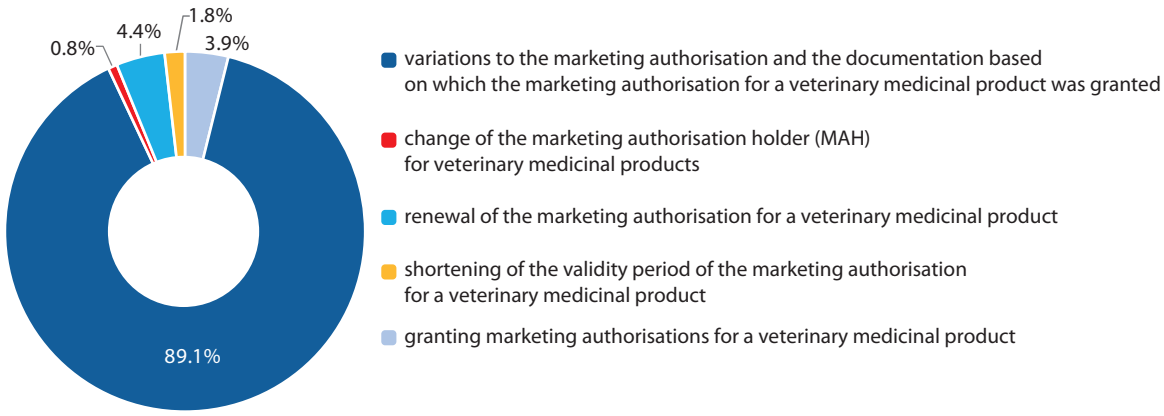
The majority of the proceedings considered by URPLWMiPB regarding variations to marketing authorisation and variations to the dossier on which the marketing authorisation of a veterinary medicinal product was based concerned variations not requiring an assessment (VNRA) and resulted in the acceptance of 1 427 VNRA variations.

[1] Number of proceedings not including number of variations. The number of proceedings including the number of variations is 2,918.

Table 6.2: Number of completed authorisations, renewals, shortenings and post-authorisation variations of veterinary medicinal products from 1 January 2024 to 31 December 2024

Type of proceedings	Number of completed proceedings
granting marketing authorisations for a veterinary medicinal product	104
variations to the marketing authorisation and to the documentation based on which the marketing authorisation for a veterinary medicinal product was granted	2,397[2]
change of the marketing authorisation holder (MAH) for veterinary medicinal products	22
renewal of the marketing authorisation for a veterinary medicinal product	117
shortening of the validity period of the marketing authorisation for a veterinary medicinal product	49
Total	**2,689**

Graph. 6.3: Percentage of completed proceedings concerning veterinary medicinal products from 1 January 2024 to 31 December 2024



In addition, 635 decisions varying the marketing authorisation for a veterinary medicinal product or the documentation were issued to complete the procedures concerning variations requiring assessment (VRA) carried out under Regulation 2019/6.

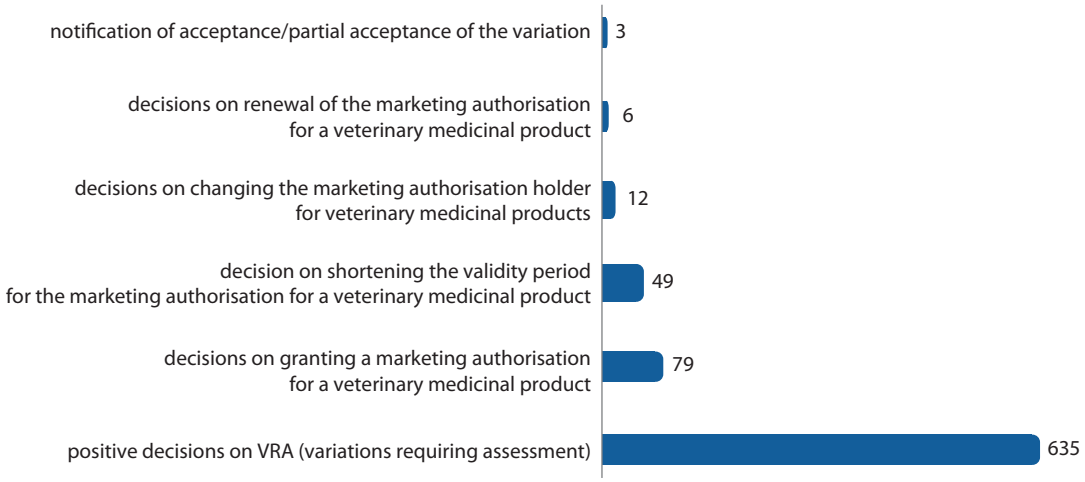
In addition, 126 decisions varying the marketing authorisation for a veterinary medicinal product were issued in the course of variations not requiring assessment (VNRA) under Regulation 2019/6 and of variations to marketing authorisation of veterinary medicinal product under Regulation 1234/2008.

It should be noted that, in the case of procedures conducted under Regulation 2019/6, a decision is issued to close every procedure concerning variations requiring assessment (VRA) and selected variations not requiring assessment (VNRA) whose outcome has been recorded in the Union database of veterinary medicinal products (UPD) and which necessitate an amendment to the provisions of the marketing authorisation decision for the veterinary medicinal product. In the case of variation procedures conducted in accordance with Regulation 1234/2008, the decision shall be issued in relation to the procedures completed with notification.

In accordance with Article 152 sec.1 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, marketing authorisations for veterinary products and registrations of homeopathic veterinary medicinal products issued in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before 28 January 2022 shall be deemed to have been issued in accordance with this Regulation and shall therefore be subject to the relevant provisions of this Regulation.

[2] Number of completed proceedings not including number of variations. Number of variations 2,626.

Graph. 6.4: Number of positive decisions/notices concerning veterinary medicinal products from 1 January 2024 to 31 December 2024

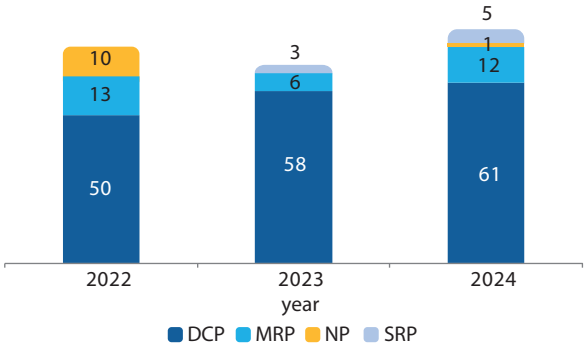


In 2024, there were 79[3] positive marketing authorisation decisions for a veterinary medicinal product, the highest number in the decentralised procedure (DCP).

The safety, efficacy and quality of a veterinary medicinal product shall be assessed before a decision on the marketing authorisation of the product is granted. The evaluation shall take place on the basis of the dossier submitted by the marketing authorisation holder.

An additional requirement for medicinal products for food-producing animals (farm animals) is the submission of documentation confirming the safety of products from treated animals for consumers of food of animal origin (meat, milk, eggs, honey), i.e. documentation on the length of the withdrawal period. These products are subject to veterinary prescription. Veterinary medicinal products classified as subject to veterinary prescription accounted for 100% of the veterinary medicinal product marketing authorisations issued.

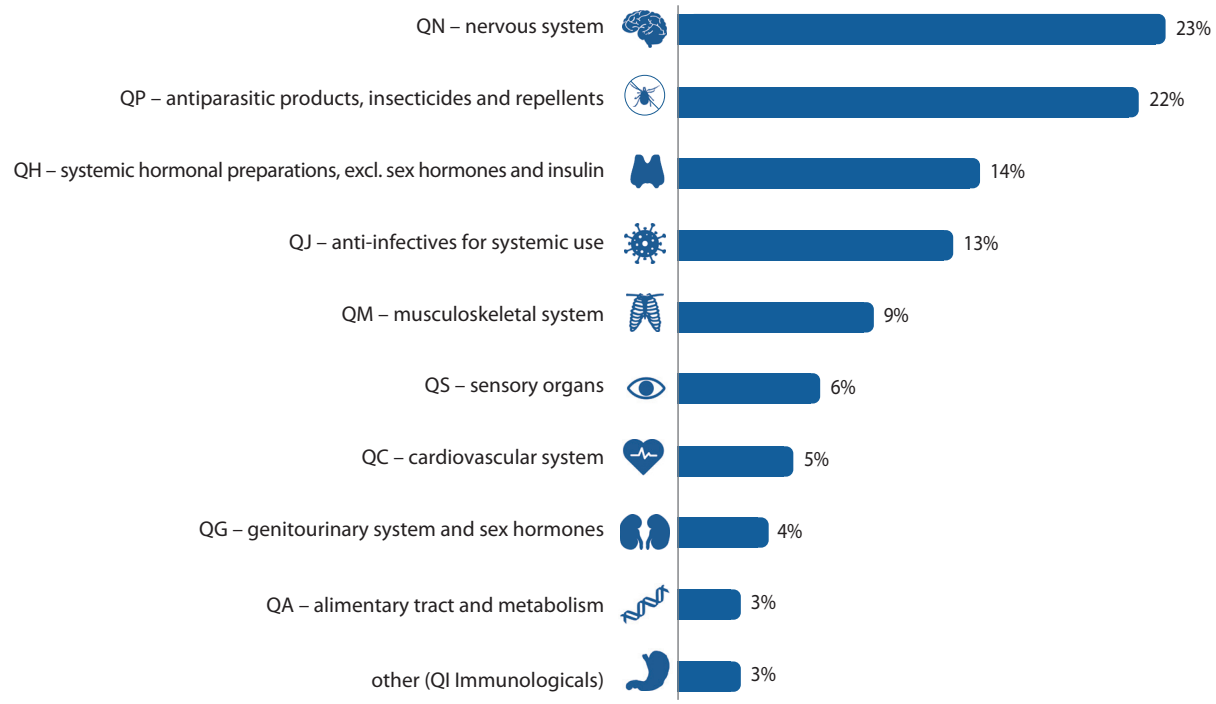
Graph. 6.5: Number of decisions on granting marketing authorisations for veterinary medicinal products, by procedure, in 2022 - 2024



Among veterinary medicinal product authorisations granted in 2024, authorisations for medicines for diseases of the central nervous system predominated, with 23%, and authorisations for antiparasitic, insecticidal and repellent medicines, with 22% (Graph. 6.6).

[3] In accordance with Article 152(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, marketing authorisations for veterinary products and registrations of homeopathic veterinary medicinal products issued in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 before 28 January 2022 shall be deemed to have been issued in accordance with this Regulation and shall therefore be subject to the relevant provisions of this Regulation.

Graph. 6.6: Percentage of decisions on granting marketing authorisations for veterinary medicinal products by ACTvet codes, issued from 1 January 2024 to 31 December 2024



Harmonisation of reference summaries for veterinary medicinal products

In 2024, URPLWMiPB, in cooperation with the Coordination Group on Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv), carried out tasks related to the procedure for harmonisation of the characteristics of reference veterinary medicinal products. In 2024, the Office received 5 applications for the harmonisation of the characteristics of reference veterinary medicinal products and 3 decisions were granted in this regard.

Maintaining the Register of Medicinal Products, providing information and publication of bulletins and lists concerning veterinary medicinal products authorised in the territory of the Republic of Poland

The Office maintains the Register of Medicinal Products Authorised for Marketing in the territory of the Republic of Poland, which includes veterinary medicinal products in addition to the human medicinal products already mentioned.

The Register of Veterinary Medicinal Products is a database of authorised veterinary medicinal products. Information shall be entered in the register about the veterinary medicinal product in accordance with the marketing authorisation decision together with all variations accepted after the medicinal product was authorised. The Summary of Product Characteristics of Veterinary Medicinal Products, which is a detailed description of the product characteristics, is also part of the Register.

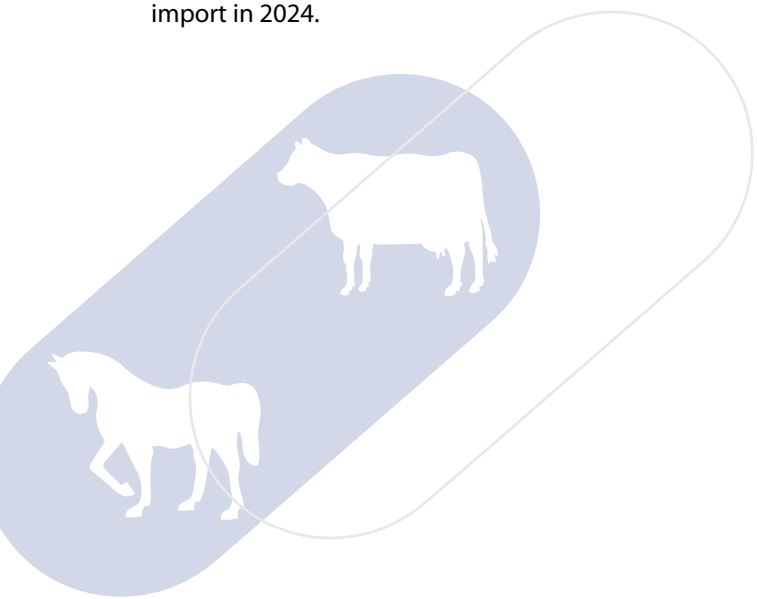
The Register is maintained in the form of record books as well as in the form of an IT system and is a publicly accessible database. The Register is made available in electronic form on the website: https://rejestrymedyczne.ezdrowie.gov.pl/rpl/search/public. Information on new marketing authorisations granted is published on the Office's website.

Based on the information collected in the Register, monthly bulletins are published on the Office's website containing a list of veterinary medicinal products that have been authorised during the relevant period.

The Register of Medicinal Products is used as the basis for preparing the Official List of Medicinal Products Authorised in Poland, with a separate list of veterinary medicinal products, which is published as an announcement of the President of the Office in the Official Journal of the Minister for Health. In 2024, an announcement of 20 December 2024 was published containing data as at 1 January 2024. In the part concerning veterinary medicinal products, the document contains: a list of veterinary medicinal products authorised for marketing in the territory of the Republic of Poland under the national and European procedures, the total number of which is 1,814 products, a list of veterinary medicinal products authorised for marketing on the basis of authorisations issued by the Council of the European Union or the European Commission, the number of which is 488 and a list of veterinary medicinal products which obtained parallel import licences, in the number of 3 products.

Granting of parallel import licences in veterinary medicinal products

The parallel import procedure is dedicated to wholesalers who, having obtained a parallel import licence for a veterinary medicinal product, obtain the product from one Member State (Member State of origin) and wish to distribute it in another Member State (Member State of destination), provided that the parallel imported product has a common origin with a veterinary medicinal product already authorised in the Member State of destination.
The Office did not receive any applications for parallel import in 2024.



Procedures concerning granting the authorisations for veterinary clinical trials and maintaining the Central Register of Clinical Trials (CRCT) for veterinary medicinal products

Veterinary clinical trials aim to provide reliable data on the safety or efficacy of a veterinary medicinal product.

Pursuant to Article 37 ah(4) of the Pharmaceutical Law, a veterinary clinical trial may be commenced or conducted after obtaining authorisation from the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The test may be carried out with an authorised or non-authorised veterinary medicinal product with an active substance that is known, new or not previously used in veterinary medicine.

The way clinical trials are conducted must comply with the standards of Good Veterinary Clinical Practice (Regulation of the Minister of Health of 6 July 2012. on the requirements of Good Veterinary Clinical Practice). Clinical trials are conducted with the target animal species.

In 2024, the Office received 3 new applications for clinical trials of veterinary medicinal products.

1 entry was made in the maintenance of the Central Register of Clinical Trials for investigational veterinary medicinal products.

Granting of permits by the President of the Office for importation of veterinary medicinal products from abroad for private medicinal use

In 2024, the Office received 24 applications for permission from the President of the Office to import veterinary medicinal products from abroad for private medicinal use, of which 23 were granted by the President.

Pharmacovigilance and monitoring of the safe use of veterinary medicinal products

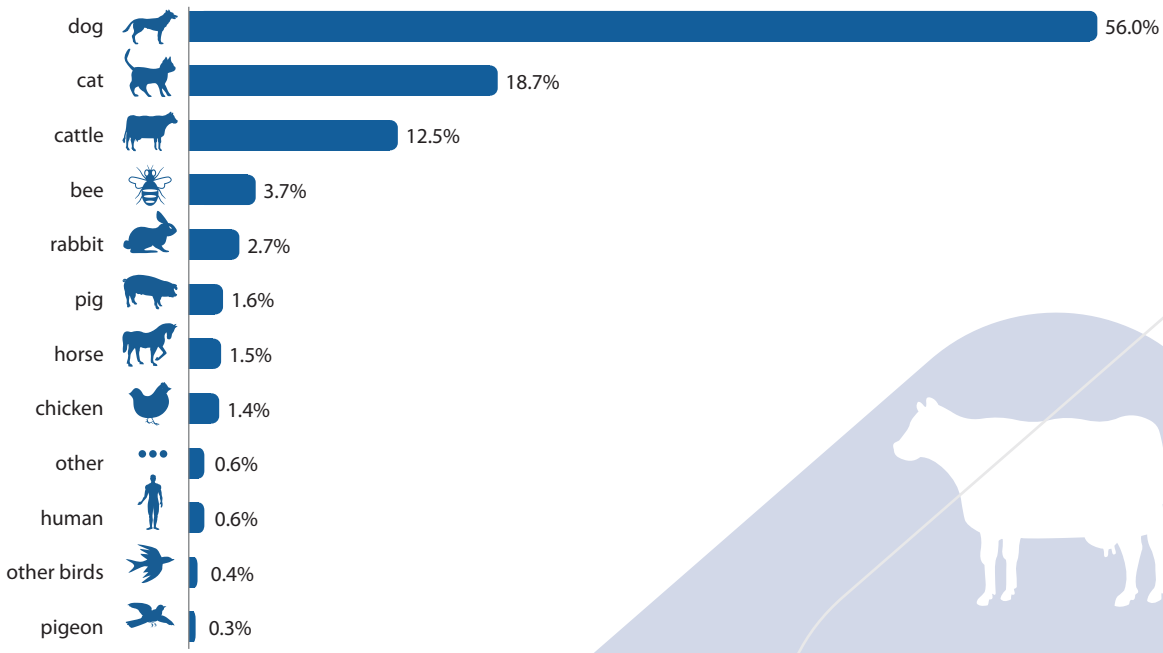
According to Article 73 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, adverse events include:

- any adverse and unintended reaction in the animal to the veterinary medicinal product;
- any suspected lack of efficacy of the veterinary medicinal product after use in accordance with or not in accordance with the summary of the product characteristics;
- any environmental incidents observed after administration of the veterinary medicinal product to the animal;
- any reactions observed in humans after contact with the veterinary medicinal product;
- any detection of an active substance or a residue of a marker in a product of animal origin at a level exceeding the maximum residue limit established in accordance with Regulation (EC) No 470/2009, after the expiry of the established withdrawal period;
- any suspected transmission of an infectious agent by the veterinary medicinal product;
- any adverse and unintended reaction in the animal to the medicinal product for human use.

As part of its monitoring of the safety of veterinary medicinal products, the Office collects information on adverse reactions associated with the use of medicinal products in animals, as well as incidents of concern in humans due to contact with the medicinal product or the treated animal. Reports of adverse events to medicinal products can be sent by users to the Office[4] or directly to marketing authorisation holders.

Reports of adverse events related to medicinal products are now submitted both by the Office and marketing authorisation holders directly to the EU pharmacovigilance database, and these reports are then analysed by the individual registration agencies in the Member States. This

Graph. 6.7: Summary of reports of adverse events to veterinary medicinal products in 2024 by animal species



[4] Users reported 39 adverse events related to the use of veterinary medicinal products to the Office.

includes both serious and non-serious events. Reportin adverse events related to a veterinary medicinal product can be done via a form on the Office's website at: https://www.gov.pl/web/urpl/zglos-zdarzenie-niepozadane or via an electronic form on the ICT systems page of the eHealth Centre: https://smz2.ezdrowie.gov.pl/.

In 2024, a total of 791 adverse event reports for veterinary medicinal products were submitted to the Union Pharmacovigilance Database. 95.2% of the reports came from the marketing authorisation holders. Only 38 reports were submitted by the Office.

As part of monitoring the safety of veterinary medicinal products, 5 cases were completed for non-urgent NUI.

In addition, information on the safety of veterinary medicinal products was provided on an ongoing basis.

2024 was another year of the Pilot-Signal Management Expert Group, which was tasked with developing a new process for the supervision of the procedure for the management of signals concerning the safety of veterinary medicinal products, which is governed by Article 81 of Regulation (EU) 2019/6. The collaboration of experts resulted in the creation of a new process involving the evaluation of signals by individual national agencies with the support of a European expert group.

Issuing product qualification opinions

In 2024, the Office received 76 applications for product qualification, of which 72 opinions were issued in this regard.

Chapter 7

AREA OF COMPETENCE OF THE VICE-PRESIDENT OF THE OFFICE FOR MEDICAL DEVICES

Sebastian Migdalski
Vice-President of the Office for Medical Devices

In 2024, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products implemented several actions and initiatives in the field of medical devices, following the principles of good administrative practice and meeting the growing needs of the device market. Among the most important of these, it is worth mentioning the organisation of the first meeting of the President of the URPLWMiPB with Representatives of Bioethics Committees operating on the territory of the Republic of Poland. Its aim was to increase the awareness of members of bioethics committees regarding the dynamically changing regulations on clinical trials of medical devices and in vitro diagnostic device performance tests, as well as to exchange experience gained and identify future challenges in this area.

Another 'milestone' in the activities of the medical devices division was the continuation and development of the tradition, initiated in previous years, of joint discussions with representatives of notified bodies for the certification of medical devices, as well as with representatives of bodies that are yet to apply for such notification.

In August 2024, as part of a cooperation agreement between the URPLWMiPB and the Moldovan Agency for Medicines and Medical Devices (AMDM), a visit was made to the Office by representatives of the Moldovan agency and the POLMED National Chamber of Commerce of Medical Devices. Key topics included the impact of artificial intelligence on the life cycle of medical devices and ways to strengthen regulatory cooperation.

In describing the activities of the Medical Devices division, it is impossible to ignore the participation of staff in the Joint Action for Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices (JAMS 2.0) project set up under the EU for Health – EU4Health programme, which aims to strengthen market surveillance of medical devices (MDs) and in vitro diagnostic (IVD) devices between Member States and harmonise approaches across the European Union.

Major developments in the digitisation of medical device processes also continued. Fully digital solutions have been implemented instead of the previous paper-based workflow, which meets the expectations of medical device market players in relation to the expected reduction of the administrative burden. Above all, the transition periods related to systems for collecting information on distributors of medical devices importing products from other EU Member States, collecting information on entities conducting

business and professional activities importing or importing a product to Poland and systems for collecting information on manufacturers of custom-made products have ended. At the same time, steps have been taken to adapt the Distributors' List to the comments and proposals for changes made by the entities using them, e.g. with regard to the possibility of creating multiple user profiles and the possibility of generating a confirmation of entry into the Distributors' List, which may be useful when these entities cooperate with their customers. From mid-2024, the use of these systems is mandatory.

Another issue was also the commencement of cooperation with customs authorities by means of the PUESC system (Fiscal and Customs Electronic Services Platform). This has made it easier to cooperate with customs authorities in terms of issuing opinions on whether the definition of a medical device is met, which in turn has translated into faster processing of cases and will make it possible to standardise the rules of procedure by the tax authorities in the future.

Sebastian Migdalski
Vice-President of the Office for Medical Devices

Performance of tasks in the area of medical devices

In the field of medical devices, a total of 15,536 applications were accepted in 2024 and 6,056 proceedings were completed.

Collection of data on devices and entities from reports and notifications

The obligation to submit reports and notifications about medical devices, active implantable medical devices, in vitro diagnostic medical devices, systems and treatment sets composed of medical devices, hereinafter referred to as devices, is regulated by the provisions of the Medical Devices Act of 7 April 2022 (Journal of Laws 2024, item 1620).

Data from reports and notifications are collected by the President of URPLWMiPB on adequately protected data storage devices.

In 2024, the Office received 5,591 cases: reports, notifications and amendments to the data of reports and notifications concerning medical devices. The largest number of cases, 71%, concerned notifications pursuant to Art. 58 sec. 3 and 4 of the Act on Medical Devices.

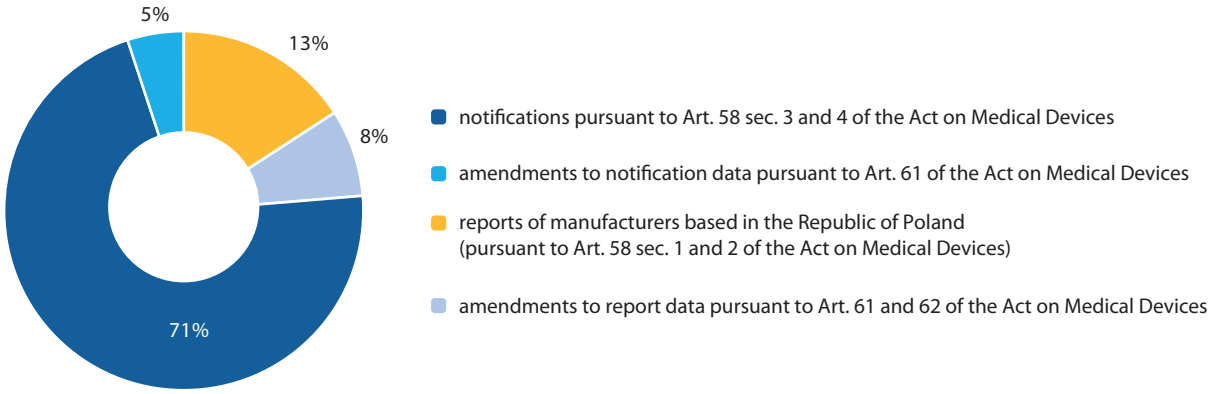
Table 7.1 and Graph 7.1 below present a breakdown of the received cases by category.

Table 7.1: Cases received in the period from 1 January to 31 December 2024

Case category	Number of cases
reports of manufacturers based in the territory of the Republic of Poland (pursuant to Art. 58 sec. 1 and 2 of the Medical Devices Act)	885
amendments to the data in the reports pursuant to Art. 61 and 62 of the Medical Devices Act	439
notifications pursuant to Art. 58 sec. 3 and 4 of the Medical Devices Act	3,984
amendments to the data in the notification pursuant to Art. 61 of the Medical Devices Act	283
Total	**5,591**

Cases of reports, notifications and amendments to the data of reports or notifications are verified by the Office for formal deficiencies and whether the report or notification concerns a medical device, an active implantable medical device, an in vitro diagnostic medical device, a treatment system or kit, sterilised medical devices, treatment systems or kits or does not concern a device within the meaning of the Medical Devices Act. The Office also verifies the labells of the devices, the instructions for use and promotional materials accompanying reports and notifications, with regard to compliance with the requirements set out in the Medical Devices Acts.

Graph 7.1: Percentage breakdown of cases received in the period from 1 January to 31 December 2024



In 2024, 724 cases of reports, notifications and amendments to report and notification data were verified and completed.

Additionally, as of 1 July 2024, the transition periods for the device and entity data collection systems, i.e. the List of Distributors, the List of Users of Medical Devices and the Register of Manufacturers, Authorised Representatives and Importers of custom-made devices, ended. Thus, the collection of notifications from distributors and reportss from manufacturers of custom-made devices ceased from that date.

Issuing of the Certificates of Free Sale

A Certificate of Free Sale is a certificate issued by the President of the Office at the request of a manufacturer or its authorised representative residing or based on the territory of the Republic of Poland in order to facilitate export. This document is confirms that the product indicated therein is or could be placed on the market and used on the territory of the Republic of Poland on the date of issuing the certificate. The Certificate of Free Sale is issued for a product marked with the CE mark. The President of the Office shall issue the Certificates of Free Sale pursuant to Art. 67 of the repealed Act of 20 May 2010 on medical devices for medical devices covered by the transitional provisions: Art. 120 of Regulation (EU) 2017/745 and Art. 110 of Regulation (EU) 2017/746 and pursuant to Art. 30 of the Act of 7 April 2022 on medical devices for medical devices meeting the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

In 2024, the Office received 863 applications for the Certificates of Free Sale. The President of the Office issued 757 certificates.

Issuing certificates concerning a report, notification or application of report or notification

The President of the Office, pursuant to Art. 145 of the Act of 7 April 2022 on medical devices pursuant to Art. 91 of the repealed Act of 20 May 2010 on medical devices, discloses data identifying entities that made notifications, the date of notification and information on trade names: devices, sterilised devices, systems and treatment sets composed of medical devices, sterilised systems and treatment sets composed of medical devices. Information on the safety of devices provided to recipients or users of devices and contained in certificates of conformity and information on the issue, amendment, supplementation, suspension and withdrawal of certificates of conformity shall also be disclosed.

In 2024, the Office received 217 applications for certificates confirming a report, notification or submission of a report or notification application under Art. 217 of the Code of Administrative Procedure; 209 certificates were issued in that case.

Provision of information on medical devices and information on advertising of medical devices

In 2024, the Office received 1,880 enquiries regarding medical device information and medical device advertising information, while 1,827 responses were provided in that regard.

Conducting administrative proceedings in the field of advertising and administrative penalty

Advertising of medical devices is regulated by Regulation 2017/745, Regulation 2017/746, the Medical Devices Act and the Regulation of the Minister of Health of 21 April 2023 on the advertising of medical devices. Pursuant to Art. 7 of the aforementioned regulations, in the advertising of devices, it is prohibited to use texts, names, trademarks, images and symbols or other signs that may mislead the user or patient as to the intended use, safety and performance of the device by: attributing to the device functions and characteristics that the device does not have; giving a false impression as to treatment or diagnosis, functions or characteristics that the device does not have; failing to inform the user or patient of the probable risks associated with the use of the device in accordance with its intended use; suggesting uses of the device other than those stated to be part of the intended use for which conformity assessment has been carried out.

In addition, the Act and the Regulation also regulate additional rules for the advertising of medical devices, such as the prohibition of advertising of devices intended for use by users other than lay persons, or the need to include the information provided for in these acts in advertising.

Supervision of advertising rules is carried out by the President of the Office in accordance with Art. 58 sec. 3 of the Medical Devices Act. The President of the Office is the only administrative body to supervise the advertising of medical devices, with the exception of possible violations in advertising of other regulations of a general nature, e.g. violation of consumer rights.

In terms of advertising and administrative penalty, the President of the Office issued 8 administrative decisions.

Issuing opinions on medical devices at the request of customs authorities

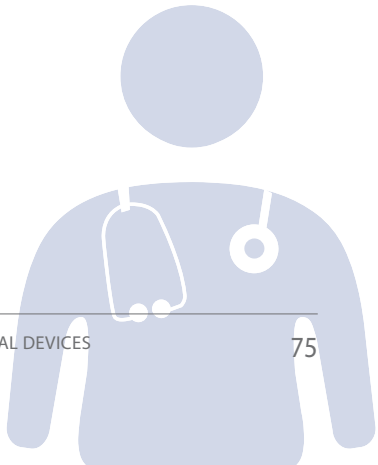
In order to prevent the importation into the territory of the Republic of Poland of medical devices that pose a risk or do not meet the requirements, the Customs Office, in the event of suspicion that the imported medical device does not meet the requirements specified for it, shall request an opinion from the President of the Office as to whether the medical device meets the specified requirements.

In 2024, the URPLWMiPB received 435 requests on this issue and the President of the Office issued 445 such opinions.

Conducting clinical trials and medical device performance studies

In 2024 the President of the Office received 74 applications for authorisation to conduct a clinical trial or a medical device performance study and 64 applications for authorisation to amend a clinical trial or a medical device performance study. The President of the Office issued 69 decisions authorising the commencement of a clinical trial of a device and 82 decisions authorising amendments to a clinical trial of a medical device.

In addition, with regard to the monitoring of clinical trials and performance studies of medical devices, 7 certificates under Art. 36 of the Medical Devices Act authorising the import of devices for clinical trials were issued at the request of the sponsor, 5 final reports on the performance of clinical trials and performance studies were evaluated, and 63 information on serious adverse events in clinical trials and performance studies were assessed.



Supervision of medical devices and medical incidents and actions concerning the safety of medical devices marketed and/or used in Poland

The President of the Office collects and analyses reports of serious incidents, information on risks caused by medical devices and any other information relating to the safety of medical devices.

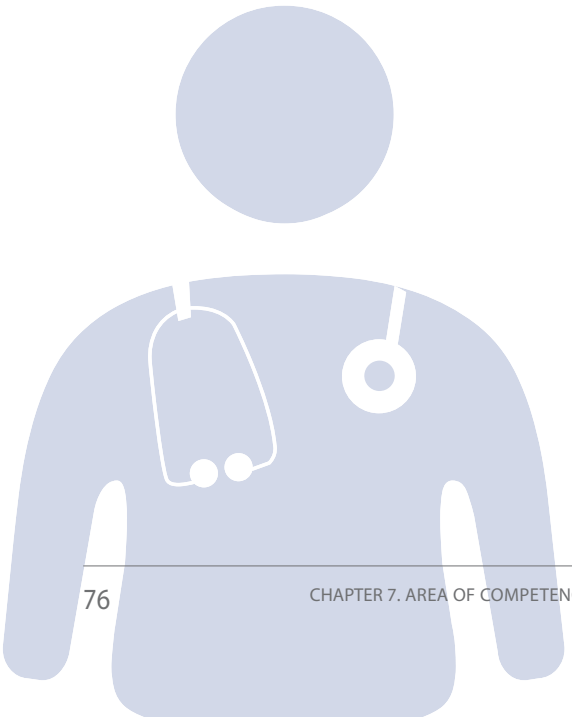
The URPLWMiPB website publishes information on the safety of medical devices, including but not limited to safety notes and announcements by the President of the Office.

In 2024, the URPLWMiPB received 6,275 medical device surveillance cases and serious incidents and actions concerning the safety of medical devices marketed and/or in use in Poland, including 5,168 notifications from users, distributors, importers and manufacturers.

1,722 proceedings were completed in that regard, including 1,410 actions relating to products on the market and/or in use in Poland, and 22 decisions were issued, including 1 decision regarding a change in the period of designation as a notified body.

Conducting inspections

As part of the surveillance of medical devices and medical incidents and actions concerning the safety of medical devices marketed and/or in use in Poland, the URPLWMiPB conducted 14 inspections. Compared to 2023, this is more than a threefold increase in the number of inspections in the area of medical devices.



Assessment of reports on the safety of medical devices manufactured using tissues of animal origin

In 2024, the President of the Office received 27 reports from notified bodies for assessment concerning the evaluation of reports on the safety of medical devices manufactured using tissues of animal origin.

Issuing scientific opinions at the request of notified bodies

In the procedure for assessing the conformity of a medical device containing as an integral part a substance which, if used separately, is concidered to be a medicinal product and which may have an ancillary effect on the human body in relation to the device, the notified body is required to obtain an opinion on the quality and safety of that substance, including the clinical benefit-risk balance. Pursuant to Art. 29 of the Medical Devices Act, the aforementioned opinion is obtained from the Office competent for medicinal products in the Member State or from the European Medicines Agency. In the territory of the Republic of Poland, the Office competent to issue such an opinion is the President of the Office. In 2024, the URPLWMiPB received 2 requests from notified bodies for scientific opinions. The President of the Office issued 1 opinion in this scope.

Issuing opinions on standards for medical devices

In 2024, the URPLWMiPB, after analysing the drafts of Polish (PN), European (EN) and international (ISO) standards received, as well as legal acts and guidelines on medical devices, received 104 opinions on such drafts.

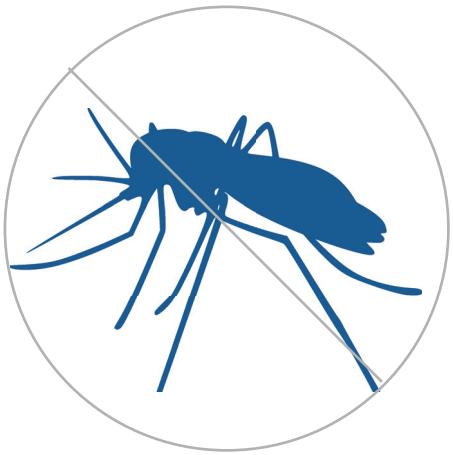
Monitoring of notified bodies

A notified body is a body that assesses the conformity of a medical device with the requirements of Regulation 2017/745 or Regulation 2017/746 and issues a certificate of conformity.

In 2024, 2 inspections were carried out as part of the monitoring of notified bodies.

Chapter 8

AREA OF COMPETENCE OF THE VICE-PRESIDENT OF THE OFFICE FOR BIOCIDAL PRODUCTS



Aleksandra Wilczyńska
Vice-President of the Office for Biocidal Products

In 2024, the Biocidal Products Division continued its activities related to the granting of authorisations for the placing of a biocidal products on the market under national procedures and authorisations to make biocidal products available on the market and to use them under the so-called European procedures, which is in line with the objectives of the 2024 URPLWMiPB activity plan, i.e. ensuring access to biocidal products of adequate quality, safety and efficacy and monitoring the safety of their use.

The implementation of the above-mentioned tasks is closely linked to the progress of the work involving the systematic evaluation of existing biocidal active substances in the EU, known as the Review Programme. The Commission Delegated Regulation (EU) 2024/1398 published by the European Commission on 22 May 2024 with a new end date for the Review Programme resulted in the need to carry out an amendment procedure for a significant number of biocidal product authorisations by extending their expiry date to 31 December 2030, involving a significant amount of work in a short period of time.

In parallel, as part of the ongoing Review Programme in the Division, work continued on the evaluation and preparation of final evaluation reports for 15 sets of dossiers on 8 active substances.

Further work was also carried out on the draft Act amending the Act on Biocidal Products and activities related to preparations for Poland's Presidency of the EU structures.

In 2024, numerous enquiries about biocidal products from domestic and foreign stakeholders were answered, as well as substantive support to the biocidal enforcement.

As part of cooperation with government administration bodies, representatives of the Division conducted training courses in the field of biocidal products for, among others, employees of the National Fiscal Administration and the State Sanitary Inspection.

Efforts were also underway to obtain approval of efficacy test methodologies for biocidal products by applicant companies. In 2024, 176 applications for methodology approval were considered at the Biocidal Products Committee.

The List of Biocidal Products was also maintained, supplemented and updated on an ongoing basis.

The autumn of 2024 brought catastrophic flooding in south-western Poland. The division was involved in outreach on the use of biocidal products in flood recovery.

A valuable experience was the exchange of information on the management of chemicals in the EU during the Heads of Chemicals Competent Authorities Meeting and the Shaping Tomorrow Conference organised by the European Chemicals Agency in Helsinki.

Representatives of the Division also attended a meeting organised by the Bureau of Chemicals in April 2024 during the visit of Dr. Sharon McGuinness Executive Director of ECHA, where they presented the scope of the Division's cooperation with ECHA.

In 2024, the Division's staff participated actively in the work of the EC and ECHA, through activities in the Biocidal Products Committee (BPC), as well as activities in BPC expert working groups, e.g. on efficacy testing, analytical methods and physicochemical testing, human health and environmental exposure assessment. Activities in the Coordination Group (CG) were also carried out with great dedication. The staff of the Division took an active part in commenting on the assessment reports of biocidal products (prepared by other member countries) under the mutual recognition procedure, as well as commenting on and initiating objections to the authorisation conditions issued.

Another activity was the participation in meetings of representatives of the Competent Authorities (CA) and the Standing Committee on Biocidal Products (SCBP). Within the HelpNet Steering Group, a representative of the Division gave a presentation on Poland's experience with mutual recognition of authorisations and the authorisation of the same biocidal products. Another meeting of the Member State Communicators' Network was also attended.

Aleksandra Wilczyńska
Vice-President of the Office for Biocidal Products

Performance of tasks in the area of biocidal products

A biocidal product may be made available and used in the territory of the Republic of Poland with relevant authorisation. The first option is to apply for authorisation for the placing of a biocidal product on the market based on the national procedure, the rules of which are established by the Act on Biocidal Products. The second option is the submission of an application for authorisation for the making available on the market and use of a biocidal product in accordance with the procedures established by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

In the area of biocidal products, a total of 1,587 applications were accepted in 2024 and 5,859 proceedings were completed.

Granting authorisations for for the placing of biocidal products on the market under Article 19 sec. 1 and Article 16 sec. 2 of the Act of 9 October 2015 on biocidal products (Journal of Laws of 2021, item 24)

During the transitional period, until 31 December 2024, authorisations for the placing of biocidal products on the market are granted by the President of the Office on the basis of the aforementioned Act on Biocidal Products.

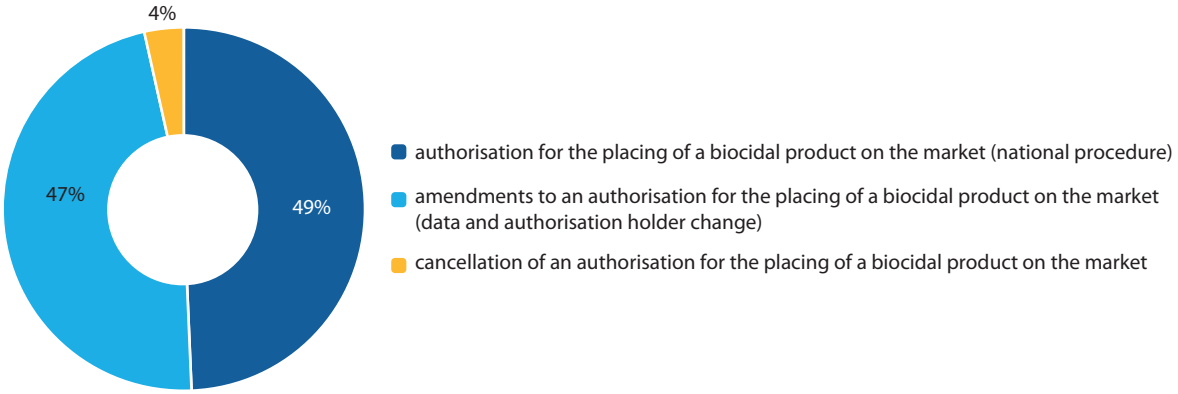
In 2024 the Office received 801[1] applications the authorisation for the placing of biocidal products on the market (Table 8.1). Applications for authorisation for the placing of biocidal products on the market accounted for 49% of all applications submitted in this area.

[1] The figure of 801 does not take into account the 8 applications submitted at second instance for the expiry of the biocidal product authorisation.

Table 8.1: Number of applications for the authorisation for the placing of biocidal products on the market between 01 January and 31 December 2024

Type of proceedings	Number of applications
authorisation for the placing of a biocidal product on the market (national procedure)	395
amendments of the biocidal product authorisation (data and authorisation holder amednment)	378
cancellation of a an authorisation for the placing of a biocidal product on the market	28
Total	**801**

Graph 8.1: Accepted applications, as a percentage, for biocidal product authorisations in the period from 1 January 2024 to 31 December 2024



Graph 8.2: Completed proceedings, as a percentage, concerning the authorisation for the placing of biocidal products on the market from 1 January 2024 to 31 December 2024

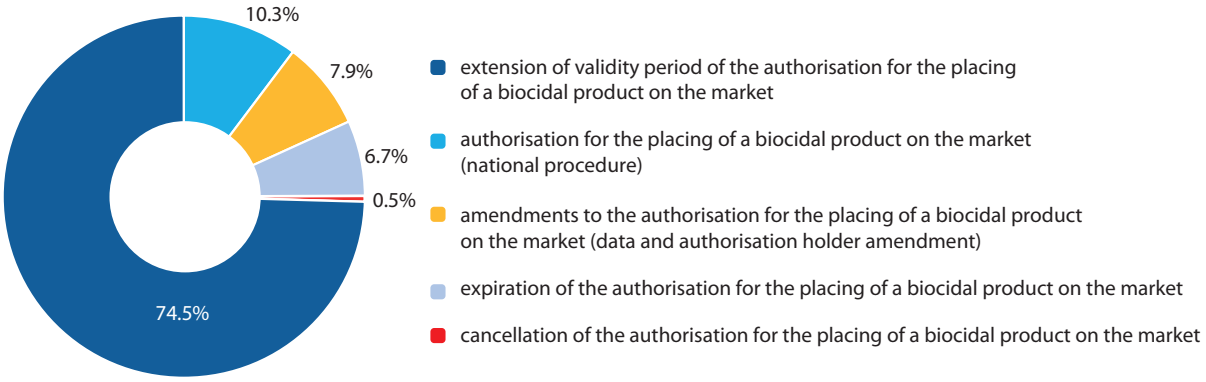
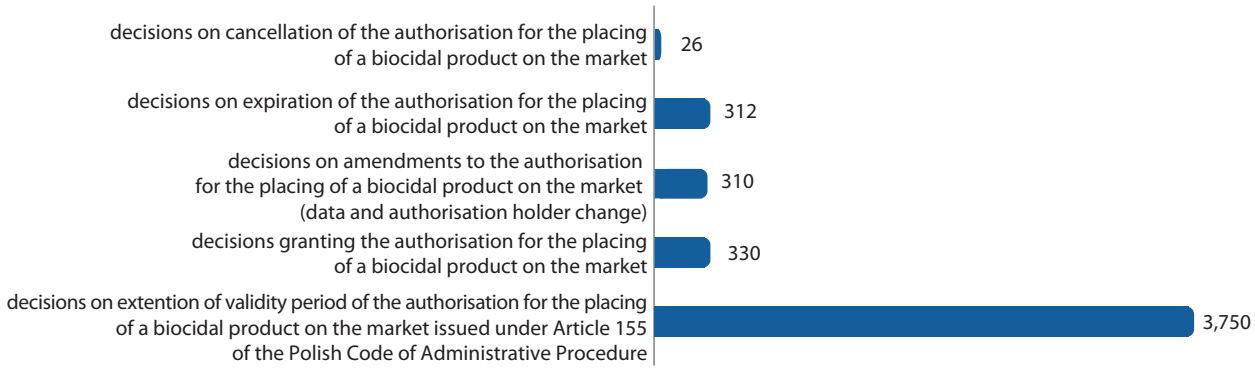


Table 8.2: Number of completed proceedings for authorisation for the placing of biocidal products on the market from 1 January 2024 to 31 December 2024.

Type of proceedings	Number of completed proceedings
authorisation for the placing of a biocidal product on the market (national procedure)	517
amendments to the authorisation for the placing of a biocidal product on the market (data and authorisation holder amendment)	399
expiration of the authorisation for the placing of a biocidal product on the market	338
cancellation of the authorisation for the placing of a biocidal product on the market	27
extension of validity period of the authorisation for the placing of a biocidal product on the market	3,750
Total	**5,031**

Graph 8.3: Number of decisions issued on the authorisation for the placing of biocidal products on the market from 1 January 2024 to 31 December 2024



In 2024, a total of 5,031 proceedings for the authorisation for the placing of biocidal products on the market were completed (Table 8.2).

Proceedings for authorisation for the placing of biocidal products on the market accounted for 10.3% of all completed proceedings. Within the completed proceedings in the scope of biocidal product authorisation, 330 decisions on the authorisation for the placing of biocidal products on the market were issued, (Graph 8.3).

There were 310 decisions to amend the authorisation for the placing of biocidal products on the market (data and authorisation holder change).

Granting authorisation for the making available on the market and use of biocidal products

Since 1 September 2013, authorisations under European procedures have been issued in accordance with the procedures established in Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 on the making available on the market and use of biocidal products.

In 2024, a total of 224 applications according to the procedures established in Regulation (EU) No 528/2012 (European procedures) have been submitted, including 112 applications for the authorisation of biocidal products for the making available on the market and use (Table 8.3).

Applications for authorisation for the making available on the market and use of biocidal products accounted for half of all applications in European procedures (Graph 8.4).

In 2024, a total of 362 proceedings into the making available on the market and use of biocidal products were completed.

In connection with the proceedings for granting authorisations or amending the data covered by these authorisations, the Office reviewed and evaluated application dossiers (physicochemical, toxicological and ecotoxicological and concerning the efficacy of the biocidal product in question). Information was also provided on an ongoing basis on the required documentation and activities in the biocidal product authorisation process.

Table 8.3: Number of applications submitted for authorisations for the making available on the market and use of biocidal products from 1 January to 31 December 2024

Type of proceedings	Number of applications
authorisation for the making available on the market and use of a biocidal product	112
amendments to an authorisation for the making available on the market and use of a biocidal product	84
renewal of the authorisation for the making available on the market and use of a biocidal product	28
Total	**224**

Graph 8.4: Accepted applications, as a percentage, for the authorisation for the making available on the market and use of biocidal products from 1 January to 31 December 2024

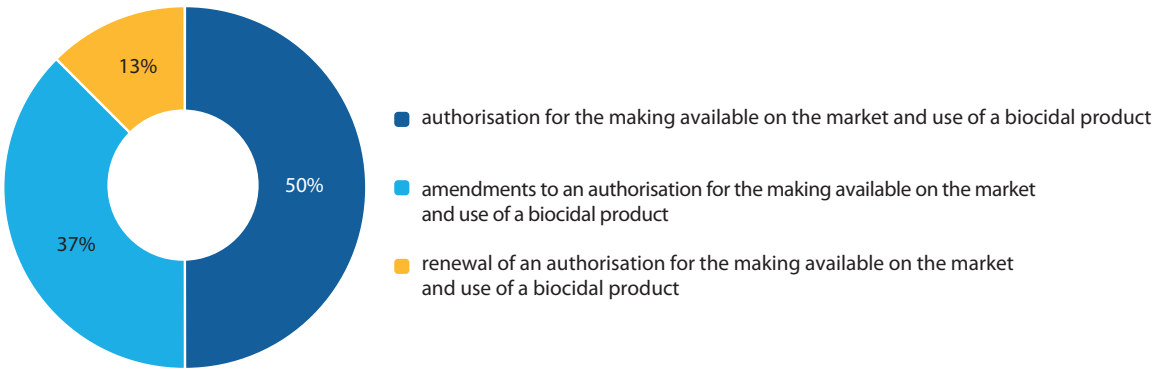
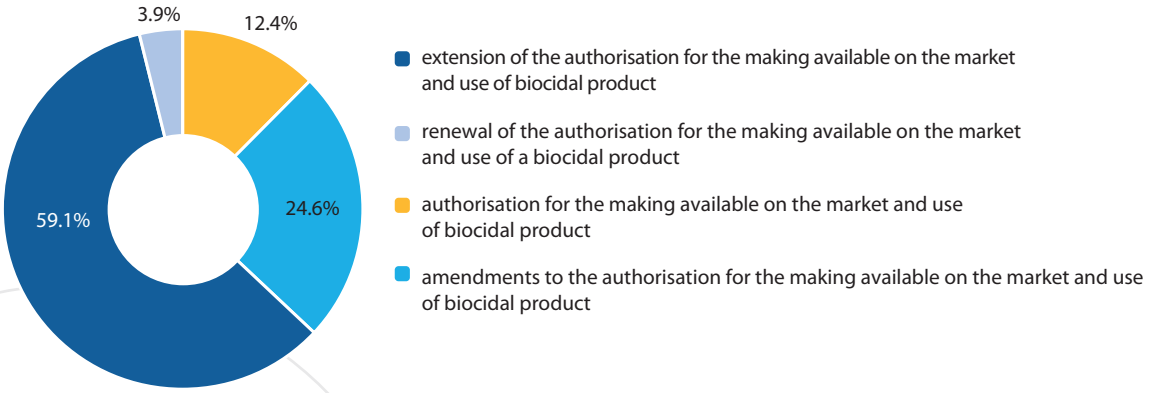


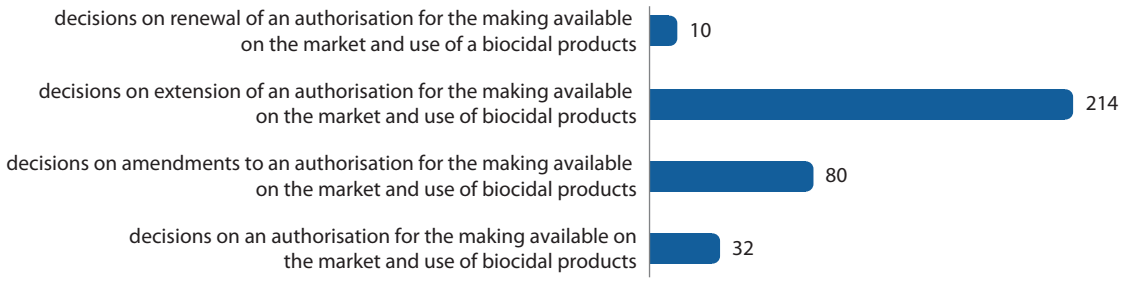
Table 8.4: Number of completed proceedings for the making available on the market and use of biocidal products from 1 January to 31 December 2024

Type of proceedings	Number of completed proceedings
authorisation for the making available on the market and use of biocidal product	45
amendment of the authorisation for the making available on the market and use of biocidal product	89
extension of validity period of the authorisation for the making available on the market and use of biocidal product	214
renewal of the authorisation for the making available on the market and use of a biocidal product	14
Total	**362**

Graph 8.5: Completed proceedings, as a percentage, concerning the authorisation for the making available on the market and use of biocidal products from 1 January to 31 December 2024



Graph 8.6: Number of decisions issued on the making available on the market and use of biocidal products from 1 January to 31 December 2024



Evaluation of biocidal active substance dossiers

As part of the European programme for the review of existing active substances, carried out under the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 on the making available on the market and use of biocidal products, the Office is responsible for preparing final assessment reports for eight active substances (of 15 product-types).

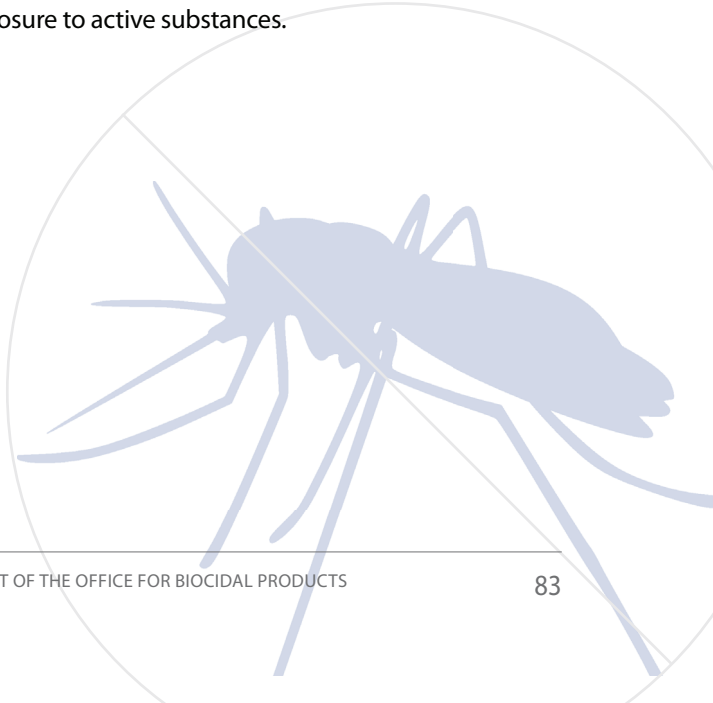
In 2024, active substance assessment activities consisted of continuous work on the accumulated dossiers for all active substances to be assessed. The analysis and evaluation of these dossiers focused on endocrine disrupting properties to ensure compliance with the guidelines for the implementation of hazard-based criteria for the identification of endocrine disruptors. In this regard, intensive work was carried out on the evaluation of the active substance mecetronium ethyl sulphate (MES) evaluated for Product Group 1, for which the Office, as evaluating competent authority was involved, under a mandate from the European Commission, in the preparation of the ECHA opinion under Article 75 sec. 1 (G) of Regulation 528/2012 "Evaluation of endocrine disrupting properties of mecetronium ethyl sulphate" in 2024. In addition, the Office continued its work on the evaluation of the active substances rotenone and cinnamal adlehyde, for which the Office took over the role of competent authority after the UK's exit from the European Union.

Provision of information on the possibility of placing and making available on the market and using biocidal products and treated articles

In 2024, the Office received a total of 549 applications for written information regarding the possibility of placing on the market, making available and using biocidal products and treated articles. A total of 463 written responses were provided.

Advice on information on the possibility of adapting the data requirements laid down in Article 6 and Article 20 of Regulation 528/2012 and the method of preparing the application (resulting from Article 81 sec. 2 of Regulation 528/2012)

In 2024 the Office has not received any requests for advice on the preparation of a biocidal product *dossier* prepared in accordance with the guidelines laid down in Appendix 3 to Regulation No 528/2012 for the following dossiers: physicochemical, toxicological, ecotoxicological, efficacy as well as intended use and exposure to active substances.



Keeping the List of Biocidal Products and publication of the Official List of Biocidal Products Authorised in the Republic of Poland

According to Article 7 sec. 1 of the Act on Biocidal Products, biocidal products made available on the market and used in the territory of the Republic of Poland are subject to entry in the List of Biocidal Products. The List of Biocidal Products is maintained by the President of the Office, who makes entries and changes to entries in the List on the basis of final administrative decisions. The List includes products which have received authorisation for placing on the market of a biocidal product pursuant to Article 16 of the Act on Biocidal Products and products that have been authorised for making available on the market and use in accordance with the procedures set in Regulation No 528/2012, (European procedures). The list consists of two sections:

– Section 1 provides information on biocidal products for which authorisations for placing on the market of a biocidal products were granted;
– Section 2 provides information on biocidal products authorised in accordance with the provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

The data collected in both Sections of List I and II of the Inventory were published monthly on the website of the Office and the website of the Public Information Bulletin of Public Information (BIP).

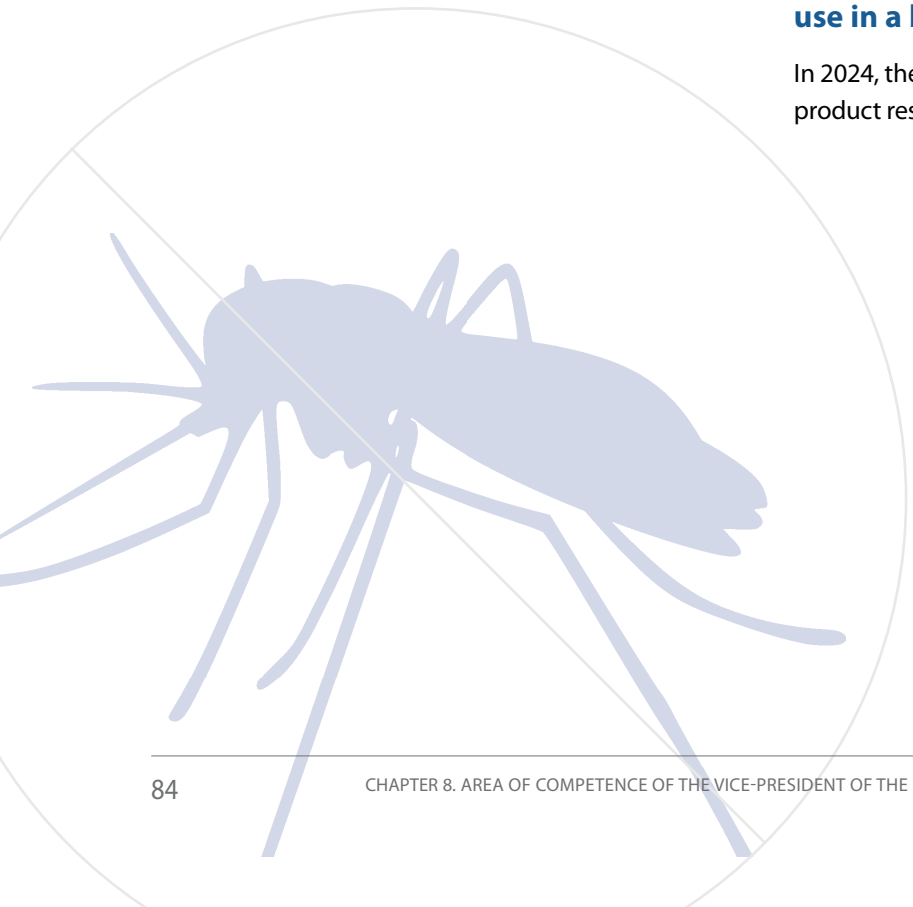
The List of Biocidal Products includes 1,577 marketing authorisation holders (national procedure) and 206 authorisation holders (European procedures). Biocidal products registered in the territory of the Republic of Poland can be marketed: under the Polish national procedure – 5,752, under the European (national) procedure – 492, under the union procedure – 436 and notified under the simplified procedure – 46.

Biocidal Product Poisoning Control System

Based on data obtained from semi-annual reports sent to the Office by the Poison Control Centres in Warsaw, Gdańsk, Poznań and Kraków, which collect and archive reports of suspected or confirmed cases of poisoning with biocidal products in their voivodeships, a total of 205 cases of suspected or confirmed poisoning with biocidal products were reported in 2024. None of the poisoning cases were fatal.

Keeping records of research and development with a view to the placing on the market of a biocidal product or an active substance intended exclusively for use in a biocidal product

In 2024, the Office has conducted 1 case in biocidal product research and development.



Chapter 9

AREA SUPERVISED BY THE DIRECTOR GENERAL

Magdalena Wojciechowicz
Director General

The year 2024 was another year of hard work for the Director General's Division in the area of ensuring the operation of the Office, and thus a period of high commitment and intensive work for all organisational units of the Division.

In view of the prolongation of the heightened terrorist and cyber threat on the territory of the Republic of Poland, issues of ensuring information security at the Office, including activities aimed at educating and raising the competence of employees, remained an important focus of the Director General's Division.

Considering the integration of systems and the development of the governmental e-administration platform, in 2024, the URPLWMiPB website and the Public Information Bulletin website were moved to the gov.pl portal, run by the Ministry of Digital Affairs. There was also a major overhaul of the way information is presented, with a view to increasing the transparency and information value of the Office's website and bringing it in line with current accessibility requirements.

In terms of human resources development, a result of a number of organisational and management measures, the objective set out in the quality management system of significantly improving the stability of human resources has been achieved, and a real increase in the workforce has been achieved through the allocation and filling of new posts. Job offers were also made more attractive by increasing the salary rates offered to candidates interested in joining the Office. As a result of the measures carried out, the level of staff turnover, when compared to 2023, decreased from 9.92% to 4.3%, while the percentage of vacancies that were filled increased from 33% to 47%.

Thanks to the extensive use of non-financial motivation tools, particularly in terms of flexible organisation of working time and place of work (remote or hybrid working), the Office as an employer enabled employees to maintain a proper work-life balance, in line with the work-life balance directive, which had a positive impact on motivation, efficiency and job satisfaction. The solutions introduced have made the Office a more friendly and attractive place to work, also for people with special needs.

Magdalena Wojciechowicz
Director General

Performance of tasks in the area supervised by the Director General

The main areas of competence of the Director General include:

- Keeping the accounts and managing the finances of the Office, including the preparation of a draft budget plan of revenue and expenditure;
- Handling of personnel affairs associated with employment relationships and responsibilities in connection with the implementation of the provisions of the Act on civil service;
- Coordination of activities in the area of management control and quality management;
- Management of the drafting process and adoption of the internal policies of the Office, including ordinances of the President and Director General and the development and implementation of internal procedures concerning the organisation of work within the Office;
- Administration of the property of the Office, including commissioning services and making purchases for the Office as well as keeping of the record of assets of the Office;
- Ensuring the right work environment for Office staff in terms of occupational health and safety, ensuring fair quality of secretarial services in the Office and keeping of the Institutional Archives;
- Ensuring maintenance of the ICT infrastructure and systems of the Office;
- Handling of matters related to internal audits and controls in the Office.

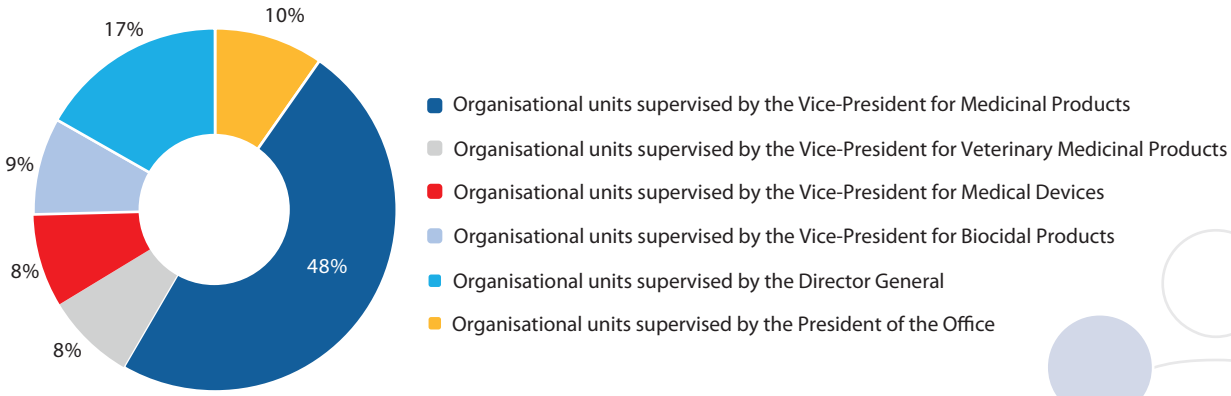
Employment structure in the Office

Despite the dynamic changes in the labour market, the Director General's Division continued to deliver uninterrupted employment of qualified staff in 2024. As at 31 December 2024, the Office had 571 employees, 81% of the staff being female and 19% male. As the largest number of applications submitted to the Office were for medicinal products, nearly half of the staff (48%) were employed in the organisational units supervised by the Vice President for Medicinal Products (Graph. 9.1).

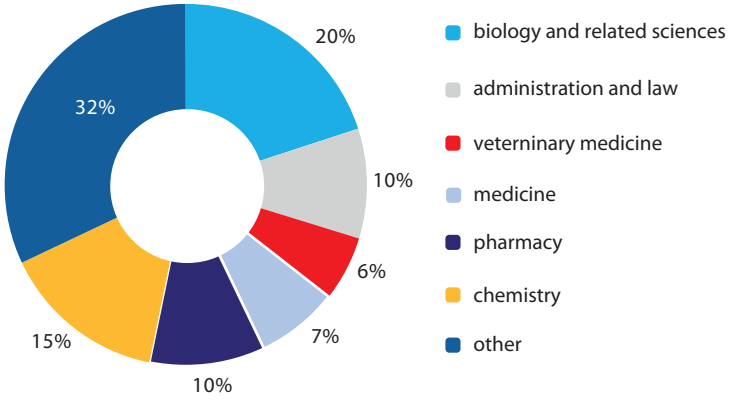
The Office's remit, which includes tasks of a decision-making, consultative, control and informational nature, entails the need to employ an optimal number of specialists in various fields. The predominant field of education of employees was biological and related sciences (20%), chemical (15%), pharmaceutical (10%), administrative and legal (10%), and medical (7%) (Graph. 9.2)

In 2024, the Office employed 131 internal experts and cooperated with 129 external experts responsible for assessing the documentation submitted to the Office. The largest group of experts held medical degrees, including physicians and pharmacists (60%). A significant portion also comprised biologists and biotechnologists (20%). In addition, the Office's experts

Graph. 9.1: Employment as a percentage by area of activity (as of 31 December 2024)



Graph. 9.2: Type of education of employees in the Office as a percentage (as of 31 December 2024)

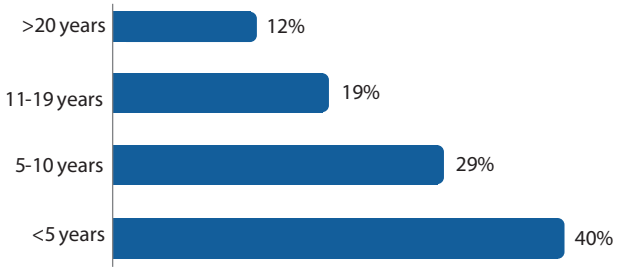


included, among others, chemists (14%) and veterinary doctors (6%).

Nearly 10% of the Office's staff held a doctoral degree. Employees appointed within the Civil Service constituted 1.4% of the Office's personnel, marking an increase compared to the previous year.

The Office comprises a team of both young, ambitious professionals and highly experienced specialists. Over half (51%) of its personnel are under the age of 40. At the same time, 60% have more than five years of professional experience at the Office, with 31% having served for over ten years, including 12% with more than twenty years of service (Graph 9.3).

Graph. 9.3: Professional experience of the employees of the Office (as of 31 December 2024)

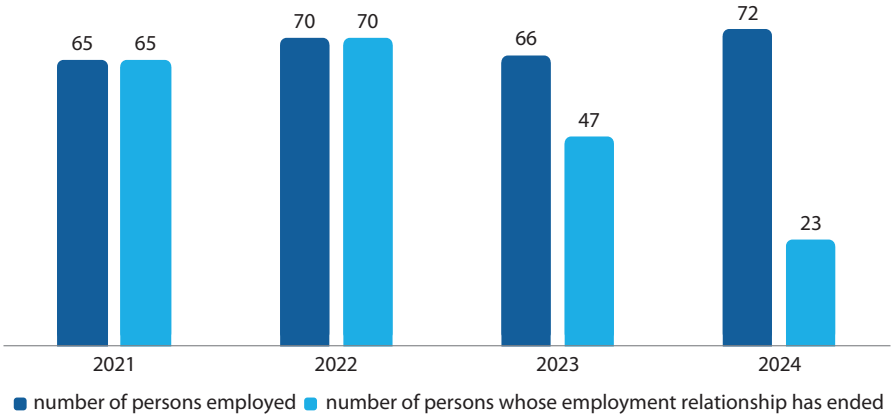


One of the elements of the personnel policy is the Human Resources Management Programme, implemented at the Office to ensure the sustainable and consistent development of employees. Within the framework of this Programme, the Office has provided employees with a wide catalogue of national and international training courses, within the scope of available financial capacity. During the period under review, employees of the Office took part in 289 national and 99 international training courses, including 17 outbound foreign training courses. External individual and group training courses, as well as internal training courses conducted by Office employees, were an important element of the staff professional development system. It should be noted that the high prices of some specialised training courses constituted a significant impediment to the implementation of tasks related to ensuring appropriate professional development of employees. A form of support for the development of the Office's employees' professional competences was also the funding of studies and applications, which had been implemented for many years. In addition, in order to support the professional development of people entering the labour market and to build a positive employer image and encourage potential future candidates to respond to job offers at the Office, 12 professional internships were carried out.

In view of the high importance of language skills for most jobs at the Office, an English language course for employees has been organised since 2012, delivered during working hours of the Office. In 2024, 160 employees benefited from the opportunity to improve their English language skills in groups. In addition, the Office provided the opportunity for 21 people to benefit from individual English language courses.

An important factor influencing the functioning of the Office and the smooth execution of its statutory tasks has been, and continues to be, the highly specialized nature of the Office's work and the resulting high level of demands placed on employees, particularly those in substantive departments.

Graph. 9.4: Employee turnover in 2021-2024



Despite an improvement in remuneration levels, salaries remained less attractive compared to those offered in the private sector or in other public administration entities with a similar specialization profile. This led to difficulties in filling vacant positions.

Despite these challenges, the Office made every effort and undertook active measures to gradually improve the staffing situation, as evidenced by a 56% decrease in staff turnover in 2024 compared to 2023 (down to 4.3%), as illustrated in the graph below.

One important element of non-wage motivation for Office employees was the possibility to work in a hybrid system. The modern work organisation model, combining elements of remote and stationary work, was used by as many as 60% of employees.

Financial statements of the Office

Implementation of the revenue and expenditure plan for 2024

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, as a state budget-funded entity, being an administrator of the third level, for its statutory activities receives funds from the Ministry of Health (under heading 46 – Health), while it transfers its revenues to the state budget account. The primary sources of revenue for the Office are the fees charged as part of its statutory activity, in particular in connection with the authorisation of medicinal products for human use and veterinary medicinal products, granting of parallel import licences for medicinal products for human use and veterinary medicinal products, authorisation of clinical trials, veterinary clinical trials, clinical trials of medical devices, reports and notifications of medical devices, authorisation of biocidal products and sales of "Polish Pharmacopoeia" publications.

Actual budget revenue

In 2024, the revenue of the Office amounted to PLN 178,513,267.67, which represents 96.66% of the annual plan of PLN 184,679,000. On account of the realised revenues, the Office transferred the amount of PLN 178,513,267.67 to the central account of the state budget.

Actual budget expenditure

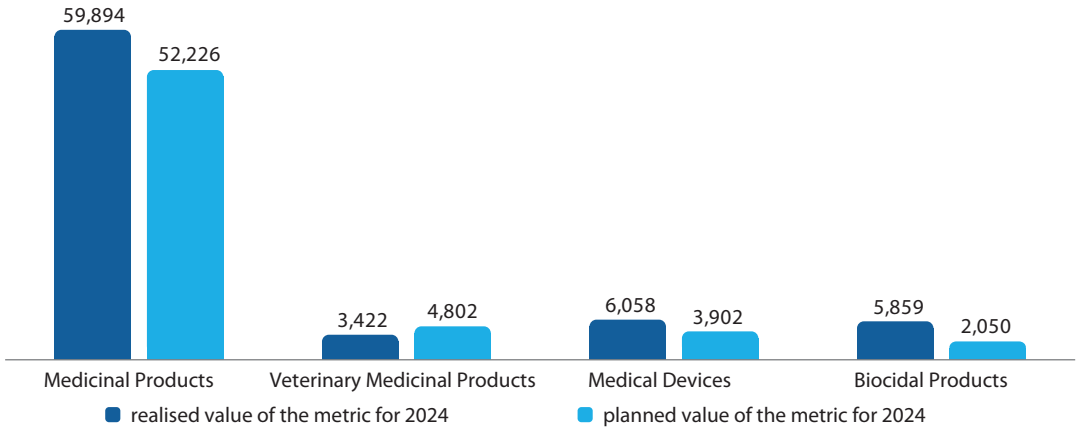
According to the decision of the Minister of Health, the Office's expenditure plan for 2024 amounted to PLN 119,068,057.95,
of which:

- current expenditure – PLN 116,517,343.76;
- investment expenditure – PLN 2,390,000.00;
- Presidency – PLN 160,714.19.

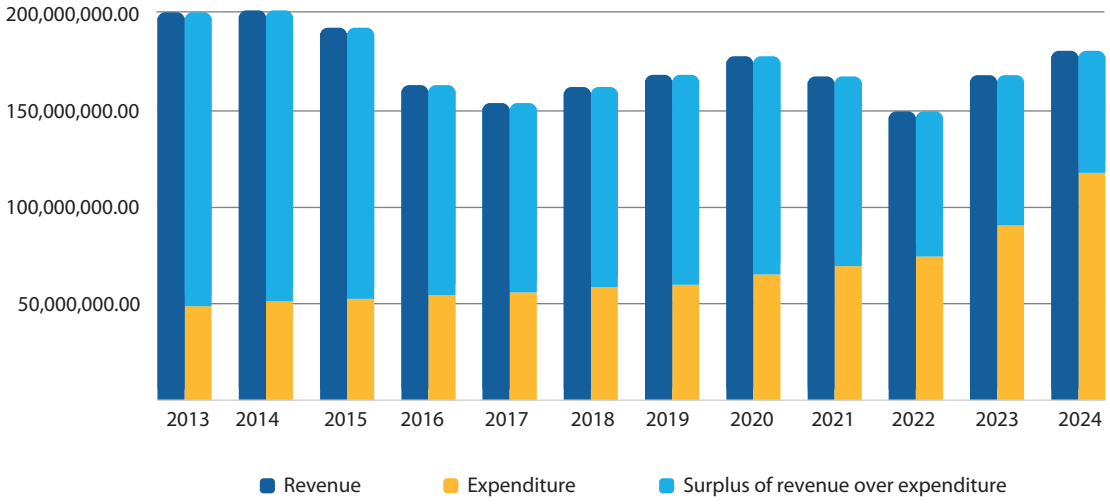
In 2024, expenditure amounted to PLN 117,964,811.19:

- current expenditure of PLN 116,049,972.15, which represents 99.60% of the annual plan for current expenditure;
- investment expenditure of PLN 1,800,855.25, representing 75.35% of the annual plan for investment expenditure;
- expenditure on the Presidency amounting to PLN 113,983.79, representing 70.92% of the annual plan for expenditure on the Presidency.

Graph. 9.5: Performance of the 2024 target metric in terms of the number of procedures conducted



Graph. 9.6: Projected and actual revenue and expenditure in 2013–2024



Plan for 2025

The financial plan for 2025 received from the Ministry of Health[1] assumes:

- budgetary revenue – PLN 186,342,000;
- current expenditure – PLN 114,829,000.

Summary

The surplus of income over expenditure in 2024 represented a total of PLN 60,548,456.48.

The implementation of the assumed value of the measure for 2024, in terms of the number of proceedings conducted, is presented in Graph. 9.5.

A summary of the Office's budget plans and the implementation of income and expenditure from 2012 to 2024 is presented in Graph. 9.6.

Activities related to Office management and IT support

In 2024, the activities carried out in the administrative field, focused on ensuring the proper functioning of the Office in the conditions of the extension of the obligatory period of the second alert level of the CRP (2nd degree CHARLIE-CRP) and the second alert level (2nd degree BRAVO) on the territory of the Republic of Poland. The persistence of the situation of heightened terrorist and cyber threats entailed the need to intensify work in the administrative services of the Office. In

[1] At the time of writing this Report, the reported capital expenditure requirement for 2025 had not yet been allocated by the Ministry of Health.

addition, standard tasks were carried out, related to the administrative and economic service of employees and technical and IT support.

The Information Technology Office carried out tasks related to the maintenance and development of the Office's ICT systems.

In the area of the Office's IT support, Office software was kept up to date, and work was carried out to prepare for the expiry of Microsoft Windows 10 and Microsoft Office versions 2016 and older in 2025. The Office's key IT resources were also maintained. Internally, the IT Office resolved 10,075 Helpdesk requests.

As of 1 October 2024, the Office's website and BIP page were migrated to the government service gov.pl. run by the Ministry of Digital Affairs for all government administration units.

The enhanced IT security infrastructure has allowed the Office's resources to be effectively protected against attacks under heightened cyber threat conditions. As part of maintaining a high level of preparedness in this area, protection systems for workstations and mobile devices were expanded. The Office was also challenged to ensure that employees were able to work remotely in a cyber-secure manner. In line with the Office's internal standards, remote working could only be carried out by employees on appropriately secured work equipment, which enabled an adequate level of security to be maintained.

On the basis of the Public Procurement Law and in accordance with the Public Procurement Regulations, all 10 procurement procedures, as well as 20 enquiry procedures, were conducted electronically through an IT platform (Marketplanet) made available to the Office on the basis of an agreement concluded with the Open Electronic Market S.A (a joint-stock company).

In 2024, there were 85,454 pieces of incoming correspondence received by the Office and 21,769 pieces of outgoing correspondence.

With regard to the operation of the Archive, an increase in the archival stock by 32,642 archival units was recorded. The company archive made 550 loans of archival documentation to the organisational units of the Office and 581 returns of documentation loaned to organisational units.

In the area of health, safety and fire protection, training was provided to 108 employees and trainees in 2024. Training included health promotion and health education in the workplace.

In addition, the infrastructure was prepared for the introduction, in accordance with the Minister of Digitalisation's timetable, of e-communication as a new electronic channel of communication with the Office and all employees were trained in this area.

It is also the responsibility of the Director General's Division to run the Library of the Office, providing staff with access to professional literature and academic journals, including foreign journals, also in electronic format. The Office acquired 69 new library materials, and the Library's holdings at the end of 2024 amounted to 1,956 volumes of compact publications and 6,029 volumes of continuous publications.

Activities related to information security at the Office

Ensuring information security is a particularly important task for any public administration unit, especially in an era of dynamic technological development and heightened international threats. Through the successive implementation and development of integrated information security solutions, the Office ensures effective protection of the information and data it processes.

In addition to the development of systems and software, the Office also attaches importance to raising awareness of the risks arising from the use of technology and emphasises the development of appropriate attitudes and the effective implementation of security procedures among its staff, as well as providing opportunities for staff to participate in training in this area.

As in previous years, in 2024, an independent information security audit was conducted at the Office to verify compliance with the requirements of the PN-ISO/IEC 27001 standard, the Regulation of the Council of Ministers of 12 April 2012 on the National

Interoperability Framework, minimum requirements for public registers and information exchange in electronic form and minimum requirements for ICT systems), the Act of 17 February 2005. on the computerisation of the activities of entities performing public tasks, the Act of 5 July 2018 on the National Cyber Security System, the Regulation of the European Parliament and of the Council (EU) 2016/679 of 27 April 2016 on the protection of natural persons in relation to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) – GDPR and the internal Information Security Policy in force at the Office, based on international standards. An external audit carried out at the Office in 2024, together with the performance of a number of technical tests and verification of organisational aspects, demonstrated the Office's achievement of a positive level of security of information processed at the Office, including a high level of technical security. At the same time, recommendations for further improvement of the Office were identified and are being implemented on an ongoing basis.

A two-day information security training course was held for all Office staff in 2024 to raise competencies and strengthen awareness.

Activities related to organisation and internal regulations

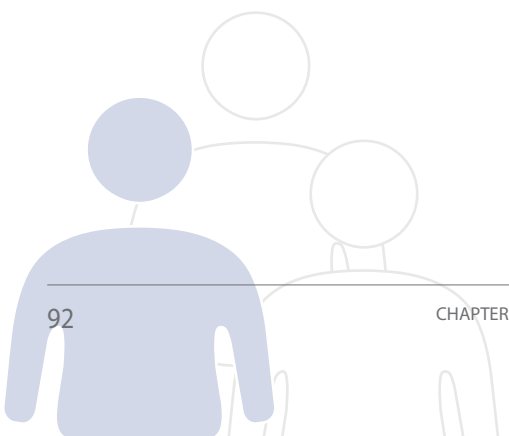
The Organisation and Quality Office carried out tasks, related to the organisation of the unit's operation and the development and issuance of internal regulations, i.e. orders of the President of the Office and the Director General and the repeal of standard operating procedures of organisational units. In 2024 at the Office, 14 new internal regulations were issued regulating the work of the unit, including five orders of the President and nine orders of the Director General. In addition, due to the need to adapt existing regulations to changes in legislation and organisational needs, 89 existing orders were amended, including 30 orders of the President and 59 orders of the Director General, and a total of 13 orders were repealed. It should be noted that due to the systematic replacement of Standard Operating Procedures by process charters, 23 new applications were assessed and 23 standard procedures were repealed in 2024. In addition, as part of activities related to the organisation of the unit's work and delegation of authority, a total of 349 authorisations and powers of attorney were issued to the Office President and the Director General, and 34 authorisations were revoked or terminated. As part of tasks in the area of internal organisation, service cards were also issued to Office employees carrying out controls or inspections.

Tasks related to the handling and recording of complaints, applications and petitions were also carried out as part of the Office's consideration of signals from citizens. In 2024, 11 such cases were handled.

In the first half of 2024, the Annual Report of the President's Annual Report was prepared and published as a printed bilingual publication. The report was submitted to the Minister of Health and circulated to cooperating units, as well as made available on the Office's website. Four summary quarterly reports on the unit's activities were also prepared and submitted to the Office's Management.

The remit of the Organisation and Quality Office also includes the maintenance of a list of external experts cooperating with the Office in the area of dossier evaluation. Twelve new experts were added to the database of external experts and five updates were made to the register of external experts. In addition, in terms of the register of external experts, 336 applications for civil law contracts for external expertise were assessed in 2024.

The Organisation and Quality Office also carried out tasks in cooperation with other units in the Office, e.g. in the implementation of the recommendations of the information security audit, including education of employees in this area, health promotion, as well as cooperation with the Polish Association of the Deaf, in the provision of sign interpreter services, and in the provision of factual material for the Office's speeches and publications, and coordinated many projects related to the provision of data and information on the Office's work.



Quality management and management control activities at the Office

In 2024, in order to unify and improve the solutions implemented at the Office within the Quality Management and Management Control System, an Integrated Quality Management and Management Control System was introduced, in line with the requirements of PN-EN ISO 9001:2015 and the management control standards set out in Communication No. 23 of the Minister of Finance of 16 December 2009 on management control standards for the public finance sector.

The following tasks were performed in the field of quality management and ensuring appropriate standards of functioning of management control at the Office:

- a report on the implementation of the activity plan of the Office for 2023 was prepared and posted on the Office's Public Information Bulletin in accordance with the requirements of the Regulation of the Minister of Finance of 29 September 2010 on the activity plan and the report on its implementation;
- the achievement of the targets set for 2024 was monitored;
- the risks set for the 2024 targets and the implementation of the actions identified in the 2024 risk management plan were monitored;
- a plan of the Office's activities for 2025 was prepared and posted on the Office's Public Information Bulletin, as required by the Regulation of the Minister of Finance of 29 September 2010 on the activity plan and the report on its implementation;
- a risk analysis was carried out for the objectives contained in the Office's 2025 business plan;
- conducted a management control self-assessment for 2023 and prepared a self-assessment report for Office Management;
- An evaluation questionnaire on the application of management control standards in the Office for 2023 was prepared and submitted to the Ministry of Health;
- the Office President's statement on the state of management control for 2023 was prepared and submitted to the Ministry of Health;

Integrated Quality Management and Management Control System

- core, management and support processes were reviewed and mapped.

Implementation of process management

In 2024, process management development activities continued within the framework of the Integrated Quality Management and Management Control System. A diagram of the activities carried out is shown in Figure 9.1.

As part of the implementation of process management, a process architecture was developed and validated, detailing the following process types: management processes, main (statutory) processes, supporting processes.
A detailed breakdown of the processes is presented in the architecture model shown in Figure 9.2.

In the course of the work, 184 processes were identified, of which 85 were validated and made available to staff in the process management support system – ADONIS. All employees were trained in process management and the use of process maps. In 2024, 52 process maps have been approved.

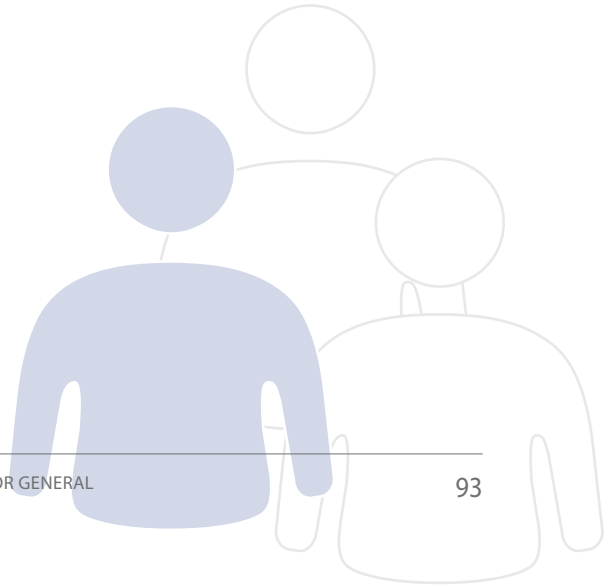


Figure 9.1: Implementation of process management at the Office

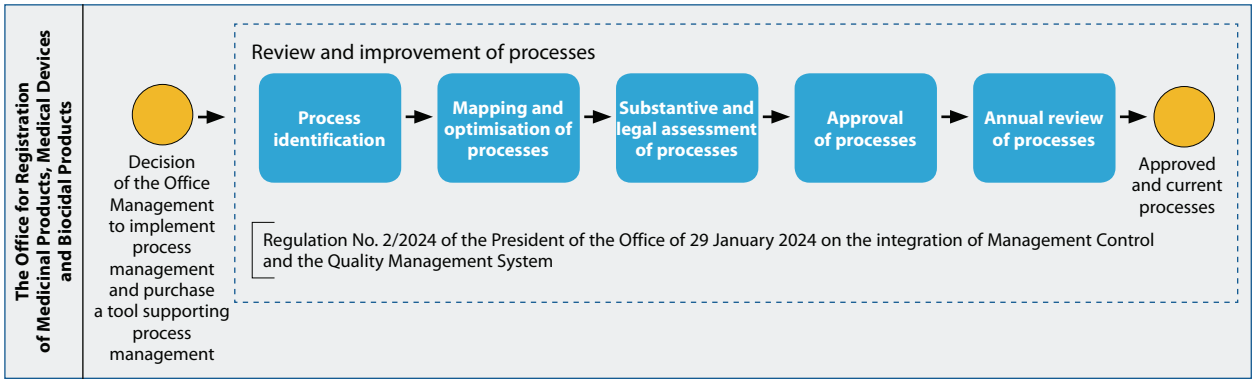
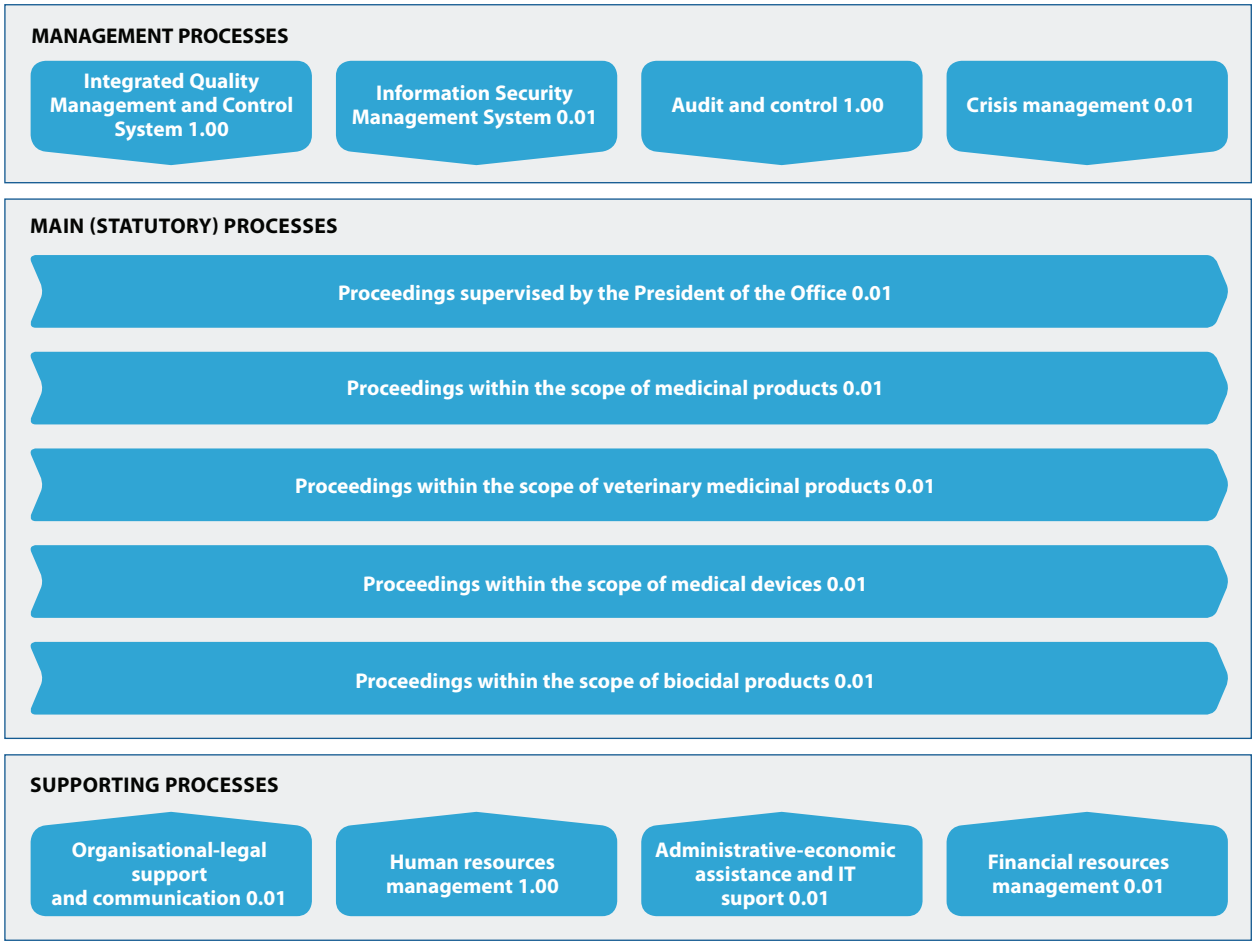
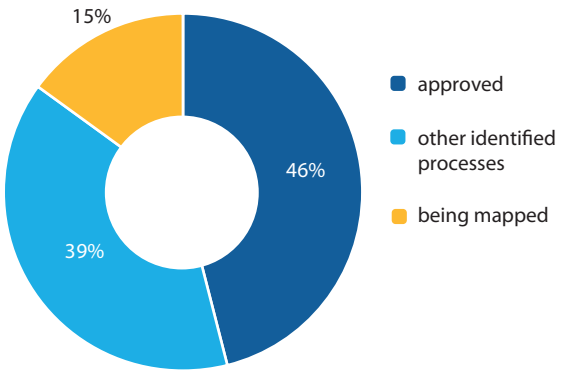


Figure 9.2: Process architecture of the Office



Graph. 9.7: Percentage of the process mapping work status of the Office



Anti-corruption measures

In 2024, as they do every year, Office employees were asked to submit asset declarations and managers of the Office's organisational units were asked to submit information on how to deal with attempts to give gifts to Office employees. Both the asset declarations and the information were subject to analysis. Office employees were also asked to make declarations regarding possible activities or occupations contrary to the Civil Service Act, the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products Act or that could undermine confidence in the civil service. In addition, the Office monitored the possible existence of conflicts of interest related to the duties performed by Office employees. Newly recruited Office employees were required to undergo e-learning training on corruption and anti-corruption, and all Office employees were provided with information material ethics and anti-corruption through the Internal Information Portal. The anti-corruption coordinator reviewed draft laws and regulations of the Minister of Health and the Office's internal legal acts in terms of corruption risks. The anti-corruption coordinator participated in a conference on conflict of interest.

Measures to ensure accessibility

Accessibility measures are an important part of the Office's work, which is, among other things, the principle of equal treatment of citizens and the focus on implementing measures to help people with disabilities. In 2024, the Office carried out tasks for improving accessibility for persons with special needs under the Act of 19 July 2019 on ensuring accessibility for persons with special needs and the Act of 4 April 2019 on digital accessibility of websites and mobile applications of public entities.

To date, a number of improvements have been implemented at the Office, opening up the Office to the needs of people with disabilities, including the possibility for people who are deaf or hard of hearing to use the services of a Polish Sign Language (PJM) interpreter and an induction loop, as well as an interpreter-guide for people who are deaf-blind, should the need arise. The Office has also complied with the obligation to post the required accessibility declarations on the website and information about the Office's activities in Polish Sign Language translation, machine-readable version and easy-to-read format.

The Office's website, having been transferred to the government's gov.pl website, has been adapted to meet digital accessibility requirements. Information on the website is published in accordance with Order No. 7/2022 of the Director General on the development, approval and publication of content on the Office's website for Registration of Medicinal Products, Medical Devices and Biocidal Products.

In addition, every effort is being made to successively remove all ICT and digital architectural barriers, increasing the Office's accessibility as part of our equal opportunities policy.

Audit and control at the Office

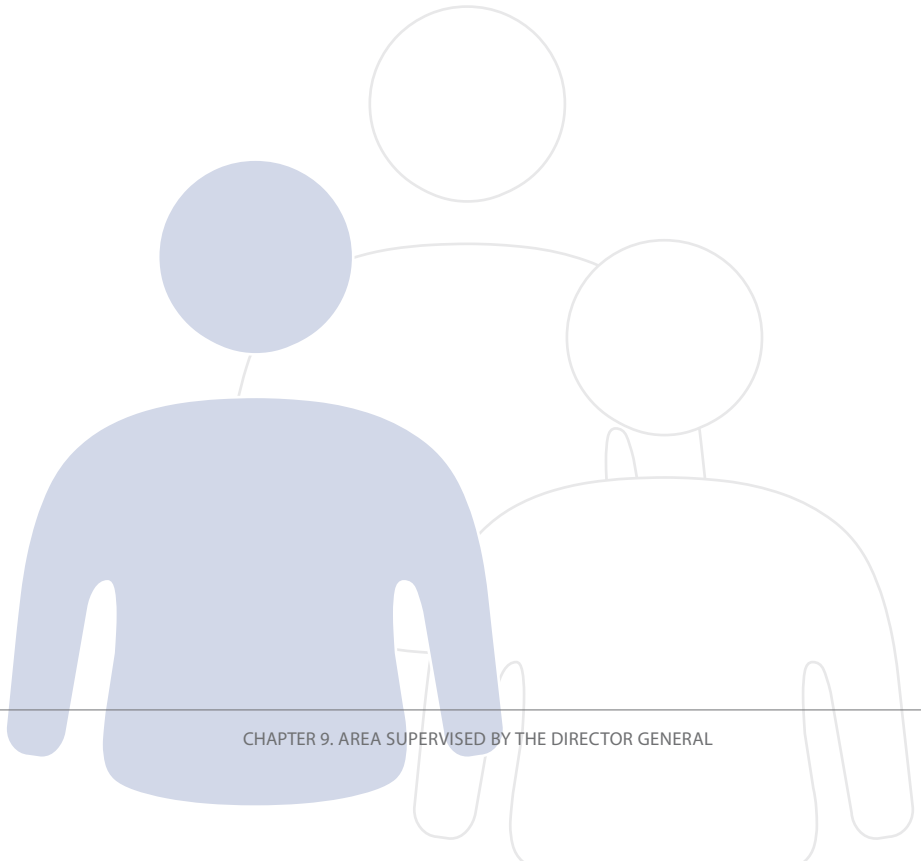
In 2024, in terms of reporting tasks, internal audit prepared a report on the conduct of internal audit for 2023 and prepared and submitted information on the performance of internal audit tasks in 2023 to the Minister of Finance. A self-assessment of the Office's internal audit for 2023 was carried out, providing

an assessment of the efficiency and quality of the audit function, with an indication of opportunities for improvement of the operation and further development, in line with internal audit regulations and standards and the expectations of the Office's Management. As part of the planning tasks, an internal audit plan for 2025 was developed. On the basis of the 2024 audit plan, all three assurance tasks (including the internal audit commissioned by the Minister of Finance and the Audit Committee priority for the government department – Health) were completed. One of the two advisory activities included in the 2024 Audit Plan has been carried out and the second one has been initiated (it continues in 2025). All planned follow-up activities (four) and two in addition, outside the audit plan, were completed (including follow-up activities to task ref: AW.0931.4.2023 entitled ˝Audit of security, including information and IT systems˝ which is a priority of the Audit Committee for the 2023 plan). Monitoring of the implementation of recommendations was carried out for eight tasks resulting in recommendations in 2017, 2019, 2020 and 2022-2024.

In terms of internal control, an audit was carried out in 2024 to verify the implementation of the recommendations from the 2022 audit of the Office by the Minister of Health. Two internal audits on biocidal products and veterinary medicinal products were initiated. In addition, the status of the implementation of recommendations from internal and external audits carried out in previous years was monitored. The Office was not audited by external bodies in 2024. A self-assessment of the Office›s internal controls for 2023 was carried out, which identified proposals for improving operations and development. In addition, an internal control plan for 2025 was developed.

Health promotion among employees

The year 2024 was also another year in which the General Manager's Division continued its occupational health prevention activities. An important manifestation of the measures implemented with employee health in mind was the provision, for the fifth consecutive year, of the opportunity for Office employees to receive free flu vaccinations, to which 87 employees submitted. In addition, in view of the positive impact of animals on people's mental and physical health, it was made possible for Office employees to be in the workplace with a pet. The Office's management provided conditions and supported employees in maintaining a work-life balance. The Office continuously encouraged preventive health care for its employees, including through the possibility, provided for in the Work Regulations, of taking 2 days off per calendar year for medical examinations not related to occupational medicine.



Chapter 10

OTHER ACTIVITIES CARRIED OUT BY THE PRESIDENT OF THE OFFICE

Communication

In 2024, communication activities of the Office were focused on informing the public about new medicinal products, decisions of the European Medicines Agency (EMA) and committees acting within the Agency. Some of the posts on social media were devoted to providing the public with information on broadly understood health prevention and the ongoing activities of the President of the Office for the benefit of patients' health. As part of the continuation of activities related to the following campaigns conducted by the Office: „Safe Medication" campaign and „Safe Medication Through the Eyes of a Child", social media services of the Office also published information on safe pharmacotherapy, antibiotic resistance, vaccinations, the need to report adverse reactions to medicinal products, announcements and information from the President of the Office, and relevant data published by the European Medicines Agency and government institutions, including the Ministry of Health and the Chancellery of the Prime Minister.

During 2024, 416 posts were published on Facebook, most of them in the form of graphics and videos, while 273 posts were published on X from the Office's account and 313 posts from the account run by the Office's press spokesperson. These were mainly text-based, containing links to announced information. The Office is also present on LinkedIn, where approximately 84 publications were posted in 2024. The year 2024 resulted in considerable interest in the activities of the Office among media representatives. During the period under review, a total of 67 questions from journalists were received by the press spokesperson of the Office.

Information campaigns – ″Safe Medication″ and ″Safe Medication through the Eyes of a Child″

Since 2006, the Office has been running an information campaign called ″Safe Medication″, which aims to raise awareness about the safe and effective use of medicinal products.

The campaign aims to make the public aware of the principles of appropriate use of medicines, to prevent their inappropriate use and to eliminate the use of medicinal products from illegal sources which have not been registered by the President of the Office in accordance with the applicable safety regulations.

In 2016, as part of the ″Safe Medication″ campaign, the Office launched an educational campaign entitled ″Safe Medication Through the Eyes of a Child″.

As part of the above-mentioned campaign, numerous educational activities are carried out, including the publication of posts and educational films on the website and social media of the Office concerning the safety of pharmacotherapy and the reporting of adverse reactions to medicinal products. In addition, as part of the Safe Medication campaign, the Office regularly publishes a quarterly "Almanach".

Lek Bezpieczny

Campaign: "Safe medications – safe animals – safe people"

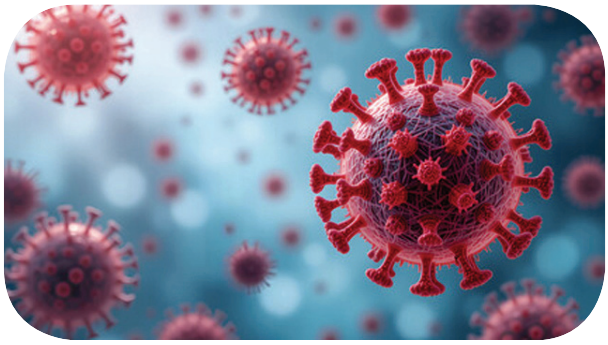
The campaign is led by the POLPROWET Association under the patronage of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and Polish National Veterinary Chamber.

The aim of the campaign is to raise public awareness of the responsible use of veterinary medicines and to present the role of veterinarians and other entities responsible for ensuring the safety of these products. As part of this campaign, a webinar was held on 15 May 2024.

Information material published on the social media profiles of the Office, available at facebook.com/urplwmipb

Promotion and protection of health in the workplace

Health education for employees and support for preventive healthcare in the workplace, as in previous years, were part of the comprehensive activities carried out by the Office to protect patient health. As part of these activities, for the fifth consecutive year, the Office provided its employees with free flu vaccinations.



Publications of the Office

The tasks of the President of the Office also include the development and publication of the Polish Pharmacopoeia, which specifies the basic quality requirements and testing methods for medicinal products (including veterinary medicinal products) and their packaging, as well as pharmaceutical raw materials, and contains provisions on the preparation of medicines in pharmacies. This is a highly specialised publication, and therefore a wide range of specialists from domestic universities and scientific institutions are involved in its preparation. More information on this subject can be found in Chapter IV, ˝Area supervised by the President of the Office˝, in the subchapter ˝Polish Pharmacopoeia˝.

Supplement 2024
Polish Pharmacopoeia XIII

As part of its information activities, since 2006 the Office has also been publishing a quarterly "Almanach" – a scientific journal addressed primarily to people professionally involved in health care and interested in issues related to the statutory activities of the unit. The journal mainly publishes information on the safety, quality and efficacy of medicinal products, medical devices and biocidal products, as well as review articles on medicinal products, medical devices and biocidal products. "Almanach" is listed in the IC Journal Master List (IC JML). In 2024, a single combined issue of the "Almanach" was published.

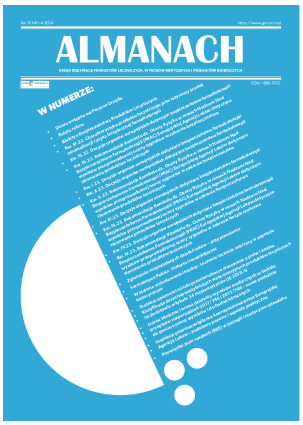


Photo of the cover of the Office's quarterly "Almanach"

In 2024, the Annual Report of the President of the Office on the activities of the Office in 2023 was issued, which was submitted to the Minister of Health and to institutions cooperating with the Office. The report is available in electronic form on the website of the Office.

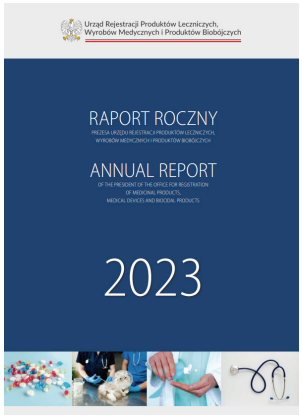
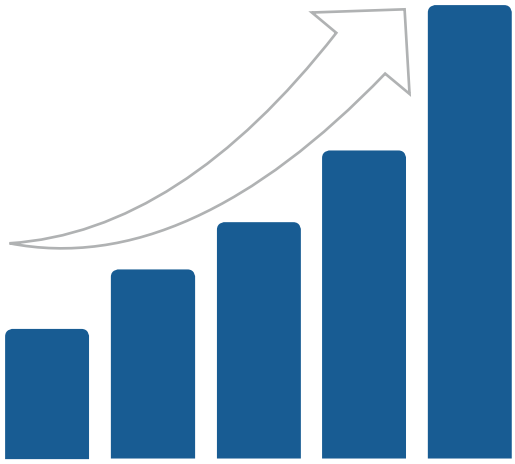


Photo of the 2023 Annual Report of the President of the Office

Chapter 11

OBJECTIVES FOR 2025



The primary objectives of URPLWMiPB are to ensure access to medicinal products, veterinary medicinal products and biocidal products that meet the appropriate standards of safety, quality and efficacy, as well as monitoring the safety of their use and exercising supervision over medical devices. The achievement of the objectives is based on conducting proceedings in accordance with legal requirements and internal regulations, in each of the Office's statutory areas of activity, as well as through improvement and optimising the Office's work. The 2025 plan also includes seeking to improve the Office's staffing situation and developing international relations.

The following objectives have been included in the 2025 plan:

Ensuring access to, and monitoring the safety of, medicinal products of high quality, safety and efficacy, and monitoring the safety of their use

Ensuring access to veterinary medicinal products of proper quality, safety and efficacy and monitoring the safety of their use

Supervising medical devices manufactured, marketed and used on the national territory

Ensuring access to biocidal products of proper quality, safety and efficacy, and monitoring the safety of their use

Ensuring access to basic quality requirements and test methods for medicinal products and their packaging as well as pharmaceutical raw materials

Developing international relations

Improving the stability of human resources

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https://www.gov.pl/web/urpl/raport-roczny

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