

2025

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



From the left: Sebastian Migdalski – Vice-President of the Office for Medical Devices,
Magdalena Wojciechowicz – Director General,
Grzegorz Cessak – President of the Office,
Aleksandra Wilczyńska – Vice-President of the Office for Biocidal Products,
Marcin Kołakowski – Vice-President of the Office for Medicinal Products,
Agata Andrzejewska – Vice-President of the Office for Veterinary Medicinal Products

FOREWORD BY THE PRESIDENT OF THE OFFICE



Ladies and Gentlemen,

We are pleased to present the Annual Report of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMIpB) for 2025 – a document that summarises a particularly challenging year, while also confirming the Office's growing role within the national, European and global regulatory framework.

The year 2025 saw the Office engage in intensive and wide-ranging activities, both in the exercise of its statutory powers and through its active participation in shaping the European and international regulatory environment. The scale and pace of the activities reflected the evolving challenges facing the healthcare system, as well as the growing expectations placed on the institutions responsible for the safety of pharmacotherapy.

A particular testament to the Office's growing standing on the European stage was the Polish Presidency of the Council of the EU, during which the Office hosted meetings of committees and groups that are key to the European regulatory framework for medicinal products, medical devices and biocidal products. Representatives of the Office also played an active role in the

work of the Council's working group responsible for revising the EU's pharmaceutical legislation. Thanks to their commitment, this process yielded significant results.

The Office has consistently carried out its key tasks relating to the authorisation of medicinal products, under both national and European procedures, while maintaining a high substantive standard and the efficiency of its decision-making processes.

The structure of the decisions issued, in which products used to treat central nervous system disorders accounted for a significant proportion, reflects the current health needs of the population and the direction of development in modern pharmacotherapy. The parallel measures being implemented regarding the authorisation of pharmaceutical inputs for marketing are part of the strategic objective of enhancing medication safety and ensuring continuity of treatment.

A significant regulatory challenge was the legislative changes concerning post-marketing variations to medicinal products for human use. The entry into force of the amendment to Commission Regulation (EC) No 1234/2008 and the publication of new implementing guidelines, supplemented by the recommendations of the Coordination Group on

Mutual Recognition and Decentralised Procedures (CMDh), necessitated the alignment of regulatory practice with the new standards. Consequently, the backlog of applications at the end of the year placed a significant operational burden on the Office, which was effectively managed thanks to the commitment and expertise of its specialist teams.

At the same time, efforts were stepped up in the area of additional risk minimisation (aRMM) measures, including through the updating of guidelines, the development of digital tools and the introduction of standardised labelling for educational materials. These initiatives enhance the quality of regulatory communication and the safety of medicinal products, forming part of a long-term strategy focused on patients and healthcare professionals.

The year 2025 also marked the completion of a key phase in the implementation of Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials. The completion of the migration of clinical trials to the Clinical Trials Information System (CTIS) represents a significant step towards full transparency and harmonisation within the European clinical trials landscape.

The Office has also stepped up its activities in the area of inspection and supervision, covering clinical trials, medical devices and veterinary medicinal products, including tasks carried out in cooperation with European partners and on behalf of the European Medicines Agency.

The Office's international activities were of particular significance in connection with Poland's Presidency of the Council of the European Union. The Office not only actively participated in the work of the European network of regulators but also organised key cooperation forums that set the agenda for debate in areas such as preventive healthcare, digital transformation, mental health and the future of pharmaceutical legislation.

As I mentioned earlier, the Polish Presidency of the Council of the EU was for the Office a period of intense work, international cooperation and active involvement in shaping European health policy.

Over the course of six months, the Office organised or co-organised 18 events attended by 1,162 experts and representatives of institutions from the 27 EU Member States and candidate countries. The discussions focused, among other things, on the mental health of children and young people, digital transformation, health security, advanced therapies, rare diseases and the One Health approach.

In the Presidency's reviews provided by our European partners, the Office's work was highly rated across the board; however, we were particularly commended for our professionalism, high standards of expertise and Poland's active contribution to the development of the European regulatory framework.

At the same time, we have been developing bilateral and regional cooperation, achieving tangible results – ranging from the conclusion of new international agreements to a real impact on legislative and institutional changes in partner countries. Support for Ukraine in the process of aligning its regulatory framework with the *acquis communautaire* was of particular importance. In this context, a key initiative was the launch of a European Union-funded Twinning project, implemented by Poland, Lithuania and Germany, aimed at establishing a modern and independent Ukrainian State Control Office for Medicines, Medical Devices and Cosmetics (SCA), in line with EU standards.

The URPLWMiPB plays a key role in the project, providing expertise and coordination, and supporting the development of regulatory frameworks, institutional capacity-building, the formulation of management and communication policies, and the process of aligning Ukrainian regulations with the *acquis communautaire*. The project is a key element in supporting Ukraine's integration into the European regulatory and healthcare system.

Experts from the Office continued to actively participate in the work of the European Medicines Agency's scientific committees, contributing to the evaluation process for innovative and therapeutically important medicinal products. Their contribution covered both the pre-registration stages and the assessments leading to marketing authorisation, including in the areas of advanced therapies, rare diseases and oncology.

Thanks to the high quality of its assessments and its active involvement in the work of the European Medicines Agency, Poland has maintained a strong, leading position among the Member States participating in the scientific evaluation of medicinal products under the centralised procedure.

The scale, scope and quality of the measures taken in 2025 clearly demonstrate that the Office remains a stable, reliable and expert pillar of the healthcare system, both at national level and within the European and global regulatory community.

The year 2025 was a time of rapid change, requiring decisive action, a sense of responsibility and the ability to adapt. It was also a year that strengthened the Office's position as a modern regulatory body, capable of operating effectively in a dynamic and demanding environment.

The following pages of the 2025 Annual Report also provide comprehensive information on all areas of the Office's operations over the past year, including data relating to its activities concerning medicinal products for human use, medical devices, biocidal products and veterinary medicinal products.

Grzegorz Cessak, PhD, President of the Office

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



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

The Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products was established in 2002. Since then, the scope of the Office President's duties and responsibilities has evolved. A significant change was the entry into force of 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), as a result of which, with effect from 1 May 2011, the President of the Office acquired the status of a government administrative body. The President of the Office is currently responsible for matters relating to:

- the authorisation of medicinal products, excluding medicinal products authorised for marketing without the need for a marketing authorisation – within the scope specified by the Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws of 2025, item 750, as amended);
- the authorisation of veterinary medicinal products – within the scope set out in 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 UE Journal Law 4 of 7 January 2019, p. 43, as amended), hereinafter referred to as 'Regulation 2019/6';
- the placing on the market and use of biocidal products – within the scope specified by the Act of 9 October 2015 on biocidal products (Journal of Laws of 2021, item 24, as amended);
- clinical trials, including veterinary clinical trials within the scope defined by the Act of 6 September 2001 –

Pharmaceutical Law, the regulations on medical devices, and the Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws of 2026, item 2) and 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 (Official UE Journal Law 158 of 27 May 2014, p. 1, as amended);

- medical devices, medical device accessories, medical systems and kits, products without an intended medical purpose, including their clinical trials, safety, placing on the market and putting into service, and their supervision within the scope of Regulation (EU) 2017/745 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 UE Journal Law 117 of 5 May 2017, p. 1 amended), hereinafter referred to as 'Regulation 2017/745';
- in vitro diagnostic medical devices and accessories for in vitro diagnostic of 5 May 2017, performance studies,

safety, and the placing on the market and putting into service of such devices, as well as their supervision, within the scope of Regulation (EU) 2017/746 of the European Parliament and of the Council (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Official UE Journal Law 117 of 5 May 2017, p. 176, as amended), hereinafter referred to as 'Regulation 2017/746';

- notification, in accordance with Article 42(2), (5) and (8) of Regulation 2017/745 and in accordance with Article 38(2), (5) and (8) of Regulation 2017/746;
- within the scope specified by the relevant legislation for the above-mentioned areas¹.

The adoption of the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also resulted in a change to the organisational structure of the body, introduced by the new statutes issued by Order No. 37 of the Prime Minister of 14 June 2011 on the adoption of the statutes of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Journal of Laws of 2019, item 681, as amended)².

Description of the Office's core activities

In accordance with the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the Office's statutory remit comprises three main areas, namely:

Conducting proceedings and carrying out activities relating to medicinal products for human use and veterinary medicinal products, in particular:

- issuing, by way of a decision, marketing authorisations for medicinal products;
- issuing, by way of a decision, marketing authorisations for veterinary medicinal products;



- issuing notifications of the acceptance or rejection of post-registration amendments,
- issuing decisions on post-registration changes and on the extension or shortening of the validity of marketing authorisations;
- providing information on the documentation and procedures required for the marketing authorisation of medicinal products and veterinary medicinal products;
- issuing, by way of a decision, authorisations for the parallel import of medicinal products;
- issuing, by way of a decision, authorisations for the parallel trade in veterinary medicinal products;
- issuing of marketing authorisations for homeopathic veterinary medicinal products;

¹ The Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws of 2025, item 750, as amended), the Act of 9 October 2015 on biocidal products (Journal of Laws of 2021, item 24, as amended), the Act of 7 April 2022 on medical devices (Journal of Laws of 2024, item 1620), the Act of 9 March 2023 on clinical trials of medicinal products for human use (Journal of Laws of 2026, item 2).

² The Statute was amended by Order No. 62 of the Prime Minister of 15 September 2014 amending the order on the adoption of the Statute of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (Official Journal of 2014, item 833), by Order No. 172 of the Prime Minister of 16 November 2017 amending the order on the adoption of the Statute of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P. 2017, item 1064) and Order No. 63 of the Prime Minister of 11 June 2024 amending the order on the adoption of the statutes of the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products (M.P. of 2024, item 466).

- maintaining the Register of Medicinal Products Authorised for Marketing in the Republic of Poland and issuing decisions refusing access to that register;
 - issuing, by way of a decision, of authorisations to conduct a clinical trial or a veterinary clinical trial;
 - maintaining the Central Register of Clinical Trials;
 - conducting inspections of clinical trials to ensure their compliance 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 safety update reports on medicinal products and gathering information on adverse reactions to medicinal products and investigational medicinal products;
 - overseeing the safety of medicinal products and monitoring their safety;
 - conducting audits of the system for monitoring the safety of medicinal products;
 - oversight of the pharmacovigilance of veterinary medicinal products and monitoring of the pharmacovigilance system;
 - collecting reports of suspected adverse reactions to veterinary medicinal products and forwarding these reports to the EU database on pharmacovigilance;
 - annual analysis of data on the safety of veterinary medicinal products;
 - the publication, at least once a year, in the Official Journal of the Minister responsible for health, of the Official List of Medicinal Products Authorised for Marketing within the territory of the Republic of Poland, including a separate list of veterinary medicinal products;
 - publishing, once a month in the Public Information Bulletin, a list of medicinal products that have been granted a marketing authorisation by the President of the Agency;
 - participation in the harmonisation of the characteristics of veterinary medicinal products in accordance with the rules laid down 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 such information which, when assessed with due care, can be considered medically reliable;
 - the development and maintenance of a dedicated website providing information on safety aspects relating to the use of medicinal products, excluding veterinary medicinal products;
- Conducting proceedings and carrying out activities relating to product supervision, product safety, and the placing on the market and use of products, in particular:**
- issuing decisions relating to medical devices;
 - the collection of data from reports and notifications concerning medical devices;
 - the verification of applications in accordance with Article 31(2) of Regulation 2017/745 and Article 28(2) of Regulation 2017/746, and the issuing of unique registration numbers;
 - maintaining the register of distributors referred to in Article 21(1) of the Act of 7 April 2022 on medical devices (Journal of Laws of 2024, item 1620), collecting information on devices, systems and procedure kits referred to in Article 22(1) of that Act, and the registration of manufacturers of custom-made devices, their authorised representatives and importers referred to in Article 23(1) of that Act;
 - supervising products manufactured, placed on the market, put into service or submitted for performance evaluation within the territory of the Republic of Poland;
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- issuing, by way of a decision, authorisation for the placing on the market or putting into service within the territory of the Republic of Poland of individual devices which are essential for achieving necessary preventive, diagnostic or therapeutic objectives, and for which no conformity assessment procedures have been carried out to confirm that those devices meet the relevant requirements;
 - overseeing serious incidents, as defined in Regulation 2017/745 or Regulation 2017/746, and product safety measures;
 - publishing safety notices and administrative decisions concerning product safety;
 - the issuance of free sale certificates referred to in Article 60 of Regulation 2017/745 and Article 55 of Regulation 2017/746;

- issuing, at the request of the customs authorities, opinions on whether a product meets the requirements specified for it;
- the granting of authorisations to conduct clinical trials or performance studies, and authorisations to make changes to such trials;
- entering details of clinical trials into the Central Register of Clinical Trials;
- the collection and analysis of information on serious adverse events that have occurred in connection with the conduct of a clinical trial of a medical device or an active implantable medical device, and of the final reports on the conduct of such a clinical trial;
- conducting inspections of clinical trials and performance studies;
- issuing, at the request of notified bodies, opinions on the quality and safety of a substance that forms an integral part of a device but which, if used on its own, would constitute a medicinal product;
- issuing, at the request of notified bodies, the opinions referred to in Section 5.4 of Annex IX to Regulation 2017/745;
- issuing, at the request of notified bodies, opinions on the suitability of a product for use in targeted therapy in relation to a given medicinal product;
- carrying out activities relating to the supervision, designation, notification and monitoring of notified bodies;
- conducting an assessment of the documentation submitted in order to obtain the Union authorisation referred to in Article 3(1)(n) of Regulation 528/2012;
- submitting objections to the coordination group in accordance with Article 35 of Regulation 528/2012;
- issuing opinions on scientific research and development that may involve or result in the release of a biocidal product into the environment;
- keeping a record of reports on reported cases of poisoning caused by biocidal products;
- providing information on the documentation and procedures required for the authorisation of biocidal products;
- the prohibition referred to in Article 65(3) of Regulation 528/2012 is introduced.

The President of the Office is also responsible for:

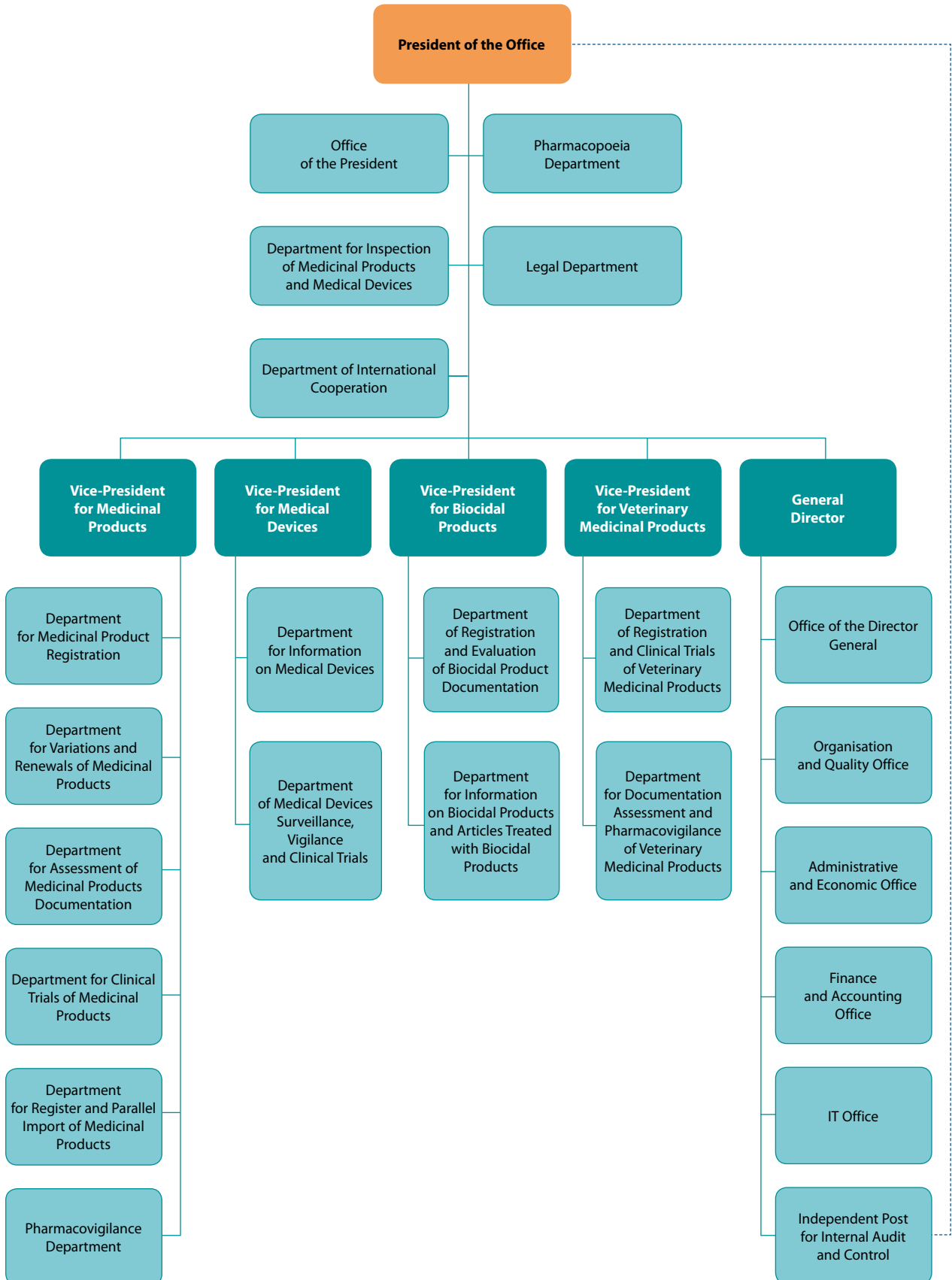
- the appointment of experts referred to in Article 40 of Regulation 2017/745 and in Article 36 of Regulation 2017/746;
- issuing an opinion on a foodstuff's failure to meet the requirements for a medicinal product, as referred to in Article 31(2) of the Act of 25 August 2006 on food and nutrition safety (Journal of Laws of 2023, item 1448, as amended);
- preparing and publishing the Polish Pharmacopoeia and announcing, by way of a notice in the Public Information Bulletin, the date from which the requirements set out therein come into force;
- cooperation with public authorities and research institutes;
- cooperation with the 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), the competent authorities of the Member States of the European Union, the Swiss Confederation and the Member States of the European Free Trade Association (EFTA) – 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, covering quality, clinical and non-clinical aspects, post-marketing safety surveillance of medicinal products, or methodological issues relating to ongoing or planned studies.

Conducting proceedings and carrying out activities relating to biocidal products, in particular:

- issuing of national permits by way of a decision;
- issuing, by way of a decision, of authorisations pursuant to Article 26 of Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (Official UE Journal Law 167 of 27 June 2012, p. 1, as amended), hereinafter referred to as 'Regulation 528/2012';
- issuing, by way of a decision, authorisations for parallel trade;
- issuing, by way of a decision, authorisations for the placing on the market of biocidal products;
- maintaining the Register of Biocidal Products;
- conducting an assessment of the dossiers for active substances submitted for approval in accordance with the provisions of Regulation 528/2012;

Organisational chart of URPLWMiPB

as of 31 December 2025





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KEY TASKS AND EVENTS
IN 2025

JANUARY 2025



3 January

Warsaw, Poland

The official opening ceremony of the Polish Presidency of the Council of the European Union

A gala event marking the start of Poland's Presidency of the Council of the European Union was held at the Grand Theatre – National Opera in Warsaw. The event was attended by representatives of the top levels of government, European institutions and the diplomatic corps. Among the invited guests was also Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The ceremony marked the symbolic start of Poland's six-month presidency of the Council of the EU and highlighted the importance of European cooperation in the face of contemporary challenges.

23 January

Warsaw, URPLW MiPB headquarters, Poland

The 119th meeting of Heads of Medicines Agencies (HMA) under the Polish Presidency of the EU

The 119th meeting of the HMA took place during the Polish Presidency of the EU. The discussion covered regulatory challenges, the review of the pharmaceutical package, regional cooperation, and the mental health of children and young people. The meeting set out the direction for the network of regulators' future activities. The role of cooperation as the cornerstone of health security in the EU was emphasised.



30 January

Publication of the Bulletin of Medicinal Products for Human Use and the Bulletin of Veterinary Medicinal Products for 2024.



FEBRUARY 2025



24–26 February

Tashkent, Uzbekistan

The 8th meeting of the Polish–Uzbek Intergovernmental Commission for Economic Cooperation and the Poland–Uzbekistan Business Forum

Representatives of the URPLW MiPB took part in the work of the Poland–Uzbek Intergovernmental Commission and the accompanying Business Forum. Among other things, the meetings were focused on cooperation in the pharmaceutical sector and efforts to reduce barriers to entry into the Uzbek market, including in the area of drug registration procedures. The event supported the growth of exports of Polish medicinal products and economic dialogue.

27–28 February

Amsterdam, Netherlands

The ‘Medicines for Europe – Regulatory Affairs Conference 2025’

A representative from URPLW MiPB attended a conference on the future of medicines regulation in Europe, including legislative changes, supply security, digitisation and the use of data. The event provided an opportunity for experience sharing with regulators and industry representatives and strengthened Poland’s involvement in the debate on the future direction of the EU regulatory framework.



MARCH 2025



4–5 March

Warsaw, URPLW MiPB headquarters, Poland

Meeting of the EDQM Working Group on Borderline Products during the Polish Presidency of the Council of the EU

A meeting of the EDQM Working Group on Borderline Products was held as part of the Polish Presidency of the Council of the EU. The challenges associated with the classification and regulation of borderline products were discussed, including SoHO regulations and the detection of undisclosed active substances. The findings of the meeting strengthened the consistency of the regulatory approach across Member States.

6–7 March

Warsaw, Poland

Meeting of IT Directors from National Medicines Agencies.

A meeting of the IT Directors of the National Medicines Agencies was held as part of the Polish Presidency of the Council of the EU. The discussion covered cybersecurity, interoperability and the use of artificial intelligence in regulatory systems. The meeting strengthened digital cooperation within the European network of regulators. The role of digitisation as a key element of the regulatory resilience of the system was emphasised.



9–15 March

London, United Kingdom

Participation in the inspection under the PIC/S Programme for Group 160 and Group 162

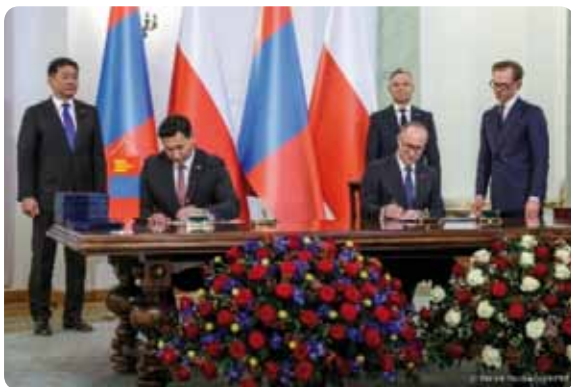
The Department for the Inspection of Medicinal Products and Medical Devices took part in an inspection in the United Kingdom as part of an international project aimed at standardising inspection and audit procedures within the framework of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Poland cooperates in this area with Canada, the United Kingdom, Spain and Denmark.

13 March

Amsterdam, headquarters of the European Medicines Agency (EMA), Netherlands

127th meeting of the Management Board of the European Medicines Agency (EMA)

The 127th meeting was held to discuss the key priorities of the Agency as part of the EMA Management Board's work. The Strategy for the Network of European Medicines Agencies up to 2028 has been adopted. Discussions focused on the development of clinical trials, the use of data and artificial intelligence, and crisis preparedness. The decisions of the Council have set out the priorities for the further modernisation of the European network.



13 March

Warsaw, Presidential Palace, Poland

Memorandum of Understanding signed between the URPLW MiPB and the Mongolian Medicines and Medical Devices Regulatory Agency (MMRA)

In the presence of the Presidents of the Republic of Poland and Mongolia, a formal signing ceremony was held for the Memorandum of Understanding between the URPLW MiPB and the Mongolian Agency for the Regulation of Medicinal Products and Medical Devices. The agreement established a framework for cooperation on regulation, clinical trials and safety oversight. The event has strengthened the international standing of the Office and the role of Poland in the regulatory dialogue.

20 March

online meeting

Meeting with representatives of the Rwanda Food and Drugs Authority regarding the establishment of cooperation

A virtual meeting was held with representatives of the Rwanda Food and Drugs Authority to discuss opportunities for cooperation in the area of the registration of medicinal products and medical devices. The discussion was focused on the exchange of expert insights and the prospect of signing a formal agreement between the institutions. The Ambassador of the Republic of Rwanda to Poland opened the meeting.



27 March

online meeting

The 40th meeting on homeopathic medicines, Homeopathic Medicinal Product Working Group (HMPWG)

The 40th meeting of the group took place as part of the Polish Presidency of the Council of the EU, being also the second meeting organised by Poland. The following representatives from URPLW MiPB took part: Ewa Antkiewicz – the representative of Poland at the HMPWG, PhD (Pharmacy), Monika Trojan – Director of the Department for Assessment of Medicinal Products Documentation and Vice-President for Medicinal Products – Marcin Kołakowski. The participants also included representatives from the following countries: Austria, Belgium, Bulgaria, Croatia, the Czech Republic, Cyprus, Finland, France, Germany, Ireland, Italy, the Netherlands, Portugal, Romania, Slovenia, Sweden, Switzerland, a representative of the European Medicines Agency (EMA) and the European Directorate for the Quality of Medicines (EDQM). In addition, representatives of certain agencies responsible for the evaluation of veterinary homeopathic medicines attended the meeting.

31 March – 1 April

Warsaw, Poland

SAWP SRLM meeting held under the Polish Presidency of the Council of the EU

A meeting of the SAWP SRLM focusing on the mental health of children and young people was held as part of the Polish Presidency of the Council of the EU. The development and evaluation of paediatric medicines were discussed, including clinical trials, data extrapolation, biomarkers and the inclusion of patients' voices in scientific advisory procedures.

The meeting reinforced a patient-centred approach. These discussions have helped to identify more innovative approaches to the development of paediatric therapies.



APRIL 2025



1–2 April

Warsaw, Poland

PRAC & CMDh Strategic Meeting as part of the Polish Presidency of the Council of the EU

As part of the Polish Presidency of the Council of the EU, a strategic meeting was held between PRAC and CMDh to discuss key challenges in pharmacovigilance and regulatory procedures. The discussion covered the safety of medicines in children, including rare diseases, the optimisation of procedures, and ICT solutions. The meeting strengthened cooperation between European regulators in the interests of patient protection. The event confirmed Poland's role as an active participant in the European regulatory dialogue.

3–4 April

Warsaw, Poland

Meeting of the working group of lawyers from European medicines agencies on cooperation in legal and legislative matters – EMACOLEX – held as part of the Polish Presidency of the Council of the EU

As part of the Polish Presidency of the Council of the EU, a meeting of the EMACOLEX group was held, bringing together legal experts from the HMA network. The discussion covered key legislative challenges, case law, digitisation in healthcare and the classification of borderline products. The meeting strengthened cooperation on health security within the EU. The issues discussed will help to harmonise the interpretation of the rules across Member States.



8–9 April

Warsaw, Poland

Meeting of the competent authorities of the EU, candidate countries and the EEA on medical devices (CAMD)

As part of cooperation between European authorities, a CAMD meeting was held to address key challenges in the field of medical devices. The discussion covered cybersecurity, the evaluation of combined products, incident reporting and advertising regulations. The event has strengthened the coordination of efforts to protect patients. The meeting laid the foundations for further harmonisation of requirements across the EU.

28–30 April

Warsaw, Poland

Strategic meeting of the CHMP/PDCO scientific committees during the Polish Presidency of the Council of the EU

A strategic meeting of the CHMP and PDCO scientific committees was held as part of the Polish Presidency of the Council of the EU, focusing on prevention and the mental health of children and young people. The discussion covered the challenges of clinical trials, data extrapolation and the use of modelling in the development of paediatric medicines. The event set a new course for the regulation of paediatric treatments in the EU. The meeting highlighted the importance of scientific evidence in regulatory decision-making.



MAY 2025



5 May

Warsaw, Presidential Hotel, Poland

A meeting of 'One Health & Health Security' stakeholders held in conjunction with the 120th meeting of the HMA during the Polish Presidency of the Council of the EU

A meeting of stakeholders on the 'One Health' concept and health security was held in Warsaw for representatives of the EMA, the European Commission, patient organisations, and the scientific and industry communities. The discussions focused on cooperation between regulators and partners in the fields of human, animal and environmental health. The need to develop a strategic approach to implementing the One Health principles within the EU regulatory framework has been highlighted. The meeting strengthened cross-sectoral dialogue and cooperation in support of integrated public health.

5 May

Warsaw, URPLW MiPB headquarters, Poland

Visit by the Executive Director of the EMA, Ms Emer Cooke, to the headquarters of the URPLW MiPB

The Executive Director of the EMA paid a visit to the URPLW MiPB headquarters, underscoring Poland's strong partnership with the European regulatory system. Common priorities were discussed, including digital transformation, access to medicines and the implementation of the EU Pharmaceutical Strategy. The meeting strengthened the URPLW MiPB position as an active participant in the European network of regulators. The visit opened up new opportunities for further institutional cooperation.



6–7 May

Warsaw, Warsaw Citadel, Poland

The 120th meeting of Heads of Medicines Agencies (HMA) as part of the Polish Presidency of the Council of the EU

The 120th meeting of the HMA – a key strategic forum for the European network of regulators – took place as part of the Polish Presidency of the Council of the EU. The discussion covered the mental health of children and young people, digitisation, artificial intelligence and the challenges related to clinical trials. The meeting highlighted the importance of joint efforts in building a modern and resilient regulatory system in the EU. The event set the direction for future cooperation within the European network of agencies.

8 May

Warsaw, URPLW MiPB headquarters, Poland

International meeting of regulators in the field of medicinal products and public health: 'Ukraine and Friends'

A meeting of representatives from regulatory bodies in Poland, Ukraine, Croatia, Denmark, Sweden and France took place at the URPLW MiPB headquarters. Discussions focused on cooperation in the areas of medicinal products and public health, as well as the exchange of experience. The event strengthened partnerships and solidarity in the face of global health challenges. The meeting helped to forge lasting ties and further integrate regulatory efforts across Europe.



8–9 May

Warsaw, National Stadium, Poland

Joint meeting of the CVMP Committee and the CMDv Coordination Group as part of the Polish Presidency of the Council of the EU

A joint meeting of the CVMP and the CMDv was held as part of the Polish Presidency of the Council of the EU, focusing on the safety and development of veterinary medicinal products. The discussion covered innovative procedures, digitisation and the challenges posed by drug resistance. The meeting highlighted the importance of cooperation in the field of animal health and public health within the EU.

13–14 May

Warsaw, URPLW MiPB headquarters, Poland

Meeting of the Committee on Herbal Medicinal Products (HMPC) of the EMA during the Polish Presidency of the Council of the EU

As part of the Polish Presidency of the Council of the EU, a meeting of the HMPC Scientific Committee was held to assess the quality, efficacy and safety of herbal medicinal products. The discussion covered regulatory solutions, safety issues and the direction of future work in the context of changes to pharmaceutical legislation. The discussions helped to identify the key challenges facing the regulation of plant-based products. The meeting laid the foundations for further expert collaboration within the EMA network.



15 May

Warsaw, National Stadium, Poland

The importance of biocidal products in our lives – an exchange of views between competent authorities – a meeting held as part of the Polish Presidency of the Council of the EU

A meeting was held on the role of biocidal products in disease prevention and public health safety. The discussion covered regulatory challenges, the active substance review programme and initiatives to raise public awareness. The event strengthened cooperation between authorities and stakeholders across the EU. The meeting highlighted the importance of education as a key element of effective prevention.

JUNE 2025



3 June

Ulaanbaatar, Mongolia

Working meeting between URPLWmiPB and MMRA on the implementation of the Memorandum of Cooperation

A delegation from URPLWmiPB attended a meeting with the management of the Mongolian agency MMRA regarding the implementation of the Memorandum of Cooperation. The meeting discussed measures relating to marketing authorisation, pharmacovigilance, the quality of herbal raw materials, and efforts to prevent medicine shortages. The discussions helped to clarify the practical directions of future cooperation. The meeting strengthened the regulatory partnership between Poland and Mongolia.

4 June

Ulaanbaatar, Mongolia

Bilateral meeting with the Mongolian Minister of Health on the development of regulatory cooperation

A meeting was held with the Mongolian Minister of Health to discuss ways to reinforce the cooperation established under the Memorandum of Cooperation signed in Warsaw.

The discussions focused on the exchange of regulatory experiences in the field of medicines and medical devices, the safety of pharmacotherapy, and the quality of plant-based raw materials. Joint initiatives in the areas of training, study visits and measures to address shortages of medicinal products were also discussed. The meeting reinforced the strategic nature of the partnership between Poland and Mongolia in the field of public health.



4 June

Warsaw, URPLWmiPB headquarters, Poland

A meeting of the IntCoP international cooperation platform

A meeting of the IntCoP platform was held at the URPLWmiPB headquarters, attended by representatives of the EMA, the European Commission and national regulatory authorities. The discussion covered global regulatory initiatives, the security of the supply of medicines, and international relations. The event reinforced the coordination of activities in the field of health and medicines. The meeting highlighted the importance of the EU speaking with one voice in international dialogue.



11–12 June

online meeting

128th meeting of the Management Board of the European Medicines Agency (EMA)

The 128th meeting of the EMA Management Board was held in conjunction with the first-ever meeting with the Executive Board of the African Medicines Agency. The discussion covered international cooperation, efforts to improve access to medicines, antimicrobial resistance, and progress in clinical trials. The meeting highlighted the global dimension of the European regulatory network. The event marked the start of a new chapter in cooperation between Europe and Africa.



12 June

Utrecht, Netherlands

IDMP Community of Experts (CoE) Meeting

The first face-to-face (F2F) meeting of the IDMP Community of Experts (CoE), whose members include experts from the EMA and national agencies. The aim of the group is to collaborate, coordinate and exchange experience regarding the implementation of the IDMP standard at the level of national agencies.

17 June

Publication of the Annual Report of the President of URPLW MiPB for 2025.



25 June

Amsterdam, headquarters of the European Medicines Agency (EMA), Netherlands

Scientific conference 'Medicines, Regulation and the Future' – EMA's 30th anniversary

An anniversary conference on the future of regulatory science and the evaluation of medicines in the EU was held at the headquarters of the EMA. The event brought together representatives from institutions, academia, industry and patient organisations. The discussions focused on innovation, the One Health approach and the challenges facing future treatments. The conference highlighted the importance of collaboration between science, regulation and health policy in Europe.

JULY 2025



3 July

Warsaw, Ministry of Health headquarters, Poland

Ministerial summary of the Presidency in the Ministry of Health

A meeting was held at the Ministry of Health to review the implementation of the priorities of the Polish Presidency of the Council of the EU. The report outlines the contribution of the URPLW MiPB to activities at the European level, including its involvement in work on the pharmaceutical package and the implementation of initiatives relating to mental health, digitisation and prevention. The meeting highlighted the significant role of the Office and expert involvement in implementing the priorities of the Presidency.

6–10 July

Madrid, Spain

Participation in the inspection under the PIC/S Programme for Group 160 and Group 162

The Department for Inspections of Medicinal Products and Medical Devices took part in an inspection in Spain as part of an international project aimed at standardising inspection and audit procedures within the framework of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Poland cooperates with Canada, the United Kingdom, Spain and Denmark.



10–11 July

Rome, Italy

Participation of the URPLW MiPB in the Ukraine Recovery Conference 2025 (URC2025)

A delegation from the URPLW MiPB attended an international conference on the reconstruction and modernisation of Ukraine. The pharmaceutical workshop covered the Critical Medicines Act initiative, supply security and international cooperation. The meeting highlighted the importance of the health sector in the reconstruction process of the country. The discussions have strengthened the dialogue on the resilience of pharmaceutical systems in Europe.

SEPTEMBER 2025



September–December

online meeting

Implementation of a project funded by an EMA grant to strengthen regulatory systems – collaboration between URPLW MiPB and BoMRA

Coordination meetings were held between URPLW MiPB and BoMRA regarding the preparation of training courses on marketing authorisation and clinical trials. The events were a continuation of previous project meetings held as part of the collaboration with the EMA to strengthen regulatory systems. The schedule of activities, the scope of the work and the ongoing transfer of expertise were discussed. The initiative strengthens long-term international cooperation.

10–12 September

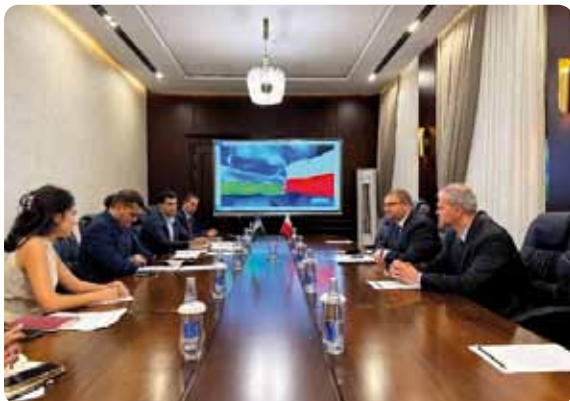
Copenhagen, Denmark

121th meeting of the Heads of Medicines Agencies (HMA) under the Danish Presidency of the Council of the EU

The 121st meeting of the HMA, focusing on the future of medicinal product regulation in Europe, took place in Copenhagen. The meeting covered EMANS' strategic planning up to 2028, cooperation with the EMA and the European Commission, and challenges relating to data, innovation and clinical trials. The meeting reinforced cooperation within the network of regulators. The discussions also covered veterinary medicines and the impact of pharmaceuticals on the environment. The importance of joint action in ensuring high standards of public health was emphasised.



photo source: Heads of Medicines Agencies (HMA) LinkedIn profile



11–13 September

Tashkent, Uzbekistan

Meeting with the Uzbek Minister of Health and URPLW MiPB partner institution under the Memorandum of Understanding (MoU) of the Centre for Pharmaceutical Product Safety

A meeting was held to discuss plans for cooperation between Poland and Uzbekistan aimed at improving the quality of medicinal products and enhancing pharmaceutical safety. The possibility of carrying out a twinning project and sharing expertise on the implementation of EU standards was discussed. The parties confirmed their willingness to develop expert cooperation. Poland has declared its support as a potential lead partner in a future project.

16 September

Warsaw, headquarters of the Ministry of Development and Technology, Poland

A formal review of the efforts to harmonise regulations on medicinal products in Uzbekistan, introducing equal treatment for all EU Member States

A meeting was held at the Ministry of Development and Technology, attended by representatives of the government, the Embassy of Uzbekistan and the pharmaceutical sector. The discussion covered pharmaceutical market regulations in Uzbekistan, cooperation under the Memorandum, and support for the export of Polish products. The meeting opened up new prospects for regulatory and investment cooperation. The talks strengthened the dialogue aimed at developing joint initiatives in the field of clinical research and the safety of drug therapy.



17 September

World Patient Safety Day 2025

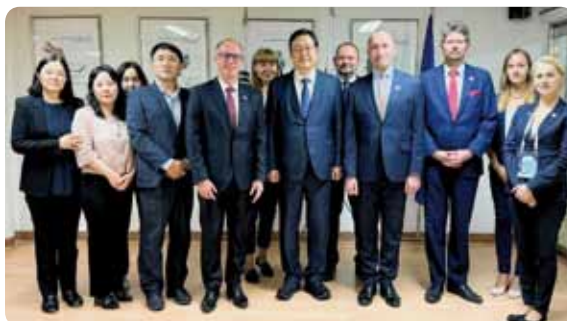
The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products was the main partner of the World Patient Safety Day. As part of the Polish edition of the campaign, information and educational activities were carried out, targeting parents, carers, teachers and healthcare professionals, with the aim of raising awareness about the safety of medication in children. Educational materials and expert events have also been organised, including an open webinar on the safe use of medicines in very young patients.

22–25 September

Seoul, South Korea

22–25 September 2025, Seoul, South Korea Institutional meetings of the URPLWMIpB and participation in the KoNECT 2025 conference as part of the Poland–Korea Strategic Partnership

A delegation from the URPLWMIpB held working meetings with representatives of the National Institute of Food and Drug Safety Evaluation (NIFDS) on regulatory cooperation, clinical trials, innovative therapies and the use of AI. Participation in the KoNECT 2025 conference provided an opportunity to exchange experiences with global regulators. The event strengthened international relations and expert dialogue. The meetings laid the foundations for further cooperation in the field of clinical research and innovation.



23–26 September

Toronto, Canada

Participation in the inspection under the PIC/S Programme for Group 160 and Group 162

The Department for Inspections of Medicinal Products and Medical Devices took part in an inspection in Canada as part of an international project aimed at standardising inspection and audit procedures within the framework of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Poland cooperates with Canada, the United Kingdom, Spain and Denmark.

OCTOBER 2025



1 October

Vilnius, Lithuania

Baltic States Meeting – the annual meeting of medicines regulators from the Baltic States

A meeting of representatives from regulatory authorities across the Baltic region was held in Vilnius to discuss cooperation in the field of medicinal products. The discussions focused on joint efforts to promote patient safety and the exchange of experience. The meeting strengthened regional regulatory dialogue. The participants emphasised the importance of coordinated action in addressing common health challenges.

2 October

online meeting

129th meeting of the Management Board of the European Medicines Agency (EMA)

The 129th meeting of the EMA Management Board was held, focusing on key initiatives of the regulatory network.

The discussion covered the acceleration of assessment procedures, international cooperation, and activities within the ICMRA and the OPEN framework. The first data strategy for the network has been adopted, along with measures to strengthen the capacity of national authorities. The meeting confirmed the importance of data and cooperation as the cornerstones of modern regulation.



21–24 October

Amsterdam, headquarters of the European Medicines Agency (EMA), Netherlands

The Annual Summit of the International Coalition of Medicines Regulators (ICMRA)

The annual ICMRA Summit during which the EMA handed over the chairmanship to Australia's TGA took place in Amsterdam. The discussion covered global regulatory challenges, including drug safety, the use of AI, collaboration under the reliance model, and scientific communication. The meeting confirmed the growing importance of the ICMRA as a global forum for dialogue and coordination among regulators.

27–30 October

Kyiv, Ukraine

Inauguration of the twinning project titled 'Support for the establishment of a state authority for the control of medicines and medical devices (SCA)' – Ukraine

A strategic twinning project supporting the establishment of an independent regulatory body, the SCA, in Ukraine has been inaugurated in Kyiv. The initiative involving Poland, Lithuania and Germany is of crucial importance for alignment with EU law and patient safety. The project provides tangible support for Ukraine on its path towards integration with the European Union.



NOVEMBER 2025



3-9 November

The URPLWMIpB's active participation in the tenth, anniversary edition of the global Med Safety Week campaign, coordinated by the Uppsala Monitoring Centre (UMC) as part of the WHO Global Drug Monitoring Programme.

The campaign aimed to raise awareness of the importance of reporting adverse reactions to medicinal products by patients and healthcare professionals, and to improve the safety of pharmacotherapy. The Office ran information campaigns on social media and on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, reminding the public that they could report adverse reactions. The campaign highlighted the vital importance of public involvement in the system for monitoring the safety of medicines and in building up knowledge about their adverse reactions.

20-21 November

online meeting

4th HMA/EMA Multi-Stakeholder Workshop on Artificial Intelligence – HMA and EMA workshop on artificial intelligence in the regulation of medicinal products

The EMA and HMA organised a workshop on the use of artificial intelligence in the regulatory system. The current state of AI development, changes in the regulatory environment, and the network's activities in the field of data and AI were presented. The practical applications of AI throughout the entire lifecycle of medicinal products were discussed. The meeting provided an opportunity for experts and stakeholders to exchange views.



Source: European Medicines Agency (EMA)



24 November

online meeting

122nd meeting of the Heads of Medicines Agencies (HMA) under the Danish Presidency of the Council of the EU

The 122nd meeting of the HMA was held under the Danish Presidency, focusing on the current activities of the European Medicines Regulatory Network. Reports from the EMA, the European Commission and working groups were discussed, as was the implementation of the EMANS strategy up to 2028. The role of megatrends and artificial intelligence in shaping the future of regulation was also discussed. The meeting strengthened coordination between Member States.

23–26 November

Warsaw, URPLW MiPB headquarters, Poland

Participation in the inspection under the PIC/S Programme for Group 160 and Group 162

The Department for Inspections of Medicinal Products and Medical Devices hosted the project as the representative of Poland and carried out an audit as part of an international project aimed at standardising audit and inspection processes as part of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Poland cooperates in this area with Canada, the United Kingdom, Spain and Denmark.



26 November

Publication of the annual edition of the Polish Pharmacopoeia, namely Supplement 2025 to FP XIII with the cumulative electronic version of FP XIII, containing the Polish version of the texts published in Supplements 11.6, 11.7 and 11.8 of the European Pharmacopoeia, as well as national requirements whose effective date was announced in the Official Journal of the URPLW MiPB dated 26 November 2025.

DECEMBER 2025

4 December

Copenhagen, Denmark

Meeting of the EMACOLEX working group under the Danish Presidency of the Council of the EU

A meeting of the EMACOLEX group, which brings together legal experts from European medicines agencies, was held in Copenhagen. The discussion covered key legislative changes,

EU case law and the experience of Member States in the regulation of medicinal products. The meeting helped to further harmonise the legal approach across Europe.

The discussions strengthened expert collaboration in the field of pharmaceutical law.



9 December

Vilnius, Lithuania

Conference 'UA–EU: Strategic Partnership in the Pharmaceutical Sector'

A conference on strengthening the EU–Ukraine regulatory partnership in the pharmaceutical sector was held in Vilnius. The discussion covered harmonisation with EU law, pharmaceutical safety, supply chains and investment. The event highlighted Ukraine's strategic importance for the future of the European medicines market. The meeting set out the direction for further regulatory integration and institutional cooperation.

10 December

Helsinki, ECHA, online meeting

Meeting of the Heads of Chemicals Authorities
Strengthening chemical safety across the EU relies on close cooperation between authorities at national and EU level. As its remit expands, ECHA works with Member State authorities, other EU agencies, the European Commission and industry to implement evolving legislation and ensure a consistent approach to chemical safety. The meeting of heads of chemical regulatory bodies provided an opportunity to strengthen cooperation, discuss shared priorities and exchange best practices.



17–18 December

Amsterdam, Netherlands

130th meeting of the Management Board of the European Medicines Agency (EMA)

At the 130th meeting of the EMA Management Board, the work programme and the multiannual framework for 2026–2028 were adopted, setting out the direction for the implementation of the new pharmaceutical legislation. The discussion covered digitisation, data, AI, clinical trials and the new responsibilities of the EMA. The meeting confirmed the readiness of the network for the transformation of the regulatory system in the EU. The decisions of the Council have laid a solid foundation for the further development of the European system for the regulation of medicines.

Key legislative developments in 2025



1 January

Commencement of application of Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024 amending Regulation (EC) No 1234/2008 as regards the examination of changes to the terms of marketing authorisations for medicinal products for human use.

The amendment introduced significant procedural changes regarding the implementation of post-registration variations pursuant to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the assessment of variations to the terms of marketing authorisations for medicinal products for human use.

11 March

A draft Regulation of the European Parliament and of the Council – the Critical Medicines Act (2025/0102(COD)) was presented at a plenary session of the European Parliament. The proposal was presented to Parliament on 11 March 2025 and to COREPER (the Council) on 14 March 2025, and was subsequently discussed at an informal meeting of European health ministers on 25 March 2025.

The main elements of the proposal:

- 1) the establishment within the EU of industrial 'strategic projects' aimed to create, expand or modernise existing production capacities for critical medicines or their active ingredients, or contributing to the implementation of key technologies in the manufacturing process, which will benefit from financial incentives and easier access to EU funding;
- 2) public procurement measures aimed to strengthen the resilience of supply chains for critical medicines



or improve access to other medicines of common interest;

- 3) new international 'strategic partnerships' between the EU and a third country, a group of third countries or international organisations, aimed to diversify the supply chain and reduce dependence on individual suppliers;
- 4) joint procurement, in particular, with the possibility for Member States to request the Commission's support in using joint procurement tools (cross-border procurement) to address disparities in the availability of and access to medicines of common interest;
- 5) 'Critical Medicines Coordination Group' to facilitate the implementation of the Regulation.

On 2 December 2025, the Council adopted a general approach.

20 April

Commencement of application of the Commission Implementing Regulation (EU) 2025/163 of 30 January 2025 amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.

The update was intended to identify the changes and the documentation to be submitted in relation to those changes, arising from the need to ensure compliance with



Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council (EU) 2019/6 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.

4 June

The EU Council has agreed on its negotiating position (negotiating mandate) regarding the Pharmaceutical Package:

- a) a directive of the European Parliament and of the Council on the EU code relating to medicinal products for human use (2023/0132(COD));
- b) a Regulation of the European Parliament and of the Council laying down EU procedures for the authorisation and supervision of medicinal products for human use and establishing rules concerning the European Medicines Agency (2023/0131(COD)).



A provisional agreement on the final form of the new legislation was reached between the Council, the European Commission and the European Parliament on 11 December 2025.

The package marks the first reform of EU pharmaceutical law in 20 years.

22 September

A new 'Guideline on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 concerning the examination of changes to the



terms of marketing authorisations for medicinal products for human use and on the documentation to be submitted under these procedures (C/2025/5045); specifying that they shall apply from 15 January 2026.

27 October

Published in the Official Journal of the European Union:

- 1) Commission Implementing Regulation (EU) 2025/2154 of 17 October 2025 laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council;
- 2) Commission Implementing Regulation (EU) 2025/2091 of 17 October 2025 laying down good manufacturing practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council. The above Regulations shall apply from 16 July 2026.



5 December

Publication in the Journal of Laws of the Republic of Poland of the Act of 7 November 2025 amending the Act on Biocidal Products (Journal of Laws, item 1716).

The purpose of the above-mentioned Act is to implement the judgment of the Court of Justice of the European Union of 23 November 2016 in Case C-442/14 concerning access to information on the release into the environment of plant protection products and biocidal products, and

to clarify the provisions governing the proper application of Regulation 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, and to simplify the provisions of the current Biocidal Products Act. The changes introduced are intended to make things easier for businesses. The Act entered into force on 6 February 2026.



16 December

A draft Regulation of the European Parliament and of the Council has been drawn up – on establishing measures to strengthen the EU's biotechnology and biomanufacturing sectors (European Biotechnology Act) (2025/0406(COD)) The proposed regulation aims to simplify the existing regulatory framework and remove regulatory burdens that hinder innovation and competitiveness among economic operators in the EU, in particular, this involves simplifying and shortening procedural deadlines throughout the entire development cycle and ensuring

a flexible regulatory environment for the rapidly growing innovation sector (e.g. through regulatory sandboxes and enabling the increasingly widespread use of data and artificial intelligence). Consequently, all stakeholders and businesses in particular will benefit from a more predictable EU regulatory framework, namely greater legal certainty, shorter procedural deadlines, and a flexible and cooperative regulatory environment. Support measures are also tailored to the needs of SMEs, start-ups and scale-ups.



16 December

A draft Regulation of the European Parliament and of the Council has been prepared to amend Regulations (EU) 2017/745 and (EU) 2017/746 with regard to the simplification and reduction of the burdens arising from the legislation on medical devices and in vitro diagnostic medical devices, and to amend Regulation (EU) 2022/123 as regards the European Medicines Agency's support for expert panels on medical devices, and Regulation (EU) 2024/1689 as regards the list of EU harmonisation legislation referred to in Annex I thereto (2025/0404(COD)) Both of the aforementioned amended regulations introduced revolutionary changes – compared to the previously applicable directives – to the requirements for economic operators and medical devices, as well as for notified bodies, which are responsible for certifying specific classes of devices (certain devices in Classes I, IIa, IIb and III). The new requirements have led to a significant increase in the costs of

product marketing, particularly certification costs, but also the costs of preparing technical documentation; this, in turn, is driving up product prices and prompting manufacturers to decide to discontinue niche products, particularly paediatric ones. In 2025, the Commission carried out an assessment of the aforementioned legislation, the results of which highlighted weaknesses in the new system; these could lead to product shortages and a lack of competitiveness among European manufacturers (mostly micro, small and medium-sized enterprises). Furthermore, the European Parliament called on the Commission in October 2024 to take steps to revise the legislation. The aim of the proposed amendment is to simplify the rules, reduce the administrative burden, improve the predictability of processes and the cost-effectiveness of the system whilst maintaining a high degree of health protection.



3

ACTIVITIES OF THE OFFICE DURING THE POLISH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION



During the Polish Presidency of the Council of the European Union, initiatives in the field of public policy, including in the health sector, were carried out within the broader strategic framework set out by the Presidency's motto: 'Security, Europe!' This concept referred to seven dimensions of security, comprising:

- external;
- internal;
- for information purposes;
- economy;
- energy;
- food;
- health-related.

The Polish Presidency focused, inter alia, on the digital transformation of healthcare systems, the development of cross-border eHealth services, issues related to the cybersecurity of medical devices, the mental health of children and adolescents, as well as health promotion and disease prevention.

These activities were implemented within the framework of the Presidency Trio mechanism, established following the entry into force of the Treaty of Lisbon in 2009. As part of the Trio cooperation, Poland, Denmark and Cyprus adopted a common approach to the analysis of challenges facing the European regulatory system for medicinal products and medical devices, based on the assessment of megatrends.

An important role in the implementation of these priorities was played by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPLWMIpB), which actively participated in work related to the functioning of the European regulatory system for medicinal products and medical devices. As part of the activities related to the Presidency, eighteen meetings were held, attended by approximately 1,100 participants. The total duration of intensive discussions amounted to 36 days, filled with a multi-voiced debate, the exchange of best practices, dynamic panel sessions, and bilateral consultations involving leading European experts.

Thanks to the dedication and open-minded approach of the team, the activities of the Office have helped to ensure the smooth organisation of the European dialogue and to promote modern forms of cooperation. The professionalism and organisational diligence of the Office staff made it possible to organise a series of meetings, conferences, working sessions and expert forums, which not only addressed the key challenges facing modern Europe but also laid the foundations for the further development of EU health strategies.

The events organised by URPLW MiPB played a significant role in presenting Poland as an active and knowledgeable participant in the European health regulation system. These meetings not only provided an opportunity to present the priorities of national health policy, but also to further deepen cooperation with key institutional partners, such as the European Commission (EC), the European Medicines Agency (EMA), and the Heads of Medicines Agencies (HMA), as well as with scientific and academic communities and patient organisations.

Each of the events was designed to reflect a deep understanding of the challenges facing the European healthcare system, ranging from issues related to access to therapies, through digitalisation and innovation, to ethics, legislation, and the future of advanced therapies. The Office effectively seized this unique opportunity to assert its position in the European health dialogue as a Polish institution and to present Poland as a country that is not only competent, but also proactive, modern, and strategically minded.

Through the activities of the URPLW MiPB, the Polish Presidency demonstrated that an ambitious vision, supported by thorough preparation, can be recognised and valued at the European level, contributing to constructive dialogue and strengthening the role of Member States in shaping health priorities. One of the key areas was the issue of mental health among children and young people – a topic of exceptional social and strategic importance, which forms part of the priorities of the Polish Presidency of the Council of the European Union. During the CHMP/PDCO Strategic Review and Learning Meeting, the SAWP SRLM, and the 119th and 120th meetings of the Heads of Medicines Agencies (HMA), the mental health of young children was a central focus of the discussions. The meeting was attended by representatives of the EMA key scientific committees: the CHMP and PDCO, the EMA, the European Commission, the EMA Scientific Advisory Working Group, national regulatory authorities, as well as representatives from the scientific and clinical communities.

A comprehensive analysis was undertaken of the barriers limiting the development of innovative therapies in child and adolescent psychiatry, ranging from ethical and organisational challenges associated with conducting clinical trials in the paediatric population, through difficulties in the collection of clinical data, to gaps in support systems for

children and families of patients suffering from mental health disorders.

Particular attention was paid to modern methods of data modelling and the extrapolation of research findings from adult populations to younger patient groups. It was indicated that the development of advanced analytical tools, such as pharmacokinetic modelling, simulations, and data meta-analyses, may contribute to shortening the time required for the authorisation of paediatric therapies while maintaining safety requirements. There was also discussion of the role of biomarkers as tools for more precise monitoring of treatment outcomes, and of their potential use as endpoints in clinical trials.

As part of Polish efforts to improve the mental health of children and young people, the SAWP Strategic Review and Learning Meeting (SRLM), held on 31 March-1 April 2025 at PGE Narodowy in Warsaw, played a particularly significant role. The event brought together experts from the European Medicines Agency (EMA), national regulatory authorities and representatives of the scientific community, focusing on the challenges and opportunities associated with the development and authorisation of medicinal products for the paediatric population. The key issues included difficulties in conducting conventional clinical trials in paediatric populations, as well as the extrapolation of data from studies conducted in adults to the paediatric and adolescent population. Particular interest was also generated by the topic of biomarkers as potential endpoints in clinical trials, as well as the issue of data completeness in the case of rare and ultra-rare diseases.

The SAWP SRLM meeting also provided an opportunity to present EMA initiatives supporting the development of innovative therapies, including the PRIME scheme, which enables an accelerated regulatory pathway for medicines addressing unmet medical needs.

The conclusions and recommendations drawn from the SAWP SRLM meeting constitute an important contribution to the development of more effective, flexible, and patient-oriented regulatory frameworks for the development of paediatric medicines in Europe. This meeting – as one of the key events of the Polish Presidency – clearly highlighted the importance of the mental health of children and young people as a strategic priority at European level.

The second key theme of the events organised by URPLW MiPB was the digital transformation of the healthcare system, which currently represents one of the most significant challenges and opportunities in the context of modern health policies. This issue, encompassing both technological and regulatory aspects, was the subject of intensive discussions during several key events organised under the Polish Presidency of the Council of the European Union.



Strategic Review and Scientific Meeting – Scientific Advice Working Party (SAWP), 1 April 2025, National Stadium in Warsaw

Meetings of the IT Directors of National Medicines Agencies, EMACOLEX, CAMD, and the HMA plenary sessions enabled an in-depth analysis of the state of digitalisation of regulatory procedures, the interoperability of IT systems, the role of artificial intelligence (AI) in data analysis and regulatory decision-support, as well as cybersecurity risks in the area of medical devices and Internet of Medical Things (IoMT) devices.

Particular interest was given to the UNICOM II project, which aims to implement the EU system for the identification of medicinal products (IDMP) and to harmonise medicinal product data structures across the entire European Union. The discussions covered both technical aspects (data structures, information exchange models) and legal aspects (the basis for updating implementing regulations). The website of the Presidency, which outlines the progress of national work in this area, has been commended for its systematic approach and its integration with projects run by the EMA and the European Commission.

Within the digital transformation priority, cybersecurity represents a key area, which was addressed during meetings organised by URPLWMIpB in the context of the increasing use of digital solutions in medical devices, including wearable



Scientific Meeting and Strategic Review – CHMP and PDCO, 29–30 April 2025, National Stadium in Warsaw

devices and telemonitoring systems. Case studies related to security incidents were presented, risks associated with unauthorised access to medical data were discussed, and possible directions for the development of EU guidelines on certification and auditing of digital security in the medical devices sector were outlined.

At the same time, as part of the Polish Presidency activities, the Office undertook an initiative to examine, in the Member States, the coherence of procedures related to conformity assessment and cybersecurity of medical devices.

Poland, through the active role of representatives of URPLWMIpB, has established its presence as a leader in promoting uniform, safe, and innovative digital solutions in the regulation of medicinal products and medical devices. In the speeches delivered by the delegations, emphasis was repeatedly placed on the importance of protecting patients' personal data, the need to harmonise approaches to artificial intelligence in medicine, and the role of education and training for experts assessing solutions based on digital technologies.



Meeting of the European Medicines Agencies working group on legal and legislative cooperation – EMACOLEX, 3 April 2025, National Stadium in Warsaw

Digital transformation was also an overarching theme during other Presidency events, such as the EMACOLEX meeting, where the legislative implications of the digitalisation of healthcare processes were discussed, including the use of information systems in the management of regulatory data and the impact of rapidly evolving technologies on existing legal frameworks.

Within the meeting of the Heads of Medicines Agencies, discussions focused on strengthening the European data governance framework, expanding interoperable infrastructure, developing data analytics and AI tools, as well as promoting innovation and the digital transformation of the regulatory sector, with a view to ensuring a more efficient, transparent, and data-driven future for the European health system.

As part of the digital transformation, it is essential to develop artificial intelligence tools to support regulatory decision-making processes, accelerate the assessment of the safety and efficacy of medicinal products, and support the personalisation of therapies. In this context, it is planned to develop and publish guidelines on artificial intelligence throughout the medicinal product lifecycle, as well as to establish framework tools for the assessment of AI, which is of key importance for the standardisation and adoption of these technologies in the regulatory process.

The third priority guiding the agendas of meetings organised by URPLWMIpB was health promotion and preventive measures, which constitute one of the pillars of effective national health policy. The initiatives undertaken by URPLWMIpB in this area aimed both to raise public awareness and to develop systemic solutions for disease prevention.

The meeting dedicated to biocidal products brought together representatives of competent authorities from EU Member States, representatives of Polish institutions responsible for chemical safety, and representatives of industry organisations. The discussions focused on the importance of biocidal products as a preventive tool in public health protection. In three thematic blocks, their role in reducing the risk of the spread of infections, the regulatory challenges associated with the assessment of active substances, and measures aimed at raising public awareness and education on the safe use of these products were discussed. In the context of pandemic threats and increasing mobility within the EU, the role of a coordinated information policy as an element of building population resilience was emphasised.



The 119th meeting of the HMA, 23 January 2025, at the headquarters of URPLWMIpB in Warsaw

During the meetings of the CVMP and the CMDv, as well as their joint session, the focus was on prevention in the animal health sector, with particular emphasis on its impact on human health. The issue of antimicrobial resistance (AMR) was discussed, with an analysis of best practices from Denmark and educational campaigns aimed at reducing the inappropriate use of veterinary medicines. An exchange of experiences took place regarding the implementation of

educational activities for veterinarians, animal breeders, and owners of companion animals. Discussions also focused on measures aimed at improving the reporting of adverse events and the development of systems for monitoring the effects of veterinary products.

The proceedings demonstrated a strong commitment among Member States to coordinating preventive actions in the field of human and animal health, while taking environmental considerations into account, which constitutes an integral part of the 'One Health' approach. URPLWMIpB actively promoted an approach based on education, the interoperability of monitoring systems, and the exchange of best practices, emphasising the role of national institutions in building a resilient and health-literate society.

The final thematic area covered horizontal and specialised issues which constitute highly important elements of the European Union regulatory system and enabled the deepening of international cooperation and expert exchange at the highest level.

The meeting of the borderline products working group of the European Directorate for the Quality of Medicines (EDQM), organised by URPLWMIpB, was dedicated to issues concerning the classification of borderline products, i.e. devices and products whose legal status is not clearly defined and which are increasingly subject to interpretative uncertainty in EU Member States. In the face of rapid market growth and technological innovation, there has been a clear need to establish more precise criteria for distinguishing between medicines, medical devices, food supplements, cosmetics and other product categories.

Particular attention was paid to products containing substances of human origin (SoHO), herbal and natural preparations, as well as products whose claimed effects and form of presentation place them on the borderline between cosmetics and medicinal products.

The EMACOLEX meeting brought together legal experts and representatives from the legislative departments of the relevant authorities. The discussion focused on the challenges associated with the implementation of new EU regulations, the case law of the Court of Justice of the European Union, and legislative changes resulting from the revision of European pharmaceutical law. Issues related to civil and criminal liability in the event of incidents involving medicinal products were also discussed, as well as the need to develop common interpretative tools to facilitate the uniform implementation of legislation across all Member States.

Meanwhile, the meetings of the Committee for Orphan Medicinal Products (COMP) and the Committee for Advanced Therapies (CAT) served as a forum for presenting the latest scientific and regulatory developments in the field of gene and cell therapies, as well as personalised medicine.

Discussions focused on the future of CAR-T therapies, the possibilities of shortening regulatory approval pathways while ensuring a high level of patient safety, as well as the role of small and medium-sized enterprises (SMEs) as a driver of innovation in the field of advanced therapy medicinal products (ATMPs).

Particular attention was given to the need to develop flexible yet robust regulatory frameworks that would enable the development of therapies for rare and ultra-rare diseases, while maintaining appropriate evidentiary standards.

The meeting of the HMPWG (Homeopathic Medicinal Products Working Group) discussed the current state of regulation of homeopathic products in EU Member States. The need to establish a harmonised approach to the assessment of the quality and safety of these products, as well as to standardise the rules on labelling, advertising, and adverse event reporting, was highlighted. The attendees drew attention to significant differences in national practices, which lead to interpretative inconsistencies and limit the transparency of the system for both patients and manufacturers.

Issues related to communication concerning homeopathic products were also discussed, including discrepancies in permitted health claims, their modes of presentation, as well as differences in regulations on advertising and information addressed to patients.

Another key topic of discussion was the role of pharmacovigilance systems in relation to homeopathic products.

The meeting concluded with a joint call for the development of up-to-date EU guidelines on homeopathic products, which would take into account both their specific legal status and expectations regarding safety, quality and transparent information for users. The Polish delegation actively

participated in the discussions, sharing the experience of the country in the supervision and registration of such products and expressing its willingness to continue cooperating in the development of a common EU position.

The IntCoP (International Cooperation Platform) meeting focused on relations with EU candidate countries, cooperation with the African Medicines Agency (AMA), and the role of the European Union in promoting global standards for the registration and supervision of medicinal products. During the proceedings, possibilities for knowledge and experience transfer to developing countries, as well as for strengthening regulatory systems in countries with lower institutional capacity, were discussed. The participants emphasised the importance of a sustainable partnership based on the exchange of experts, technical support and the creation of joint risk and quality assessment platforms.

Particular interest was shown in the topic of enhanced cooperation with the African Medicines Agency (AMA), which in recent years has become a key partner for the EU in the field of public health at a global level.

In the context of global health challenges, the participants of the meeting emphasised the need for the EU to play an active role in international initiatives such as the ICMRA (International Coalition of Medicines Regulatory Authorities), the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and the WHO Prequalification Programme. It was pointed out that engagement with these platforms not only strengthens the global consistency of standards but also helps to improve the availability and quality of medicines worldwide.

The IntCoP platform has been recognised as an effective instrument for promoting European interests in health policy on the international stage and as a tool for fostering regulatory solidarity. As the organiser and host of the meeting, Poland was commended for creating a forum



Strengthening European cooperation in the field of medicinal products – 120th HMA meeting, 6 May 2025, Warsaw Citadel

for open dialogue, the exchange of best practices and the identification of shared priorities in the face of global health threats and inequalities in access to medicines.

In the context of implementing commitments arising from EU enlargement strategies and the objective of integrating candidate countries into the European regulatory system, URPLW MiPB engaged representatives of regulatory authorities from Moldova and Ukraine in the dialogue.

These meetings not only served to deepen dialogue and foster integration within the European regulatory framework, but also to highlight the role of Poland as an active participant and co-creator of common health policy. Through the organisation of and active participation in these events, URPLW MiPB demonstrated its contribution to shaping EU regulatory strategies and promoting high standards of quality, safety, and efficacy of medicinal products.

Among the cross-cutting themes, it is worth highlighting the importance of the stakeholder meeting held on 5 May 2025 at the Presidential Hotel in Warsaw, which constituted a side event to the 120th meeting of the Heads of Medicines Agencies (HMA). The meeting, held under the theme 'One Health and Health Security – Shared responsibility for better future', became one of the key forums for dialogue under the Polish Presidency.

The event provided a unique platform for in-depth discussion on the interdependencies between human, animal and environmental health, as well as on the need to implement integrated regulatory approaches in line with the One Health principle. Its aim was to promote cooperation between regulatory authorities and a broad range of stakeholders involved in the lifecycle of medicinal products, from development, through assessment, to post-authorisation surveillance, both in human and veterinary medicine.

The meeting was attended by representatives of the European Medicines Agency (EMA), the European Commission (EC), the HMA Management Group, representatives of patient organisations, industry and pharmaceutical associations, as well as experts in public and environmental health.

The meeting highlighted that effectively addressing challenges such as climate change, rising antimicrobial resistance and new pandemic threats requires an interdisciplinary approach and close cooperation between regulators, industry, the scientific community and patients.

The meetings and events held, both expert and decision-making in nature, were carefully planned and conducted with impressive attention to substantive, protocol, and communication details. Their scale, thematic diversity and depth of analysis mean that they can be regarded as some of the most comprehensive and ambitious initiatives undertaken during the Presidency in the field of healthcare.

The high level of engagement among participants – representing key European institutions in the fields of medicinal products, medical devices and biocidal products, national regulatory authorities, the scientific community, stakeholders and patient organisations – contributed to the creation of a unique platform for dialogue, which not only facilitated the exchange of knowledge and experience but also resulted in tangible proposals for systemic improvements. The wide-ranging and multifaceted debate was conducted with the utmost respect for the participants' expertise and in a spirit of shared responsibility for the future of the European healthcare system.

From an institutional perspective, Poland has gained recognition as an active, competent and innovative Member State. As host and coordinator of most of the events, URPLW MiPB demonstrated not only its capacity for efficient organisation, but above all a deep understanding of the regulatory and strategic challenges facing the European Union in a rapidly changing world. The outcomes of the individual working and plenary sessions, expressed in the form of joint conclusions, recommendations, and cooperation plans, have every indication of becoming a lasting foundation for the continuation of activities beyond the end of the Presidency.

The conclusions drawn from these meetings confirm that an integrated approach to health policy, encompassing regulatory, scientific, technological, and social aspects, is not only feasible but also necessary. During the Presidency, it was possible not only to identify areas requiring further harmonisation, but also to propose concrete courses of action that may serve as model solutions for the entire EU.

During the Polish Presidency, the activities of URPLW MiPB created a platform for a tangible influence on the directions of development of the European Union health policy. It was a period of intensive work, in-depth reflection, and joint development of solutions that have the potential to bring long-term benefits to healthcare systems across all Member States.



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AREA SUPERVISED BY THE PRESIDENT OF THE OFFICE



Grzegorz Cessak
President of the Office

Advisory Commissions of the President of the Office

Pursuant to 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), the following six consultative and advisory Commissions assist the President of the Office:

- 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 pursuant to 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 Commission operating under 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 rules of procedure of the individual Commissions.

In 2025, a total of 20 meetings of the aforementioned Commission were held.

Commission on Medicinal Products

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

- carrying out a substantive assessment of the documentation relating to medicinal products submitted by the President of the Office, primarily with regard to efficacy and safety, as set out in the marketing authorisation application;
- reviewing assessment reports on medicinal products authorised for marketing, submitted by the President of the Office;
- conducting a substantive assessment of documentation regarding compliance with the relevant requirements set out in the Act of 6 September 2001 - Pharmaceutical Law, in relation to products which are absorbed systemically or whose metabolites are absorbed systemically by the human body, in order to achieve their intended use.

In 2025, the Commission on Medicinal Products held four meetings (5 March 2025, 19 September 2025, 17 October 2025, and 19 December 2025), during which seven cases relating to the registration of medicinal products and post-registration variations were considered. At each meeting of the Commission on Medicinal Products, a summary of the most important current publications and guidelines (including safety communications from the PRAC) was presented.

Commission on Veterinary Medicinal Products

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

- carrying out a substantive assessment of the documentation relating to veterinary medicinal products submitted by the President of the Office, primarily with regard to efficacy, safety and suitability for therapeutic use of the veterinary medicinal product as set out in the marketing authorisation application;
- analysing veterinary medicinal products in terms of their suitability for treatment and the availability of the latest generation of veterinary medicinal products;
- submitting requests to the President of the Office aimed at ensuring appropriate standards for assessing the characteristics of veterinary medicinal products;
- providing opinions on assessment reports concerning veterinary medicinal products authorised for marketing, submitted by the President of the Office;
- providing opinions on the risk assessment regarding the presence of residues of veterinary medicinal products in food of animal origin;
- carrying out other tasks assigned by the President of the Office in relation to veterinary medicinal products.

In 2025, no meetings of the Commission on Veterinary Medicinal Products were held.

Commission on Medical Devices

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

- relating to the quality, efficacy and safety of products;
- relating to conformity assessment, clinical evaluation and performance evaluation of devices; the need to carry out the necessary tests and evaluations of devices;
- regarding labelling, instructions for use, advertising and promotional materials relating to products;
- on the validity of authorisation for the placing on the market or putting into service within the territory of the Republic of Poland of products for which no conformity assessment procedures have been carried out to confirm that they meet the relevant requirements;
- whether the product is a device, a system or a treatment kit;
- on the classification of products;
- whether the product is a measuring instrument;
- on actions taken or necessary actions regarding product safety, including external safety corrective actions;
- regarding serious incidents within the meaning of Article 2(65) of Regulation 2017/745 and Article 2(68) of Regulation 2017/746;
- regarding serious adverse events within the meaning of Article 2(58) of Regulation 2017/745 and Article 2(61) of Regulation 2017/746;
- regarding the quality and safety of the substance, including the clinical benefit-risk profile, in the case of a device that incorporates, as an integral part, a substance which, if used on its own, would be a medicinal product;
- regarding a clinical trial or a performance study of a device;
- regarding the suitability of the product for diagnostic use in targeted therapy in relation to the medicinal product in question.

In 2025, no meetings of the Commission on Medical Devices were held.

Commission on Biocidal Products

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

- reviewing methodologies for assessing the efficacy of biocidal products;
- assessing the safe scope and methods of use of biocidal products, as well as their effect on human health and the environment;
- conducting a methodological assessment of the studies included in the dossiers submitted for the registration of biocidal products.



Membership of the Commission on Borderline Products

In 2025, the Commission on Biocidal Products held 12 meetings (19 February 2025, 26 March 2025, 24 April 2025, 28 May 2025, 25 June 2025, 30 July 2025, 3 September 2025, 24 September 2025, 22 October 2025, 26 November 2025, 10 December 2025, 17 December 2025). The meetings were held remotely, in the form of videoconferences. A total of 149 applications for the approval of non-standardised methods for testing the efficacy of biocidal products were submitted to the Commission on consideration.

Commission on Borderline Products

The tasks of the Commission on Borderline Products include examining cases where a product meets both the criteria for a medicinal product and the criteria for another type of product, in particular:

- issuing opinions on the classification of a product as a medicinal product, a medical device or a biocidal product;
- issuing opinions on whether a substance that forms an integral part of a medical device or an active implantable medical device, when used separately, would constitute a blood-derived product or another medicinal product, and whether it may act on the human body in a manner ancillary to the medical device or active implantable medical device.
- proposing a list of pharmaceutical raw materials, medicinal products and their packaging, including those published in the European Pharmacopoeia, for which the essential requirements regarding test methods, composition and quality should be published in the Polish Pharmacopoeia, and updating the Polish Pharmacopoeia in this regard;
- initiating the experimental work required to establish appropriate test methods and basic requirements regarding test methods, composition and quality for individual pharmaceutical raw materials, medicinal products and their packaging, and, on the basis of this material and the results of the experimental work, preparing pharmacopoeial monographs containing the established methods or requirements;
- 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 thereof, or as supplements to the current edition of that Pharmacopoeia;
- participating in the work of the European Pharmacopoeia Commission and cooperation with the pharmacopoeia commissions of other countries with a view to international harmonisation of the aforementioned test methods.

In 2025, the Commission held one meeting (17 April 2025), during which it considered 13 applications concerning the assessment of products that meet both the criteria for a medicinal product and the criteria for another type of product.

Pharmacopoeia Commission

The tasks of the Pharmacopoeia Commission include, in particular:

- proposing testing methods used to determine the quality of medicinal products and their packaging, as well as pharmaceutical raw materials, including methods established by the European Pharmacopoeia, which should be included in the Polish Pharmacopoeia, and updating the Polish Pharmacopoeia in this regard;
- In 2025, the Pharmacopoeia Commission held three meetings (11 April 2025, 1 July 2025 and 11 December 2025), as well as 17 meetings of the Pharmacopoeia Commission's (PhCom) expert groups. The work of the Pharmacopoeia Commission and its expert groups in 2025 was related to preparation materials for the Supplement 2025 to the XIII Edition of the Polish Pharmacopoeia (Supplement 2025 Ph. Pol. XIII), published in November 2025, as well as on developing materials for the main part of the new XIV Edition of the Polish Pharmacopoeia of 2026 (Ph. Pol. XIV 2026), scheduled for publication in November 2026, and the development of further national monographs for the Polish Pharmacopoeia. The meetings also consider issues related to the application of the Pharmacopoeia.



Meeting of the Pharmacopoeia Commission, on 11 December 2025

Polish Pharmacopoeia

The elaboration and publication of the Polish Pharmacopoeia are tasks carried out by the Office in the Pharmacopoeia Department (PhDep), in cooperation with the Pharmacopoeia Commission (PhCom) and its expert groups. The Pharmacopoeia defines basic quality requirements and testing methods for medicinal products (including veterinary medicinal products) and their packaging as well as 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 (Ph. Eur.), supreme in Europe, developed by the European Pharmacopoeia Commission at the Council of Europe. The Pharmacopoeia Department participates in the work of the 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 2025, work was carried out on the Supplement 2025 Ph. Pol. XIII, which supplements the main part of the XIII edition of the Polish Pharmacopoeia of 2023 (Ph. Pol. XIII 2023) and the Supplement 2024 Ph. Pol. XIII. The Supplement 2025 Ph. Pol. XIII was published in print in November 2025, together with a cumulative electronic version of the Ph. Pol. XIII on a pen drive.

The publication system of the European Pharmacopoeia (since the 12th edition, the Ph. Eur. has been published online, in the form of 3 annual issues) makes it necessary to systematically update the Polish Pharmacopoeia, hence work was carried out simultaneously on the available texts of Ph. Eur. 12, on the materials for the main part of the new XIV edition of the Polish Pharmacopoeia of 2026 (Ph. Pol. XIV 2026), which will contain all the materials published in Ph. Eur. 12.1, 12.2 and 12.3.

The Supplement 2025 Ph. Pol. XIII contains the Polish version of the texts published

in Supplements 11.6, 11.7 and 11.8 of the European Pharmacopoeia, as well as national requirements. The "National Monographs" section includes three new texts: "Unguentum molle", "Unguentum Paraffini" and "Zinci mollis pasta", as well as the revised monograph "Drugs prepared in the pharmacy", which has been reclassified from "informative" to "mandatory", after consultation process. The sections "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 2025; hence this list is complementary to the data published in Ph. Pol. XIII 2023 and in Ph. Pol. XIII Supplement 2024. Ph. Pol. XIII Supplement 2025 includes 28 general chapters, 9 general monographs, 6 general monographs on dosage forms and 202 individual monographs.

The date from which the requirements of Supplement 2025 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 Office for Registration (Public Information Bulletin), and is 1 June 2026. In the case of the requirements of Supplement 2025 of Ph. Pol. XIII, which are in line with Supplements 11.6 – 11.8 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 and Ph. Pol. XIV 2026 materials, elaborated by the PhDep and by external specialists, draft of new and revised texts were discussed at meetings of the expert groups of the Pharmacopoeia Commission in Office. In the case of Supplement 2025 of Ph. Pol. XIII, the PhDep prepared and submitted for verification to the PhCom the Draft of this Supplement (in terms of chapters and monographs, new and revised to a major extent); and then directly participated in the publishing process, including technical verifications of the material.



Activities related to the inspections of clinical trials on medicinal products¹ and medical devices, and the control of the pharmacovigilance system for medicinal products¹

The scope of inspection covers clinical trials of medicinal products for human use and veterinary medicinal products, as well as clinical trials of medical devices and pharmacovigilance systems for medicinal products, including veterinary medicinal products. Supervision of the audits and inspections carried out is exercised by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

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

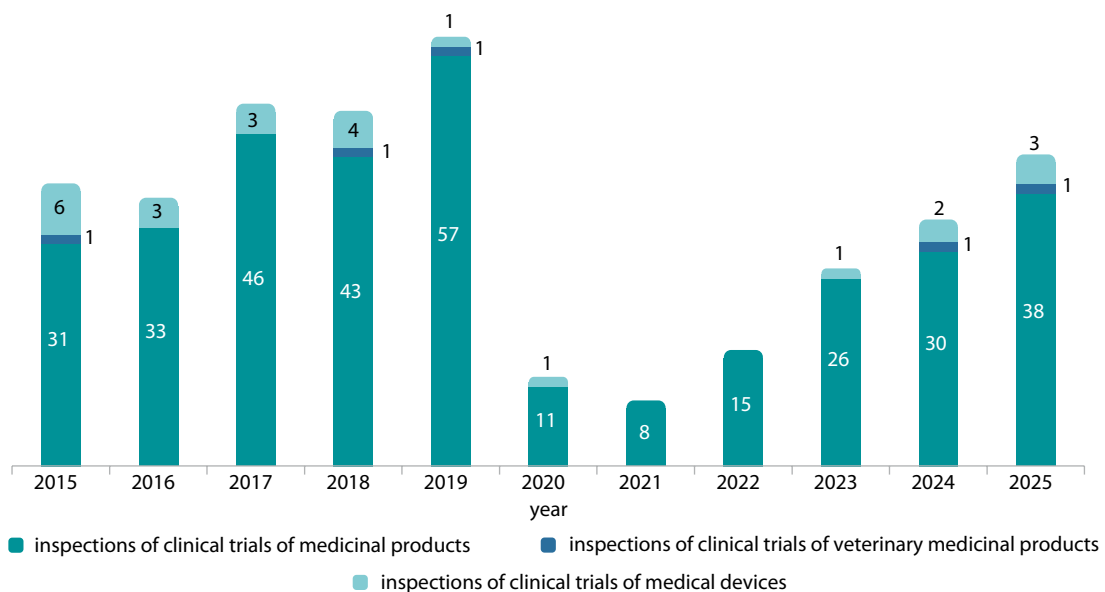
In 2025, a total of 38 inspections of clinical trials of medicinal products for human use were carried out, including 19 on behalf of the European Medicines Agency (EMA), 1 inspection of clinical trials of veterinary medicinal products, and 3 inspections of clinical trials of medical devices (Chart 4.1).

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

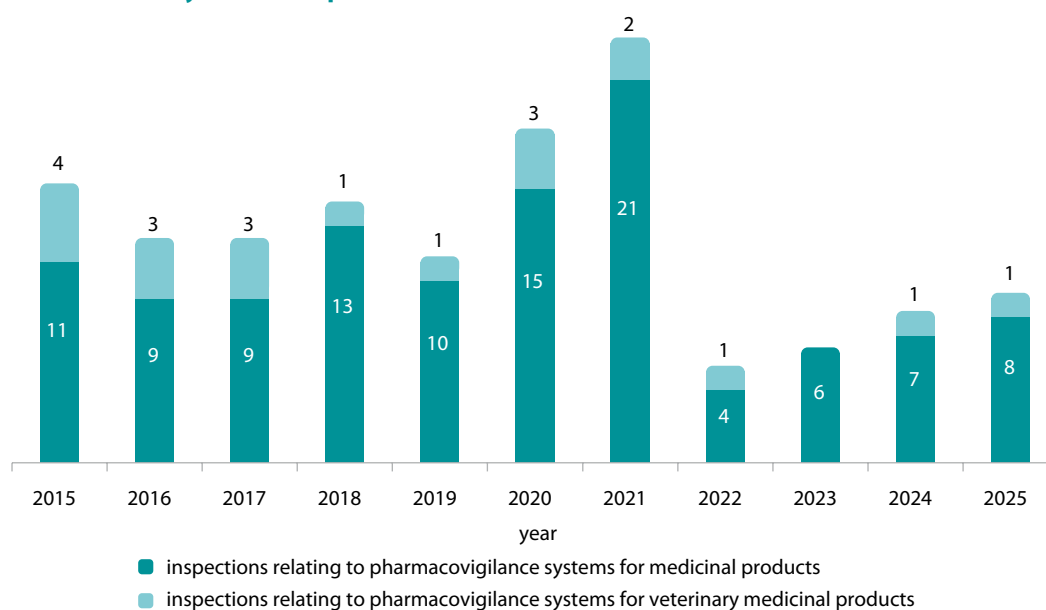
In the area of pharmacovigilance, 8 inspections of the pharmacovigilance system were carried out in 2025, including 1 carried out at the request of the European Medicines Agency and 1 inspection relating to the pharmacovigilance system for veterinary medicinal products carried out at the request of the European Medicines Agency (Chart 4.2).

In 2025, the Department for Inspections of Medicinal Products and Medical Devices took part in an international project aimed at standardising control and inspection processes within the framework of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The project is being carried out

Chart 4.1: Number of conducted inspections of clinical trials on medicinal products, veterinary medicinal products, medical devices and active implantable medical devices in 2015-2025



¹ Including veterinary medicinal products

Chart 4.2: Number of conducted inspections relating to pharmacovigilance systems for medicinal products and veterinary medicinal products in 2015-2025

in collaboration with Canada, the United Kingdom, Spain and Denmark. The scope of cooperation includes the exchange of experience and inspection practices as part of the inspection of the system for the supervision of the safety of medicinal

products – inspection of the pharmacovigilance system. As part of their work, Polish inspectors took part in inspections: in the United Kingdom, Spain, Canada and Poland as project hosts.



The PIC/S Group, comprising inspectors from Spain and Denmark, the President of URPLW MiPB and the Director of the Department for Inspections of Medicinal Products and Medical Devices at the URPLW MiPB, 24 November 2025, the URPLW MiPB, Warsaw.

Legislative work

The year 2025 was a time of intense work in terms of legislation, not only in the area of national regulations, but especially at the EU level. In the first half of 2025, the EU Member States, under the Polish Presidency, adopted a common position on the revision of the pharmaceutical package. The pharmaceutical package is the first major

reform of EU legislation governing the pharmaceutical sector since 2004. Experts from the Office took a direct and active part in the work supporting the negotiations conducted by the Polish Presidency of the Council of the European Union and concerning granting the Presidency a mandate from the Council of the European Union to negotiate the

pharmaceutical package with the European Parliament and the European Commission as part of the so-called trilogues. The above-mentioned work related to the following projects: Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, and Proposal for a 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 establishing 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, intended to replace Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, respectively. After being granted the mandate of the Council of the European Union in June 2025, the Office supported the Ministry of Health and the Permanent Representation of the Republic of Poland in Brussels in maintaining the compromise reached in the negotiations between the Danish Presidency and the European Parliament and the European Commission. The negotiations were concluded in December 2025. The

experts of the Office also supported the Ministry of Health in its work within the Council of the European Union on the Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (the so-called Critical Medicines Act). Negotiations on the above-mentioned act within the Council of the European Union concluded with a compromise being reached in December 2026.

At national level, the work on amending the Biocidal Products Act has been successfully completed (Act of 7 November 2025 amending the Biocidal Products Act, Journal of Laws 2025, item 1716). In 2025, legislative work continued on: the draft Act on veterinary medicinal products implementing 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, the draft act amending the Pharmaceutical Law in the context of introducing the institution of "compassionate use", as well as deregulation measures, including the issue of electronic patient information leaflets.

International cooperation

Summary of activities carried out within the framework of international cooperation for 2025

Due to the EU Presidency, the past year has been the most interesting and busiest in the last 14 years, i.e. since the Polish Presidency of the Council of the European Union in 2011. However, the intensive activities within the European sphere have not slowed down the work of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in non-European areas of international cooperation, whether bilateral or institutional.

We have significantly strengthened our cooperation with Uzbekistan, which has enabled us to effectively promote the high regulatory standards of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products during bilateral meetings and to convince the

highest authorities that the European Union as a whole, together with its Member States, upholds the same high regulatory standards, which means regardless of the EU country, regulatory decisions are based on the same legal foundations and represent the same high regulatory standard.

We have formally launched our partnership with Mongolia by signing a Memorandum of Understanding in the presence of the Presidents of both countries, thereby opening up opportunities for the exchange of experts, introducing a reliance system for Polish regulatory decisions in Mongolia, and building the regulatory maturity of our new partner; Poland, on the other hand, gained a source of knowledge and experience in the field of herbal medicinal products and their use in accordance with traditional Eastern medicine, which will support our work within the EDQM.



We have also renewed our collaboration with our Korean partner, the National Institute of Food and Drug Safety Evaluation, by initiating a dialogue on clinical trials and AI-based solutions for regulatory processes. Given its strategic partnership at the intergovernmental level and significant technological progress, South Korea is currently the ideal partner for institutional development aimed at improving access to modern, effective and safe medicinal products.

In the area of international projects, we have taken on challenges in three new areas: Africa – by implementing two EMA-funded grants for Botswana and Ethiopia, the Caribbean – supporting a project to build regulatory systems in Barbados and Guyana; and in our immediate neighbourhood – in Ukraine, undertaking a twinning project aimed at establishing a Ukrainian regulatory authority responsible for medicinal products, medical devices, blood products and cosmetics.

Within the framework of this broad cooperation, the ICMRA remains a priority, serving as a forum for developing strategic decisions and approaches for over 44 regulators from around the world. Through its active involvement in this organisation, the Agency plays a part in global regulatory harmonisation processes, in preparing for and responding to public health crises, and in adapting its administrative framework to the rapidly evolving ecosystem of medicinal products and medical devices.

European Medicines Regulatory Network (EMRN)

The European Medicines Regulatory Network (EMRN) establishes an integrated system of cooperation between the European Medicines Agency (EMA), the European Commission and the national competent authorities of EU and EEA countries. This network forms the basis of a common European approach to the evaluation, supervision and monitoring of the safety of medicinal products, ensuring regulatory consistency, the exchange of expertise and a rapid response to public health threats.

In 2025, the activities of EMRN focused on implementing the European Medicines Agencies Network Strategy to 2028 (EMANS 2028), which aims to prepare the regulatory system to operate in an environment of dynamic technological, legal and social change. Priority was given to initiatives in the areas of digitalisation and data management, including the development of interoperable solutions, the use of real-world data, and the development of expertise in artificial intelligence within regulatory processes.

Another key focus of the work was to strengthen the scientific and operational capacity of the network through new models of cooperation, the development of Centres of Excellence, and better coordination of expert resources between

agencies. These measures were aimed at increasing flexibility of the network, ensuring a fairer distribution of the burden, and improving the quality of regulatory assessments across Europe.

At the same time, the EMRN has been developing initiatives to support the availability of medicines, the security of supply chains and preparedness for health crises, including in the context of new challenges relating to antimicrobial resistance and cross-border threats. International cooperation also remained a key element, strengthening the position of the European regulatory system as a reliable partner in the global dialogue on public health.

Through these initiatives, in 2025 the EMRN consolidated its role as a modern, integrated and science-based network, capable of effectively supporting innovation, protecting patients and achieving the strategic health objectives of the European Union.



European Medicines Agency (EMA)

The European Medicines Agency (EMA) is a decentralised agency of the European Union responsible for the scientific evaluation, supervision and safety monitoring of medicinal products for human and veterinary use. Operating within the European Medicines Regulatory Network (EMRN), it coordinates cooperation between national competent authorities, supports the harmonisation of procedures and the development of common regulatory standards, ensuring that patients have access to safe and effective treatments.

The EMA Management Board is the main decision-making body of the Agency, responsible for strategic and organisational oversight. In 2025, its work focused on preparing the regulatory framework for the implementation of new EU pharmaceutical legislation and on implementing the European Medicines Agencies Network Strategy to 2028 (EMANS 2028). Particular attention was paid to the long-term planning and budgeting of the EMA, ensuring the consistency of its programme documents and the financial stability of the Agency.

Another key area of work was digital transformation, including the use of health data, big data and artificial intelligence in regulatory processes, as well as the development of the CTIS and the ACT EU initiative. The Board also took action in the areas of risk management, auditing and transparency, strengthening control mechanisms and independence. Another key aspect was the development of international cooperation, including dialogue with the African Medicines Agency (AMA).

Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, played an active role in the work of the Board, representing Poland and contributing to the analysis of the policy documents of the Agency as part of the Topic Coordinators group on the budget and work programme.

In order to ensure that it retains the right to participate in decision-making on strategic matters relating to the evaluation and marketing authorisation of medicinal products intended for both human and veterinary use, and in compliance with the provisions of, inter alia, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use, we have ensured appropriate representation on the Agency's seven Scientific Committees:

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

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

- Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh);
- Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv);
- CHMP Quality Working Party (QWP);
- Pharmacovigilance Working Party (PhVWP-V);
- Name Review Group (NRG);
- Working Group on Quality Review of Documents (QRD);
- Pharmacovigilance Inspectors Working Group (PhV IWG);
- GCP Inspectors Working Group (GCP IWG);
- Joint CHMP/CVMP Quality Working Party (QWP);
- Harmonisation of RMP Project Group;
- Executive Steering Group on Shortages of Medical Devices;
- Emergency Task Force (ETF);
- CMDv SPC Harmonisation Working Group;
- IT Directors Group;
- CMDh Working Party on Variation Regulations;
- CVMP AWP Antimicrobials Working Party;
- Biologics Working Party (BWP);
- Scientific Advice Working Party (SAWP);
- Central Nervous System Working Party;
- Patients' and Consumers' Working Party (PCWP).



The European Commission, the Council of the European Union

In carrying out the tasks of a Member State, the Office's delegates represented Poland in the work of the European Union's institutions and took part in meetings of the following groups:

- Clinical investigation and evaluation, performance studies and evaluation (CIEPSE);
- Unique Device Identification (UDI);
- Borderline and Classification (B&C);
- Medical Device Coordination Group (MDCG);
- Working Group on International Matters;
- Market Surveillance (MS);
- European Medical Device Nomenclature (EMDN);
- New Technologies;
- Post-market Surveillance and Vigilance (PMSV);
- "Annex XVI" Products;
- Standards;
- In vitro Diagnostic Medical Devices (IVD);
- EUDAMED Working Group;
- Notified Bodies Oversight (NBO);
- Working Party on Pharmaceuticals and Medical Devices;
- Committee on the Approximation of the Laws of the Member States relating to Medical Devices - Standing Committee on Medical Device;
- Pharmaceutical Committee;
- Meetings of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products;
- Standing Committee on Biocidal Products;
- Standing Committee on Veterinary Medicinal Products (SCVMP);
- Clinical Trial Advisory Group;
- Coordination Group on the in vitro Diagnostic Medical Devices Regulation.



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

The Heads of Medicines Agencies (HMA) of the European Union and the European Economic Area is a key forum for cooperation between national regulatory authorities responsible for medicinal products for human and veterinary use. Within the framework of the HMA, common positions are developed, the activities of the entire European Medicines Regulatory Network (EMRN)

are coordinated, and the direction of the regulatory development of the system is determined in response to changing legal, technological and social conditions.

In 2025, the work of the HMA focused on implementing the European Medicines Agencies Network Strategy to 2028 (EMANS 2028) and on preparing the multi-annual action plan of the network, covering, amongst other things, the development of Centres of Excellence, strengthening scientific and regulatory capacity, the digitalisation of processes, the use of data and artificial intelligence, and improving access to medicines and the resilience of the system to health crises. Particular attention was also paid to health security, including ensuring the stability of supply chains, developing initiatives related to the Critical Medicines Act, and preparing the network for the implementation of the new EU pharmaceutical legislation.

Another key area of the work of the HMA was digital transformation, encompassing the development of the network data strategy of the EMRN, system interoperability, the implementation of IDMP standards, and the development of expertise in artificial intelligence through joint training programmes within the EU Network Training Centre. At the same time, work was carried out to streamline regulatory procedures, including in the areas of clinical trials, post-registration variations and the coordination of processes within European procedures.

Within the HMA framework, there is EMACOLEX (European Medicines Agencies Co-operation on Legal and Legislative Issues) – a working group comprising representatives from the legal departments of medicines agencies, whose aim is to support the harmonisation of the interpretation and application of EU pharmaceutical law and to facilitate the exchange of experiences on legal and legislative matters.

Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, serves as a mentor to EMACOLEX, supporting the group's development and strengthening cooperation between agencies in the field of pharmaceutical law and regulation. In line with their areas of expertise, staff members participate in the work of the following HMA working groups:

- Heads of Medicines Agencies;
- Clinical Trials Coordination Group (CTCG);
- European Medicines Agencies Co-operation on Legal and Legislative Issues (EMACOLEX);
- Homeopathic Medicinal Products Working Group (HMPWG);
- IDMP Community of Expertise (CoE);
- Working Group of Communication Professionals (WGCP);
- Working Group of Quality Managers (WGQM);
- EU Innovation Network (EU-IN);
- Veterinary Strategy Focus Group (VSFG).



Group of Competent Authorities for Medical Devices (CAMD)

Competent Authorities for Medical Devices serve as a forum for cooperation between the National Competent Authorities of the European Economic Area and the European Commission, with the aim of strengthening and harmonising the supervision of medical devices and ensuring the consistent and effective implementation of medical device legislation within the EU.



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 concerning the making available on the market and use of biocidal products. Member States contribute to the Agency's work, inter alia, through their membership in numerous working groups.

The cooperation forums within the European Chemicals Agency are the Committee for Biocidal Products (BPC) and the following working groups:

- HelpNet Steering Group;
- Member State Communicators' Network;
- Ad hoc Working Group – Assessment of Residue Transfer to Food;
- Ad hoc Working Group - Human Exposure;
- WG of Biocidal Products Committee: Analytical Methods and Physico-chemical Properties;
- WG of Biocidal Products Committee: Environment;
- Hoc Working Group - Environmental Exposure;
- WG of Biocidal Products Committee: Efficacy;
- Biocidal Products Committee;
- Working Group of Biocidal Product Committee - Human Health.



Council of Europe

In 2025, the Office for 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. European Pharmacopoeia (Ph. Eur.) is prepared in accordance with the Convention on the Elaboration of a European Pharmacopoeia, to which Poland acceded in 2006.



World Health Organisation (WHO)

In 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products continued its collaboration within the WHO IRCH (International Regulatory Cooperation for Herbal Medicines) working group as part of the WHO Traditional, Complementary and Integrative Medicine (TCI) programme. In 2024, the work plan of the IRCH for 2025 was drawn up by three working groups, with tasks assigned to each group:

- Working Group 1. Safety & Regulation of Herbal Medicines, with the task of organising one workshop by India;
- Working Group 2. Quality & Sustainability of Herbal Medicines, with the task of organising one workshop by China;
- Working Group 3. Efficacy & Intended Use of Herbal Medicines, with the task of organising one workshop by Brazil.

As Brazil was unable to host the workshops, India took over and organised a joint workshop in August 2025 for Working Groups 1 and 3. A workshop on the safe and effective use of traditional medicines was held in Ghaziabad (a satellite town of New Delhi, home to numerous medical and research centres) in August 2025. The workshop featured two short

presentations on the organisation of healthcare in Poland (a European Union member state) and the registration of herbal medicines under the Polish legal framework. The lectures on safety, toxicology, and clinical efficacy and effectiveness were followed by discussions.

Indonesia has agreed to host the annual IRCH conference in October 2025. The conference featured presentations on the regulation of herbal medicines within various legal frameworks across different continents. The representative of the Office highlighted the need to continue work on the fundamental definitions and concepts that are in use worldwide and which require agreement on basic terminology.

Experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also took part in the WHO International Herbal Pharmacopoeia (IHP) initiative, which is responsible for developing basic quality standards and monographs for substances used in countries that do not have national or regional pharmacopoeias.



International Coalition of Medicines Regulatory Authorities (ICMRA)

The ICMRA is a strategic organisation established to support regulatory authorities in addressing existing challenges and in managing and preventing emerging challenges relating to public health safety in the context of medicinal products and medical devices. The ICMRA provides strategic, ongoing, transparent and institutional guidance on areas and activities common to the mandates of regulatory bodies worldwide. The coalition provides opportunities for better communication, information sharing, crisis response and the resolution of issues relating to regulatory science. The ICMRA is also involved



Summit of the International Coalition of Medicines Regulatory Authorities, 21 October 2025, Amsterdam

in initiating changes to guidelines and recommendations for the registration of medicinal products, including collaboration on the development of recommendations regarding the composition of adapted COVID-19 vaccines. The topics most frequently discussed at the ICMRA meetings and summits include: antimicrobial resistance, communication, medicine shortages, innovation, pharmacovigilance, reliance on and recognition of regulatory outcomes, big data, adverse reaction reporting, building public confidence in vaccination, the 3Rs (reduction, replacement and refinement) to limit the use of animals in scientific research, supply chain integrity, and the response to emerging public health threats.

The members of the ICMRA are the leading authorities responsible for the registration and safety oversight of medicinal products from around the world (currently 38), including bodies such as the European Commission, the European Medicines Agency (EMA) and the World Health Organisation (WHO).

In October, the President of the Office attended the ICMRA summit in Amsterdam, which underscores active role of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in international regulatory dialogue and its contribution to shaping the global direction of regulatory systems. The meeting discussed the role of regulatory bodies in scientific communication and building public trust, as well as the need for a balanced approach to the development and evaluation of innovative therapies.

Another key topic was the use of artificial intelligence in regulatory activities, including the analysis of clinical data and drug evaluation processes, whilst emphasising the need for clear ethical standards and transparent oversight. Participants also discussed the concept of "reliance", which involves relying on the assessments of other credible regulatory authorities, thereby enabling a reduction in the time taken to register medicines, a more efficient use of resources, and faster access to treatments for patients.

Bilateral cooperation

Korea

In 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products continued its cooperation with its Korean counterpart. As part of efforts to strengthen these ties, Grzegorz Cessak, President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, visited the Republic of Korea, where he met with Seogyoun Kang, Director General of the National Institute of Food and Drug Safety Evaluation (NIFDS).



A meeting with Dr Seogyoun Kang, Director General of the National Institute of Food and Drug Safety Evaluation, Seoul, 24 September 2025

The discussions focused on opportunities to strengthen institutional cooperation between the Office and the NIFDS, based on the provisions of the Memorandum of Understanding signed in 2013, and in the context of implementing the Strategic Partnership between the Republic of Poland and the Republic of Korea for the period 2025–2028.

During the meeting, potential areas for joint action were discussed, in particular with regard to mitigating the risk of medicinal product shortages, increasing access to innovative therapies, developing the clinical trials sector, strengthening pharmacovigilance, and implementing modern technological solutions to support regulatory processes.



A meeting with Seogyoun Kang, Director General of the National Institute of Food and Drug Safety Evaluation, Seoul, 24 September 2025

In addition, from 22 to 24 September 2025, the President of the Office attended the 2025 KoNECT International Conference, organised in Seoul by the Korea National Enterprise for Clinical Trials (KoNECT) in collaboration with the Ministry of Health and Welfare of the Republic of Korea and the Ministry of Food and Drug Safety. The event served as an international platform for dialogue on clinical trials, pharmaceutical innovation and regulatory challenges, facilitating the exchange of experiences and best practices between regulatory authorities and stakeholders from different regions of the world.

Kazakhstan

In 2025, contact was established with representatives of the Kazakh side following an international conference in Tashkent. Discussions on potential regulatory cooperation are scheduled to take place in 2026.

Ukraine

In 2025, cooperation of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products with Ukraine was consistently developed, encompassing both activities supporting the development of the regulatory framework for medicinal products and medical devices, and the direct involvement of the Office in the process of establishing a new regulatory body (State Control Authority – SCA).

In February 2025, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products took part in an inspection mission by European medicines agencies to Ukraine, organised at the invitation of the State Expert Center of the Ministry of Health of Ukraine (SECMoH). The visit was part of efforts to strengthen cooperation and exchange experiences with a view to further developing the regulatory framework and aligning it with the solutions in place within the European Union. Polish accession experiences and practical aspects of the operation of the system were presented, including the concept of consolidating supervisory functions within a single body – the Single Competent Authority (SCA).

During the Polish Presidency of the Council of the European Union (first half of 2025) Ukraine was included in a selection of high-level events, including meetings of the Heads of Medicines Agencies (HMA), CAMD and events focusing on biocidal products. The participation of Ukrainian representatives enabled direct contact with European regulatory bodies and provided an opportunity to gain a deeper understanding of how the EU system operates.

In March 2025, meetings were held in Warsaw between the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Minister and Deputy Minister of Health of Ukraine, as well as the Director of SECMoH. The discussions focused on future areas of cooperation, including the development of the regulatory framework, the establishment of the SCA, and the participation of the Ukraine in EU initiatives relating to pharmaceutical safety.

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also hosted the meeting “Ukraine and Friends – Together We Are Stronger”, attended by representatives of regulatory authorities from

Poland, France, Denmark, Sweden, Croatia and Ukraine. The joint statement confirmed a commitment to further developing regulatory cooperation and supporting Ukraine in its integration with the EU.

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also attended the Ukraine Recovery Conference 2025 (URC2025) in Rome, where he presented Polish experience in the field of pharmaceutical safety, the supply chain for critical medicines, and the measures being taken at EU level in this area.

A key element of the cooperation was the launch in October 2025 of the twinning project “Support for the Establishment of the SCA”, carried out by a consortium comprising Poland, Lithuania and Germany. The project, with a budget of €1.5 million and a duration of 18 months, provides for comprehensive support in establishing an independent regulatory body operating in accordance with European Union law.

In December 2025, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products attended the UA–EU conference: Strategic Partnership in the Pharmaceutical Sector in Vilnius, reaffirming Polish commitment to assisting Ukraine in its efforts to ensure medicine safety.

Mongolia

In 2025, cooperation between the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and Mongolia was significantly stepped up, encompassing both high-level dialogue and operational activities aimed at developing the partner’s regulatory capabilities.

A key event was the signing, on 13 March 2025 in Warsaw, of a Memorandum of Understanding between the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Mongolian Medicines and Medical Devices Regulatory Agency (MMRA), in the presence of the Presidents of Poland and Mongolia. The document set out a framework for long-term cooperation in the field of the regulation of medicinal products and medical devices, covering, amongst other things, the exchange of regulatory information, cooperation on clinical trials and pharmacovigilance, measures to address medicine shortages, and the development of expert cooperation, including in the field of traditional medicine.

The visit was accompanied by meetings between the Mongolian Minister of Health and the MMRA delegation at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, during which the guidelines



Signing of the Memorandum of Understanding between Poland and Mongolia on the registration of medicinal products and medical devices, 18 March 2025, Warsaw.

for implementing the provisions of the Memorandum were agreed and a technical dialogue was initiated.

This cooperation continued with a visit by a delegation from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products to Mongolia in June 2025, which included participation in an international conference and a series of bilateral meetings with representatives of the government administration and institutional partners. The discussions focused on ways of aligning the Mongolian regulatory system with EU standards, including in the areas of marketing authorisation procedures, the quality of medicinal products, measures to prevent shortages, and the use of reliance mechanisms based on WHO-Listed Authority status.

The Mongolian side expressed interest in expert support from Poland in the process of building and strengthening regulatory capacities, including through training and substantive advice. The discussions also covered issues relating to drug safety, the quality of plant-based raw materials, and the potential for cooperation in the field of products based on traditional medicine.



Meeting at the Parliament with Nyamdava Khurelbaatar, Senior Adviser to the President of Mongolia, 6 June 2025, Ulaanbaatar.

Uzbekistan

In 2025, cooperation between the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the Republic of Uzbekistan continued and was further developed, encompassing not only expert dialogue but also practical initiatives.

The consistent regulatory dialogue conducted by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and other Polish government bodies in response to the unequal treatment of certain European countries, including Poland, has highlighted the need to ensure transparent and non-discriminatory rules for the registration of medicinal products in Uzbekistan, whilst emphasising the role of Poland as part of the European regulatory system, all member states of which have been recognised for their high regulatory standards and included on the "WHO-Listed Authority". Ultimately, the efforts of Poland were met with understanding by the Uzbek authorities, who introduced a reliance mechanism based on the WHO-Listed Authority in the amended legislation.

In 2025, representatives of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products took part in a series of events organised by the Uzbek side, the common aim of which was to strengthen regulatory cooperation by sharing experience and knowledge in key areas of activity of the authorities responsible for medicinal products in both countries, such as: the quality of medicinal products, combating falsified medicinal products, the digitalisation of regulatory processes, and the alignment of regulations with international standards.

Participation in international projects in 2025

Twinning

In 2025, a strategic twinning project with Ukraine was officially launched, representing one of the key areas of international cooperation. As part of the project launch, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products attended the kick-off meeting, which took place in Kyiv. The aim of the project is to strengthen the Ukrainian healthcare system and protect patients' interests by ensuring access to high-quality, safe, effective and innovative medicinal products, medical devices and cosmetics.

The key objective of the project is to support the establishment of an independent State Competent Authority (SCA), a central regulatory body capable of operating in accordance with the *acquis communautaire* and of participating in the EU network of competent authorities following Ukraine's accession to the EU. The project involves

aligning Ukraine's national legal framework with the *acquis communautaire*, establishing the organisational structure and operational models of the SCA, and developing its institutional and expert capacities based on EU best regulatory practices.



Official launch of the twinning project with Ukraine, "Support the establishment of the state control authority for medicines and medical devices", 27–30 October 2025, Kyiv.

Polish experts and the experience of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products – gained both during Poland's accession to the European Union and through the implementation of previous projects of this kind – play a significant role in the implementation of the project. Poland is leading the work under Component 2 – "Definition of the structure and operational parameters of the State Competent Authority (SCA)" – which focuses on developing an organisational model for the new institution, a management system and operational procedures in line with EU regulatory best practices.

As part of this component, Polish experts will draw up recommendations regarding the structure of the SCA, funding mechanisms, internal management and remuneration systems, and will also develop a communication strategy to ensure effective cooperation with stakeholders at both national and international levels. They will also take part in benchmarking activities under the BEMA (Benchmarking of



Meeting with the Minister of Health of Ukraine, Mr. Viktor Liashko, and with the directors of key departments of the Ministry of Health of Ukraine under the leadership of Minister Maryna Slobodnichenko, 27–30 October 2025, Kyiv.

European Medicines Agencies) initiative and provide expert support on the development of internal policies, including the management of conflicts of interest and standards of good governance.

Cooperation under the twinning project is one of the cornerstones of Poland's long-term commitment to reconstruction of Ukraine and European integration, and is based on lasting institutional relations, the systematic exchange of knowledge, and a shared commitment to achieving high regulatory standards.

The "Support to Strengthen Regulatory Frameworks in the Caribbean" project

In 2025, work began on the "Support to Strengthen Regulatory Frameworks in the Caribbean" project (February 2025 – February 2029), which aims to strengthen regulatory systems in the countries of the Caribbean region, particularly in Guyana and Barbados. The project supports the development of regulatory capacity in the field of medicinal products, the establishment of modern regulatory institutions, and alignment with European Union standards.

In May 2025, the Inception Phase was completed; during this phase, an in-depth analysis of existing and proposed regulations was carried out, the scope of work was updated, and detailed work plans were drawn up. Further activities are scheduled to run until February 2026, with the possibility of adapting them to the beneficiaries' needs.

The project aims, among other things, to provide support in creating a legal and institutional framework, developing regulatory functions (including marketing authorisation, pharmacovigilance, market surveillance and inspections), and building regional and international cooperation, including through reliance and mutual recognition mechanisms.

Institutions from EU Member States, including the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, are involved in the project alongside partners from Lithuania and Italy. The project is coordinated by the Lithuanian Central Project Management Agency (CPMA), and its activities include expert missions (both remote and on-site), the development of regulatory recommendations, and the organisation of training courses, seminars and study visits.

The project helps to strengthen cooperation between the EU and the Latin American and Caribbean region by supporting the development of regulatory frameworks and creating conditions conducive to improving access to medicinal products.

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

In 2025, he was also involved in a project funded by a grant from the European Medicines Agency (EMA) entitled “Medicines regulatory systems strengthening in Sub-Saharan Africa”, carried out in collaboration with the Botswana Medicines Regulatory Authority (BOMRA) and, in parallel, with the Ethiopian Food and Drug Administration (EFDA).

The project focuses on developing expertise in the qualitative, non-clinical and clinical evaluation of medicinal products, in the areas of clinical trial authorisation and regulatory oversight, as well as in the pharmacovigilance. Project activities are developed in close consultation with partner institutions to ensure they align with their strategic priorities and practical operational needs. An important element of the project is a partnership approach based on the exchange of knowledge, experience and good practices, while respecting the achievements and autonomy of the beneficiary institutions.



The project is being implemented through a combination of webinars and face-to-face workshops organised both in the partner countries and in Poland, which facilitates in-depth expert collaboration and the direct exchange of experiences. As part of the collaboration with BOMRA, two one-day online training sessions were held, whilst one one-day online training session was organised in collaboration with EFDA. The training activities carried out constitute the first phase of the project, which aims to ensure the sustainability of the results by making the training materials available in electronic form and ensuring their continued use in regulatory practice. Further activities relating to the project are scheduled for 2026.

Simultaneous National Scientific Advice (SNSA) Programme

The Office is involved in a pilot programme for the Simultaneous National Scientific Advice (SNSA). The aim of the SNSA is:

- to provide international scientific and regulatory advice, and enhancing the services offered by regulatory bodies

to support developers of innovative medicinal products and related technologies,

- to enhance the coherence and effectiveness of national scientific advice provided by the relevant national authorities, with a view to maximising the potential of the SNSA pilot concept.

The pilot programme for Simultaneous National Scientific Advice aims to develop procedures intended for applicants who wish to seek scientific advice from two countries at the same time.

JAMS 2 Project

Staff at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products are participating in the Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices (JAMS 2.0) established under the EU Health Programme – EU4Health, which aims to strengthen market surveillance of medical devices and in vitro diagnostic devices by harmonising the practices of competent authorities across the European Union. In parallel with the ongoing implementation of the regulations, the measures being taken will lay the foundations for enhanced dialogue and facilitate coordination and cooperation between the competent authorities through the adoption of tailored and consistent working methods. The project will thus help to improve the safety of medical devices, thereby making an effective contribution to the protection of public health.

The project is divided into four administrative modules and four technical working modules covering various aspects of market surveillance. Poland is leading one of the administrative modules – WP3 Evaluation. This task involves preparing and carrying out a project evaluation; in particular, it involves analysing whether the project objectives have been achieved and the project plan has been implemented. Each working module facilitates the exchange of information on best practices, expertise and resources between the competent authorities. The working modules cover the following areas: market surveillance campaigns, inspections



of economic operators, analysis of information received through monitoring, and training for staff of the competent authorities.

AI – USE IN THE OFFICE

In 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products actively participated in the work and discussions held within the European Medicines Regulatory Network (EMRN) concerning the use of artificial intelligence (AI) in regulatory processes. This involvement included participation in initiatives coordinated by the HMA/EMA Joint Big Data Steering Group, including the implementation of the multi-annual work plan for AI for the period 2023–2028, aimed at developing common approaches to data analysis, decision support and the automation of regulatory processes.

As part of its cooperation with the European Medicines Agency, the experts of the Office took part in an exchange of experiences and the development of regulatory approaches to the use of AI throughout the entire life cycle of a medicinal product, including in areas such as pre-clinical and clinical development, data analysis, manufacturing and post-marketing surveillance. Particular attention was paid to issues relating to data quality, model validation, risk management, transparency and ensuring compliance with applicable guidelines, including the principles of good clinical practice and statistical requirements.

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also took part in discussions

on the safe and responsible use of generative AI tools, including large language models (LLMs), in line with the recommendations of the EMA and HMA. The need to maintain expert oversight of the results generated by AI and to ensure data integrity and confidentiality was emphasised.

In the field of medical devices, a key focus was on work relating to Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence in relation to AI systems that are medical devices or in vitro diagnostic devices subject to Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR).

These measures form part of a broader effort to establish a coherent, risk-based regulatory framework for AI within the European Union and to strengthen expertise in the use of advanced data analytics in healthcare.



Coordination of the centralised procedure

In 2025, the Office's experts worked closely with all the Scientific Committees of the European Medicines Agency (EMA), carrying out assessments of medicinal products for both human and veterinary use. They also played an active role in the evaluation of medicinal products recommended in 2025 by the CHMP for marketing authorisation by the European Commission (EC).

Ewa Bałkowiec-Iskra, MD, PhD, DSc, Poland's delegate to the Committee for Medicinal Products for Human Use (CHMP), and the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products – Grzegorz Cessak, PhD, Poland's alternate delegate to the CHMP – have been assigned a total of 16 new registration procedures to oversee in 2025. In 2025, 19 registration procedures were completed.

Of the 104 medicines granted with marketing authorisations in 2025 by the European Commission, 19 products were

assessed by experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Ewa Bałkowiec-Iskra, MD, PhD, DSc has been asked to review 29 post-registration variations. By the end of 2025, 11 post-registration variation procedures had been completed, with experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products taking part.

Polish experts were assigned to develop 124 scientific comments on the assessment reports prepared by the countries acting as Rapporteurs and Co-Rapporteurs in the individual registration procedures. By the end of 2025, Polish experts had published 122 comments.

Experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products also played a part in the pre-registration development of new medicinal

products for human use. In the Scientific Advice Working Party (SAWP), Ewa Bałkowiec-Iskra, MD, PhD, DSc in her role as Vice-Chair, has worked with her team of specialists to draw up 50 scientific recommendations, including nine criteria for granting PRIME (PRiority MEDicines) status.²

In 2025, Ewa Bałkowiec-Iskra, MD, PhD, DSc, a member of the multidisciplinary group of experts known as the Emergency Task Force (ETF), played an active role in the group's work, which involved providing scientific advice and reviewing scientific data on medicinal products intended for use in emergency situations.

In the Central Nervous System Working Party (CNSWP), Ewa Bałkowiec-Iskra, MD, PhD, DSc, acting as chair, coordinated the work and chaired the party's meetings.

As part of the collaboration with the Pharmacovigilance Risk Assessment Committee (PRAC), Prof. Adam Przybyłkowski, PhD, DSc, the Polish delegate to PRAC, was assigned in 2025 to assess 2 new medicinal products submitted for registration (initial), 1 product submitted for re-registration, 18 post-marketing variations, and 38 periodic safety update reports (PSURs). Polish experts were also tasked with producing 34 comments on the periodic safety update reports. By the end of 2025, the following had been completed: the assessment of 3 medicinal products submitted for registration, the assessment of 2 re-registration procedures, the assessment of 36 post-

registration variations, and the assessment of 33 periodic safety update reports. A total of 33 comments were also issued on the periodic safety update reports.

Prof. Ewa Augustynowicz, PhD, DSc, the Polish delegate to the Committee for Veterinary Medicinal Products (CVMP), has been assigned nine new medicinal products submitted for registration, four post-registration variations and nine registration procedures for review in 2025 for issuing comments. By the end of 2025, the following had been completed: evaluations of 11 registration procedures, evaluations of three post-registration variations, and 28 comments on evaluation reports had been issued.

Wojciech Dmowski, PhD, the Polish delegate to the Committee on Herbal Medicinal Products (HMPC), was tasked in 2025 with preparing: 2 new plant monographs, reviews of 4 plant monographs, and updates to 2 plant monographs. By the end of 2025, four plant monographs had been completed, four plant monographs had been reviewed, and three plant monographs had been updated.

In 2025, experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products were tasked with verifying the translations of 799 information leaflets from the CHMP, 9 from the PRAC and 107 from the CVMP. By the end of 2025, the verification of 796 translations of information leaflets for the CHMP, 9 for the PRAC and 97 for the CVMP had been completed.

² PRIME is a programme run by the European Medicines Agency aimed at accelerating the development and approval of innovative medicines.

5

AREA SUPERVISED BY THE VICE-PRESIDENT OF THE OFFICE FOR MEDICINAL PRODUCTS



Marcin Kołakowski
Vice-President of the Office for Medicinal Products

In recent years, Poland has maintained a strong position in the European pharmaceutical sector, ranking fourth in the European Union (EU) in terms of the number of marketing authorisation applications submitted for medicinal products. The number of marketing authorisations issued for medicinal products and pharmaceutical raw materials is also rising steadily – in 2023, the President of the Office granted 595 authorisations, in 2024 – 637, and in 2025 – 685. In response to the growing interest in Poland as a Reference

Member State (RMS) in European procedures, from 2025 onwards, the procedure for allocating places in the RMS calendar (so-called slots) will be launched twice a year, which will improve the planning of registration strategies by marketing authorisation holders and the management of the Office's expert resources.

For the Department for Variations and Renewals of Medicinal Products (DZL), the key event of 2025 was the amendment to Commission Regulation (EC) No 1234/2008 concerning variations to the terms of marketing authorisations. An obligation to submit an annual report covering Type IA variations has been introduced; the possibility of forming so-called super-grouped Type IA variation has been extended to include national procedures; and a mandatory worksharing procedure has been established for variations concerning products registered in more than one Member State. These changes are intended to harmonise assessments across the EU, reduce duplication of national analyses and enhance the consistency of regulatory decisions. A new guideline has also been published, clarifying the rules for classifying variations



and the documentation requirements. In 2025, 26,127 variations were processed and 2,410 decisions for variation to marketing authorisations for medicinal products were issued (in accordance with Commission Regulation (EC) No 1234/2008 concerning variations to the terms of marketing authorisations). Another significant achievement was the launch of a new database to manage changes to European procedures.

The Pharmacovigilance Department focused on improving the effectiveness of Additional Risk Minimisation Measures (aRMMs). The guidelines for their assessment and approval were updated, and the digital distribution of educational materials was expanded, with the introduction of a standard logo to distinguish approved tools from promotional content. These measures enhance the safety of pharmacotherapy and the quality of communication with healthcare professionals and patients.

In the field of clinical trials, 2025 marked the end of the transitional period provided for in Regulation (EU) No 536/2014. The trials conducted under Directive 2001/20/EC have been brought into line with the new regulations and incorporated into the Clinical Trials Information System (CTIS). Following an analysis of the data, it was confirmed that the requirements of the Regulation regarding the ongoing trials had been met.

The Department for Register and Parallel Import of Medicinal Products focused on improving the quality of data in the Register of Medicinal Products and on collaborating with the e-Health Centre on the implementation of the IDMP standard and integration with European registers. Representatives from the Department actively participated in the work of the HMA Community of Experts (IDMP). In 2025, 406 new parallel import licenses were also issued.

Representatives of the Medicinal Products Division actively participated in the work of the European Medicines Agency's working parties (including QWP, BWP and HMPWP), helping to formulate joint positions of the EU regulatory agencies. Educational activities also continued at the Faculty of Pharmacy of the Medical University of Warsaw, covering topics such as the registration of medicines, post-authorisation variations, clinical trials, parallel imports and sources of information on medicines.

The past year has been a period of intense work and significant regulatory and organisational changes. These results are the outcome of the commitment shown by the staff and management of the Medicinal Products Division to carrying out tasks aimed at ensuring the safety and quality of pharmacotherapy in Poland.

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 48,698 applications were accepted in 2025, and 55,980¹ proceedings were completed.

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

Decisions on marketing authorisations for medicinal products are issued by the President of the Office.

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.



¹ The number of proceedings includes the number of variations.

Table 5.1: Number of applications, by procedure, for marketing authorisation, renewal, shortening of the authorisation period, and for post-authorisation variations to medicinal products from 1 January to 31 December 2025

Type of proceedings	Type of procedure			Number of applications received
	PN	MRP	DCP	
regarding the process of marketing authorisation for a medicinal product/pharmaceutical raw material	157	110	836	1,103
regarding the process of renewal of the marketing authorisation for a medicinal product		555		555
regarding the process of withdrawal of the marketing authorisation for a medicinal product		411		411
regarding the process of variation to the marketing authorisation holder (MAH)		179		179
regarding the process of variation to the authorisation and the underlying dossiers of the marketing authorisation for a medicinal product	3,114	8,461		11,575
regarding the process of variation to the package leaflet or labelling of medicinal products (notifications)	1,143	107		1,250
Total			15,073	

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 2025, 15,073 applications were registered for marketing authorisations, extensions, shortenings, and post-authorisation variations of medicinal products. Detailed data are presented in Table 5.1 and Chart 5.1. The largest group of applications (77% of applications) consists of applications for post-authorisation variations to the marketing authorisation and the documentation on which the marketing authorisation for the medicinal product is based (Chart 5.1).

In 2025, the Office received 1,070 applications for marketing authorisation for a medicinal product and pharmaceutical raw material, of which 152 in the national procedure, 106 in the mutual recognition procedure and 812 in the decentralised procedure (Chart 5.2).

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 2025, a total of 32,187 variations were submitted as part of 13,004² 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.

In addition, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products received 565 submission regarding the Republic of Poland's role as a Reference Member State (RMS). The submission concerned the MRP/DCP. A total of 524 proceedings were completed in this regard, of which 220 resulted in the approval of the submission.



² This figure includes applications submitted in the following areas: 1) variations to the marketing authorisation and underlying documentation for a medicinal product, 2) variations to the package leaflet or labelling of medicinal products (notifications), 3) changing the Marketing Authorisation Holder (MAH), including applications under Articles 133 and 135 of the Code of Administrative Procedure.

Chart 5.1: Number of applications accepted, as a percentage, concerning marketing authorisation, renewal, shortening of the authorisation period, and for post-authorisation variations to medicinal products from 1 January 2025 to 31 December 2025

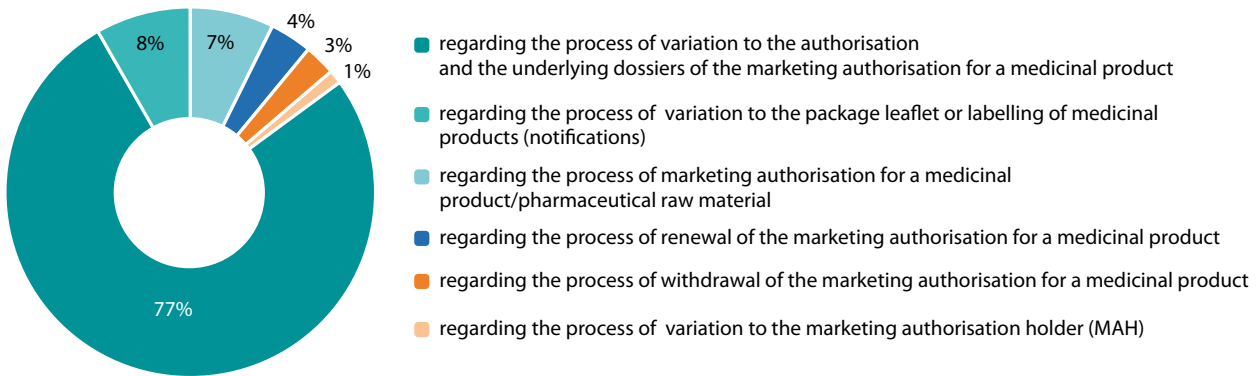
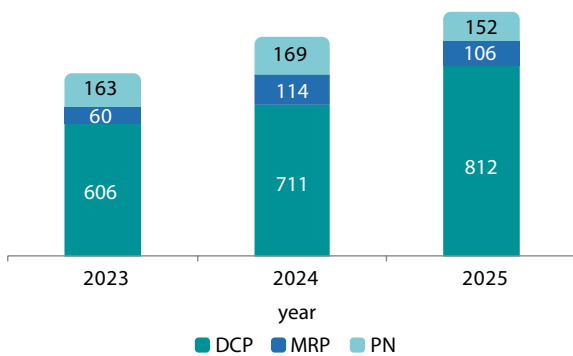


Chart 5.2: Number of applications concerning medicinal product/pharmaceutical raw material³ authorisations, by procedure, in 2023–2025



With regard to the non-expiry of the marketing authorisation of the medicinal product sunset clause, 558 applications were submitted. A positive decision was issued in 560 proceedings.

In 2025, a total of 13,574 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 – 76% (Chart 5.3).

A total of 26,127 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 2025, 9,750 proceedings were completed this way.

Table 5.2: Number of completed proceedings for marketing authorisation, renewal, shortening of the authorisation period, and for post-authorisation variations to medicinal products from 1 January 2025 to 31 December 2025

Type of proceeding	Number of completed proceedings
regarding the process of granting the marketing authorisation for a medicinal product/pharmaceutical raw material	894
regarding the process of renewal of the marketing authorisation for a medicinal product	545
regarding the process of withdrawal of the marketing authorisation for a medicinal product	390
regarding the process of variation to the authorisation and the underlying dossier of the marketing authorisation for a medicinal product	10,333
regarding the process of variation to the package leaflet or the labelling of medicinal products	1,155
regarding the process of variation to the marketing authorisation holder	257
Total	13,574

³ Applications submitted at the second instance are included.

Chart 5.3: Number of completed proceedings, as a percentage, concerning marketing authorisations, renewals, shortening of the validity period of authorisations, and variations to medicinal products during the period from 1 January to 31 December 2025

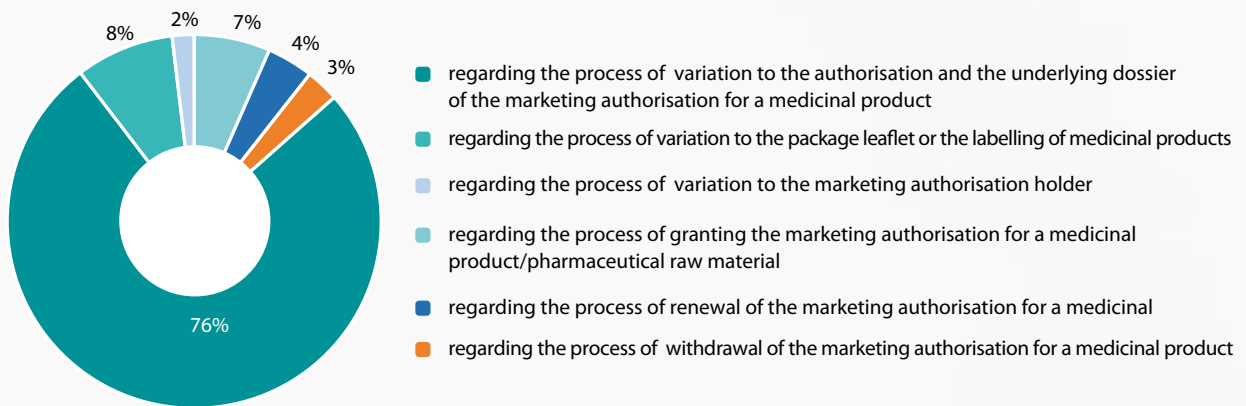
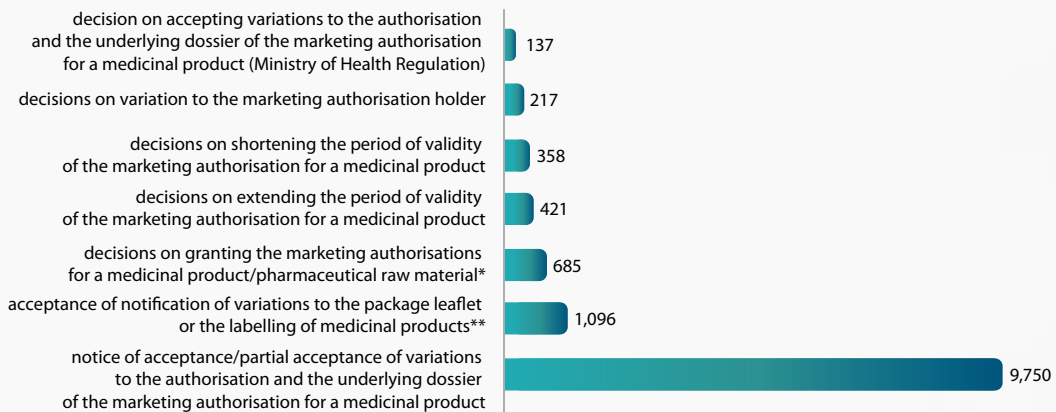


Chart 5.4: Number of favourable decisions/notices concerning marketing authorisation, renewal, shortening of the validity period of authorisations, and variations to medicinal products from 1 January 2025 to 31 December 2025



*Decisions on granting the marketing authorisations for a medicinal product – 650, decisions on granting the marketing authorisations for a pharmaceutical product – 35; **notification of acceptance of notification – 905 and acceptance of notification without issuance of notification (including CMS) – 191

In addition, as regards variations to the authorisation and the underlying dossier on which the marketing authorisation for the medicinal product, 2,410 decisions were issued to amend the data covered by the marketing authorisation for the medicinal product on the basis of Commission Regulation (EC) No 1234/2008. This decision is issued in respect of specific proceedings concerning variations concluded by a notification.

In 2025, 655 medicinal product marketing authorisation decisions and 30 pharmaceutical raw material marketing authorisations were issued. Of the medicinal products authorised for marketing, the majority – 84% – were products dispensed under medical prescription (Rp, Rpw, Rpz), including 19% of products for restricted use, i.e. with the Rpz availability category, and 1% of products containing narcotic or psychotropic substances (Rpw). OTC medicinal products accounted for 12% of all marketing authorisations granted (Chart 5.6).

Chart 5.5: Number of decisions on granting the marketing authorisation for a medicinal product/ pharmaceutical raw material by procedure in 2023 – 2025

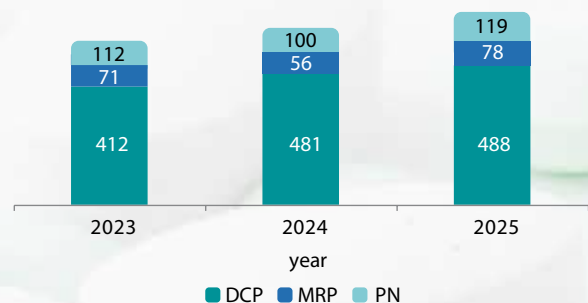


Chart 5.6: Number of authorised medicinal products, as a percentage, by availability category in the period from 1 January 2025 to 31 December 2025

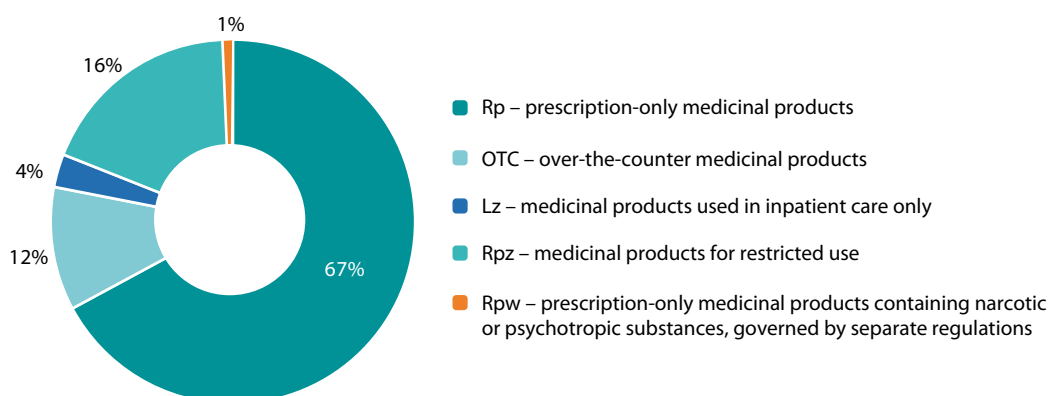
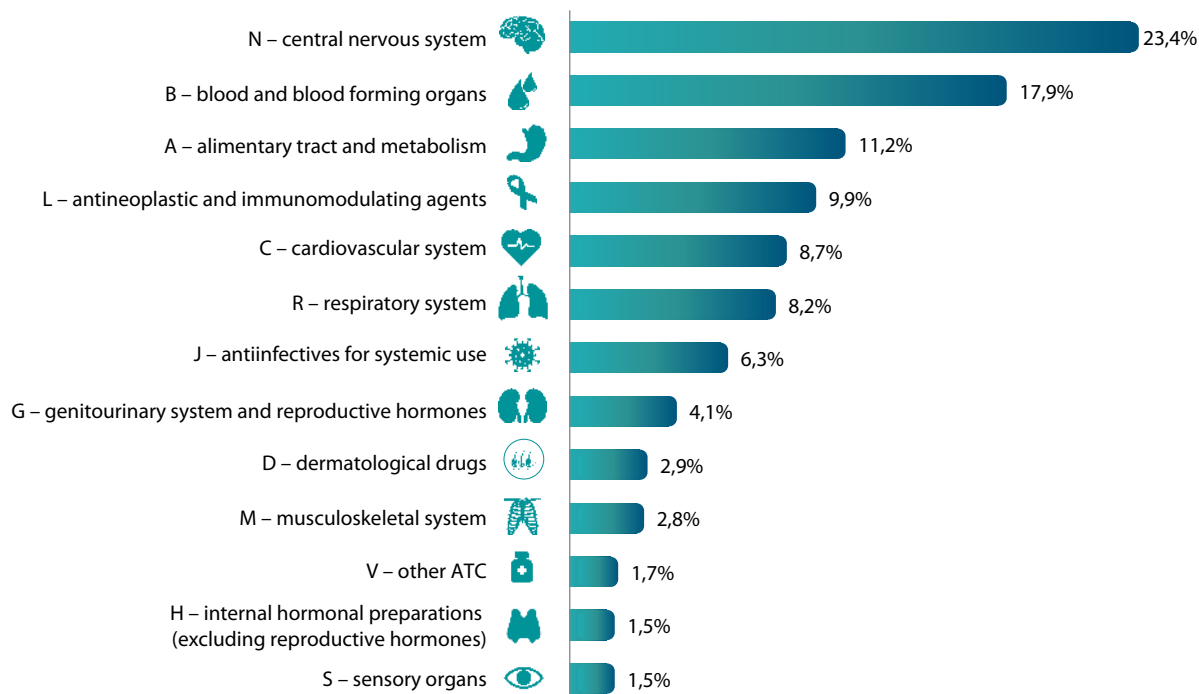


Chart 5.7: Number of decisions on granting the marketing authorisation for a medicinal product by ATC⁴ code from 1 January 2025 to 31 December 2025



Among the marketing authorisations granted in 2025, the largest number was granted for medicinal products for

the treatment of the central nervous system (23.4%), blood and haematopoietic diseases (17.9%), and the alimentary tract and metabolism (11.2%) (Chart 5.7). For the group of antineoplastic and immunomodulating agents, 40% fewer decisions were granted than in 2024.

⁴ Anatomical Therapeutic Chemical (ATC) Classification System – a system used to classify medicinal products and other substances and products used in medicine according to their anatomical, therapeutic and chemical characteristics.



Provision of scientific advice

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 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, nonclinical aspects, pharmacovigilance or methodological issues of ongoing or planned studies. In 2025, the Office received 17 requests for scientific advice, of which 15 were granted.

In addition, in 2024 the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products 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.

Issuing opinions on whether a food product meets or does not meet the requirements of a medicinal product specified in the Pharmaceutical Law, in accordance with the provisions of the Food and Nutrition Safety Act

In 2025, the Office received 11 requests for opinions on whether a food product meets or does not meet the requirements of a medicinal product, and 9 opinions were issued in this regard.

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 (Journal of Laws of 2025, item 750, as amended), the Register of Medicinal Products Authorised on the territory of the Republic of Poland is maintained by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. 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://rejstry.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 for Registration of Medicinal Products, Medical Devices and Biocidal Products in the Official Journal of the Minister of Health. In 2025, a notice dated 16 December 2025 was published, containing data as at 1 January 2025. 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 10,541 products, a list of medicinal products authorised on the basis of permits issued by the European Commission in the number of 3,414 permits and a list of medicinal products which obtained parallel import permits in the number of 3,108.

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 (Journal of Laws of 2025, item 750, as amended). In Poland, the parallel import licence is issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

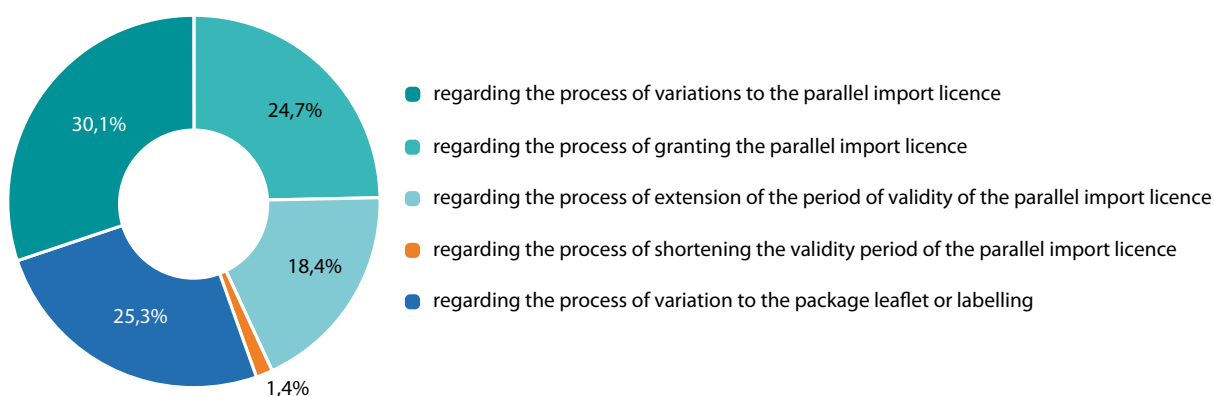
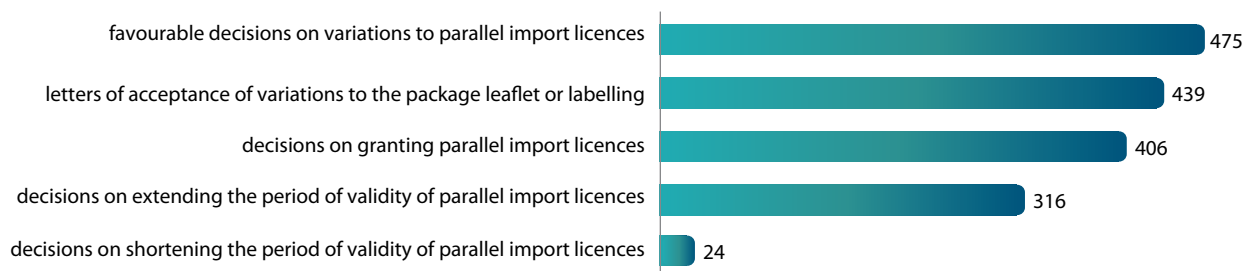
In 2025, the Office received 1,906 applications for parallel imports of medicinal products, including 577 applications for parallel import licences.

Within the filed applications, a total of 1,735 proceedings were completed, including 406 decisions on the authorisation of parallel import of a medicinal product.

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

Table 5.3: Number of completed proceedings concerning parallel import from 1 January 2025 to 31 December 2025

Type of the proceedings	Number of procedures concluded
regarding the process of granting the parallel import licence	428
regarding the process of extension of the period of validity of the parallel import licence	320
regarding the process of shortening the validity period of the parallel import licence	25
regarding the process of variation to the package leaflet or labelling	439
regarding the process of variations to the parallel import licence	523
Total	1,735

Chart 5.8: Number of completed proceedings, as a percentage, concerning parallel import from 1 January 2025 to 31 December 2025**Chart 5.9: Number of favourable decisions/letters issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products concerning parallel import from 1 January 2025 to 31 December 2025**

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 18% of licences issued (Chart 5.10).

In 2025, the largest number of parallel import licences were issued for medicinal products from Latvia, Spain and the Czech Republic (Chart 5.11).

Considering the classification of medicinal products in terms of ATC code, the predominant number of parallel import licences in 2025 was for medicinal products for cardiovascular diseases – 17,7% (Chart 5.12).



Chart 5.10: Number of parallel import licences, as a percentage, issued by availability category from 1 January 2025 to 31 December 2025

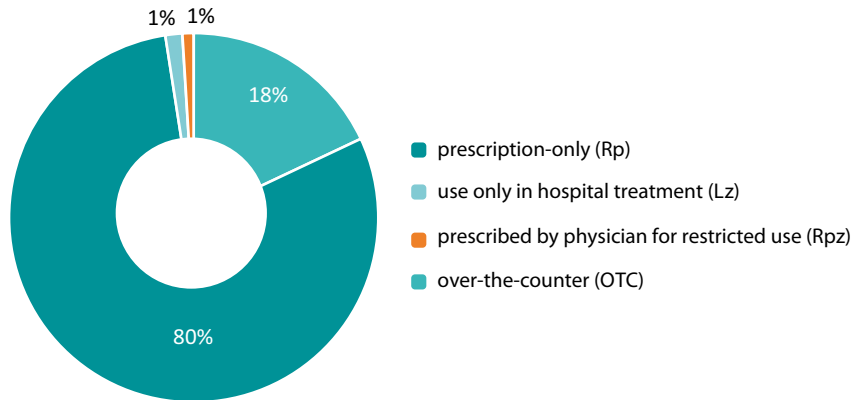
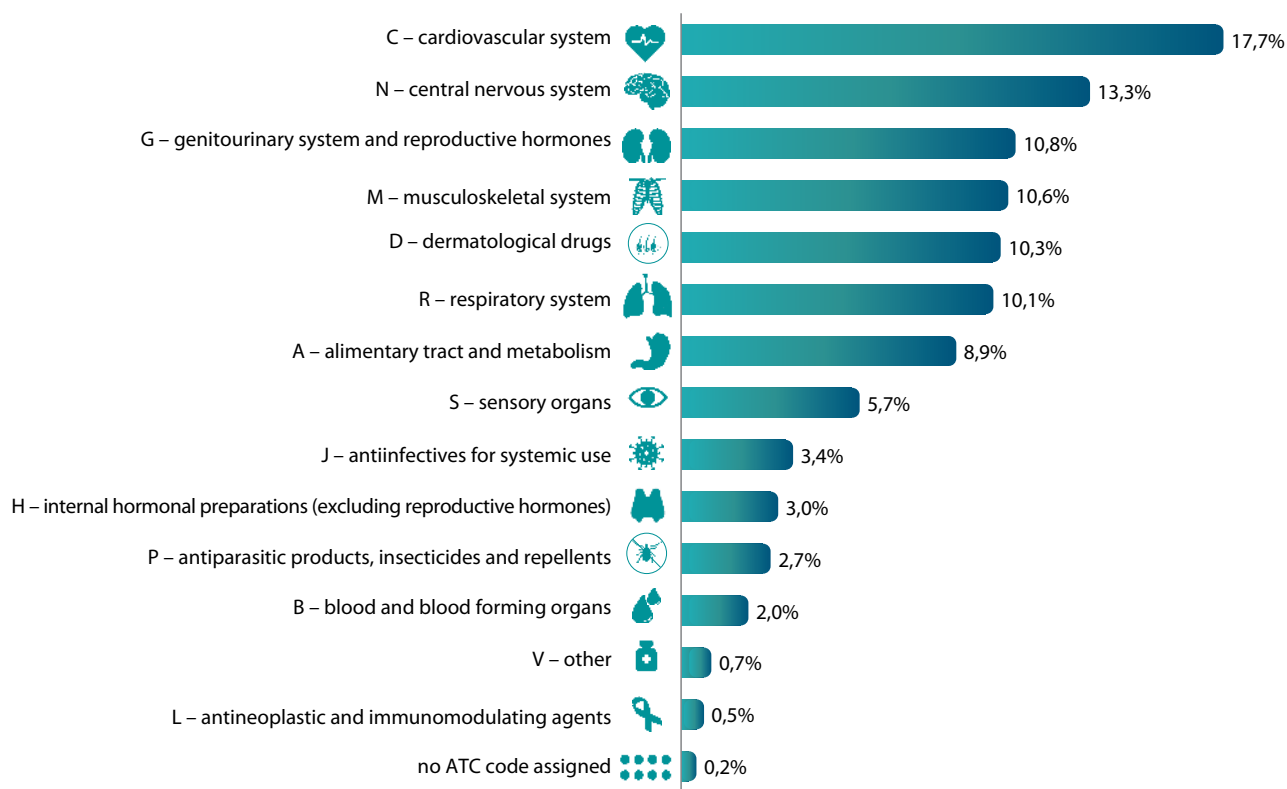


Chart 5.11: Number of parallel import licences issued by country of export from 1 January 2025 to 31 December 2025



Chart 5.12: Number of parallel import licences issued, by ATC code, in the period from 1 January 2025 to 31 December 2025



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 4b⁵ and 4c of the Pharmaceutical Law

In 2025, the Office received 808 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 475 approvals for importing medicines from abroad for private medicinal use, 120 approvals under Article 4b and 213 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

⁵ Article 4b of the Pharmaceutical Law Act: "The President of the URPLWMIpB may authorise the use of foreign-language labelling for a specified number of packages of orphan medicinal products referred to in Regulation (EC) No 1411/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products."

exceptional circumstances, the marketing authorisation holders submit a notification of the temporary or permanent suspension of marketing of a given medicinal product. In 2025, the Office received 4,343 such notifications.

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. The Office 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 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: <https://www.gov.pl/web/urpl/monitorowanie-bezpieczenstwa-lekow2>, 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 2025, 14,625 reports of adverse reactions to medicinal products were submitted directly to the Office, including 7,681 from healthcare professionals, 2,903 from patients or their carers and 4,041 from the State Sanitary Inspectorate, concerning vaccine adverse events (Table 5.4).

In addition, 11,171 reports of adverse reactions to medicinal products were collected by the marketing authorisation holders and submitted directly to the EudraVigilance database, including 3,651 reports on severe adverse reactions.

The percentage of reports of individual cases of adverse reactions to medicinal products in Poland in 2025 is presented in Chart 5.13.

A total of 15,569 assessed adverse reaction reports were sent to the EudraVigilance database.

As regards the evaluation of potential signals, the Office received 212 eRMR reports prepared by the EMA concerning substances allocated to Poland under the division of labour. These reports contained 2,102 adverse reactions requiring assessment by the Office. All potential signals contained in the EMA reports were analysed. The data analysed by the Office has been confirmed for two signals.

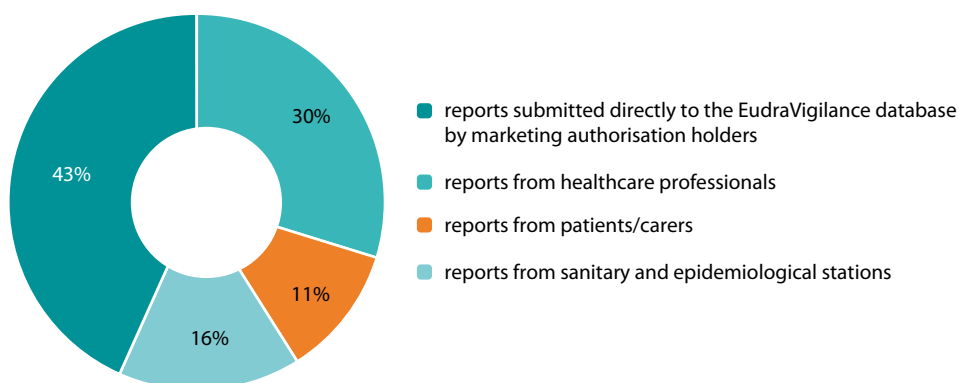
Furthermore, pharmacovigilance activities included reviewing and evaluating 19 safety communications and 219 educational materials prepared by marketing authorisation holders.

In addition, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products received 138 Periodic Safety Update Reports (PSURs), of which 99 were assessed.

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 2025 to 31 December 2025

Type of report	Number of severe cases reported	Number of non-severe cases reported	Total
reports from healthcare professionals	2,048	5,633	7,681
reports from patients/carers	933	1,970	2,903
reports from sanitary and epidemiological stations	914	3,127	4,041
		Total	14,625

Chart 5.13: Number of reports of individual cases of adverse reactions to medicinal products, as a percentage, in Poland from 1 January 2025 to 31 December 2025



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 2025 was the last year of the transition period provided for in 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 (Regulation 536/2014). During this period, sponsors of clinical trials were able to bring ongoing trials, authorised under Directive 2001/20/EC, into line with the current requirements set out in Regulation 536/2014. This process enabled the transfer of these trials to the CTIS.

In 2025, the Office received 666⁶ applications to initiate clinical trials of a medicinal product and completed 663⁷ proceedings.

In addition, 2,657⁸ 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 2,551 procedures in this regard were proceedings were completed in this regard, including the issuance of 2,538 favourable decisions.

⁶ The figure of 666 includes 648 applications to start clinical trials (new applications), 6 applications (Transitional Trials applications) and 12 applications submitted at second instance.

⁷ The figure of 663 includes 571 decisions granting approval for clinical trials (issued on the basis of new applications), 19 decisions granting approval for clinical trials issued in response to Transitional Trials applications, and 15 decisions granting approval for applications submitted at second instance.

⁸ The figure of 2,657 also includes one application submitted at second instance.

In terms of monitoring the safety of medicinal products during clinical trials, the Office received 4,078 cases.

In accordance with the applicable legislation, in particular 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 setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials, 45 new active substances requiring safety assessment Member State (so-called saMS) monitoring were allocated to Poland during 2025.

At the end of 2025, the total number of active substances monitored by Poland was 207. Among other things, this resulted in the need to prepare 2,734 datasets for the screening of suspected unexpected serious adverse reactions (SUSAR screening) with the resulting assessments. A total of 5,019 individual reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) were assessed.

In addition, in 2025, 38 Annual Safety Reports and 359 Final Clinical Trial Reports were received.



6

AREA SUPERVISED BY THE VICE-PRESIDENT OF THE OFFICE FOR VETERINARY MEDICINAL PRODUCTS



Agata Andrzejewska

Vice-President of the Office for Veterinary Medicinal Products

The year 2025 was a period of intense activity for the Veterinary Medicinal Products Division, with implications at both national and European level. One of the key events was our involvement in the preparation and implementation of tasks related to Polish presidency of the Council of the European Union. Meetings of the Committee for Veterinary Medicinal Products (CVMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv), both operating under the European Medicines

Agency (EMA), were held in Warsaw. These meetings served as an important forum for exchanging experiences and developing common approaches to the regulation of veterinary medicinal products, particularly in the context of combating antimicrobial resistance and responding to new threats posed by infectious animal diseases. The events were attended by representatives of national regulatory authorities, the European Commission (EC), the EMA and veterinary experts.

A key focus of the Division's work remained the continued implementation of the provisions of Regulation (EU) 2019/6. In 2025, intensive work continued on bringing information on veterinary medicinal products into line with the requirements set out in the aforementioned regulation. This process has reached an advanced stage – around 20% of marketing authorisations remain to be finalised, which represents significant progress in the process of adapting the documentation for veterinary medicinal products to the new regulatory requirements.



In 2025, we continued our work on refining and improving the functionality of the Union Product Database (UPD). The activities were carried out in close cooperation with the EMA. Last year, the priority was to improve the quality of the data in the database and to update it with new information, with the aim of obtaining the most comprehensive knowledge possible about veterinary medicinal products. We have continued our work on developing the Register of Medicinal Products (RPL), enhancing it with new features that enable further optimisation. In addition, in collaboration with the e-Health Centre, steps were taken to ensure the integration of data on veterinary medicinal products between the RPL and the UPD, with a view to ensuring a swift and efficient process for updating information in both databases.

Another key aspect of the Division's activities was the participation of experts in numerous meetings of working groups operating under the EMA, as well as in meetings organised by the Standing Committee on Veterinary Medicinal Products, operating under the European

Commission. This involvement enabled them to exert a real influence on the shape of the regulations and guidelines concerning veterinary medicinal products.

These regulatory measures were complemented by educational initiatives and dialogue with the professional community. Representatives of the Division took part in scientific conferences on veterinary medicinal products and organised the latest edition of the event "Veterinary Day at the Office of Registration...", which focused on the challenges of using medicinal products in animals and the practical aspects of implementing new regulations.

To sum up the past year, I would like to emphasize the professionalism, substantive preparation and commitment of the Division's employees, which were crucial for the efficient implementation of our tasks.

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

Performance of tasks in the area of veterinary medicinal products

In 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products received a total of 4,908 applications relating to veterinary medicinal products, and 5,813 proceedings were completed (this figure includes the number of variations).

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

The 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 great emphasis on ensuring a high level of protection and safety for public health through the implementation of a range of measures in line with the "One Health"¹ approach, and, above all: monitoring the reduction of the uncontrolled use of antibiotics in animals, establishing a list of antibiotics reserved for human use only, and consequently limiting the rise in antimicrobial resistance.

A veterinary medicinal product is placed on the market following the granting of a marketing authorisation by the President of the Office for Registration of Medicinal Products,

Medical Devices and Biocidal Products under the National Procedure (NP), a Decentralised Procedure (DCP), a Mutual Recognition Procedure (MRP) for marketing authorisations granted under the national procedure, a Subsequent Recognition Procedure (SRP) for marketing authorisations by additional Member States, or a Centralised Procedure (CP).

In 2025, a total of 3,328 applications were registered for marketing authorisation of veterinary medicinal products, the extension or shortening of marketing authorisations, and variations to veterinary medicinal products.

As in previous years, the largest category of applications – over 93% – consisted of applications for variations to marketing



¹ The One Health concept is an integrated and coherent approach aimed at maintaining a sustainable balance and ensuring optimal health for humans, animals and the environment.

authorisations for medicinal products or variations to the documentation forming the basis for the granting of marketing authorisations for veterinary medicinal products (Chart 6.1).

Both in national and European procedures, it is possible to group variations. Under this procedure, it is possible to submit more than one variation as part of a single application. In 2025, 3,488 variations were submitted as part of 3,158 applications for variations to the marketing authorisation and the documentation forming the basis for the marketing authorisation of a veterinary

medicinal product, as well as for changes to the Marketing Authorisation Holder (MAH).

Applications for marketing authorisation for veterinary medicinal products accounted for 2.4% of all applications for veterinary medicinal products. In 2025, the Office received 70 applications for marketing authorisation for veterinary medicinal products. Most applications in this area are submitted under the Decentralised Procedure (DCP) (Chart 6.2), which allows for the granting of a marketing authorisation in several EU countries simultaneously.

Chart 6.1: Percentage breakdown of applications submitted for marketing authorisations, renewals, shortenings of authorisations and post-authorisation variations of veterinary medicinal products during the period from 1 January to 31 December 2025

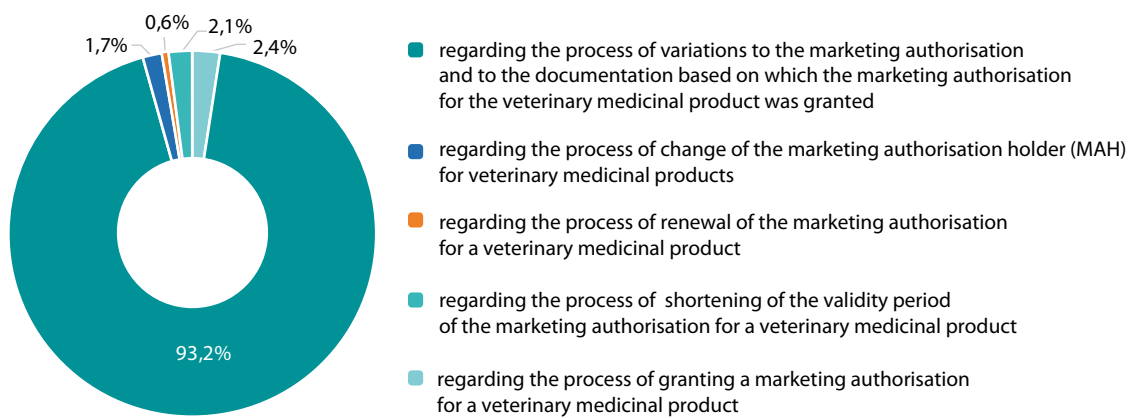
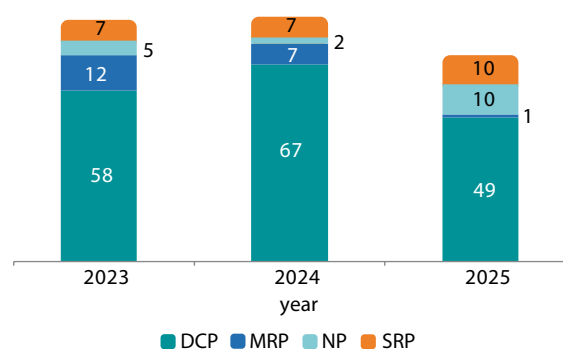


Table 6.1: Number of applications submitted for marketing authorisations, renewals, shortenings of authorisations and post-authorisation variations of veterinary medicinal products during the period from 1 January to 31 December 2025

Type of application	Number of applications
regarding the process of granting a marketing authorisation for a veterinary medicinal product	81
regarding the process of variations to the marketing authorisation and to the documentation based on which the marketing authorisation for the veterinary medicinal product was granted	3,102
regarding the process of change of the marketing authorisation holder (MAH) for veterinary medicinal products	56
regarding the process of renewal of the marketing authorisation for a veterinary medicinal product (NP, MRP, DCP)	20
regarding the process of shortening of the validity period of the marketing authorisation for a veterinary medicinal product	69
Total	3,328



Chart 6.2: Number of applications for marketing authorisation of veterinary medicinal products accepted, broken down by procedure, for the years 2023–2025



In 2025, a total of 3,864² proceedings were completed in the area of marketing authorisation for veterinary medicinal products, as well as in the areas of variations and re-registration, of which over 93% were proceedings relating to variations to the marketing authorisation and the documentation forming the basis for the marketing authorisation of a veterinary medicinal product. Detailed data on completed proceedings are presented in Table 6.2 and Chart 6.3.

Most of the proceedings concerning variations to authorised data and variations to the documentation forming the basis for the marketing authorisation of a veterinary medicinal product, as examined by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, related to variations not requiring assessment (VNRA) and resulted in the approval of 2,191 VNRA.

The President of the Office issued 953 decisions amending the particulars covered by a marketing authorisation for a veterinary medicinal product or amending the

documentation in order to conclude proceedings for a variation requiring assessment (VRA) and 270 decisions changing data covered by the marketing authorisation for a veterinary medicinal product in the course of proceedings for a variation not requiring assessment (VNRA).

With regard to variations requiring assessment (VRA) submitted and considered under Regulation (EU) 2019/6, a decision concluding the proceeding is issued for all such proceedings. This may be a decision amending the marketing authorisation or rejecting the variation. With regard to variations not requiring an assessment (VNRA), for which the outcome is recorded in the Union Product Database (UPD) on veterinary medicinal products, a decision to amend the marketing authorisation is issued only where the approved variation necessitates a change to the terms of the marketing authorisation for the veterinary medicinal product.

In accordance with Article 5(2) 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, a marketing authorisation for a veterinary medicinal product is valid for an indefinite period. However, in accordance with Article 152(1) of Regulation (EU) 2019/6, marketing authorisations for veterinary medicinal 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. Consequently, with the entry into force of Regulation (EU) 2019/6, marketing authorisations for veterinary medicinal products issued in accordance with Directive 2001/82/EC are valid indefinitely by operation of law, and new applications for the renewal of such authorisations are no longer submitted. In the case of marketing authorisations issued for a fixed term, the President of the Office shall amend the final decision regarding the

Table 6.2: Number of completed authorisations, renewals, shortenings and post-authorisation variations of veterinary medicinal products from 1 January to 31 December 2025

Type of proceedings	Number of completed proceedings
regarding the process of granting a marketing authorisation for a veterinary medicinal product	104
regarding the process of variations to the marketing authorisation and to the documentation based on which the marketing authorisation for a veterinary medicinal product was granted	3,601 ³
regarding the process of change of the marketing authorisation holder (MAH) for veterinary medicinal products	45
regarding the process of renewal of the marketing authorisation for a veterinary medicinal product	50
regarding the process of shortening of the validity period of the marketing authorisation for a veterinary medicinal product	64
Total	3,864

² The number of proceedings, excluding the number of variations.

³ The number of completed proceedings, excluding the number of variations. Number of variations: 4,002.

Chart 6.3: Percentage of completed authorisations, renewals, shortenings and post-authorisation variations of veterinary medicinal products during the period from 1 January to 31 December 2025

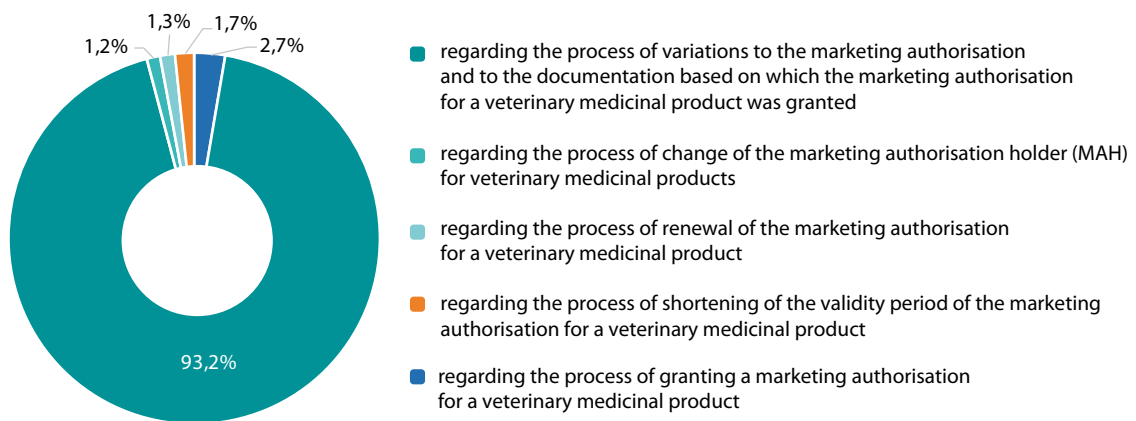
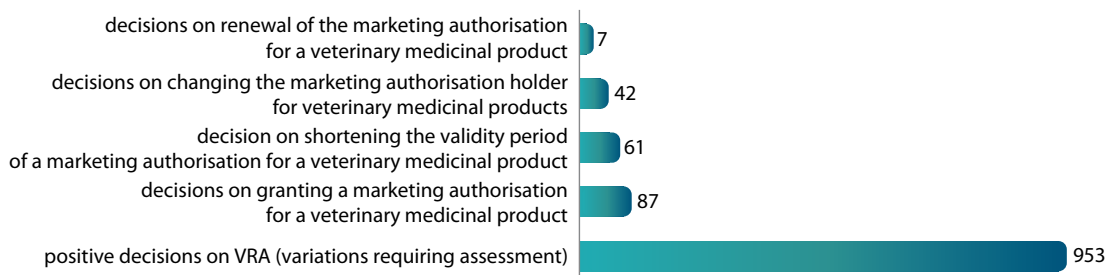


Chart 6.4: Number of positive decisions/notifications regarding marketing authorisation, renewal, shortening of the validity period of a marketing authorisation, and variations to veterinary medicinal products in the period from 1 January to 31 December 2025



authorisation period of validity pursuant to Article 155 of the Act of 14 June 1960 – Code of Administrative Procedure. Such procedures are initiated at the request of a party or ex officio.

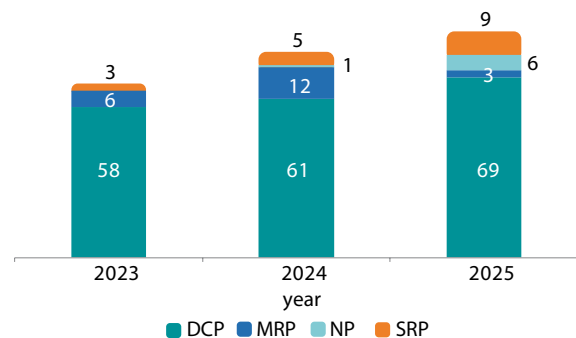
In 2025, the President of the Office issued 87⁴ decisions granting marketing authorisations for veterinary medicinal products, 78% of which were granted under the decentralised procedure (DCP).

Before a decision is issued granting a marketing authorisation for a veterinary medicinal product, the safety, efficacy and quality of the product in question are assessed. The assessment is based on the documentation submitted by the responsible entity.

An additional requirement for medicinal products intended for food-producing animals (farm animals) is the submission

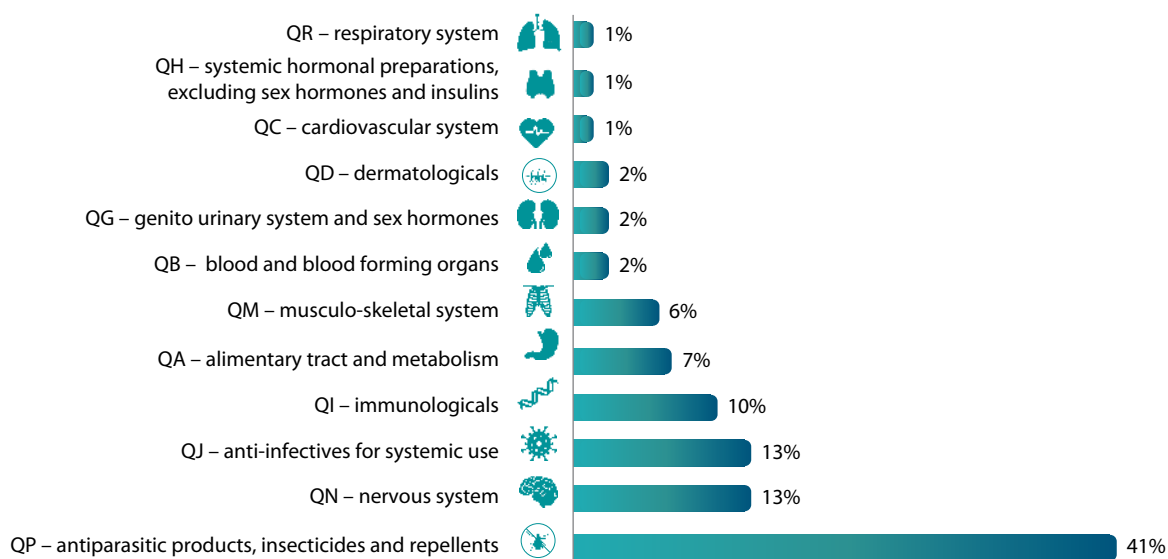
⁴ In accordance with Article 152(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, marketing authorisations for veterinary medicinal products and registrations of homeopathic veterinary medicinal 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 granted in accordance with this Regulation and shall therefore be subject to the relevant provisions of this Regulation.

Chart 6.5: Number of marketing authorisation decisions issued for veterinary medicinal products, broken down by procedure, for the years 2023–2025



of documentation confirming the safety of products derived from treated animals for consumers of food of animal origin (meat, milk, eggs, honey), i.e. documentation regarding the withdrawal period. These products are available on veterinary prescription. Veterinary medicinal products classified as products subject to veterinary prescription accounted for 90% of the marketing authorisations issued for veterinary medicinal products.

Chart 6.6: Percentage breakdown of the number of decisions to grant marketing authorisations for veterinary medicinal products, broken down by ATCvet codes, for the period from 1 January to 31 December 2025



Among the marketing authorisations for veterinary medicinal products issued in 2025, the majority were for anti-parasitic medicines, insecticides and repellents – 41% (Chart 6.6).

Harmonisation of the summary of product characteristics for veterinary medicinal products

In 2025, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, in collaboration with the Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products (CMDv), carried out tasks relating to the procedure for harmonising the summary of product characteristics of veterinary medicinal products. In 2025, the Office initiated two procedures concerning the harmonisation of the summary of product characteristics for veterinary medicinal products, and one decision was issued in this regard.

Maintaining the Register of Medicinal Products, providing information and publishing bulletins and lists concerning veterinary medicinal products authorised for marketing within the territory of the Republic of Poland

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products maintains the “Register of Medicinal Products Authorised for Marketing in the Republic of Poland”, which covers not only the

aforementioned medicinal products for human use but also veterinary medicinal products.

The Register of Veterinary Medicinal Products is a database of veterinary medicinal products authorised for marketing. The register contains information on the veterinary medicinal product in accordance with the marketing authorisation, together with all variations approved after the medicinal product was authorised. Another component of the Register is the Summary of Product Characteristics for Veterinary Medicinal Products, which provides a detailed description of the product’s properties.



The register is maintained in an IT system and is a publicly accessible database. The register is available in electronic form on the website: <https://rejistrymedyczne.ezdrowie.gov.pl/rpl/search/public>. Information regarding newly issued marketing authorisations is published on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

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 granted marketing authorisation during the relevant period.

Based on data from the Register, the "Official List of Medicinal Products Authorised for Marketing in the Republic of Poland" is compiled, including a separate list of veterinary medicinal products, which is published as a notice from the President of the Office in the Official Journal of the Minister of Health. In 2025, a notice dated 16 December 2025 was published, containing data as at 1 January 2025. In the section on veterinary medicinal products, the document contains: a list of veterinary medicinal products authorised for marketing in the territory of the Republic of Poland under national and European procedures, totalling 1,847 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, totalling 527 authorisations, and a list of veterinary medicinal products which have obtained authorisations for parallel import, totalling 3 products.

The granting of authorisations for the parallel trade in a veterinary medicinal product

The parallel trade procedure is intended for wholesalers who, having obtained a parallel trade authorisation for a veterinary medicinal product, will obtain the product from one Member State (the Member State of origin) and wish to distribute that product in another Member State (the Member State of destination), provided that the product subject to parallel trade shares the same origin as a veterinary medicinal product already authorised for marketing in the Member State of destination.

In 2025, the Office did not receive any applications relating to parallel trade.

Conducting procedures in matters relating to the granting of authorisations for veterinary clinical trials and maintaining the Central Register of Clinical Trials (CEBK) for veterinary medicinal products

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

In accordance with Article 37ah(4) of the Pharmaceutical Law Act, a veterinary clinical trial may be initiated or conducted only after authorisation has been granted by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The trial may be conducted using a veterinary medicinal product that is either authorised or unauthorised for marketing, containing an active substance that is known, new or has not previously been used in veterinary medicine.

Clinical trials must be conducted in accordance with the standards of Veterinary Good Clinical Practice (Regulation of the Minister of Health of 6 July 2012 on the requirements of Veterinary Good Clinical Practice). Clinical trials are conducted using the target animal species.

In 2025, the Office received three new applications for authorisation to conduct clinical trials of veterinary medicinal products. The President of the Office has issued one authorisation for a clinical trial of a veterinary medicinal product.

Issuing of authorisations by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products for the importation of veterinary medicinal products from abroad for personal therapeutic use

In 2025, the Office received 32 applications for an authorisation from the President of the Office to import veterinary medicinal products from abroad for personal medical use, of which the President granted 17 approvals.

Supervision of the safety of veterinary medicinal products and monitoring of their safety

In accordance with 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, the following are considered to be adverse events:

- any adverse or unintended reactions in the animal to the veterinary medicinal product;
- any suspected lack of efficacy of a veterinary medicinal product following use in accordance with or contrary to the summary of product characteristics;
- any adverse events observed following the administration of a veterinary medicinal product to an animal;
- any reactions observed in humans following contact with a veterinary medicinal product;
- any instances where the active substance or residues of the marker are detected in a product of animal origin at levels exceeding the maximum residue limits established in accordance with Regulation (EC) No 470/2009, after the expiry of the specified withdrawal period;

- any suspicion that a veterinary medicinal product may transmit an infectious agent;
- any adverse and unintended reactions in an animal to a medicinal product intended for human use.

As part of monitoring of the safety of veterinary medicinal products, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products collects information on adverse reactions associated with the use of medicinal products in animals, as well as cases of concerning symptoms in humans resulting from contact with a medicinal product or a treated animal. Reports of adverse reactions to medicinal products may be submitted by users to the Office or directly to the marketing authorisation holders. In 2025, users reported 278 adverse events to the Office.

Reports of adverse reactions to medicinal products are currently submitted directly to the EU database on pharmacovigilance by both the Office and the marketing authorisation holders, and these reports are then analysed by the respective registration agencies in the Member States. This applies to both serious reports and those that were not serious. Reports of adverse reactions to veterinary medicinal products can be submitted using the form available on the Office's website at: <https://www.gov.pl/web/urpl/zgloszdarzenie-niepozadane> or via the electronic form on the eHealth Centre's ICT systems website: <https://smz2.ezdrowie.gov.pl/>.

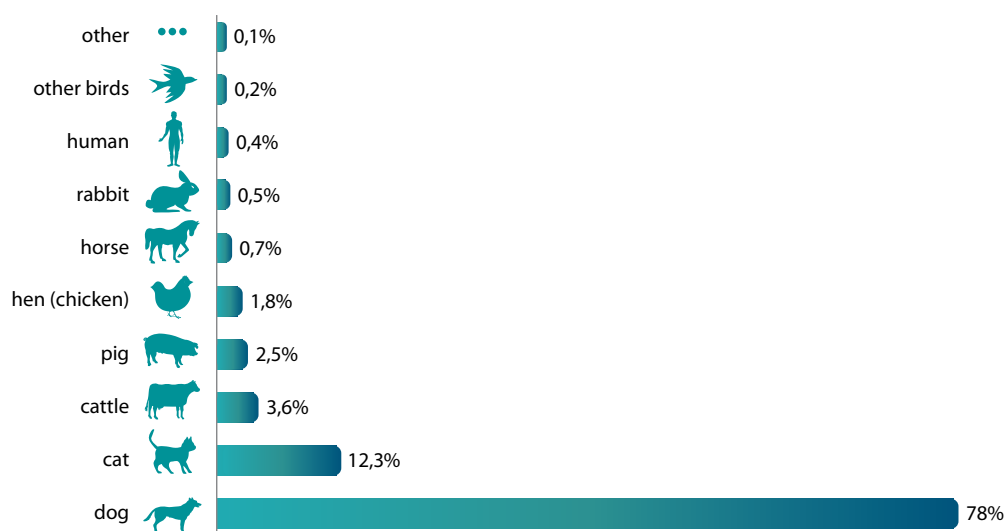


In 2025, a total of 1,140 adverse event reports for veterinary medicinal products were submitted to the Union Pharmacovigilance Database. 79% of the reports came from the marketing authorization holders. The Office submitted 306 reports of adverse reactions to the database (within the statutory deadline).

As part of the safety monitoring of veterinary medicinal products, four cases relating to Non-Urgent Information (NUI) on safety of veterinary medicinal products were processed.

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

Chart 6.7: Percentage breakdown of reports of adverse reactions to veterinary medicinal products in 2025, by animal species



In early 2025, the Pilot-Signal Management Expert Group, tasked with developing a new process for monitoring signals related to the safety of veterinary medicinal products, as regulated by Article 81 of Regulation (EU) 2019/6, concluded its work. At the same time, an Operational Expert Group on Pharmacovigilance was established to support the Pharmacovigilance Working Group of the Committee for Veterinary Medicinal Products

(PhVWP-V) in assessing the results and outcomes of signal management and the overall oversight of veterinary medicinal products (VMPs).

Issuing opinions on product qualifications

In 2025, the Office received 73 applications for product qualifications, of which 51 opinions were issued.



7

AREA SUPERVISED BY THE VICE-PRESIDENT OF THE OFFICE FOR MEDICAL DEVICES



Sebastian Migdalski

Vice-President of the Office for Medical Devices

The year 2025 was a period of intensive activities of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products aimed at strengthening the medical devices surveillance system and enhancing European cooperation.

A particular highlight was the organisation in Warsaw of the Competent Authorities for Medical Devices (CAMD) meeting, which formed part of a series of initiatives implemented under the Polish Presidency of the Council of the European

Union (EU). The event facilitated the initiation of work on the harmonisation of European legislation in the area of so-called cybersecurity, as well as the exchange of experience among the competent authorities of the Member States regarding the supervision of combined studies, advertising control, and the reporting of serious incidents. Special emphasis was placed on market surveillance.

There was an increase in the number of inspections of economic operators. Two ad hoc inspections were also conducted without prior notice. These measures, based on an analysis of reports concerning the safety of medical devices, enabled the appropriate targeting of inspection activities.

The year 2025 also saw the intensive participation of the URPLWmiPB in EU projects, including the Joint Action for Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices (JAMS 2.0) and JACOP. Within these initiatives, the experts of the Office actively participated in joint inspections and projects aimed at harmonising market surveillance practices in the Member States, as well as in the



conformity assessment of selected product categories. The experts of the Office took part in expert initiatives, including activities under the COMBINE programme on combined studies, as well as in the work of the Poland-led task force on medical device cybersecurity, the output of which served as a basis for further work within the Medical Devices Coordination Group (MDCG), the official advisory body to the European Commission. At the same time, structural cooperation with national and international institutions was further developed, encompassing the exchange of information, expert consultations, and efforts to ensure the coherence of supervisory systems. Training and information initiatives for medical device market operators and public administration were also continued, supporting the proper application of the applicable medical device legislation.

A valuable component of the activities of the Medical Devices Division was also the initiation of international cooperation under a twinning project supporting Ukraine in developing a modern, EU-compliant system for the supervision of medicinal products and medical devices. This initiative represents an important example of Poland's involvement in efforts to strengthen health security in the region.

In 2025, work on the implementation of new EU regulations was continued. In particular, intensive work continued towards achieving full operational readiness of the EUDAMED database.

With regard to the databases maintained by the Office, more than 2,000 entities and over 100,000 medical devices have already been registered in the distributors' register.

In 2025, the enforcement of provisions on the advertising of medical devices and the imposition of administrative financial penalties was further consolidated, and the Medical Devices Division conducted an increasing number of proceedings aimed at eliminating breaches of the applicable regulations. In particular, attention was focused on the online space, which, due to the nature of medical devices and the highly fragmented market, constitutes a key channel for their distribution and for providing information on medical devices. To facilitate the operation of economic operators under the new legal framework, the Office, in cooperation with industry organisations, issued guidelines on the implementation of the relevant provisions, aimed at improving knowledge of the law and promoting compliance among entities engaged in the trade of medical devices.

Overall, 2025 was a period of intensive work, development of supervisory practices, and strengthening of European and international cooperation, contributing to the continued enhancement of medical device safety.

Sebastian Migdalski
Vice-President of the Office for Medical Devices

Performance of tasks in the area of medical devices

In the area of medical devices, a total of 13,575 applications were received in 2025, and 8,983 proceedings were completed.

The collection of data on medical devices and economic operators arising from notifications and submissions

The obligation to submit notifications and reports concerning medical devices, active implantable medical devices, *in vitro* diagnostic medical devices, and systems and procedure packs composed of medical devices (hereinafter referred to as "devices") is governed by the provisions of the Act of 7 April 2022 on medical devices (Journal of Laws 2024, item 1620).

Data arising from notifications and submissions are stored by the President of the Office on appropriately secured electronic data storage media.

In 2025, 3,699 cases were received by the Office, including notifications, submissions, and amendments to notification and submission data concerning medical devices.

The largest proportion of cases (63%) concerned notifications under Article 58(3) and (4) of the Act on Medical Devices.

Table 7.1 and Chart 7.1 present the classification of the cases received by category¹.

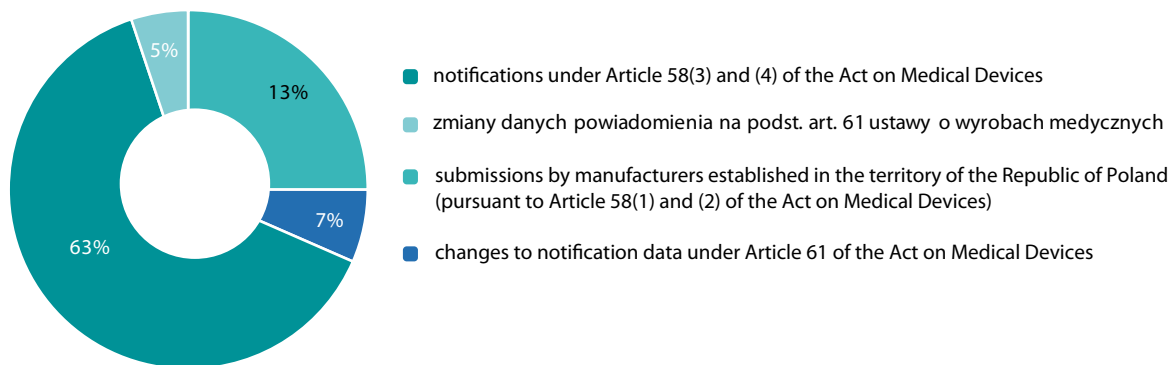
Cases concerning submissions, notifications, and amendments to submission or notification data are



¹ The cited provisions concerning notifications and submissions relate to the repealed Act of 20 May 2010 on medical devices, which have been kept in force under Article 138 of the currently applicable Act.

Table 7.1: Number of cases received during the period from 1 January to 31 December 2025

Case category	Number of cases
submissions by manufacturers established in the territory of the Republic of Poland (pursuant to Article 58(1) and (2) of the Act on Medical Devices)	925
changes to submission data under Articles 61 and 62 of the Act on Medical Devices	242
notifications under Article 58(3) and (4) of the Act on Medical Devices	2,343
changes to notification data under Article 61 of the Act on Medical Devices	190
Total	3,699

Chart 7.1: Percentage distribution of cases received in the period from 1 January to 31 December 2025

reviewed by the Office for formal deficiencies and to determine whether the submission or notification relates to a medical device, an active implantable medical device, an *in vitro* diagnostic medical device, a system or procedure pack, sterilisation of medical devices, or systems or procedure packs, or whether it does not constitute a product within the meaning of the Act on Medical Devices. The Office also verifies device labelling, instructions for use, and promotional materials attached to submissions and notifications, with regard to compliance with the requirements set out in medical device legislation.

In 2025, 1,197 cases relating to submissions, notifications, and amendments to submission and notification data were reviewed and concluded.

Issuance of Free Sale Certificates

A Free Sale Certificate is a certificate issued by the President of the Office at the request of a manufacturer or authorised representative established or residing in the territory of the Republic of Poland, in order to facilitate export. This document serves as confirmation that the device specified therein is, or may be, placed on the market and made available for use in the territory of the Republic of Poland on the date of issuance of the certificate. A Free Sale Certificate is issued for a device bearing the CE marking. The President

of the Office issues Free Sale Certificates under Article 67 of the repealed Act of 20 May 2010 on Medical Devices for medical devices subject to transitional provisions under Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (EU) 2017/746, and under Article 30 of the Act of 7 April 2022 on Medical Devices for medical devices complying with Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

In 2025, 1,006 applications for the issuance of Free Sale Certificates were received by the Office. The President of the Office issued 976 certificates.



Issuance of certificates confirming the submission, notification, or filing of a submission or notification

The President of the Office, pursuant to Article 145 of the Act of 7 April 2022 on Medical Devices and in accordance with Article 91 of the repealed Act of 20 May 2010 on Medical Devices, publishes data identifying the entities that submitted notifications, the date of submission, and information on the trade names of medical devices, sterilised medical devices, systems and procedure packs composed of medical devices, and sterilised systems and procedure packs composed of medical devices. Information subject to disclosure also includes safety-related information concerning devices, provided to recipients or users of devices and contained in certificates of conformity, as well as information on the issuance, amendment, supplementation, suspension, and withdrawal of certificates of conformity.

In 2025, 104 applications for the issuance of certificates confirming submission, notification, or filing of a submission or notification were received by the Office under Article 217 of the Code of Administrative Procedure, and 90 such certificates were issued.

Provision of information concerning medical devices and the advertising of medical devices

In 2025, the Office received 1,929 enquiries regarding information on medical devices and the advertising of medical devices and provided 1,904 responses in this area.

Conduct of administrative proceedings relating to advertising and the imposition of administrative penalties

The regulations governing the advertising of medical devices are laid down in Regulation (EU) 2017/745, Regulation (EU) 2017/746, the Act on Medical Devices, and the Regulation of the Minister of Health of 21 April 2023 on the advertising of medical devices. In accordance with Article 7 of the above-mentioned European Regulations, the advertising of devices shall be prohibited to use text, names, trade marks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by: ascribing functions and properties to the device which the device does not have; creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have; failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

In addition, the Act and the Regulation also regulate further rules for the advertising of medical devices, including a prohibition on advertising devices intended for use by users other than laypersons, and the requirement to include in advertisements the information prescribed in those legal acts.

Oversight of the rules on the advertising of medical devices is exercised by the President of the Office in accordance with Article 58(3) of the Act on Medical Devices. The President of the Office is the sole administrative authority responsible for supervising the advertising of medical devices, except for possible infringements of other general provisions, such as consumer protection regulations.

In the area of advertising and administrative penalties, the President of the Office issued 40 administrative decisions, and 1 proceeding was discontinued.

Provision of 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 comply with the applicable requirements, the customs authority, where it suspects that an imported medical device does not meet the applicable requirements, submits a request to the President of the Office for an opinion on whether the medical device complies with the specified requirements.

In 2025, 345 applications in the above-mentioned matter were received by the URPLW MiPB, and the President of the Office issued 359 such opinions.

Conduct of proceedings in matters relating to clinical investigations and performance studies of medical devices

In 2025, the Office received 97 applications for authorisation to conduct a clinical investigation or performance study of a medical device, and 97 applications for authorisation to introduce amendments to clinical investigations or performance studies of medical devices. The President of the Office issued 74 decisions authorising the initiation of a clinical investigation of a medical device and 117 decisions authorising amendments to a clinical investigation of a medical device.

Furthermore, in the field of monitoring clinical investigations and performance studies of medical devices, 8 certificates under Article 36 of the Act on Medical Devices were issued at the request of Sponsors² authorising the import of devices

² 'Sponsor' means a natural person, company, institution, or organisation that is responsible for initiating a clinical investigation or performance study, as well as for its management and for arranging its financing.

intended for clinical investigation; 15 final reports on clinical investigations and performance studies were assessed; and 95 reports on serious adverse events occurring in clinical investigations and performance studies were reviewed.

Oversight of medical devices, medical incidents, and safety-related activities concerning medical devices placed on the market and/or in use in Poland

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

Information on the safety of medical devices, including safety notices and communications issued by the President of the Office, is published on the website of the URPLW MiPB.

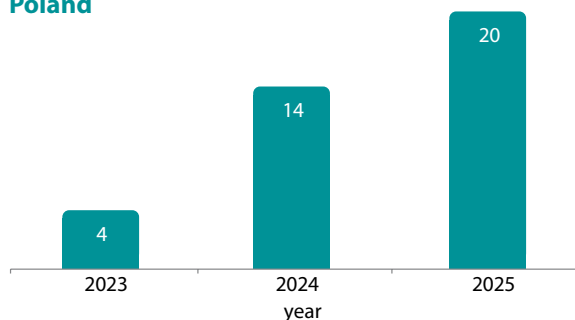
In 2025, the Office received 6,206 cases concerning the supervision of medical devices, as well as serious incidents and safety-related activities relating to medical devices placed on the market and/or in use in Poland, including 5,281 reports submitted by users, distributors, importers, and manufacturers.

A total of 4,003 proceedings in this area were concluded, including 3,670 actions concerning devices placed on the market and/or in use in Poland, and 25 decisions were issued, including one decision concerning an amendment to the designation period as a notified body.

Carrying out inspections

Within the framework of supervision of medical devices, as well as serious incidents and safety-related activities concerning medical devices placed on the market and/or in use in Poland, the Office conducted 20 inspections.

Chart 7.2: Number of inspections conducted in 2023–2025 within the framework of supervision of medical devices, as well as serious incidents and safety-related activities concerning medical devices placed on the market and/or in use in Poland



Assessment of safety evaluation reports (SER) concerning medical devices manufactured using animal-derived tissues

In 2025, the President of the Office received 19 reports from notified bodies regarding the assessment 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 conformity assessment procedure for a medical device containing, as an integral part, a substance that, if used separately, would be a medicinal product and that may act on the human body in a manner that is supportive of the device, the notified body is obliged to obtain an opinion on the quality and safety of this substance, including the clinical benefit-risk ratio. Pursuant to Article 29 of the Act on Medical Devices, the above-mentioned opinion is obtained from the competent authority for medicinal products in a Member State or from the European Medicines Agency. In the territory of the Republic of Poland, the authority competent to issue such an opinion is the President of the Office. In 2025, the Office received 3 applications from notified bodies for issuing scientific opinions. The President of the Office issued 1 opinion in this regard.

Providing opinions on standards for medical devices

In 2025, URPLW MiPB received 72 drafts of Polish (PN), European (EN) and international (ISO) standards as well as drafts of legal acts and guidelines regarding medical devices. All of them were analysed, and after their evaluation, the Office issued appropriate opinions.



Assessment of bodies applying for designation and monitoring of notified bodies

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

In 2025, as part of the monitoring of notified bodies, 2 inspections were carried out.

In addition, as part of the assessment of bodies applying for the designation of a notified body, 2 applications were submitted and 1 decision was issued.

8

AREA SUPERVISED BY THE VICE-PRESIDENT OF THE OFFICE FOR BIOCIDAL PRODUCTS



Aleksandra Wilczyńska

Vice-President of the Office for Biocidal Products

In 2025, the Biocidal Products Division conducted proceedings related to the granting of authorisations for placing of biocidal products on the market under national procedure, as well as authorisations for making available on the market and use of biocidal products under the so-called European procedures.

In parallel, the evaluation process was continued and final reports were prepared for eight existing active substances under the ongoing European Union Review Programme for the systematic examination of all existing biocidal active substances.



Responses were also provided to enquiries submitted by stakeholders, including in particular those relating to the above-mentioned authorisation procedures, efficacy testing, and active substances. Substantive support for enforcement authorities was also continued through responses to correspondence from District Sanitary and Epidemiological Stations concerning the classification of biocidal products or their verification against the List of Biocidal Products.

One of the most significant developments was the completion of legislative work and the promulgation in the Journal of Laws of the Republic of Poland of the Act of 7 November 2025 amending the Act on Biocidal Products. The Act aims to implement the judgement of the Court of Justice of the European Union in Case C-442/14 concerning access to information on emissions into the environment from plant protection products and biocidal products. The Act also serves to clarify the provisions necessary for the proper application of Regulation (EU) No 528/2012 and to simplify the provisions of the currently applicable Act on Biocidal Products. The provisions of the Act on Biocidal Products were also amended by the Act of 7 November 2025 amending the Act on Plant Protection against Pests and certain other acts.

Within the framework of the Polish Presidency of the Council of the European Union, a meeting entitled 'Importance of biocidal products in our life: Exchange of experiences of the Competent Authorities' was held on 15 May 2025, organised by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. During the meeting, discussions took place under the following thematic headings: 'Biocidal Products as an Important Element of Prevention', 'Challenges Related to the Work Programme for the Systematic Examination of All Existing Biocidal Active Substances', 'Building Public Knowledge Regarding the Safe Use of Chemicals, in Particular Biocidal Products.'

Representatives of the Division also participated in fora addressing the broader scope of chemicals management, in particular in the Heads of Chemicals Authorities meeting organised by the European Chemicals Agency in Helsinki.

Representatives of the Division delivered training on biocidal products, inter alia, to staff of the Trade Inspection, the State Sanitary Inspection, and the National Revenue Administration.

Dialogue with industry representatives was also maintained, inter alia through meetings with representatives of the Polish Association of the Cosmetics and Detergent Industry and the Polish Association of Disinfection, Disinsection and Deratisation

Workers. Participation was also ensured in the European Chemical Industry Forum 2025 'From Chemistry to Security' (ECIF 2025), organised by the Ministry of Development and Technology and the Polish Chamber of Chemical Industry.

Representatives of the Division participated in meetings and conferences addressing matters within the scope of the evaluation of active substances, the assessment of ecotoxicological hazards, and IT systems, as well as in webinars concerning, inter alia, active substances generated in situ.

Activities were also undertaken to obtain approval of efficacy testing methodologies for biocidal products, in cooperation with the Biocidal Products Commission. The List of Biocidal Products was also updated on an ongoing basis.

In 2025, staff of the Division participated in the work of the European Commission and the European Chemicals Agency, including in the Biocidal Products Committee (BPC), its expert working groups, the Coordination Group (CG), as well as in meetings of Competent Authorities (CA), the Standing Committee on Biocidal Products (SCBP), and the Member State Communicators' Network.

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 on the market and used within the territory of the Republic of Poland only where it is subject to an appropriate authorisation or permit. The first option is to submit an application for the granting of an authorisation for placing a biocidal product on the market under the national procedure, the rules of which are laid down in the Act on Biocidal Products. The second route is to submit an application for the granting of an authorisation in accordance with the procedures laid down in 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 1,986 applications were received by the URPLW MiPB in 2025, and 2,493 proceedings were completed.

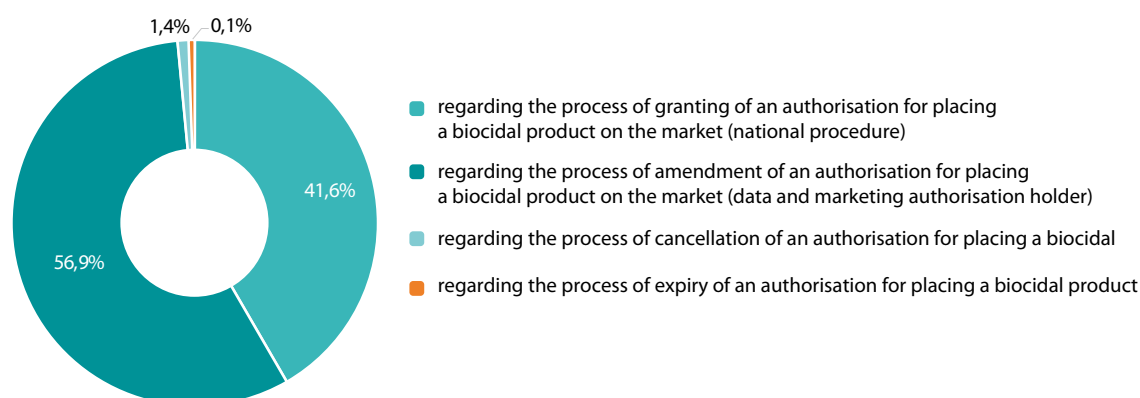
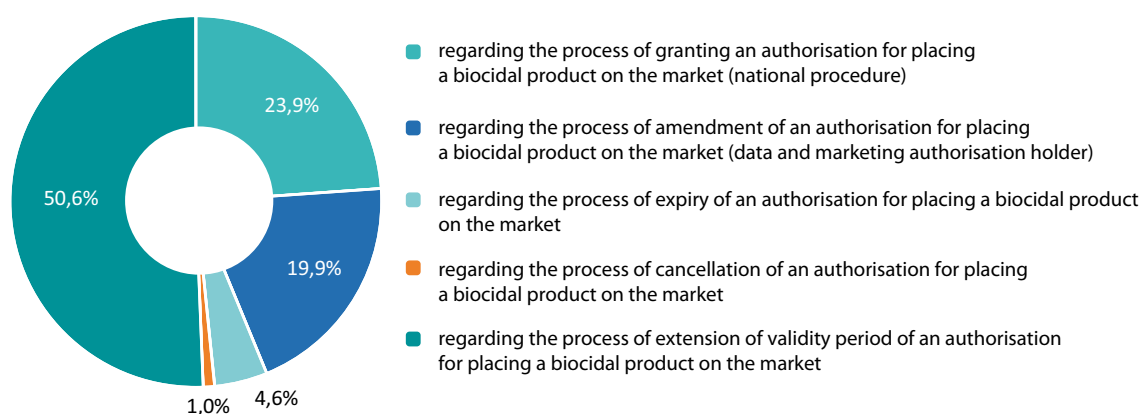
Granting authorisations for placing biocidal products on the market (national procedure) pursuant to Article 19(1) and Article 16(2) of the Act of 9 October 2015 on Biocidal Products (Journal of Laws of 2021, item 24, as amended)

In 2025, 1,136 applications concerning authorisations for placing biocidal products on the market were received by the URPLW MiPB (Table 8.1). Applications for the granting of authorisations for placing biocidal products on the market accounted for 41.6% of all applications submitted in this area, while applications for amendments to authorisations for placing biocidal products on the market accounted for 56.9% of applications (Chart 8.1).

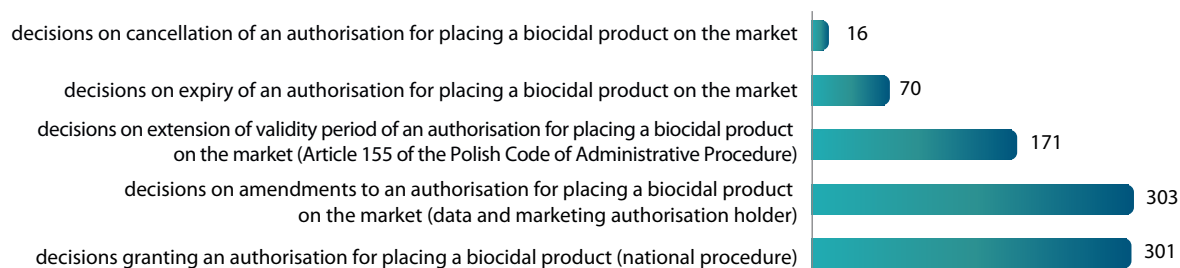
In 2025, a total of 1,695 proceedings concerning authorisations for placing biocidal products on the market were completed (Table 8.2).

Table 8.1: Number of applications for the authorisation for placing biocidal products on the market in the period from 1 January to 31 December 2025

Type of proceedings	Number of applications
regarding the process of the authorisation for placing a biocidal product on the market (national procedure)	473
regarding the process of amending authorisations for placing a biocidal product on the market (data and marketing authorisation holder)	646
regarding the process of cancellation of an authorisation for placing a biocidal product on the market	16
regarding the process of expiry of the authorisation for placing a biocidal product on the market	≤ 1
Total	1,136

Chart 8.1: Accepted applications, as a percentage, concerning authorisations for placing biocidal products on the market in the period from 1 January to 31 December 2025**Chart 8.2: Completed proceedings, as a percentage, concerning authorisations for placing biocidal products on the market in the period from 1 January to 31 December 2025****Table 8.2: Number of completed proceedings concerning authorisations for placing biocidal products on the market in the period from 1 January to 31 December 2025**

Type of proceedings	Number of completed proceedings
regarding the process of granting an authorisation for placing a biocidal product on the market (national procedure)	405
regarding the process of amendment an authorisation for placing a biocidal product on the market (data and marketing authorisation holder)	337
regarding the process of expiry of the authorisation for placing a biocidal product on the market	78
regarding the process of cancellation of an authorisation for placing a biocidal product on the market	17
regarding the process of extention the validity of an authorisation for placing a biocidal product on the market	858
Total	1,695

Chart 8.3: Number of decisions issued on the authorisation for placing biocidal products on the market in the period from 1 January to 31 December 2025

Proceedings concerning the granting of authorisations for placing biocidal products on the market accounted for 23.9% of all concluded proceedings (Chart 8.2). Within the completed proceedings, 301 decisions authorising the placing on the market of biocidal products were issued, together with 303 decisions concerning amendments to data and amendments to the marketing authorisation holder in the authorisation for placing a biocidal product on the market (Chart 8.3).

Granting authorisations for making available on the market and use of biocidal products (European procedures)

Since 1 September 2013, authorisations under the so-called European procedures have been issued in accordance with the procedures laid down 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 2025, a total of 266 applications for authorisations for the making available on the market and use of biocidal products were received by the URPLW MiPB, including 105 applications for the issuance of such authorisations and 128 applications for amendments to authorisations for the making available on the market and use of biocidal products (Table 8.3).

Applications for authorisations for the making available on the market and use of biocidal products accounted for 40% of applications submitted under European procedures, while applications for amendments to authorisations accounted for 48% of applications (Chart 8.4).



In 2025, a total of 249 proceedings concerning the making available on the market and use of biocidal products were completed (Table 8.4), including 25 decisions granting authorisation for the making available on the market and use of biocidal products, and 46 decisions concerning amendments to data in the authorisation (Chart 8.6).

Table 8.3: Number of applications submitted for authorisations for the making available on the market and use of biocidal products in the period from 1 January to 31 December 2025

Type of application	Number of applications received
regarding the process of granting an authorisation for making available on the market and use of biocidal products	105
regarding the process of amendment an authorisation for making available on the market and use of biocidal products	128
regarding the process of extension the validity period of an authorisation for making available on the market and use of biocidal products	2
regarding the process of renewal of an authorisation for making available on the market and use of biocidal products	31
Total	266

Chart 8.4: Accepted applications, as a percentage for authorisations for the making available on the market and use of biocidal products in the period from 1 January to 31 December 2025

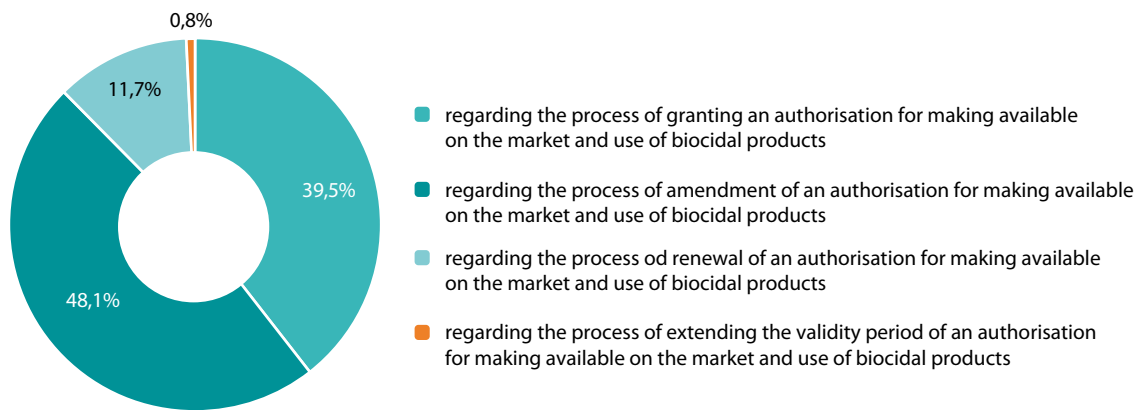


Table 8.4: Number of completed proceedings concerning the making available on the market and use of biocidal products in the period from 1 January to 31 December 2025

Type of proceedings	Number of completed proceedings
regarding the process of granting an authorisation for making available on the market and use of biocidal products	40
regarding the process of amendment an authorisation for making available on the market and use of biocidal products	46
regarding the process of extention the validity period of an authorisation for making available on the market and use of biocidal products	142
regarding the process of renewal of an authorisation for making available on the market and use of biocidal products	15
regarding the process of cancellation of an authorisation for making available on the market and use of biocidal products	6
Total	249

Chart 8.5: Completed proceedings, as a percentage, concerning authorisations for the making available on the market and use of biocidal products in the period from 1 January to 31 December 2025

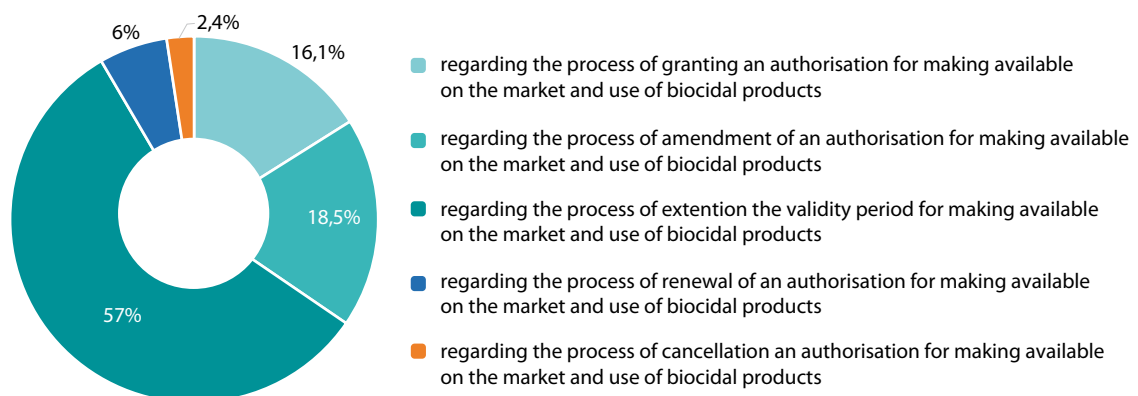
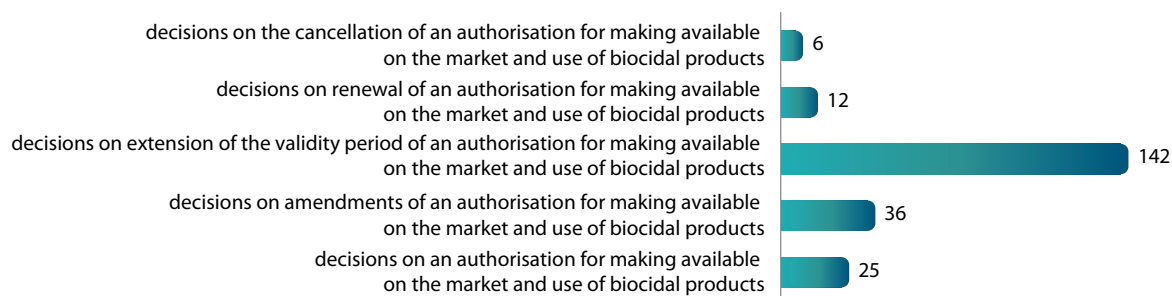


Chart 8.6: Number of decisions issued in relation to the making available on the market and use of biocidal products in the period from 1 January to 31 December 2025



In connection with ongoing proceedings for the granting of authorisations or amendments to the data covered by such authorisations, the Office carried out verification and assessment of physicochemical, toxicological and ecotoxicological documentation, as well as documentation relating to human health, the environment and the efficacy of the respective biocidal product, submitted with the applications. Information was also provided on a continuous basis regarding the required documentation and procedural steps in the biocidal product authorisation process.

Evaluation of the documentation for active substances used in biocidal products

Within the framework of the European Review Programme of existing active substances, conducted pursuant to 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 Office is responsible for the preparation of final Assessment Reports for 7 active substances (in 15 product-types) and is also responsible for the preparation of the final report for the renewal of the active substance alpha-chloralose.



In 2025, activities related to the evaluation of active substances consisted in the continuous processing and assessment of the accumulated dossiers for all active substances subject to evaluation. Within the ongoing EU active substance Review Programme, two assessment reports for the active substance DMDMH were finalised in 2025 with respect to uses in product-types: PT6 – ‘Preservatives for products during storage’ and PT13 – ‘Working or cutting fluid preservatives’. Work was also carried out on the evaluation of the active substance mecetronium ethyl sulphate (MES) in product-type PT1, for which the Office, as the competent evaluating authority, was involved, under a mandate from the European Commission, in activities concerning the preparation by the European Chemicals Agency of an opinion pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012.

Provision of information and responses to enquiries concerning biocidal products and treated articles

In 2025, a total of 574 applications for written information concerning the possibility of placing on the market, making available on the market, and use of biocidal products and treated articles were received by the URPLWmiPB. A total of 540 written responses were issued.

Providing advice on the responsibilities and obligations of applicants under the biocidal products regulations

In 2025, two applications were submitted to the URPLWmiPB and one response was issued concerning advisory services on the preparation of a biocidal product dossier drawn up in accordance with the guidance set out in Annex III to Regulation (EU) No 528/2012, covering physicochemical, toxicological and ecotoxicological documentation, efficacy, as well as intended use and exposure to active substances.

Maintenance of the List of Biocidal Products and publication of the Official List of Biocidal Products Authorised for Placing on the Market within the territory of the Republic of Poland

In accordance with Article 7(1) of the Act on Biocidal Products, biocidal products made available on the market and used within the territory of the Republic of Poland are subject to inclusion in the List of Biocidal Products. The List of Biocidal Products is maintained by the President of the URPLW MiPB, who makes entries and amendments to the List on the basis of final administrative decisions. The List of Biocidal Products contains basic information on currently authorised biocidal products that may be made available on the market and used within the territory of Poland. The list includes products that have been granted a marketing authorisation in accordance with Article 16 of the Act on Biocidal Products – the authorisation for placing of a biocidal product on the market and products for which the authorisation for making available on the market and use of biocidal products has been issued in accordance with the procedures set out in Regulation No 528/2012, the so-called European procedures. The List consists of 2 sections:

- Section I contains information on biocidal products for which an authorisation for placing of a biocidal product on the market has been granted;
- Section II contains information on biocidal products for which an authorisation has been granted 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 Sections I and II of the List were published on a monthly basis on the website of the URPLW MiPB and in the Public Information Bulletin (BIP).



The List of Biocidal Products includes 1,663 marketing authorisation holders (national procedures) and 224 authorisation holders (European procedures). Biocidal products placed on the market within the territory of the Republic of Poland include: 5,460 registered under the national procedure, 503 under European (national) procedures, 659 under the Union procedure, and 60 notified under the simplified procedure.

Biocidal Products Poisoning Control System

The control of poisonings involving biocidal products in Poland is governed by the provisions of the Act on Biocidal Products, namely Articles 40–43 thereof, as well as Regulation (EU) No 528/2012.

Responsibility for the control of poisonings involving biocidal products has been assigned to toxicological consultation and information centres in Warsaw, Gdańsk, Poznań and Kraków, which collect and archive reports of suspected or confirmed cases of poisoning involving biocidal products within the voivodeships under their jurisdiction.



Poison Control Centres submit semi-annual reports to the Office providing information on suspected or confirmed cases of poisoning involving biocidal products.

In 2025, a total of 199 cases of suspected or confirmed poisoning involving a biocidal product were recorded. No fatal cases were recorded among the reported incidents.

Issuance of authorisations for scientific research and development trials of biocidal products aimed at the placing on the market of a biocidal product or an active substance intended exclusively for use in a biocidal product

In 2025, the URPLW MiPB did not conduct any proceedings concerning scientific research and development of biocidal products.



9

AREA SUPERVISED BY THE DIRECTOR GENERAL



Magdalena Wojciechowicz
Director General

The year 2025 was a period of high commitment of all employees of the General Director's Division, whose professionalism ensured the effective functioning of the entire Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The departments overseen by the Director General ensured the smooth running of the Office's operations and the implementation of its statutory activities.



Due to the increased terrorist and cyber threats in the Republic of Poland, the issues of ensuring information security in the Office, including activities aimed at educating and improving employee competences, remained an important point of interest for the General Director's Division, as in previous years. Furthermore, as part of development work relating to information security, the documentation for the Information Security System in force at the Office has been brought into line with the requirements of the PN-ISO 9001:2023 standard. Thanks to effective management measures, the objective of improving the stability of the workforce has been achieved. The Office provided its staff with favourable conditions for maintaining a work-life balance, including a wide range of non-financial incentives, particularly in terms of flexible working time arrangements (remote or hybrid work), holiday subsidies and access to sports cards. The office is becoming an increasingly accessible and welcoming place, responding to the changing needs of the modern labour market.

To encourage staff to play an active role in developing and improving the Office's work, an internal competition was held entitled: "A project to streamline, facilitate and accelerate the work of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products", in which the two most interesting proposals for solutions were awarded, capable of practically contributing to increasing the efficiency of the Office's operations, streamlining processes, improving work organisation and making better use of available resources, without the Office having to incur additional costs. Both of the winning projects will be implemented at the Office.

The key initiatives in the area of IT development in 2025 were the migration and integration of the system environment with Microsoft cloud solutions. Moreover, a key activity was the construction of a microservices environment, which allowed the commencement of development activities in the area of systems supporting the work of substantive departments. Developing IT tools in-house will make the Office independent of external IT providers in the future and enable it to manage its limited resources flexibly in order to streamline the delivery of its key activities.

Magdalena Wojciechowicz
Director General

Performance of tasks in the area supervised by the Director General

The main areas overseen by the Director General include, in particular:

- Managing the Office's accounting and financial affairs, including the preparation of a draft budget for revenue and expenditure;
- Handling personnel matters arising from employees' employment relationships and tasks relating to the implementation of the Civil Service Act;
- Coordination of matters relating to internal control and quality management;
- Managing the process of drafting and issuing the Office's internal regulations, including orders issued by the President and the Director General, powers of attorney and authorisations, as well as drafting and implementing internal procedures relating to the organisation of the Office's work;
- Managing the Office's assets, including commissioning services and making purchases on behalf of the Office, and maintaining records of the Office's assets;
- Ensuring that the Office's staff have appropriate working conditions in terms of health and safety, ensuring the

- provision of high-quality administrative services within the Office, and maintaining the Office's records;
- Ensuring the maintenance of the Office's ICT infrastructure and systems;
- Handling matters relating to the conduct of audits and internal inspections within the Office.

Employment structure at the Office

In the context of dynamic changes in the labour market, in 2025 the Director General's Division continued to carry out tasks related to ensuring the employment of qualified personnel. As of 31 December 2025, the Office employed 583¹ employees, of whom 80% were women and 20% were men. Due to the fact that the largest number of applications submitted to the Office concerned medicinal products, nearly half of the employees, i.e. 48%, were employed in organizational units supervised by the Vice-President for Medicinal Products (Chart 9.1).

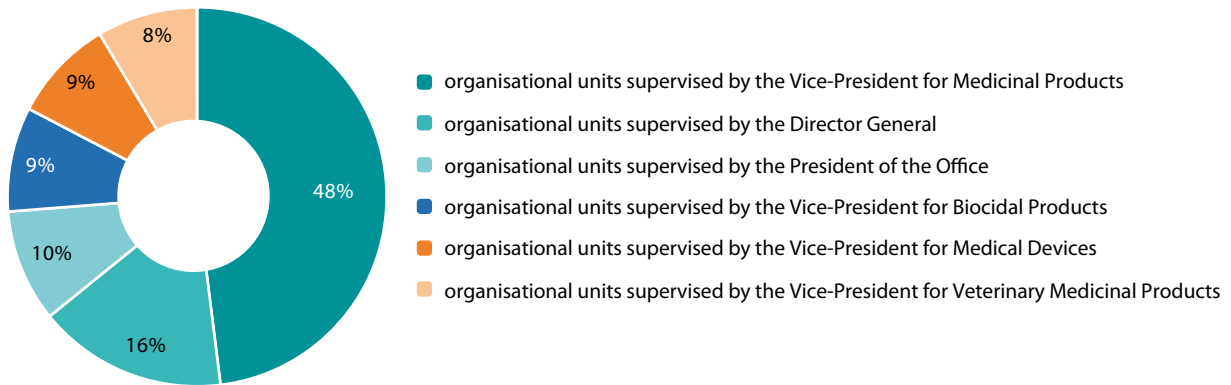
The scope of the Office's competences, including decision-making, consultative, control and information tasks, is related to the need to employ an optimal number of specialists in various fields. The predominant fields of study among employees were biology and related disciplines (21%), chemistry (15%), pharmacy (12%), administration and law (9%), and medicine (5%) (Chart 9.2).

In 2025, the Office employed 137 in-house experts and worked with 136 external experts to assess the documentation submitted to the Office. The largest group of external experts consisted of people with a medical background, including doctors and pharmacists.

¹ The number of employees including replacement employees, the number of employees excluding replacement employees at the end of 2025 was 572.



Chart 9.1: Employment at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products by area of activity (as of 31 December 2025)



9% of the Office's employees held a doctoral degree. 2% of the Office's staff were civil servants appointed to the Civil Service, which was an increase compared to the previous year.

The Office's staff is a team of both young and ambitious employees and experienced specialists. Almost half of all employees (48%) are under the age of 40. Moreover, 62% of the staff are employees with over 5 years of experience at the Office, of which 52% were employees with over 10 years of experience, including 23% with over 20 years of experience (Chart 9.3).

One of the key elements of the Office's human resources policy is the Human Resources Management Programme, which is implemented to ensure the sustainable and systematic development of staff. As part of this programme, the Office has provided staff with a wide range of domestic and international training courses, within the limits of available funding. During the period under review, the Office's staff took part in 180 domestic training courses and 198 overseas training courses, including 18 residential overseas training courses. An important component of the staff professional development programme was external training, both individual and group sessions, as well as in-house training delivered by the Office's staff. It should be noted that the high cost of certain specialist training



Chart 9.2: Educational background of employees of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (as of 31 December 2025)

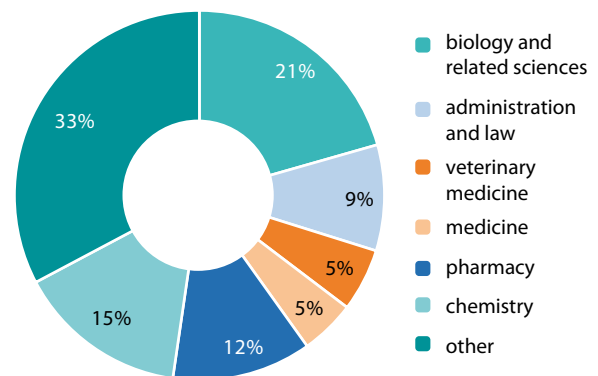
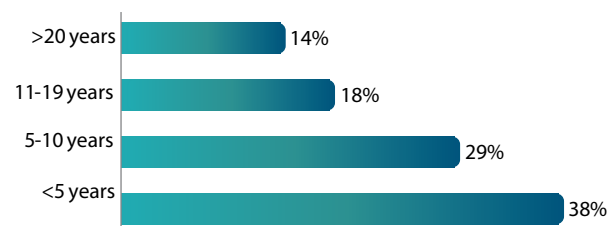
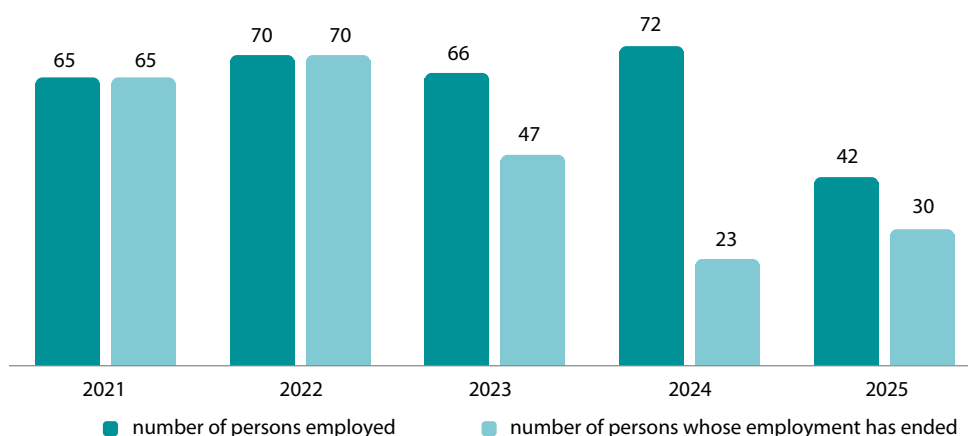


Chart 9.3: Professional experience of employees of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (as of 31 December 2025)



courses posed a significant obstacle to the implementation of measures aimed at ensuring the appropriate professional development of staff. Another form of supporting the development of professional competences of the Office's employees has been the co-financing of studies and training, which has been implemented for many years. In addition, in order to support the professional development of people entering the labour market, build a positive image of the employer and encourage potential future candidates

Chart. 9.4: Staff turnover at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products between 2021 and 2025

to respond to job offers at the Office, 6 student internships and 4 professional internships were carried out.

Due to the high importance of language skills for most job positions at the Office, since 2012 an English language course has been organised for employees, conducted during office hours. In 2025, 170 employees took advantage of the opportunity to improve their English language skills through group training. In addition, the Office arranged for 19 people to take individual English language courses.

An important factor influencing the Office's operations and the smooth fulfilment of its statutory duties has been, and continues to be, the highly specialised nature of its work and the associated high standards required of its staff, particularly those in the specialist departments.

Despite the improvement in pay levels, salaries remained less attractive compared with those offered in the private sector or in other public administration bodies with a similar specialisation profile. These challenges had an impact on the process of filling vacant positions. Despite unfavourable market conditions, the Office took active measures to stabilise employment. In 2025, there was a slight increase in staff

turnover compared with 2024 (from 4.3% in 2024 to 5.4% in 2025), as shown in detail in the chart below.

One of the key non-financial incentives for the Office's staff was the opportunity to work under a hybrid arrangement. As many as 71% of employees were using a modern working model that combines elements of remote working with office-based work.

Financial statements of the Office

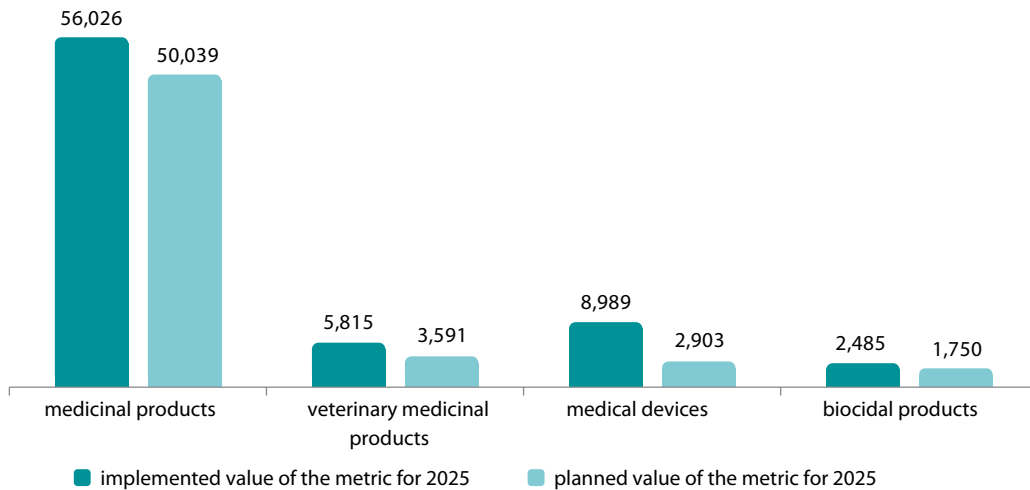
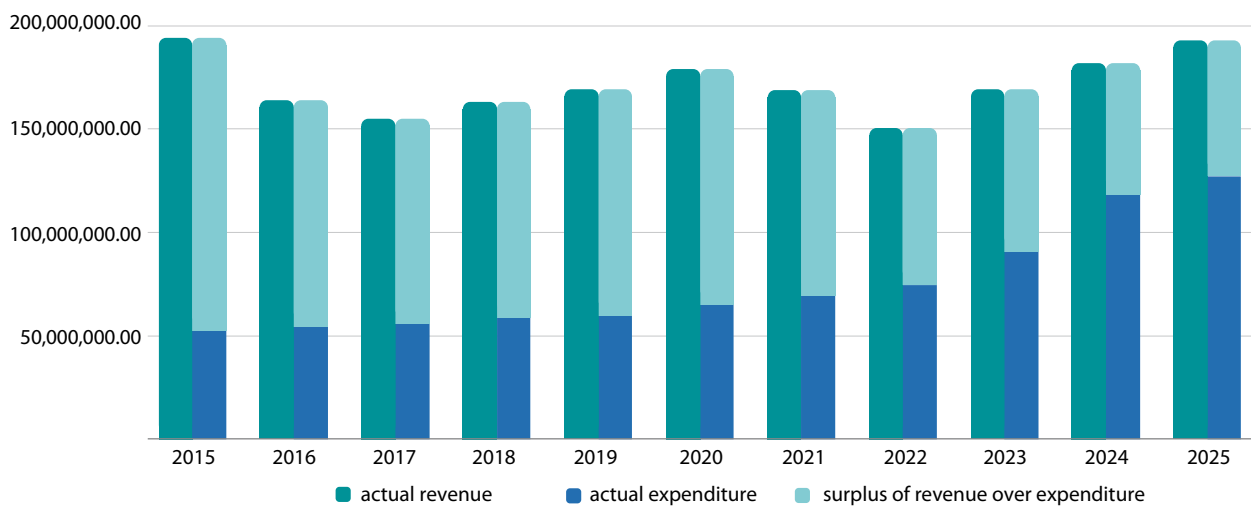
Implementation of the budget revenue and expenditure plan for 2025

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, as a budgetary entity and a third-tier budget administrator, receives funding for its statutory activities from the Ministry of Health (under Section 46 – Health), whilst it transfers its revenue to the state budget account. The Office's core revenue consists of fees charged in connection with its statutory activities, including, in particular, the authorisation of medicinal products for human use and veterinary medicinal products, the granting of parallel import authorisations for medicinal products for human use and veterinary medicinal products, and the granting of authorisations to conduct: clinical trials, veterinary clinical trials, clinical trials of medical devices, notifications and reports concerning medical devices, the authorisation of biocidal products, and the sale of the publication "Polish Pharmacopoeia".

Implementation of the budget revenue plan

In 2025, the Office generated total revenue of: PLN 189,337,469.56, which represents 101.61% of the annual target of: – PLN 186,342,000.00. The Office transferred the following amount to the central government budget account from realised revenue: – PLN 189,337,469.56.



Chart 9.5: Achievement of the target set for 2025 regarding the number of proceedings conducted**Chart 9.6: Statement of revenue and expenditure for the years 2015–2025**

Implementation of the budget expenditure plan

In accordance with the decision of the Minister of Health, the Office's expenditure plan for 2025 amounted to PLN 127,635,128.89, of which:

- current expenditure – PLN 127,079,746.21,
- capital expenditure – PLN 68,223.18,
- presidency – PLN 487,159.50.

In 2025, expenditure totalling PLN 127,286,873.69 was incurred, including:

- current expenditure amounting to PLN 126,731,491.01, representing 99.73% of the annual budget for current expenditure;
- capital expenditure amounting to PLN 68,223.18, representing 100% of the annual capital expenditure budget;
- expenditure on the presidency amounting to PLN 487,159.50, which represents 100% of the annual budget for the presidency.

Plan for 2026

The financial plan² for 2026 received from the Ministry of Health provides for:

- budget revenue – PLN 189,572,000,
- current expenditure – PLN 117,551,000.

Conclusions

The surplus of revenue over expenditure in 2025 totalled PLN 62,050,595.87.

Chart 9.5 shows the progress made towards the target set for 2025 in terms of the number of proceedings conducted. Chart 9.6 shows a comparison of the Office's budget plans and the actual revenue and expenditure for the years 2015–2025.

² At the time of drafting this Report, the requested investment expenditure for 2026 had not yet been approved by the Ministry of Health.

Activities relating to the administrative and IT support of the Office

In 2025, administrative activities focused on ensuring the proper functioning of the Office whilst the second level of the CRP alert (CHARLIE-CRP Level 2) and the second level of the alert (BRAVO Level 2) remained in force across the territory of the Republic of Poland.

The continuing situation of increased terrorist and cyber threats required intensifying work in the area of administrative support for the Office. Important routine tasks relating to the administrative and operational support of staff, as well as technical and IT support, were carried out effectively and without interruption.

The IT Office was responsible for the maintenance and ongoing development of the Office's ICT systems, particularly in response to the need to adapt them to the changing external environment. The end of vendor support for key components of this infrastructure, such as the Microsoft 2016/2019 family of systems, has necessitated migration to new IT environments. The Office has been integrated into cloud environments, taking full account of the specific nature of the data it processes. User work environments were also subject to modernisation and migration due to the end of support for Microsoft Windows 10.

Development work carried out by the Unit for IT Systems Development has enabled the design and implementation of the first microservices, which have formed the basis for the creation of applications supporting the work of specialist departments. Expanding the development team will enable us to develop applications in-house which, once integrated with existing systems, will streamline and facilitate collaboration between the various specialist departments within the Office's operational processes. Existing IT systems

are also subject to ongoing development, including the Register of Medical Device Distributors and, in collaboration with CeZ, sector-specific systems: The Register of Medicinal Products and the Risk Monitoring System.

The IT Office also maintained the Office's key systems, including: the EZD office management system, the email system, file resources and electronic repositories for registration documentation. An important step was ensuring that the repository system remained up to date. As part of its internal operations, the IT Office resolved 10,661 tickets in the Helpdesk system.

The extensive IT security infrastructure has enabled the Office's resources to be effectively protected against attacks in conditions of increased cyber threats. To maintain high readiness in this area, systems for protecting workstations and mobile devices have been expanded. Another challenge for the Office was to provide employees with the ability to work remotely in a cybersecurity-safe manner. In accordance with the internal standards adopted by the Office, staff may only work remotely using appropriately secured work equipment, which has enabled the maintenance of an adequate level of security.

The IT Office played an active role in activities related to Poland's Presidency of the Council of the EU. In addition to providing general support to organizational units in preparing their meetings, the Office organized the meeting of IT Directors of National Medicines Agencies, which took place in March 2025 in Warsaw.

Pursuant to the Public Procurement Law and in accordance with the Public Procurement Rules, all 10 procurement procedures and 20 request for proposal procedures were conducted electronically via an IT platform (Marketplanet) made available to the Office under an agreement concluded with Otwarty Rynek Elektroniczny S.A.





As part of the work of the Office's Main Chancellery in 2025, the Office recorded 93,405 incoming correspondence and 20,238 outgoing correspondence.

In terms of maintaining the Archives, an increase in archival resources was recorded, with 29,662 archival units accepted in the traditional system and 507 electronic cases accepted in the archive module. The company archives made 664 loans of archival documentation to Office employees and 593 returns of borrowed documentation.

In the field of occupational health and safety and fire protection, training was conducted for 49 employees, trainees and apprentices in 2025. The training sessions included health promotion and health education in the workplace. In addition, a first-aid training course was held for 60 staff members of the Office.

The infrastructure has been put in place to introduce e-Deliveries as a new electronic channel for communicating with the Office, and all staff have been trained in this regard.

In accordance with the Public Procurement Law and the Regulations on the Award of Public Contracts, 10 tender procedures and 23 requests for quotations were carried out, all of which were conducted electronically via an IT platform.

The Director General's Division is also responsible for running the Office's Library, which provides staff with access to specialist literature and academic journals, including foreign journals, in both print and electronic formats. In 2025, the Office acquired 7 new library items, and by the end of that year the Library's collection comprised 1,963 volumes of monographs and 6,029 volumes of periodicals.

Activities relating to information security at the Office

Ensuring information security is a particularly important task for every public administration body, especially in an era of rapid technological development and increased security risks arising from the international situation. Thanks to the integrated information security solutions that have been progressively implemented and developed, the Office ensures the effective protection of the information and data it processes.

In addition to developing systems and software, the Office also places great importance on raising awareness of the risks associated with the use of technology, and emphasises fostering the right attitudes and the effective implementation of security procedures among its staff, as well as ensuring that staff have the opportunity to participate in training in this area.

In 2025, the documentation for the Information Security Management System in place at the Office was updated to comply with the requirements of the ISO/IEC 27001:2023 standard.



As in previous years, in 2025, an independent information security audit was carried out at the Office to verify compliance with the requirements of the PN-ISO/IEC 27001:2023 standard, the Regulation of the Council of Ministers of 12 April 2012 on the National Interoperability Framework, the minimum requirements for public registers and the exchange of information in electronic form, and the 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 cybersecurity system, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard 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. The recommendations from the above-mentioned audit are being implemented on an ongoing basis. The Office is implementing the recommendations from the audit on an ongoing basis.

Activities relating to organisation and internal regulations

The Organisation and Quality Office carried out tasks relating to the organisation of the unit's operations and the drafting and issuing of internal regulations, i.e. orders issued by the President of the Office and the Director General, as well as the repeal of standard operating procedures for organisational units. In 2025, the Office issued six new internal regulations governing the work of the organisation, including three regulations issued by the President and three by the Director General. Furthermore, in order to bring existing regulations into line with changes in legislation and organisational requirements, 26 existing orders were amended – including 11 orders issued by the President and 15 orders issued by the Director General – and a total of 5 orders were repealed. It should be noted that, due to the systematic replacement of Standard Operating Procedures with process charts, 44 new proposals were reviewed and 44 standard procedures were repealed in 2025. Furthermore, as part of measures relating to the organisation of the unit's work and the delegation of powers, a total of 244 authorisations and powers of attorney were issued by the President of the Office and the Director General, whilst 35 authorisations were revoked or expired. In addition, as part of its internal organisational duties, the Office issued official identification cards to its staff carrying out checks or inspections.

Work was also carried out on tasks relating to the processing and recording of complaints, requests and petitions as part of the Office's handling of reports from the public. In 2025, 16 such cases were dealt with.

In the first half of 2025, the Annual Report of the President of the Office was being prepared; it was published in print in two language versions. The report was submitted to the Minister of Health and forwarded to partner organisations, and has also been made available on the Office's website. Four summary quarterly reports on the unit's activities were also drawn up and submitted to the Office's management.

The Organisation and Quality Office is also responsible for maintaining a list of external experts who work with the Office on the assessment of documentation. Eight new experts have been added to the external experts' database, and one update has been made to the external experts' register. Furthermore, with regard to the register of external experts, 316 applications for civil law contracts for the provision of external expert opinions were assessed in 2025.

The Organisation and Quality Office also carried out tasks in collaboration with other departments within the Office, including the implementation of recommendations from the information security audit, health promotion, and cooperation with the Polish Association of the Deaf to provide sign language interpreting services, as well as the provision of content for the Office's speeches and publications. In addition, preparations for the BEMA (Benchmarking of European Medicines Agencies) audit, scheduled for 2026, were coordinated, including the completion of the various sections of the BEMA Assessment Report by designated personnel. In addition, it coordinated a number of projects relating to the provision of data and information on the Office's work.

Activities relating to quality management and management control at the Office

In 2025, the Office continued its work based on the Integrated Quality Management and Management Control System, in accordance with the requirements of the PN-EN ISO 9001:2015 standard 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.

In the area of quality management and ensuring appropriate standards for the functioning of management control, the Office carried out the following tasks:

- a report on the implementation of the Office's work plan for 2024 has been prepared and published in the Office's Public Information Bulletin in accordance with the requirements of the Regulation of the Minister of Finance of 29 September 2010 on work plans and reports on their implementation;
- progress towards the targets set for 2025 was monitored;

- the risks identified for 2025 were monitored, as was the implementation of the measures set out in the 2025 risk management plan;
- the Office’s operational plan for 2026 has been drawn up and published in the Office’s Public Information Bulletin, in accordance with the requirements of the Regulation of the Minister of Finance of 29 September 2010 on operational plans and reports on their implementation;
- a risk analysis was carried out for the purposes set out in the Office’s 2026 operational plan;
- a self-assessment of management controls for 2024 was carried out and a self-assessment report was prepared for the Office’s management;
- an evaluation questionnaire on the application of management control standards at the Office for 2024 was prepared and submitted to the Ministry of Health;
- a statement by the President of the Office on the state of management control for 2024 was drawn up and submitted to the Ministry of Health;

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

Implementation of process management

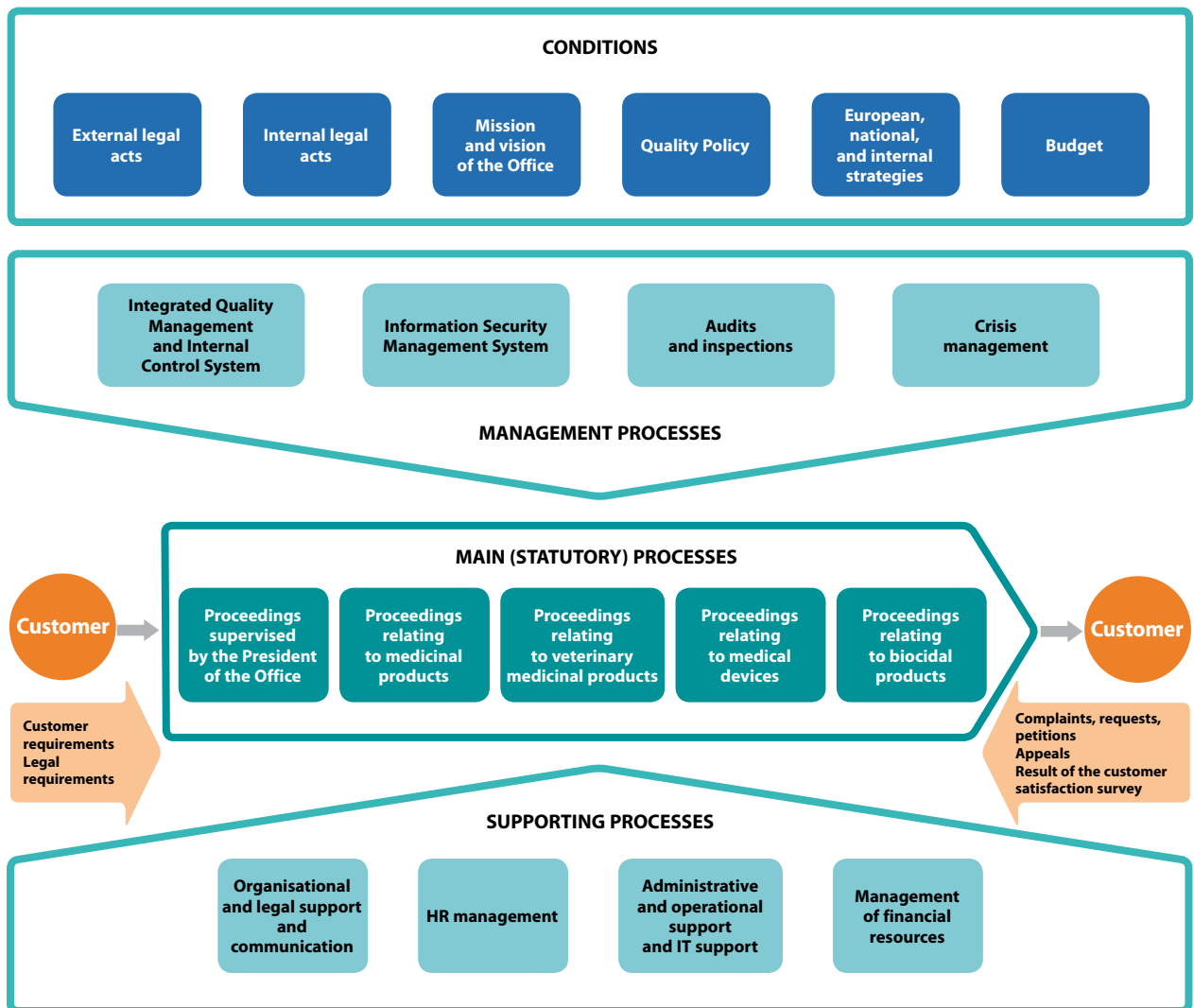
In 2025, activities were continued in the development of process management within the Integrated Quality Management and Management Control System.

As part of the implementation of process management, a process architecture has been developed and approved, setting out the following types of processes:

- management processes,
- core (statutory) processes,
- supporting processes.

The detailed breakdown of the processes is illustrated by the architectural model shown in Figure 9.1.

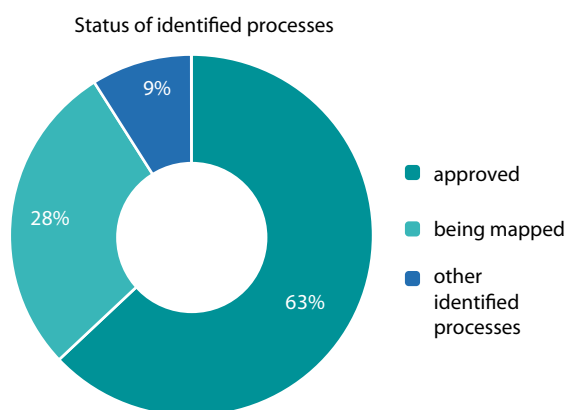
Fig. 9.1: Process architecture of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products



During the course of the work, 186 processes were identified, of which 117 were approved and made available to staff via the process management system – ADONIS.

All employees currently in active service have been trained in process management and the use of process maps. During the reporting period, 42 new process sheets and 10 updates were approved.

Chart 9.7: Percentage breakdown of the progress of work on mapping processes of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products



Anti-corruption measures

In 2025, selected staff members of the Office were required to submit declarations of financial interests, whilst heads of the Office's organisational units were required to provide information on the procedure to be followed in the event of an attempt to present a gift to Office staff. Staff at the Office were also asked to submit declarations regarding any activities or engagements that might contravene the Civil Service Act, the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, or that might undermine public confidence in the civil service. The analysis covered financial disclosure statements, statements made by employees, and information regarding any attempts to offer gifts.

The Office monitored any potential conflicts of interest arising from the duties performed by its staff. Newly recruited staff at the Office were required to complete e-learning courses on ethics and anti-corruption. In addition, all staff at the Office were encouraged to take part in webinars on ethical issues and the prevention of workplace bullying, organised as part of: "The Civil Service Knowledge-Sharing Programme". Measures taken in the area of ethical guidance were reported to the Head of the Civil Service by the Director General of the Office.



In addition, the anti-corruption coordinator reviewed draft regulations issued by the Minister responsible for health and draft internal regulations of the Office to assess the risk of corruption.

Activities to ensure accessibility

The Office's efforts to improve accessibility are a key part of upholding the principle of equal treatment for citizens; therefore, we are constantly improving the Office's accessibility for people with disabilities by implementing feasible improvements.

In 2025, the Office carried out tasks aimed at improving accessibility for people with special needs, in accordance with the Act of 19 July 2019 on ensuring accessibility for people with special needs and the Act of 4 April 2019 on the digital accessibility of websites and mobile applications of public bodies.

To date, the Office has implemented a number of improvements to make it more accessible to people with disabilities, including the provision of Polish Sign Language (PJM) interpreters and induction loops for deaf or hard-of-hearing people, as well as guide interpreters for deafblind people, should the need arise. The Office has also fulfilled its obligation to publish the required accessibility statements on its website, as well as information about the Office's activities in Polish Sign Language, in a machine-readable version and in an easy-to-read format.

The office has a website that complies with digital accessibility requirements. The information on this website is published in accordance with the Order No. 7/2022 of the Director General on the preparation, approval and publication of content on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

In addition, we are doing our utmost to gradually remove all architectural, information and communication, and digital barriers, thereby improving the Office's accessibility as part of our equal opportunities policy.

Audits and inspections at the Office

In 2025, as part of its reporting duties, the internal audit department prepared a report on the conduct of the internal audit for 2024 and prepared and submitted to the Minister of Finance a report on the implementation of internal audit tasks in 2024. A self-assessment of the internal audit at the Office for 2024 was carried out, evaluating the effectiveness and quality of the audit function and identifying opportunities for improvement and further development, in accordance with internal audit regulations and standards and the expectations of the Office's management. As part of the planning work, an internal audit plan for 2026 has been drawn up.



Following the Ministry of Finance's decision not to conduct a commissioned internal audit in 2025, the Audit Plan for 2025 has been amended, with the time allocated for the commissioned audit being reallocated to an additional assurance task. The internal audit plan for 2025 (as amended) has been fully implemented.

Implemented:

- 3 compliance tasks (including the audit of the system for monitoring the safety of medicinal products, to be carried out in 2025),
- 1 advisory service (advisory services commenced in 2024 were completed),
- 7 verification activities (including activities to verify the status of implementation of the recommendations from internal audit No. 3/2024 concerning the functioning of selected elements of the management control system),
- monitoring the progress made in implementing the recommendations relating to nine audit tasks, following which recommendations were issued in 2017, 2019, 2022, 2024 and 2025.

In the area of internal audit, three internal audits were launched in 2025, covering biocidal products, veterinary medicinal products and compliance with the code of conduct in dealings with external parties. In 2025, the Office was subject to oversight by the Ministry of Health in relation to the performance of its defence-related duties. In addition,



the Office cooperated with the Supreme Audit Office during two audits carried out by the Office at other institutions. In 2025, progress was monitored on the implementation of recommendations arising from internal and external audits carried out in previous years at the Office. An internal audit plan for 2026 has been drawn up. A self-assessment of internal controls at the Office for 2024 has been carried out, setting out proposals for improving operations and development.

Health promotion among employees

2025 was also another year in which the Director General's Division continued its work on health promotion in the workplace. An important manifestation of the activities carried out with the health of employees in mind was the provision, for the sixth year in a row, of free influenza vaccinations to persons employed at the Office, which was administered to 79 employees. Furthermore, given

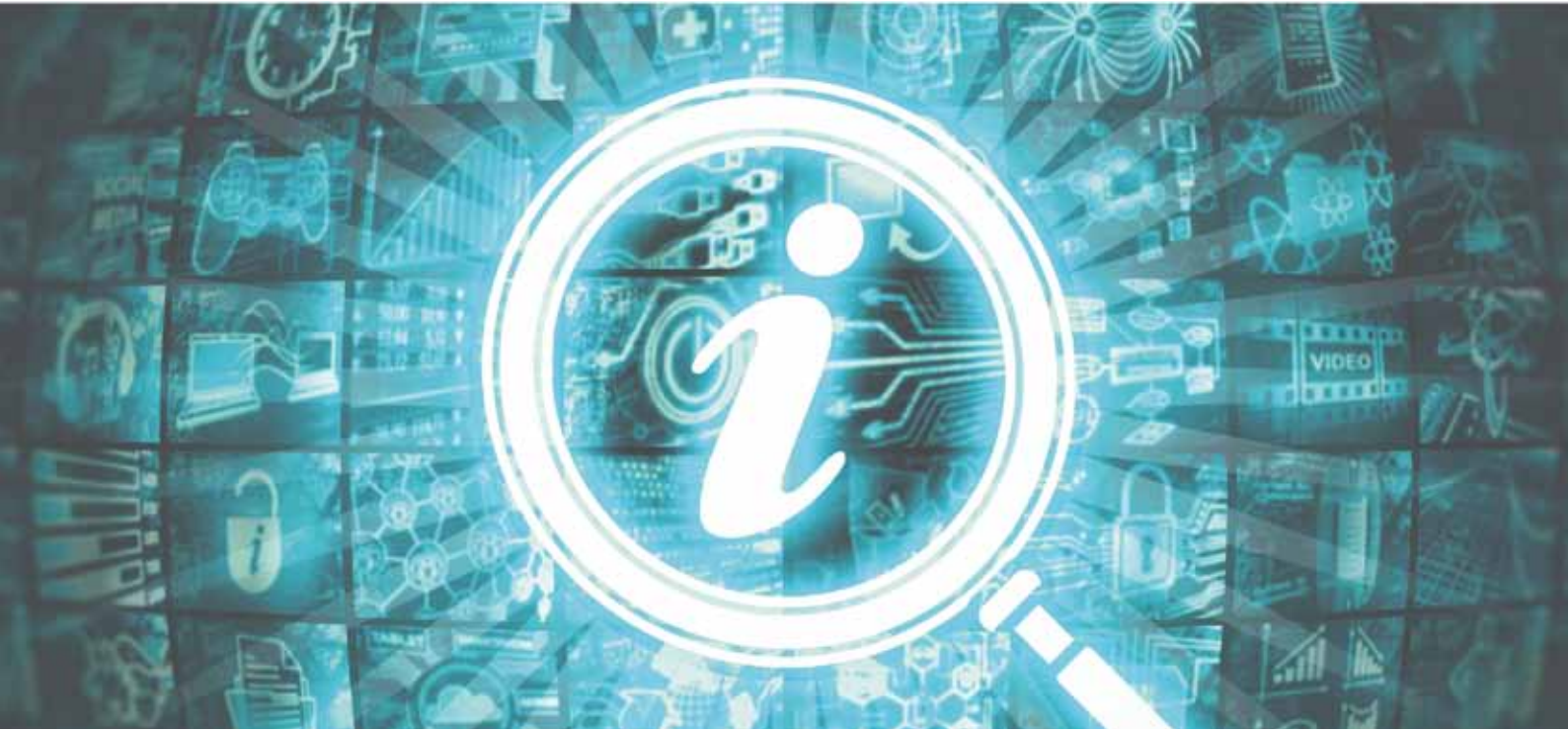


the positive impact animals have on people's mental and physical health, Office staff have been permitted to bring their pets to work. The Office's management created the right conditions and supported staff in maintaining a healthy work-life balance. The Office has consistently

encouraged staff to prioritise preventive healthcare, including by providing, as set out in the Staff Regulations, the option to take two days off work per calendar year to undergo medical examinations not related to occupational health.



10

OTHER ACTIVITIES CARRIED
OUT BY THE PRESIDENT
OF THE OFFICE

Communication activities

In 2025, communications activities of the Office focused on informing the public about new medicinal products and the decisions of the European Medicines Agency (EMA) and its committees. Some of the posts shared on social media were dedicated to informing the public about health prevention in the broadest sense and the measures the President of the Office is taking on an ongoing basis to promote patient health. As part of the ongoing activities related to the campaigns run by the Office: “Safe Medicines” and “Safe Medicines Through a Child’s Eyes”, the Office’s social media channels also featured 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 key data published by the EMA and government bodies, including the Ministry of Health and the Office of the Prime Minister.



In 2025, 295 posts were published on Facebook, the majority of which were images and videos, whilst 286 posts were published on X from the Office's account and 252 posts from the account managed by the Office's press officer. These were predominantly text-based posts containing links to the advertised content. The Office also has a presence on LinkedIn, where around 123 posts were

published in 2025. The year 2025 saw considerable interest in the Office's activities among members of the media. During the period under review, the Office's press officer received 66 enquiries from journalists.



Information campaigns “Safe Medicines” and “Safe Medicines Through a Child’s Eyes”

Since 2006, the Office has been running a nationwide information campaign called “Safe Medicines”, aimed at raising public awareness of the sensible and safe use of medicinal products. Its aim is to foster a positive attitude towards pharmacotherapy, to discourage the unjustified use of medicines, and to curb the distribution and use of products from illegal sources that have not been authorised for marketing by a decision of the President of the Office in accordance with the applicable safety regulations.

In 2016, as part of the “Safe Medicines” initiative, the Office launched a separate educational campaign entitled “Safe Medicines Through a Child’s Eyes”, aimed at young children and their carers. The activities undertaken as part of both campaigns include, amongst other things, the regular publication on the Office's website and social media of educational materials – posts and videos – focusing on the principles of safe pharmacotherapy and the procedure for reporting adverse reactions to medicinal products. These information initiatives are complemented by the Office's regular publication of the quarterly magazine “Almanach” as part of the “Safe Medicines” campaign.



“Med Safety Week” Campaign

The Office actively participated in the tenth anniversary global Med Safety Week campaign, coordinated by the Uppsala Monitoring Centre (UMC) as part of the WHO Programme for International Drug Monitoring, which took place on: 3–9 November 2025.

The campaign aimed to raise awareness of the importance of reporting adverse reactions to medicinal products by patients

and healthcare professionals, and to improve the safety of pharmacotherapy. The Office ran information campaigns on social media and on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, reminding the public that they could report adverse reactions. The campaign highlighted the vital importance of public involvement in the system for monitoring the safety of medicines and in building up knowledge about their adverse reactions.



Source: <https://www.gov.pl/web/urpl/med-safety-week-2025>

Awareness campaign for “World Patient Safety Day”

In 2025, the Polish edition of the World Patient Safety Day 2025 campaign took place for the first time. The main partner of the event was the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The aim of the initiative was to raise awareness and provide information about the safety of young patients. As part of the campaign, a nationwide

educational initiative was launched, aimed at families, children, teachers and healthcare staff, and an interview with an expert in the field of medication safety was published, entitled: “What happens to medicines once they’ve been launched?” In addition, as part of this campaign, a webinar for parents and carers on the safe use of medicines in children was held on 15 October 2025.

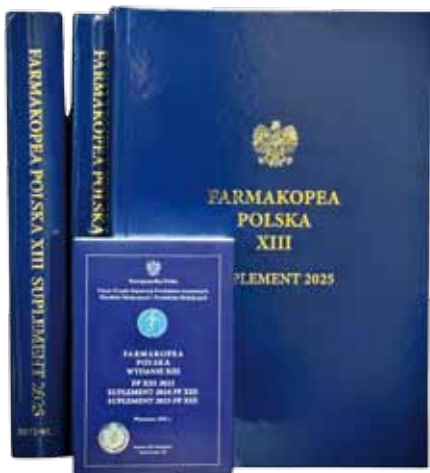


Health promotion and protection in the workplace

As in previous years, health education for employees and the promotion of preventive healthcare in the workplace formed part of the Office’s wide-ranging activities aimed at protecting patients’ health. As part of these activities, the Office provided, for the sixth year in a row, persons employed at the Office with the opportunity to be vaccinated against the influenza virus free of charge.



Publications by the Office



Supplement 2025 to the Polish Pharmacopoeia XIII

As part of its public information activities, the Office has also been publishing the quarterly journal "Almanach" since 2006 – a scientific journal aimed primarily at professionals in the healthcare sector and those interested in issues relating to the statutory activities of the organisation. The journal primarily publishes information on safety, quality and efficacy issues relating to use of medicinal products, medical devices and biocidal products, as well as review articles on medicinal products, medical devices and biocidal products. The Almanach is indexed in the IC Journal Master List (IC JML). In 2025, four issues of the Almanach journal were published, including one combined issue.



Cover photos for the Office's Almanach quarterly

The President of the Office is responsible for compiling and publishing the "Polish Pharmacopoeia", which sets out the basic quality requirements and testing methods for medicinal products (including veterinary medicinal products) and their packaging, as well as for pharmaceutical raw materials, and contains provisions on the preparation of medicines in pharmacies. This is a substantive and highly specialized publication; consequently, a wide range of experts from universities and research institutions across the country are involved in its development. Further information on this subject can be found in the chapter: "IV. The area supervised by the President of the Office", in the sub-section: "Polish Pharmacopoeia".



Cover photo of the Annual Report of the President of the Office for 2024

The Office publishes the Annual Report of the President of the Office, which constitutes the annual report on the activities of the institution. The Report is submitted to the Minister responsible for health matters pursuant to Article 25 of the Act of 6 September 2001 introducing the Pharmaceutical Law Act, the Medical Devices Act and the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. At the same time, the document constitutes an element of the transparency policy of the Office. The Report includes information summarising the annual statutory activities of the Office in the areas of authorisation of medicinal products, veterinary medicinal products, medical devices and biocidal products, as well as information on key activities carried out by the Office in the field of national and international cooperation and activities within the centralised procedure. In addition, the Report contains information concerning financial, human resources, organisational and administrative matters, as well as communication and information activities of the Office. The Report is published in both Polish and English language versions. The electronic version is available on the website of the Office.

In 2025, the Annual Report of the President of the Office concerning activities of the Office in 2024 was published and submitted to the Minister of Health, as well as to institutions cooperating with the Office.

11

OBJECTIVES FOR 2026



The primary objectives of the Office are to ensure access to medicinal products, veterinary medicinal products and biocidal products that comply with the appropriate standards of safety, quality and efficacy, as well as to monitor the safety of their use and to exercise supervision over medical devices. The achievement of these objectives is based on conducting proceedings in accordance with legal requirements and internal regulations in each area of the Office's statutory activities, as well as on the continuous improvement of processes and the optimisation of the Office's operations. In 2026, further strengthening of the Office's human capital and building of international relations are planned.

The Office's operational plan for 2026 includes the following objectives:

- ensuring access to medicinal products of high quality, safety and efficacy, as well as monitoring the safety of their use;
- ensuring access to veterinary medicinal products of appropriate quality, safety and efficacy, as well as monitoring the safety of their use;
- exercising supervision over medical devices manufactured, placed on the market and used within the territory of the country;
- ensuring access to biocidal products of appropriate quality, safety and efficacy, as well as monitoring the safety of their use;
- ensuring access to basic quality requirements and testing methods for medicinal products, their packaging and pharmaceutical raw materials;
- developing international cooperation;
- improving staff stability.

The Office's operational plan for 2026 includes the following objectives:



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