Annual Report 2024

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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2024 Statistics at a Glance

1,000,984

dosage units of fake (falsified) and other illegal medicines detained

Top 10

The HPRA was among the top 10 contributors at EU level for lead assessment of centrally authorised human medicines and scientific advice

72

The number of EMA scientific advice procedures for human medicines co-ordinated by the HPRA

82

applications issued for clinical trials of human medicines under the EU Clinical Trials Regulation

1,977

The total number of veterinary medicines authorised in Ireland at year-end

283

new human medicines authorised through Decentralised (DCP) or Mutual recognition (MRP) routes

462

new human medicines authorised during 2024

10

centrally authorised veterinary medicinal products where the HPRA was EU rapporteur or co-rapporteur

153

medical device economic operators registered with the HPRA

6,527

free sale certificates issued issued for medical devices

7,885

suspected adverse reaction reports for human medicines received

3,672

medical device vigilance reports received and assessed

176

market surveillance cases initiated for cosmetic products

83

good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances

2,553

websites, e-commerce listings and/or social media pages associated with the sale of falsified or illicit medicinal products

403

market surveillance cases undertaken in respect of medical devices

51

medicine recalls consisting of 46 human medicines and five veterinary medicines

Chairperson's Statement

As Chairperson, I am proud to present this overview of the HPRA's accomplishments throughout 2024 as well as my reflections on the current regulatory landscape and the opportunities and challenges that lie ahead. The year was one of transformation and progress for the HPRA, marked by notable forward-looking strategic initiatives and a continued commitment to ensuring public and animal health through the regulation of health products.

Strategic engagements with health system partners

Throughout 2024, the HPRA continued to work closely with our health system partners, including the Department of Health, across a variety of key strategic focus areas.

Challenges impacting the availability of medicines remain a complex, ongoing issue both nationally and internationally, impacting healthcare systems and patients worldwide. Recognising the vital importance of an effective and resilient supply chain, the HPRA continued to actively engage with the Department of Health on proposals for revised and enhanced governance to support security of supply. Discussions also continued on the need for an appropriate digital infrastructure to enable oversight of the national supply chain. Electronic transparency of the supply chain is of critical importance in identifying potential availability issues and the need for intervention. Establishment of a system of this nature would also align with relevant strategic developments nationally and within the European regulatory network, including the launch of the European Shortages Monitoring Platform in late 2024. By fostering the development of an interconnected system, we can enhance transparency, coordination, and responsiveness to potential availability issues, both nationally and across Europe.

Meanwhile, the HPRA continues to advocate for improvements in the European regulatory framework for medical devices. It is no secret that implementation of European legislation for medical devices and *in vitro* diagnostics has been marked by significant challenges. Despite the obstacles that have arisen over recent years, steady progress is being made. The HPRA has remained at the forefront of these efforts, championing practicable solutions to address the complexities of the legislation and advocating for meaningful progress at a European level. Through its leadership and commitment, the HPRA continues to drive forward a vision of a stronger, more cohesive regulatory framework for medical devices and *in vitro* diagnostics that balances innovation with patient safety.

Preparing for leadership transition and organisational continuity

In 2024, the Authority continued to prioritise forward-looking governance through comprehensive succession planning and leadership preparedness. With anticipated changes to both the Authority and the HPRA leadership team, we undertook a structured programme of preparatory work to ensure continuity, resilience, and strategic alignment.

The Authority's proactive approach will support a smooth transition in light of the upcoming changes over the year to come and ensure the HPRA's continued capacity to respond to evolving regulatory challenges and opportunities to the highest standards of excellence.

Looking ahead

Work commenced in 2024 on the development of the HPRA's next strategic plan, representing a pivotal moment in charting the future path of the organisation. This effort has involved extensive stakeholder engagement, internal consultations, and a forward-looking assessment of the regulatory landscape and the environment within which the HPRA operates. The new strategic plan, which will cover the period 2026 to 2028, will build on the achievements of the current strategy while focusing on emerging priorities, such as digital transformation, sustainability, and enhanced collaboration. By aligning our objectives with societal needs, as well as scientific and technological advancements, the plan aims to strengthen the HPRA's position as a proactive and adaptive regulator.

Over the course of 2024, the HPRA also continued its preparatory work for the national inquiry into the historical licensing and use of sodium valproate in women of childbearing potential. This inquiry, approved by government in 2023, represents a vital opportunity to hear and learn from the experiences of those affected by sodium valproate. The HPRA is dedicated to ensuring comprehensive and transparent engagement with the inquiry process once underway. We remain fully committed to supporting the inquiry's objectives and to contributing constructively to its work, with the ultimate aim of achieving meaningful outcomes for patients, families, and the wider healthcare system.

Acknowledgements

On behalf of the Authority, I wish to recognise the invaluable collaboration and partnership of the Minister for Health, the Minister for Agriculture, Food and the Marine, their advisors, and the staff of their respective departments.

Thank you also to my fellow Authority members for your time and expertise over 2024, in addition to the valuable contributions and insights of the Chairs and members of the HPRA advisory committees. Notably, 2024 saw the dissolution of the Herbal Medicines Subcommittee, and as such I wish to acknowledge and commend the outstanding work of its members. The subcommittee, which was formed in 2007, played an integral role in assisting the HPRA in successfully navigating the introduction of the Traditional Herbal Medicinal Products Directive 2004/24/EC and in establishing best practices in the area.

I also wish to take this opportunity to acknowledge the departure of Dr Diarmuid Quinlan from the Authority. Diarmuid's tenure was characterised by his dedication and commitment to public health and his insightful contributions helped guide the HPRA through complex regulatory and strategic decisions.

Finally, I extend my heartfelt gratitude to the entire HPRA team, whose expertise and dedication have been the cornerstone of the organisation's success. I also wish to acknowledge the invaluable support of our stakeholders, partners, and the public, whose trust inspires us to continually strive for better outcomes. Looking forward, 2025 promises to be an exciting year as we continue to pursue initiatives that promote public and animal health, while embracing innovation and growth. Together, we will ensure that the HPRA remains a beacon of excellence in the regulation of health products, serving the needs of society with integrity and care.

Michael Donnelly
Chairperson

Authority Members

The Authority of the HPRA is appointed by the Minister for Health in accordance with the powers conferred by subsection 2 of section 7 of the Irish Medicines Board Act, 1995. The members of the Authority during 2024 were:

Mr Michael Donnelly
Chairperson

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

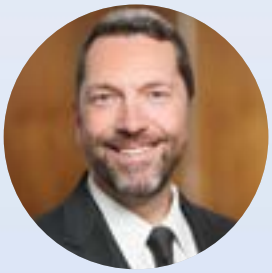
Dr Suzanne Kelly
Appointed November 2024

Dr Fiona Kiernan

Dr Paula Kilbane

Prof Sharon O'Kane

Dr Diarmuid Quinlan
Term ended October 2024



Prof Richard Reilly

Management Committee

The members of the Management Committee in 2024 were:

Dr Lorraine Nolan
Chief Executive

Ms Rita Purcell
Deputy Chief Executive

Dr J.G. Beechinor
Director of Veterinary Sciences

Ms Sinead Curran
Director of Human Products Monitoring

Mr Sean d'Art
Director of ICT and Business Services

Dr Finnuala Lonsdale
Director of Human Products Authorisation and Registration

Dr Niall MacAleenan
Director of Medical Devices

Ms Gráinne Power
Director of Compliance

Ms Elizabeth Stuart
Director of Human Resources and Development

Chief Executive's Report

For the HPRA, 2024 marked a period of strategic advancement and preparation for the future to ensure resilience and our continued effectiveness in fulfilling our vital public health role. This was achieved through informed planning and collaboration both within our organisation and across our wider national and European networks. These efforts reaffirm our commitment to delivering excellence in regulatory practice for the benefit of public and animal health while positioning ourselves to meet the challenges of a dynamic scientific and regulatory landscape.

Medicines availability

Ensuring the availability of safe and effective medicines remains a core priority for the HPRA. In 2024, we continued to face global challenges related to medicines supply, driven by a complex combination of factors such as manufacturing disruptions, increased demand, and geopolitical instability. Despite these pressures, we made meaningful progress in strengthening systems to mitigate the impact of shortages on patients and healthcare providers.

At the European level, the HPRA played an active role in initiatives coordinated by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) network. This included contribution to the development of the European Shortages Monitoring Platform, which enhances real-time data sharing and coordination across Member States. Our national experts also participated in and supported the work of the EMA's Medicines Shortages Steering Group, helping to shape policy and operational responses to critical shortages.

Through these initiatives, and through the planned introduction of new tools such as those envisaged under the revised pharmaceutical legislation and the proposed Critical Medicines Act, we continue to enhance our capacity to effectively anticipate, prevent, and mitigate against disruptions in supply. None of this progress would be achievable without robust engagement with our health system partners at a national level. Such collaboration is essential for addressing supply challenges and alleviating the impact on our health system and on patients.

Future development of our regulatory systems

The HPRA continued to play a leading role in shaping the future of regulatory systems at both national and European levels. In 2024, we contributed to several important strategic initiatives aimed at enhancing regulatory science, innovation, and collaboration.

The HPRA continued to play a pivotal role in the IncreaseNET Joint Action. This three-year initiative, co-funded by the EU4Health Programme, aims to bolster the capacity and capability of European national medicines agencies. This crucial work fosters knowledge exchange and the adoption of best practices across the European medicines regulatory network. The joint action is helping to optimise existing capacities and drive innovation, which ultimately strengthens the regulatory network and supports better access to high-quality, effective, and safe medicines for patients.

The HPRA was also a key contributor to the COMBINE project, which focuses on the regulation of combination products integrating medicinal and device components. The project marked a significant milestone in 2024 with the completion of its first phase. This phase of the project entailed an analysis of the challenges at the interface of the different legislative frameworks for medical devices, *in vitro* diagnostics, and medicines. The analysis, along with the resultant proposals for solutions to effectively address the challenges identified, lays the groundwork for the second phase of the initiative. As the project progresses, it continues to advance regulatory frameworks that acknowledge and accommodate the complexities of modern health technologies.

Additionally, the HPRA continued its leadership role within the Veterinary Strategic Focus Group of the HMA, contributing to the development of strategic priorities and regulatory approaches for veterinary medicines. This work is essential to ensuring the availability of safe and effective treatments for animals, while supporting public health, food safety, and the interconnected goals of the EU's One Health approach.

Investment in our people and systems

The HPRA's successes are only possible thanks to the people who work within our organisation. It is for this reason that successful implementation of the HPRA's People Strategy remained a key focus for us throughout 2024. The strategy was launched in 2023 and outlines how we invest in and support our people to deliver on our vision and mission, and to further embed our values. The strategy also enables organisational success by presenting a framework for developing and supporting our employees.

A key achievement under the People Strategy was the launch of HPRA Grow, our new learning and development platform. This system empowers employees to take ownership of their professional development, offering a wide range of training resources and learning pathways tailored to individual and organisational needs. We also made significant progress in the development phase of our new Career and Capabilities Framework, which is due to be launched in 2025. This framework provides a clear structure for career progression and capability development, aligning with our strategic goals and fostering a culture of continuous improvement. This work is central to supporting employee development and strengthening organisational agility.

Also over the course of 2024, the continued development of the HPRA's new website served as another major cross-organisational project. The newly designed and structured site subsequently went live at the beginning of 2025. This marks a significant milestone in the HPRA's Digital Transformation Strategy. Recognising the website as an essential tool for communication and stakeholder engagement, the redevelopment project focused on modernising its layout, improving content readability and accessibility, and enhancing interoperability with internal digital systems. The result is a platform that better serves the diverse needs of our broad range of stakeholders, while streamlining the way information is presented. This accomplishment reflects the diligence and dedication of our teams and was driven by tremendous collaborative efforts across the entire organisation.

European benchmarking exercises

In 2024, the HPRA undertook extensive preparatory work for two major European benchmarking exercises: the Benchmarking of European Medicines Agencies (BEMA) and the Joint Audit Programme (JAP). These initiatives are in place to ensure the quality, consistency, and continuous improvement of regulatory systems across the European network.

The BEMA assessment is a key initiative of the HMA to identify best practices and areas for improvement across the European regulatory network. Following a detailed self-assessment process, completed throughout 2024 and involving detailed input from across

the organisation, an onsite assessment took place in early 2025. The HPRA achieved an exceptional result, reflecting the strength of our systems and the dedication of HPRA employees.

Separately, in December 2024, the HPRA's Good Manufacturing Practice (GMP) compliance programme was audited under the JAP. This programme focuses on the consistency and harmonisation of GMP standards across Europe. This audit reviewed a wide range of activities and concluded successfully, again highlighting the robustness of the HPRA's systems.

Together, these benchmarking exercises affirm the HPRA's position as a high-performing regulator and provide valuable insights to guide our ongoing development.

Acknowledgements

As we reflect on the achievements of 2024, on behalf of the leadership team, I would like to express sincere gratitude to all of our colleagues across the HPRA. Your expertise, dedication and adaptability have been instrumental in delivering on our mission in a sometimes challenging and increasingly dynamic environment. I am continually inspired by your commitment to public and animal health and your willingness to embrace innovation and change.

I would also like to express my appreciation for the ongoing support provided by the Ministers and staff of the Department of Health and the Department of Agriculture, Food and the Marine. Finally, I wish to acknowledge the support and guidance of the Authority and its committees, whose oversight and strategic direction have been indispensable.

Looking ahead to 2025, we remain focused on our strategic priorities and on delivering a regulatory system that is responsive, resilient, and future-oriented. We will continue to invest in our people, systems, and partnerships to ensure that we can meet the evolving needs of patients, healthcare professionals and all our stakeholders.

Dr Lorraine Nolan
Chief Executive

Strategic Plan 2021 to 2025 – Key Achievements in 2024

Goal 1: Health system partnerships

Strengthening our collaborations across all areas of the health system

- Extensive work was carried out in response to medicines availability issues under the HPRA's medicines shortages framework including the consideration of business requirements for a national stock monitoring platform and continued work with the Department of Health. The HPRA is also a key contributor to activities at an EU level, which includes acting as the work package lead in the Joint Action CHESSMEN (Coordination and Harmonisation of the Existing Systems against Shortages of Medicines, European Network), as part of which a sustainability plan was developed and shared with the European Commission.

- With an obligation for shortage notification for medical devices introduced by EU Reg 2024/1860, the HPRA has participated in EU taskforces developing EU policies and procedures in this area, including a Q&A and a notification template. Several meetings were held with the Department of Health and the HSE discussing proposals for a national process. The HPRA internal process for evaluation of notifications has also been developed and implemented.

- Continued work with colleagues from across the health system to monitor and manage impacts on the supply of medicines and medical devices arising from the upcoming expiry of Brexit exemptions and the potential impact of the Windsor Framework.

- At EU level, continued to support developments to enhance the coordination of shortages and to ensure consistency in approaches and responses to medicine and medical device shortages. In conjunction with colleagues from across the national health system, the HPRA contributed to the development of an EU critical list of medicines central to the development of an availability strategy. Additionally, we led a work package, in cooperation with other national European agencies, to deliver a long-term plan to sustain these approaches to medicine shortages.

- Adopted a leadership role at EU level to ensure legislative amendments delivered to prevent disruption to supply of essential medical devices for people in Ireland, supplemented with measures to promote timely transition by manufacturers to new EU Regulations.

- Establishment of a new section within the Human Products Monitoring department with a focus on health system partnership and engagement in relation to medicine safety issues.

- The Community Pharmacy Implementation Oversight Group (IOG), of which the HPRA is a member, was established by the Minister for Health to implement recommendations related to pharmacist prescribing made by the previous Expert Taskforce. The group met on several occasions to progress this work.

- Continued as a member of the HSE National Patient Safety Alert Committee to support system-wide responses to health product issues. This included the discussion on a framework for escalation of emergent high-profile safety issues relating to medical devices within the HSE and participation in HSE-led incident management teams.

- Continued focus on the application of the 3R principles in animal-based research in Ireland, with the aim of enhancing animal welfare.

- The scientific animal protection inspections programme was strengthened with increased inspections, enhancing the role of the HPRA as an advocate for the 3R principles.

Goal 2: Progressive regulation

Increasing our use of proportionate and adaptive approaches for better patient outcomes

- Continued to support the transition to the Clinical Trials Regulation, through collaboration at: (1) national level, with the Department of Health, the National Research Ethics Committee (NREC) and national stakeholders; and (2) EU level, through the EMA/HMA Clinical Trial Coordination Group and the Accelerating Clinical Trials in the EU (ACT EU) initiative.

- Promoted effective application of the EU Medical Device Regulation and *In Vitro* Device Regulation at EU and national levels, working to ensure continued supply of essential devices for people in Ireland and collaborating with health institutions in Ireland on in-house IVD manufacturing.

- Played a leadership role in ongoing development of the EU regulatory system for medical devices. Contributed to a range of initiatives, leading work on EU coordination of safety issues, co-chairing the MDCG[1] taskforce on orphan medical devices, which published guidance with the first definition of an orphan device, and co-chairing the MDCG Post Market Surveillance and Vigilance (PMSV) Working Group. Also led the delivery of an EU joint action on clinical evidence methodologies for high-risk medical devices, as part of a Horizon 2020 funded CORE MD[2] programme.

- Following the development of a HPRA policy paper in relation to strengthening controls on the administration and use of dermal fillers in Ireland, throughout 2024 the HPRA continued to engage and discuss the proposal and explore opportunities to expedite the adoption of certain key measures.

- Continued to co-lead an International Coalition of Medicines Regulatory Authorities (ICMRA) project on a pharmaceutical quality knowledge management (PQKM) strategy which aims to standardise regulatory submissions, to harmonise regulatory assessments and inspections, and to enhance regulatory effectiveness and efficiency through strengthened international collaboration.

- Negotiation of the draft pharmaceutical legislation in the European Council continued at pace during 2024.

1 The Medical Device Coordination Group
2 Co-ordination of Research and Evaluation of Medical Devices

Goal 3: Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

- Continued collaboration and engagement with the patient community through the Patient Forum, with positive feedback from members. Continued implementation of an educational module for HPRA employees and held a Patient Speaker Programme.

- Continued our engagement with stakeholders through website, social media and newsletter updates. Proactive media engagements included enforcement activities and medicines safety. The development of a new stakeholder engagement plan will ensure our continued focus and development in this area over the coming years.

- Our digital awareness campaigns involved raising awareness of the dangers of purchasing prescription medicines online, the importance of reporting side effects to regulators and the risks of dermal fillers.

- Continued work on the redevelopment of the HPRA website. This project focused on optimising the design, structure and content of the website, to enhance information exchange and stakeholder engagement. Web content creation and accessibility training was carried out, as well as user testing with stakeholders for an enhanced website structure.

Goal 4: Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

- Continued collaboration in projects at: (1) EU level, relating to areas of innovation and research, such as Horizon-funded Core-MD where the deliverables promote the level and quality of clinical evidence supporting high risk medical devices, EU Pharmacovigilance Business Team, STARS[3] and the EU-IN Borderline Classification Group; and (2) national level, through the HPRA Innovation Office and engagement with partners, clinical researchers and sponsors.

- Adopted a leadership role within the EU Commission's COMBINE project, designed to analyse the challenges encountered by sponsors in conducting clinical research of new medicines which involve use of companion diagnostics for which clinical performance studies are required. It is also focused on identifying possible solutions to ensure applications and reviews are as clear and efficient as possible.

- Hosted the EU-Innovation Network conference in Dublin, focused on supporting life-sciences innovation, highlighting key developments, and raising awareness of regulatory supports for researchers.

- Expanded our expert network to include the onboarding of 30 additional clinical experts. Their support will assist the HPRA both in relation to the efficacy and safety of medicines and medical devices as well as ensuring an effective and informed response to scientific and technological innovation.

- The HPRA continued to actively promote the Innovation Office through engagement with a broad range of stakeholders and organisations.

3 STARS is the EU-funded project on 'Strengthening Training of Academia in Regulatory Science.'

Goal 5: Great people, great processes

Developing our organisation and people to successfully achieve our goals

- Our People Strategy, which is focused on managing, developing, and supporting employees under four strategic pillars; Purpose, Growth, Belonging and Wellbeing, entered into its second year of delivery. This framework continues to guide how we align our people practices with the HPRA's mission and vision.
- Continued our digital transformation activities focusing on integration to EU network systems, improved dataset management and core workflow consolidation.
- Strengthened our culture of continuous improvement by establishing an Operational Excellence Team, expanding Lean training across the organisation, and reviewing operations and strategies to enhance performance and value delivery.
- Under the 2021-2030 energy and sustainability project, work continued on the installation of decentralised heating, the design and preparation for the solar panel installation and the transition of all the lighting to LED and installation of PIR motion sensors.

Human Medicines

The HPRA grants licences for medicines subject to a review of their safety, quality and effectiveness and continuously monitors their use once they become available on the Irish market. We also approve and monitor clinical trials, inspect and license manufacturing sites and wholesalers, and investigate activities associated with the illegal supply, manufacture or advertising of medicines.

Authorisation and Registration

- Prior to a new medicine being placed on the Irish market, it must be assessed and authorised (licensed) by the HPRA or by the EMA, in conjunction with the European Commission. The assessment involves establishing that a medicine's health benefits outweigh its known risks. Where this is the case, it may be granted a marketing authorisation.

- There are several routes through which a product can be authorised by the HPRA. These include the national procedure, the mutual recognition procedure (MRP) and the decentralised procedure (DCP). Both MRP and DCP involve the simultaneous submission of applications in a number of EU Member States. The centralised procedure is co-ordinated by the EMA and results in an authorisation that is granted by the European Commission and which is valid across Europe. The assessment is carried out by Member States appointed as lead assessor (rapporteur), and joint lead assessor (co-rapporteur), with input also from all other Member States.

During the year in review, the total number of new medicines authorised in Ireland was 462. The 2024 figure incorporates:

- 15 new national authorisations;
- 57 parallel import authorisations;
- 1 herbal authorisation;
- 283 new medicines authorised through decentralised (DCP) or mutual recognition (MRP) routes. The HPRA continued to support the authorisation of medicines through the EU system acting as RMS for 59 DCP authorisations and 19 MRP authorisations;
- Eight rapporteurships and five co-rapporteurships under the centralised procedure;
- An additional 93 medicines authorised through the centralised procedure for which Ireland was neither rapporteur nor co-rapporteur.

- The EMA operates a scientific advice and protocol assistance procedure system for applicants on the appropriate tests and studies to perform during the development of a medicine. This is designed to facilitate the development and availability of high quality, effective and acceptably safe medicines for the benefit of patients. During 2024, the HPRA acted as co-ordinator for 72 EMA scientific advice requests across a broad range of conditions.

  Our national scientific and regulatory advice procedure functions in a similar way and assists commercial and non-commercial entities making applications for clinical trial authorisations or marketing authorisations. This service complements advice that we provide on earlier stage product development through our Innovation Office. During the year, we completed 12 such advice procedures.

- Overall, for 2024, the HPRA was among the top 10 contributors at EU level for lead assessment of centrally authorised human medicines and EMA scientific advice.

- The HPRA continued to support progressive regulation in the area of environmental risk assessment (ERA) of medicinal products for human use, as chair of the drafting group for the revision of the EMA guideline. The updated ERA guideline came into force on 1 September 2024. The HPRA also supported assessor training and stakeholder engagement on the revised guideline in 2024.

- The HPRA represented Ireland and Europe at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in Montreal as a member of the ICH Q3E Expert Working Group (EWG) for the development of a new guideline on the assessment and control of extractables and leachables. The HPRA also supported innovation in the chemical manufacturing space as a member of the Implementation Working Group for the ICH Q13 guideline on continuous manufacturing of drug substances and drug products, tasked with developing guideline training materials for ICH.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2024, we issued 82 authorisations under the new EU Clinical Trials Regulation (CTR).

- Reclassification of the legal status of medicines aims to increase the number of medicines available to patients without prescription where it is safe to do so. In 2024, four medicines were authorised for non-prescription, pharmacy-only or general sale.

- The HPRA publishes and maintains a list of interchangeable medicines to facilitate generic substitution by pharmacists and to allow for reference pricing by the HSE. By year-end, the interchangeable medicines list included 164 active substances or combinations of active substances.

- Medicines shortages are a global issue experienced by all countries regardless of size or economic status. Despite ongoing efforts of all relevant stakeholders, the situation regarding medicine shortages remains challenging and therefore subject to scrutiny by policy makers.
  - The national Medicine Shortages Framework brings together key players in the health sector with the aim of developing strategies to mitigate the effect of shortages in Ireland when they occur. 2024 saw a positive development towards improving the effectiveness of the national framework for the coordination and management of medicine shortages with the introduction of a solidified legislative requirement for the HPRA to be furnished with information for the purposes of managing medicine shortages. The introduction of this legislation has meant that the HPRA has progressed in developing a monitoring and reporting system to complement the notification system that is currently in place. This enhancement seeks to proactively address some of the limitations of the notification system, related to late notifications and the subsequent information that is then available for active case management.
  - The HPRA continues to take a prominent role in European and international initiatives to address human medicines shortages including the Medicine Shortages Single Point of Contact Working Group which was given a legal basis following new legislation expanding the EMA's remit in 2022. We also continue to contribute to the work of the EU Executive Steering Group on Shortages of Medicines (MMSG) which continued to meet and provide strategic oversight of EU activities relating to monitoring, management and mitigation of critical shortages. The HPRA remains actively involved in a European Commission-backed Joint Action on Shortages initiative. We also participate in the Critical Medicines Alliance (CMA) set up by the European Commission in 2024 as part of further efforts within the EU to prevent and address shortages effectively.
- As the use of multilingual labelling remains an important means of minimising the impact of Brexit and supporting the availability of medicines in Ireland and Europe, the HPRA remains actively involved in progressing this initiative at the HMA level through the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

- The HPRA continued to lead the CMDh Multilingual Packaging Working Group in 2024, which engaged with interested parties to facilitate the use of multilingual packaging as a tool to mitigate against shortages. The conclusion of the multilingual packaging pilot has led to the development of a standard process for these requests. Responses to queries from Member States and marketing authorisation holders (MAHs) on multilingual packaging were also prepared.

- To aid the continuity of supply to the marketplace in the event of a medicine shortage, the HPRA granted 149 batch-specific requests covering 195 products.

- Linked to Brexit, the HPRA maintained 455 notifications for human medicines under Directive (EU) 2022/642 of the European Parliament and of the Council, 12 April 2022. The amended Directives 2001/20/EC and 2001/83/EC enabling derogations from certain obligations concerning certain medicinal products for human use was made available in the United Kingdom, in respect of Northern Ireland, and in Ireland, Cyprus and Malta. As per the requirements of this Directive, the HPRA notified the European Commission and published on the HPRA website the list of medicinal products to which the HPRA applied the derogations as set out in Directive 2022/642/EC. This list is updated on a six-monthly basis.

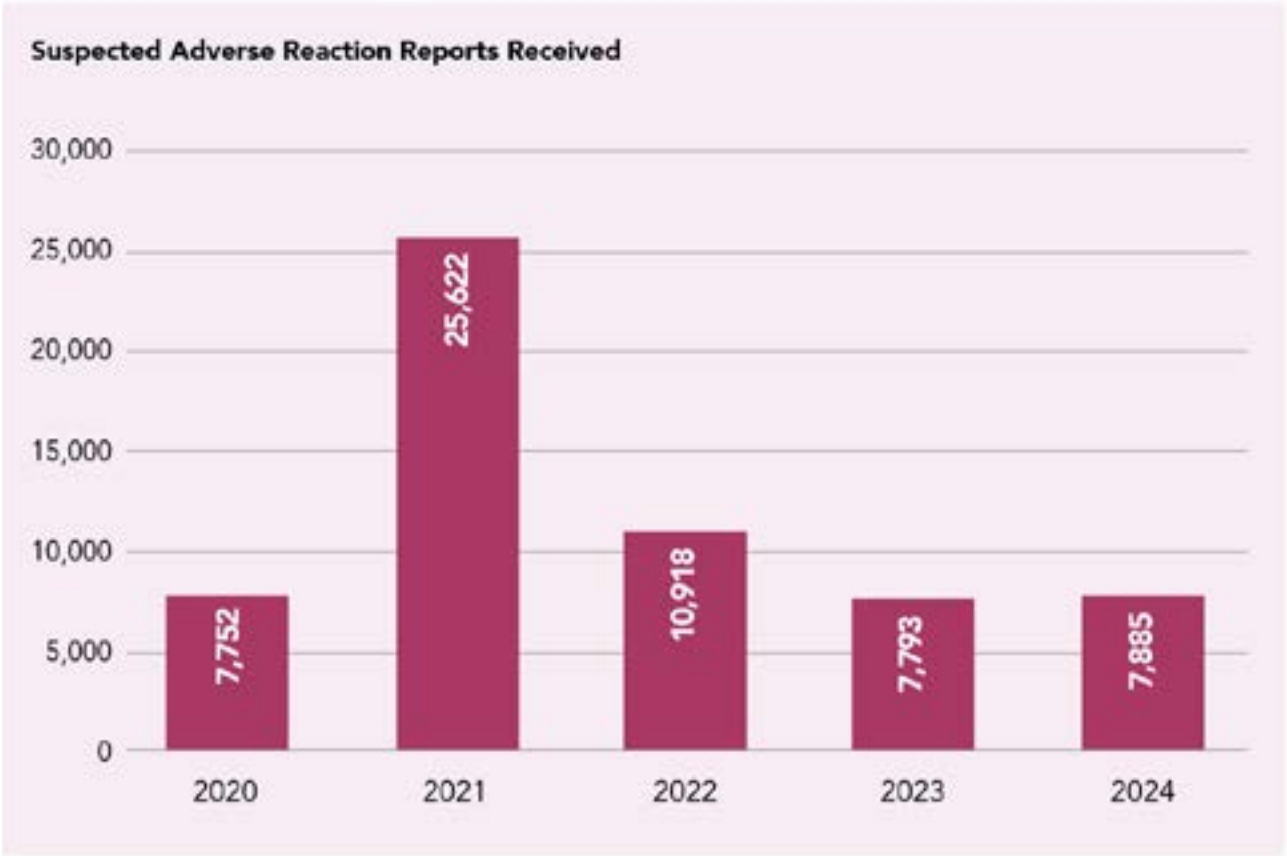
Authorisation and registration: Key figures	2022	2023	2024
Classification queries/reviews	100	72	15*
Scientific advice			
Coordinator EMA scientific advice	109	93	72
National scientific advice	15	11	12
Clinical trial applications under Clinical Trials Directive (CTD)	64	19	0
Clinical trial applications under Clinical Trials Regulation (CTR), implemented 31 January 2022	3	76	86
New medicines applications for marketing authorisations			
National (including new parallel imports)	92	64	72
Mutual recognition and decentralised RMS	57	34	78
Mutual recognition and decentralised CMS	176	152	224
Centralised Rapp/Co-Rapp	18	12	13
Traditional herbal medicinal products under the simplified registration scheme	2	1	1
Homeopathic medicines under the simplified/national rules schemes	2	0	0
Variations to marketing authorisations (Type IA, IB, II)	14,367	14,672	11,645
Articles 45 and 46 - Variations to Update Product Information	19	13	2
Renewals of marketing authorisations	232	231	201
Transfer of marketing authorisation holder	161	179	236
Manufacturers	149	151	161
Manufacturers of investigational medicinal products	82	82	89
Wholesalers	386	375	381
Registrations for active pharmaceutical ingredients			
Manufacturers	22	22	29
Importers	75	75	74
Distributors	100	98	104
Brokers	12	13	12
Export certificates	1,304	1,108	1071
Exempt medicine notifications of unauthorised medicine import	62,940 line notifications	69,912 line notifications	78,994 line notifications

* This figure is not comparable to previous years as it only outlines classification decisions by the Borderline Products Committee, due to a change in the reporting of classification queries.

Safety and Quality

- Adverse reaction reporting assists the HPRA, in co-operation with pharmacovigilance professionals in Europe and further afield, to further characterise the safety profile of authorised medicines when in clinical use. Reports submitted to the HPRA in many instances arise from concerns due to an observation of an unexpected and/or unwanted event, in the context of use of a medicine. They can also include known adverse reactions, such as those described in the product information.

- This year, a total of 7,885 suspected adverse reaction reports were received associated with the use of human medicines. This is a similar number of reports as received in 2023, and in the years prior to the mass immunisation campaigns for COVID-19.



  – Of the reports received in 2024, 7% were submitted by members of the public, 7% by healthcare professionals and 85.5% were reported by marketing authorisation holders. A further 0.5% were reported by sponsors in the context of ongoing clinical trials. It is important to note that reports received by marketing authorisation holders will have been initially notified to them by healthcare professionals or members of the public.

– Medicines subject to additional monitoring (labelled with a black inverted triangle (▼) accounted for 9.2% of the reports submitted.

– The breakdown of reports submitted directly by members of the public and healthcare professionals (excluding marketing authorisation holders) was as follows:

Sources of Suspected New Adverse Reaction Reports	%
Member of the public (patient/carer)	52
Doctor	14
Nurse	9
Pharmacist	18
Healthcare professional – Other	7

– The HPRA expresses its sincere gratitude to healthcare professionals and members of the public who take the time to report suspected adverse reactions. Such reports are a fundamental part of pharmacovigilance and support us in ongoing monitoring of the safety profile of medicines in clinical use. We continue to urge reporting through the various routes available, including through our online form or via medsafety@hpra.ie

- The medicines most frequently included in reports submitted to the HPRA as the suspect drug, and which account for approximately 80% of the suspected adverse reaction reports received in 2024, are described in the table below. It is important to note that the place of a medicine on this list cannot be taken as an indicator of safety or risk. Furthermore, the number of reports received cannot be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using a medicine, is known.

Suspect Medicine(s)/Class of Medicines	Number of Reports*
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	4,011
Medicines for the treatment of Parkinson's Disease	666
Psycholeptic medicines	575
Vaccines, including COVID-19 vaccines	475
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	392
Medicines for obstructive airway diseases	339
Medicines for the treatment of dermatological conditions	330
Medicines for the treatment of Diabetes Mellitus	178
Analgesic medicines including medicines for prevention and treatment of migraine	138
Cardiovascular medicines including anti-hypertensive, anti-arrhythmic, and lipid lowering medicines	137

* Please note that in some cases treatment may have involved more than one medicine from the groups listed.

- Of the reports received by the HPRA in 2024, 104 patients were reported to have died following treatment with a suspect medicine. The following table outlines the medicines or class of medicines most frequently described in these reports.
  - It is important to note that the place of a medicine on this list cannot be taken as an indicator of safety or risk. The number of reports received cannot be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using a medicine, is known.
  - It can be expected that fatalities due to progression of underlying disease or natural causes will continue to occur during or after treatment with medicines. This does not mean that the medicine caused the death.
  - Individual reports alone are rarely sufficient to establish causation, and it is essential that the totality of data is examined, including that from voluntary reporting systems, as well as from literature, epidemiological studies and clinical trials, to reach robust conclusions on causal relationship.
  - In many cases, where a fatality is reported, the patient concerned was described as having significant underlying illness and were treated with multiple medicines and/or surgery.

Suspect Medicine(s)/Class of Medicines	**Number of Reports***
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	61
Psycholeptic medicines	27
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	14
Vaccines, including COVID-19 vaccines	6
Cardiovascular medicines, including anti-hypertensive, anti-arrhythmic, and lipid lowering medicines	6
Antithrombotic medicines including anti-coagulant and anti-platelet medicines	5
Systemic corticosteroid medicines	<5**
Medicines for the treatment of epilepsy and neuropathic pain	<5**
Medicines for treating Parkinson's Disease	<5**
Perfusion solutions including blood substitutes	<5**

* Please note that in some cases treatment may have involved more than one medicine from the groups listed.

** For data privacy, where the number of suspected adverse reaction reports is <5, the absolute number is not published

- The HPRA also plays a key role in monitoring the safety of medicines through benefit-risk reviews and risk management over the lifecycle of products. This incorporates our contribution to the work of the Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA. During 2024, the HPRA:
  - Continued our involvement in the work-sharing initiative for signal detection within the EU, acting as lead Member State for the monitoring of 67 nationally authorised active substances;
  - Serving as PRAC rapporteur, we were also responsible for the further management of any signals detected in relation to 70 centrally authorised medicines (containing 44 active substances/combination of active substances);
  - Participated in the EU periodic safety update report (PSUR) single assessment procedure and national assessments contributing to the evaluation of 802 PSURs and leading the single EU assessment for 38 active substances or combination of active substances;
  - Participated as a PRAC Member State in three ongoing safety referrals, two of which reached a conclusion during the year;
  - Contributed to the review of 435 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures;
  - Also provided assessment input to 364 post-authorisation safety procedures (including safety study protocols, reports and other post authorisation safety-related measures).

- In addition to our role in the operational activities of the PRAC, in 2024 the HPRA also made significant contribution to the development of EU regulatory guidelines, including those related to the use of medicines in pregnancy which are under revision. The HPRA also contributed to the development of training materials for EMA's EU-Network Training Curriculum in Pharmacoepidemiology and Real-World Evidence.

- The HPRA oversees communications to healthcare professionals of any new important safety information on the safe and rational use of medicines based on recommendations following EU benefit-risk reviews. During 2024, the HPRA:
  - Approved the content and communication plan for 10 Direct Healthcare Professional Communications (DHPCs). These communications contain important new information on authorised medicines and highlight the need for healthcare professionals to take certain actions or adapt their practices in order to minimise risks to patients and optimise safe use of medicines. DHPCs are distributed by marketing authorisation holders and are available on the HPRA website;
  - Approved the content and communication plan for 103 sets of new or updated additional risk minimisation measures for medicines. These measures are recommended only when necessary to manage an important safety issue and to optimise the risk-benefit balance of a medicine. This includes, for example, educational materials for healthcare professionals, patient guides and cards, pregnancy prevention programs, and controlled distribution systems. The materials are distributed by marketing authorisation holders and are available on the HPRA website;
  - Distributed three editions of our Drug Safety Newsletter to registered healthcare professionals, which included nine articles, all of which are also published on the HPRA website. The Drug Safety Newsletter highlights important safety information to healthcare professionals with hyperlinks to product information and other relevant documents on the HPRA and EMA websites. A full index of topics covered during the past year is included in Appendix 3;
  - Provided seven articles for inclusion in the monthly MIMS (Ireland) publication in addition to two articles for the Irish Medicines Formulary (IMF). The full list of topics covered in these articles is included in Appendix 3;

  - Highlighted the PRAC monthly agendas, minutes, meeting highlights, notifications of safety reviews and signals via our website;
  - Held an information session for stakeholders within the national health system regarding the introduction of important new regulatory measures for topiramate and valproate medicines, following recommendations by the EMA's Pharmacovigilance Risk Assessment Committee. The aim of the session was to increase awareness of new recommendations and help facilitate adoption in practice. Key representatives from various stakeholder groups attended, such as the HSE, the Department of Health and patient representative groups;
  - As part of our commitment to raising awareness of important new information on medicine safety, the HPRA established a Pharmacovigilance Risk Communication and Assessment (PvRCA) section within the Human Products Monitoring (HPM) department. This new section consolidates responsibilities for pharmacovigilance safety communications, stakeholder engagement, and national educational material and Direct Healthcare Professional Communication (DHPC) assessments. The establishment of this section aligns with our strategic objective to enhance engagement across the health system and with the public.

- The HPRA's inspections programme focuses on ensuring compliance with relevant standards and legislation. This year, there were:
  - 83 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances;
  - 130 good distribution practice (GDP) inspections at wholesalers and distributors;
  - 13 good clinical practice inspections at investigator or sponsor sites;
  - Four pharmacovigilance inspections;
  - Four regulatory compliance inspections conducted at the premises of a marketing authorisation holder to determine the level of compliance with the legal requirements for the marketing and advertising of medicines.

- The risk-based sampling and analysis programme is part of the HPRA's monitoring of the quality and safety of medicines, both on the Irish market and pharmaceutical products manufactured in Ireland for export. It involves the analytical testing of products and the examination of their packaging and labelling, as well as product usability checks. In 2024, 319 cases were initiated under the programme.

- The quality defect and recall programme investigate, on a risk basis, reports of suspected quality defects in medicines and in their related active substances. It also co-ordinates recalls from the Irish market.

  The number of human medicines quality defect cases opened during 2024 was 906*. The risk classifications assigned, along with the corresponding figures for the previous years, are outlined in the following table:

Risk Classification	2022	2023	2024
High Risk quality defects	361	332	243
Moderate Risk quality defects	935	291	243
Minor Risk quality defects	705	613	406
Number of reports not justified	33	31	14
Total Number Quality Defects	2,034	1,267	906*

* Note: This figure is not directly comparable to previous year's figures, due to the introduction of a new workflow system in March 2023.

The majority of quality defect reports were submitted by other competent authorities (39%) and pharmaceutical companies, including manufacturers, distributors and/or marketing authorisation holders (36%). Reports from pharmacists accounted for 20% of cases, and 'others' accounted for 6%.

- In certain instances, it is necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 46 recall actions were taken in relation to human medicines, with the primary causes outlined in the table below:

Cause of recall	Number of recalls
Stability out of specification	5
Contamination - particulate	5
Distribution/storage - cold chain/temperature excursion	5
Distribution/storage - erroneous distribution	5
Product characteristic issues - other (non-stability OOS)	4
Distribution/storage - other	4

- Caution in Use Notifications (CIUNs), and Dear Doctor/Healthcare Professional Communications (DDLs/DHPCs) are issued for medicines with a significant quality defect, but where a recall action should not be initiated. For example, where an out-of-stock situation for the medicine in question might arise as a result of a recall action and this may pose more risk to patients than the quality defect issue. During 2024, 23 such communications were approved.

- The HPRA monitors the sale of certain consumer health products in outlets such as grocery shops, health food shops and, where necessary, pharmacies. During 2024, 31 cases were investigated, some of which involved multiple products. Of these:
  - 20 cases related to the sale of medicines that did not carry a registration number or authorisation number for the Irish market, resulting in 56 medicines being removed from sale and/or other necessary follow-up actions being taken;
  - 10 cases related to investigations into non-compliances with the paracetamol regulations as established by the Medicinal Products (Prescription and Control of Supply) Regulations 2003;
  - One case related to the classification status of a product.

  In addition, 38 queries linked to the sale of health products in Ireland were addressed.

- The advertising compliance programme for human medicines monitors and reviews the compliance of advertising and promotional activities carried out by industry. In total, 303 materials were reviewed and non-compliances, including both major and minor issues, were identified in 126 cases. Additionally, 18 advertising-related complaints were received and investigated by the HPRA. In all cases, we oversaw the necessary corrective and/or preventative actions, where relevant. A further 39 queries linked to the advertising of human medicines in Ireland were addressed.

- Under our enforcement programme:
  - We processed the detention of 1,000,984 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2024, compared to 874,945 dosage units in 2023. The products detained included anabolic steroids (20%), sedatives (15%), erectile dysfunction medicines (12%), and analgesics (11%). 4,950 enforcement cases were initiated in 2024, compared to 4,407 in the previous year;
  - The HPRA initiated two criminal prosecution cases and issued thirteen voluntary formal cautions. Prosecutions are taken where the HPRA considers that there is a significant risk to public health or where there are persistent non-compliances. Of the prosecutions taken in 2024, one related to the importation or distribution of anabolic steroids and one related to the importation or distribution of the weight loss product Saxenda. We also supported prosecutions brought by the Director of Public Prosecutions in relation to the illegal supply of medicines;
  - The monitoring of websites, online marketplace advertisements and social media sites throughout the year resulted in the amendment or shutdown of 2,553 websites, e-commerce listings and/or social media pages associated with the sale of falsified or illicit medicinal products;
  - The Interpol-coordinated Operation Pangea XVII is a year-round operation designed to enhance worldwide cooperation between health products regulators and other government agencies. The continued joint agency cooperation between the HPRA, Revenue's Customs Service and An Garda Síochána started in December 2024 and runs throughout 2025.

Legislation and Regulation

- On 26 February 2023, the EU and the UK reached political agreement on the Windsor framework. While the agreement covers trade generally, it is the requirements in respect of human medicines which may impact medicines on the Irish market. The EU regulation implementing the Windsor Framework on medicines includes the following requirements for medicines on the Northern Ireland (NI) market:
  - Prescription medicines in NI will not be permitted to carry the safety features required under the Falsified Medicines Directive (FMD);
  - New novel medicines authorised by the EU (centralised medicines) will not be permitted on the NI market. Only those authorised by the UK authorities will be permitted on the NI market;
  - All medicines on the NI market must have the words "UK only" on the packaging;
  - The new provisions are due to be implemented from 1 January 2025.

  While the Windsor Framework applies only to medicines on the NI market, it effectively prevents medicines being jointly packaged for the Irish and NI/UK markets. As there are products on the Irish market that use joint packs, the HPRA engaged with marketing authorisation holders to ensure they split their packs by 31 December 2024.

- Separately, the exemptions granted to Ireland in respect of medicines arising from the Brexit negotiations expired at the end of 2024. The HPRA continued a programme of work in 2024 to ensure that marketing authorisation holders brought their products into compliance.

- The following national activities were progressed by the HPRA during 2024 to support clinical research:
  - Continued engagement with the Department of Health and the National Office for Research Ethics Committees (NREC) regarding the implementation of the Clinical Trials Regulation (CTR) and the development of national legislation;
  - Updates on training information and information on timelines and guidance published on our website, and communicated via newsletters and social media;
  - Active participation in the Department of Health National Clinical Trials Oversight Group;
  - Removal of clinical trial fees for non-commercial sponsors;
  - Ongoing collaboration with the EMA and other Member States on the implementation of the new legislation, and the development of guidance and training materials.

- Since 9 February 2019, under the Falsified Medicines Directive, the outer pack of prescription medicines must carry safety features in the form of an anti-tamper device and a barcode containing unique identifiers that allows verification of the authenticity of the packs. In 2024, the HPRA worked with partners to ensure:
  - The full implementation of the system;
  - Ongoing engagement in the national oversight steering group of stakeholders who monitor the roll-out nationally and across the EU;
  - Representation on the EU Expert Group on Safety Features.
- The HPRA was represented on the expert taskforce to support the expansion of the role of pharmacists which published its final report in August 2024. The HPRA is also participating in the Community Pharmacy Implementation Oversight Group, subsequently established by the Department of Health to facilitate the implementation of recommendations made by the taskforce including a common conditions service.

Stakeholders and Partners

- The HPRA made a significant contribution to the EU regulatory network in the nonclinical domain in 2024 by hosting the Preclinical Assessors Meeting (PAM) in Dublin. This hybrid meeting brought more than 60 nonclinical assessors together from across the EU regulatory network for a two-day event, with an excess of 80 additional attendees registered for the live webinar option. The event included training and presentations related to regulatory guidance updates and the latest innovations of relevance to the nonclinical assessment of human medicinal products.

- As in recent years, the HPRA delivered a programme of presentations and talks at external stakeholder events such as meetings, seminars, conferences and training courses. Such presentations provide stakeholders, including healthcare professionals and regulatory professionals, with access to relevant, up-to-date regulatory and safety information. In addition, a programme of presentations was delivered to undergraduate and postgraduate students studying courses related to the role of the HPRA. A full list of all presentations delivered during 2024 relevant to human medicines is provided in Appendix 2.

- Publications and Information:
  - The Medicinal Products Newsletter provides regulatory news and updates for those working in the pharmaceutical industry. Three editions were published on our website in 2024.
  - HPRA guidance documents provide stakeholders, primarily from the industry sectors we regulate, with advice and direction in respect of legislation and regulatory requirements. Several guidance documents were issued and updated during 2024 and are available to download from our website. This includes, among others:
    - Guide to applications for a variation to a manufacturer's authorisation;
    - Guide to submitting a request for a new national application;
    - Guide to renewal of marketing authorisations for human medicines;
    - Guide to advertising compliance.

Medical Devices

As the national competent authority for medical devices, and the authority responsible for notified bodies in Ireland, the HPRA carries out a range of registration, surveillance, assessment and regulatory compliance activities. Our aim is to ensure that these health products perform as intended and do not compromise the health and safety of the patient or the person using them.

Authorisation and Registration

- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at a national and European level. In 2024, we:
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment and audits (surveillance and observed). This included several monitoring activities, an on-site surveillance assessment in June 2024 and the initiation of assessment of the redesignation to the Medical Devices Regulation (MDR). Following on from our oversight of *In Vitro* Diagnostic Medical Devices Regulation (IVDR) designation, a decision in accordance with article 42.4 of the IVDR was taken;
  - Contributed a national expert as part of a European Joint Assessment Team (JAT) for a designation application under the MDR in Sweden;
  - Continued to support the development of EU coordination of notified body designation and oversight through participation in the EU Notified Bodies Oversight (NBO) group and the Medical Device Coordination Group (MDCG);
  - Continued to work with the European Commission and the Competent Authorities for Medical Devices (CAMD) on initiatives to gather data on notified body capacity and certification workload associated with the MDR and IVDR.

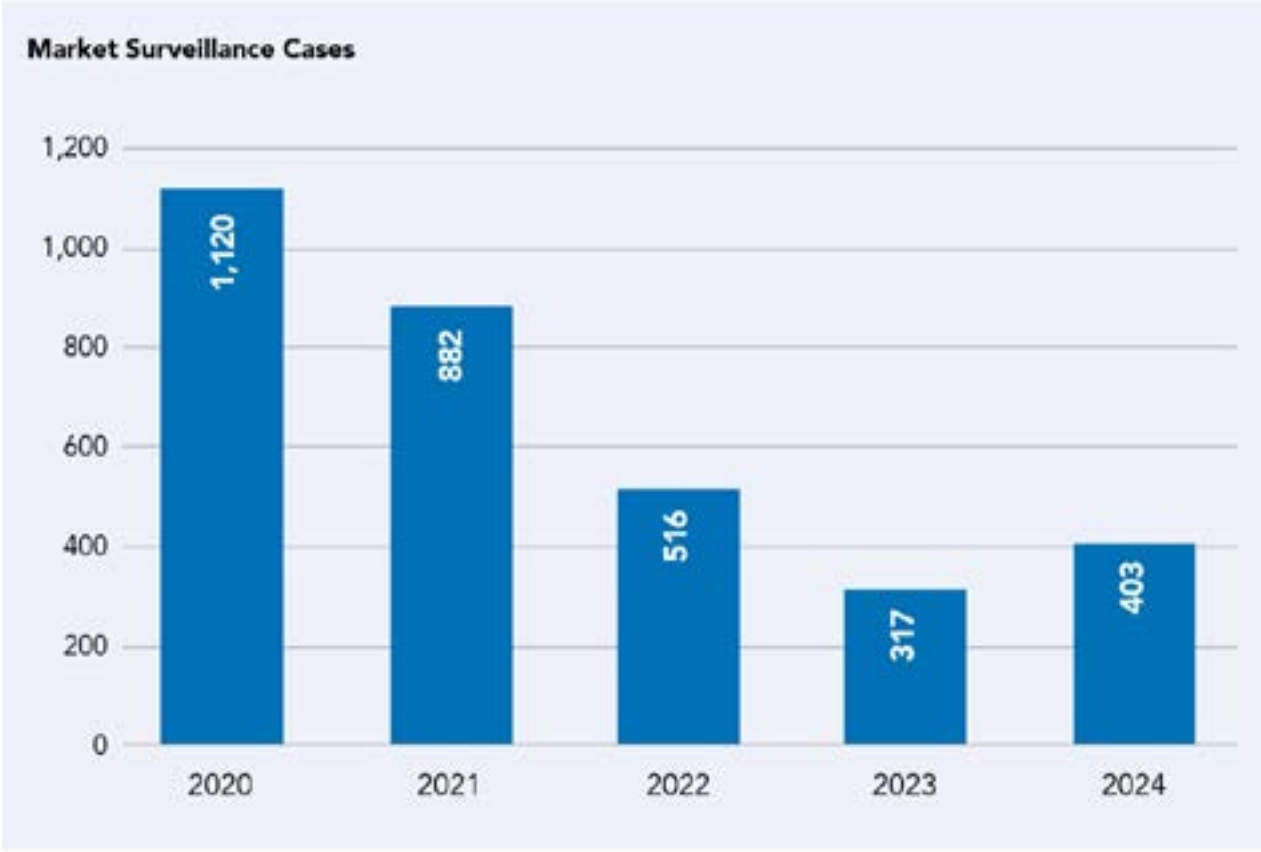
- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2024, this support included:
  - The review of applications to conduct clinical investigations of medical devices in Ireland under the new medical device regulations. We continued to review clinical investigations for innovative devices from both multi-national and academic sponsors with 11 new applications, 17 amendments to ongoing investigations and 11 post-marketing clinical investigations. The HPRA devices team also reviewed performance studies for new *in vitro* diagnostics (IVDs) under the recently implemented IVDR with 11 applications received in 2024 and anticipates that these numbers will increase further in the future;
  - A continued focus to ensure that regulatory requirements and our HPRA processes are clear and accessible to potential applicants. As part of our commitment to encourage engagement during product development and innovation of medical technologies, we offer pre-submission meetings. Activity in this area increased again in 2024, with 16 meetings with groups of innovators to discuss potential clinical investigation or performance study applications for new medical devices or *in vitro* diagnostic medical devices. This included participating in a pilot 'hypercare' programme which was initiated in 2024 to offer additional pre-submission support for sponsors conducting early feasibility studies for high-risk devices, an area of focus being developed nationally and in the EU;
  - The provision of technical, clinical and regulatory support in respect of medical devices related queries received by the HPRA Innovation Office.

- Manufacturers of certain medical devices IVDs are required to register with the HPRA via the European medical device database (EUDAMED). In 2024, 128 economic operators were validated on EUDAMED by the HPRA. There is also a requirement for other organisations to register nationally with the HPRA. We registered 153 new medical device organisations in total.

- A review of our Certificates of Free Sale process and application forms was conducted including engagement with stakeholders through a dedicated focus group to improve our service level and apply process efficiencies.

Safety and Quality

- We continue to develop and reinforce our market surveillance activities for medical devices, with a particular emphasis on proactive rather than reactive actions. Of note in 2024:
  - We further developed our lifecycle market surveillance strategy and planning mechanism to allow for more effective management, planning and reporting of these activities;
  - A total of 11 notifications were sent by the HPRA to the European network relating to medical device compliance concerns;
  - The HPRA supported the European network of authorities via the Market Surveillance Working Group and led on an initiative to develop common evaluation principles for market surveillance;
  - There were 403 market surveillance cases undertaken in 2024, an increase compared to 2023. With the implementation of the MDR, a consolidation and review of our market surveillance approach and efficiencies in processes was undertaken resulting in a change in approach to our market surveillance activities.



- We continued to focus our vigilance activities during 2024 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 3,672 medical device vigilance cases, an increase compared to 2023. Of the individual reports received in 2024, manufacturers accounted for 80%, 4% were from users and 12% came from other competent authorities. Of the 2,570 individual serious incident reports notified directly to the HPRA, 6% came from users of medical devices, including members of the public ;
  - There were 608 field safety corrective actions (FSCA) associated with the national market;
  - We issued 146 national competent authority reports to other European authorities;
  - We also issued five safety notices in relation to medical devices and 42 direct healthcare professional communications;
  - Infusion devices, surgical devices, vital signs monitoring, implants and *in vitro* diagnostic medical devices together accounted for 70% of the total individual vigilance reports received (see accompanying table).

Vigilance Report – Top 5 Product Types	**Number of Individual Reports**
Infusion devices	589
Surgical devices	546
Vital signs monitoring	537
Implants	512
In vitro diagnostic medical devices	379

- The HPRA continued in the role of co-chair of the European Working Group on Post-market Surveillance and Vigilance, a subgroup of the MDCG.

- As part of its market surveillance activities, the HPRA undertakes proactive and 'for-cause' inspections of manufacturers, notified bodies, importers, distributors and authorised representatives with the objective of monitoring compliance of devices emanating from Irish based organisations.

  During 2024, 30 such inspections were performed all of which were based on market surveillance projects and notified body surveillance/assessment. These inspections resulted in a number of significant market actions being initiated including a recall of automated external defibrillator (AED) pads which were found with unauthorised expiry labels applied outside of the manufacturers control.

Legislation and Regulation

- Our work during 2024 focused on progressing implementation and application of EU device Regulations for both medical devices and *in vitro* diagnostic medical devices at a national and European level. This included:
  - Working with the Department of Health on identifying and proposing solutions for the effective implementation of the regulatory system;
  - Supporting the Department of Health in preparing for EU Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) interventions and in the preparation of multi-lateral non-papers calling out the need for targeted solutions to ensure effective implementation of the regulations;
  - Engagement with key stakeholders in the sector to ensure awareness of the impact of the regulations incorporating the provision of information, the development of guidance and specific information sessions/webinars on MDR/IVDR implementation;
  - Participating and providing input into the EU4Health initiatives on medical device availability as part of our role as EU MDCG members. Chaired by the EU Commission, the MDCG is responsible for the overall coordination and governance of the regulatory system;
  - Participating in the EU Working Groups and task forces established to develop guidance and gather data for specific functional areas including orphan medical devices and the EU Commission's targeted evaluation. The orphan taskforce, led by the HPRA, published the first definition of an orphan device in 2024 and followed this with focused guidance on principles for clinical evidence for orphan devices.
- The HPRA continues to play a significant role in the development of EU and international regulatory systems and mechanisms to promote co-ordination, co-operation and consistency. In 2024, this included:
  - Continued participation in the Executive Group of the CAMD network;
  - Participation in the MDCG discussions on improving co-ordination and consistency of implementation of the new EU Regulations and prioritisation of implementation activities in the short, medium and long term, including priority areas such as safety and access to critical devices;
  - Continued lead role in a number of taskforces of the MDCG working groups to help identify solutions to key practical challenges with implementation.

- Throughout the year, our focus remained on identifying and promoting discussions and developing practical measures to ensure the regulatory system operates effectively in practice. We also engaged in ensuring that medium and long-term issues are prioritised and discussed within the EU network to work towards a sustainable and effective implementation of the regulations.

- In 2024, the HPRA chaired a number of EU meetings including the HMA Core Group. The focus of the HMA Core Group was to help identify short and medium term proposals for effective application of the regulations with a focus on governance and harmonisation.

- At national level, we further developed our fee-based funding model for medical devices to recover costs associated with our medical device activities.

- We continued to participate actively in initiatives to promote regulatory convergence and harmonisation of medical devices globally through the International Medical Device Regulators Forum (IMDRF). This involved:
  - Participation in the IMDRF Management Committee as part of the European delegation (along with the EU Commission);
  - Co-chaired the Adverse Event Terminology working group at IMDRF on behalf of the EU;
  - Participation in the clinical evaluation working group of the IMDRF;
  - Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review.

Stakeholders and Partners

- Our work to encourage the direct reporting of incidents and medical devices issues by device users and members of the public continued throughout 2024. We also continued our engagement with health services and healthcare professionals to raise awareness of the regulatory framework for medical devices, encourage reporting, and raise awareness of the roles and activities of the HPRA.

- The HPRA undertook a number of communication initiatives to raise awareness of the impact and requirements arising from the new EU device Regulations. During 2024, we:
  - Hosted webinars for health institutions on new MDR requirements, including the new notification requirements for reporting disruptions or discontinuations in supply of medical devices and IVDs;
  - Updated the HPRA website and social media channels to provide information and guidance regarding the new EU Regulations;
  - Launched a dermal fillers social media campaign highlighting the risks of dermal fillers for the public and those administering them;
  - Delivered briefings, advice and workshops on the devices Regulations to a range of different stakeholders including the HSE, industry and clinical associations.

- Throughout the year, we engaged in ongoing strategic, operational and communication initiatives on a bilateral and multilateral basis with European and international authorities, and the EU Commission. We also further developed our bilateral partnerships with a number of these authorities. In addition, we participated in operational and strategic discussions on developing cooperation between the CAMD and the HMA networks.

- The HPRA continues to deliver a programme of presentations, workshops and webinars to a range of external stakeholders. During 2024, this included:
  - A workshop with the HRB National Clinical Trials Office for academic and commercial sponsors conducting clinical investigations in Ireland;
  - A webinar on the topic of in-house *in vitro* diagnostic medical devices for health institutions who manufacture and use in-house IVDs was delivered in cooperation with the National Clinical Pathology Programme;
  - A number of information sessions were delivered to key health service partners (HSE, voluntary hospitals and private hospitals) on the regulatory framework for medical devices including the new 'notification of supply disruptions' requirements (Article 10a MDR/IVDR);
  - A full list of all presentations related to the regulation of medical devices that were delivered during 2024 is provided in Appendix 2.

- The HPRA contributed to a Horizon 2020 funded project, Co-ordination of Research and Evaluation of Medical Devices (CORE-MD). The project ran from 2021-2024, with the HPRA leading a work package on clinical evidence for high-risk medical devices. A number of project deliverables were presented at a closing conference to mark the successful completion of the project in March 2024 and further academic outputs from the project, co-authored by the HPRA, were published in 2024. The medical devices team has initiated a work package at the EU clinical investigation and evaluation subgroup of the MDCG to review the outputs from the CORE-MD project for adaptation into regulatory guidance in the EU.

- Several HPRA guidance documents and external communications were issued/delivered during 2024 and are available to download from our website. This includes, among others:
  - Guide for health institutions who manufacture and use in-house *in vitro* diagnostic medical devices in Ireland;
  - FAQs on notification for in-house manufacturers of medical devices and *in vitro* diagnostic medical devices.

Medical devices: Key figures	**2022**	**2023**	**2024**
Lead Competent Authority role on specific vigilance issues	93	114	146
NCARs and vigilance related communications	114	140	195
Vigilance cases received/opened	3,935	3,065	3,672
Field safety notices uploaded	324	368	437
Medical device safety/information notices	3	1	5
Medical device targeted healthcare professional communications	15	25	42
NCARs managed as IMDRF NCAR secretariat	4	N/A	N/A
CEF reports to EU network	6	8	11
Market surveillance cases	414	312	403
Notifications relating to notified body certificates	101	5#	6#
Classification requests	24	18	22
Compassionate use applications	13	27	12
Certificates of free sale	5,361	5,507	6,527
Medical device queries received	1,069	804	721
Clinical investigation (Article 62 MDR)	14	11	11
Clinical investigation (Article 82 MDR)	17	7	11
Performance study (IVDR)	N/A	7*	11

In 2023, a new process was piloted to focus HPRA review on certificate notifications from the Irish notified body resulting in a decrease in the volume of notification cases.

* Introduced in 2023 under the new *in vitro* device regulation.

Blood, Tissues and Organs

The HPRA is responsible for monitoring the safety and quality of blood and blood components, and of tissues and cells intended for human transplantation. Along with the HSE, we are joint competent authority for organs intended for transplantation.

Authorisation and Registration

- The authorisation of blood establishments, tissue establishments and organ procurement organisations/transplantation centres permits those facilities to carry out specified activities. The total number of authorisations in place at year-end for the past five years is presented by category in the accompanying table.

Number of Authorisations	2020	2021	2022	2023	2024
Blood establishments	3	3	3	3	3
Tissue establishments	25	26	26	27	27
Organ procurement/transplantation	4	4	4	4	4

Safety and Quality

- Following collaboration with the National Haemovigilance Office (NHO), we submitted an annual report of serious adverse reactions and events to the EU Commission during 2024. The report reflected information received by the NHO in 2023 and included 67 serious adverse reactions and 198 serious adverse events that met the mandatory legislative reporting requirements.

- We also submitted an annual report on serious adverse reactions and events associated with tissues and cells to the EU Commission during 2024. The report reflected information received in 2023 and encompassed 31 reports, 23 of which met the legislative reporting requirements. Of the 23 reports, 18 were serious adverse events and five were serious adverse reactions.

- We continued to liaise with the HSE lead and colleagues from Organ Donation and Transplant Ireland (ODTI) in relation to our respective roles under EU and national legislation on the Quality and Safety of Human Organs intended for Transplantation. During the past year, this included:
  - The exchange of relevant information on serious adverse reactions and events. In 2024, the HPRA received 23 reports of serious adverse reactions and events associated with organ donation/transplantation;
  - Contribution to the review of the 'Framework for the Quality and Safety of Human Organs Intended for Transplantation'.

- We inspected relevant establishments, organisations and centres to monitor compliance with applicable national and EU legislation and guidelines on the quality and safety of blood, blood components, tissues and cells, and human organs intended for transplantation. Our inspection programme in 2024 included:
  - 15 tissue establishment inspections, the majority of which were routine;
  - Seven blood establishments inspections;
  - Three inspections at an organ procurement organisation/transplant centre.

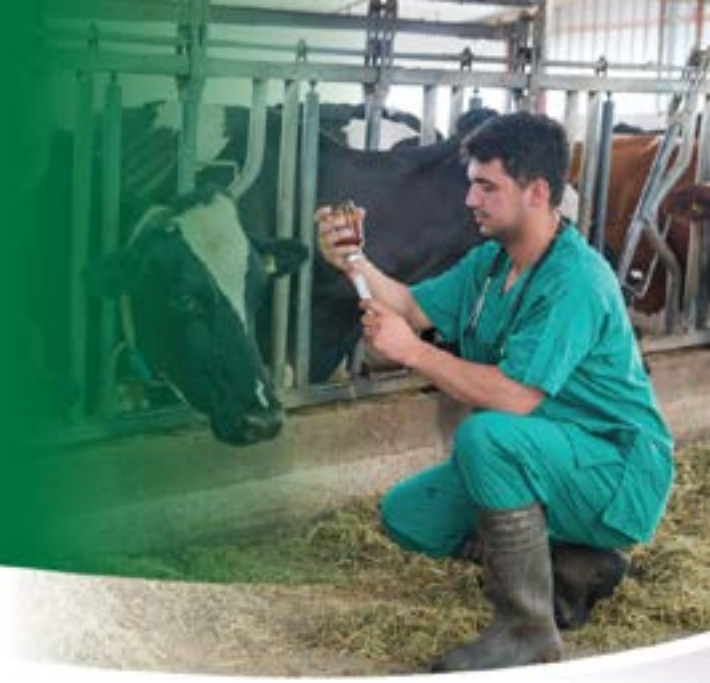
Legislation and Regulation

- We worked with the Department of Health on the development of human tissues legislation and engaged in respect of the revision of European legislation for blood, tissues and cells.

Stakeholders and Partners

- Several HPRA guidance documents were issued and updated during 2024 and are available to download from our website. This includes, among others:
  - Guide to regulatory requirements for the procurement of human tissues and cells intended for human application.

Veterinary Medicines



Our role is to grant licences for veterinary medicines subject to a review of their safety, quality and effectiveness. We continuously monitor the use of these products in animals once they become available on the market in addition to authorising clinical field trials and inspecting / licensing manufacturing sites.

Authorisation and Registration

- There are a number of procedures through which a veterinary medicine can be authorised by the HPRA. These include the national procedure, the mutual recognition procedure (MRP) and the decentralised procedure (DCP).

- The total number of veterinary medicines authorised in Ireland at year-end was 1,977. During 2024, there were:
  - Eight new national (only) applications;
  - Eighty-nine applications made under DCP. The HPRA acted as Reference (lead) Member State (RMS) for the assessment of 34 of these DCP applications;
  - Seven applications made under the MRP. The HPRA acted as RMS for the assessment of four of these MRP applications;
  - The HPRA also led a further 11 applications as RMS under the subsequent Repeat Use procedure.

  Based on the figures presented above, the HPRA was the leading national competent authority in the EU for outgoing work during 2024.

- The centralised authorisation procedure is another framework whereby veterinary medicinal products can be licensed for supply in Ireland. Experts from the HPRA acted as rapporteur or co-rapporteur in respect of 10 medicines that were authorised via this route.

- During 2024, the HPRA acted as co-ordinator or joint co-ordinator for six EMA scientific advice procedures.

- To aid the continuity of supply to the marketplace in the event of a medicine shortage, the HPRA granted 10 temporary 'batch-specific request' authorisations during 2024.

Relating to Brexit, the HPRA accepted 21 notifications for veterinary medicines under the Commission Notice on 'Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period'.

Authorisation and registration: Key figures	**2022**	**2023**	**2024**
Classification enquiries	11	8	5
Clinical trials	6	7	5
New centralised as (co-)rapporteur	8	10	10
New MR/DCP as RMS	21	42	49
New MR/DCP as CMS	41	52	64
New homeopathic applications	0	5	0
New national applications	3	2	8
Variations, national and MR	2,113	2,620	2,493
Manufacturers of veterinary medicines	34	33	32
Export certificates	144	140	33
Registrations for active pharmaceuticals ingredients			
Manufacturers	2	3	4
Importers	0	0	2
Distributors	2	4	8

Safety and Quality

- The operation of a national pharmacovigilance system for veterinary medicines is dependent on the submission of reports by veterinarians, pharmacists, licensed retailers and others involved in dispensing or using the medicines concerned as well as by animal owners. These reports may be submitted either directly to the HPRA or to the companies marketing the medicines.

- Following the introduction of Regulation EU 2019/6 in January 2022, marketing authorisation holders (MAHs) no longer submit adverse event reports directly to the HPRA, instead they are recorded by the MAH in the European Pharmacovigilance Database. However, adverse event reports from veterinarians and animal owners continue to be received directly by the HPRA. The figures for 2023 and 2024 represent the total number of reports recorded in the European Pharmacovigilance Database as occurring in Ireland, whereas the figure for 2022 relates only to reports received by the HPRA predominantly from veterinarians or animal owners:

Suspected adverse events	2020	2021	2022	2023	2024
Number of reports	391	439	29	852	899

The HPRA is grateful to veterinary healthcare professionals and animal owners who take the time to report suspected adverse events and continues to encourage this. Reports of suspected adverse events remain a fundamental part of pharmacovigilance and support us in ongoing monitoring of the safety profile of medicines used in animals.

- We continued our involvement in the pilot signal management procedure for signal detection coordinated by the EMA within the EU. We acted as lead authority and processed a total of 156 signal reviews for adverse events as lead authority in 2024.

- The HPRA oversees communications to veterinary healthcare professionals of any important new safety information to ensure the safe and effective use of veterinary medicines. During 2024, we:
  - published four safety notices on our website, three of which related to Caution-in-use Notice (CIUN) to ensure correct use of the concerned products, and one advising of the suspension of the marketing authorisation of a centrally-authorised veterinary medicine;
  - approved the content and communications plan for one Direct Animal Healthcare Professional Communications (DaHPC). The purpose of this DaHPC was to communicate important information on the correct and safe use of an authorised veterinary medicine. Further information, including links to copies of DaHPCs, are published on the HPRA website;
  - communicated important safety updates to stakeholders on pharmacovigilance-related matters via the quarterly HPRA Newsletter and dedicated a specific session on veterinary pharmacovigilance at the Veterinary Information Day held in October.

- During 2024, the HPRA continued to be represented at and contributed significantly to the work of the Committee for Veterinary Medicinal Product's Pharmacovigilance Working Party at the EMA. The working party met on eleven occasions throughout the year.

- Containing the development of antimicrobial resistance (AMR) is essential for public and animal health. Our work in this area includes monitoring the sales of veterinary antibiotics from each MAH. This information, which is collated in an EU database, is important as a benchmark and to inform future risk mitigation measures.

- The analytical testing and examination of veterinary medicines is a key component of our risk-based sampling and analysis programme. Thirty-seven veterinary medicines samples were included in surveillance programmes in 2024. Of these, 25 samples were sent for analytical testing. The testing carried out was physiochemical in nature. In addition, packaging and labelling checks were performed on 12 veterinary products. Two products were found to have been out-of-specification, and appropriate follow-up actions were taken in each case.

- There were 48 veterinary medicine quality defect cases opened in 2024.

  The risk classifications assigned to each case, along with the corresponding figures for the previous two years, are outlined in the following table:

Risk Classification	2022	2023	2024
High Risk quality defects	10	13	8
Moderate Risk quality defects	27	20	19
Low Risk quality defects	41	34	21
Number of reports not justified	1	1	0
Total Number Quality Defects	79	68	48

The 2024 figure is not directly comparable to previous year's figures, due to the introduction of a new workflow system in March 2023.

The majority of reports (52%) were submitted by other competent authorities. Pharmaceutical companies, including manufacturers, distributors and MAHs, accounted for 44% of the remaining reports received, and others 4%

- In certain cases, in order to protect animal and/or public health, it is deemed necessary to withdraw, or recall, a veterinary medicine from the Irish market. Five recall actions for veterinary products occurred during 2024, for the following reasons:

Cause of recall	Number of recalls
Distribution/Storage - Erroneous distribution	2
Stability - Out of specification	1
Product characteristic issues - Damaged/broken product	1
Other	1

- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2024, there were eight good manufacturing practice (GMP) inspections of manufacturers producing veterinary medicines.

Legislation and Regulation

- While Regulation 2019/6 was applied in the EU on 28 January 2022, a number of associated delegated and implementing acts continued to be elaborated. During 2024, we engaged further with the Department of Agriculture, Food and the Marine in respect of the development of new national legislation, including the Veterinary Medicinal Products Regulation 2024.

- We continued to implement various requirements of Regulation 2019/6 including:
  - Maintenance of product data to the EMA's Union Product Database (UPD) of veterinary medicinal products;
  - Updating of pharmacovigilance contact information in the UPD;
  - Engagement with EMA and stakeholders to improve data quality in the UPD;
  - Participation in a pilot work-sharing procedure for the centralised management of signal detection of adverse reactions at the EMA;
  - Developing indicators to measure the impact of changes required by the legislation.

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2024 we:
  - Hosted a veterinary medicines information day to keep stakeholders up-to-date and informed as regards developments with the new veterinary medicines regulation;
  - Held a series of bilateral meetings with key stakeholders to explore opportunities for enhanced customer service;
  - Conducted a survey of MAHs using our services;
  - Published a periodic blog on HPRA implementation activities, as well as those of the wider EU network, on the HPRA website;

– With regard to Brexit, we continued our focus on the HPRA's key strategic aim of protecting the availability of veterinary medicines on the Irish market while also optimising our role within the European regulatory network. During the past year, this included:
  - Refining an initiative with Spain, Portugal and France regarding medicines for unmet needs;
  - Continued engagement with the UK's Veterinary Medicines Directorate regarding requirements for labels to ensure maintenance of common labelling for medicines in Ireland and the UK post Brexit;
  - Providing regular periodic updates to the EU Commission in respect of transitional arrangements regarding products being imported into Ireland from Great Britain;
  - Liaising with stakeholders concerning the availability of veterinary medicinal products on the island of Ireland.

- Throughout 2024, we continued our involvement across the EU regulatory network, which includes active participation at the EMA and the HMA.

- As in recent years, we continued to deliver a programme of presentations to veterinarian students and veterinary nursing students on the role of the HPRA and the promotion of veterinary pharmacovigilance. We also presented at a number of industry stakeholder events. A full list of presentations for 2024 is provided in Appendix 2.

- Our Medicinal Products Newsletter provides updates for those working in the veterinary medicines sector on Irish and European legislation, new/revised HPRA regulatory publications and stakeholder events such as information days. Three editions were published in 2024.

- We also contributed a number of articles to the It's Your Field publication. Details are included in Appendix 3.

- Several HPRA guidance documents, which provide stakeholder advice and directions in respect of legislation and regulatory requirements, were issued and updated during 2024 and are available to download from our website. This includes, among others:
  – Guide to product literature standard (PLS) for veterinary medicinal products;
  – Guide to joint labelling for veterinary medicinal products for use in Ireland and the UK;
  – FAQs on processing the labelling and package leaflet for veterinary medicinal products.

Scientific Animal Protection

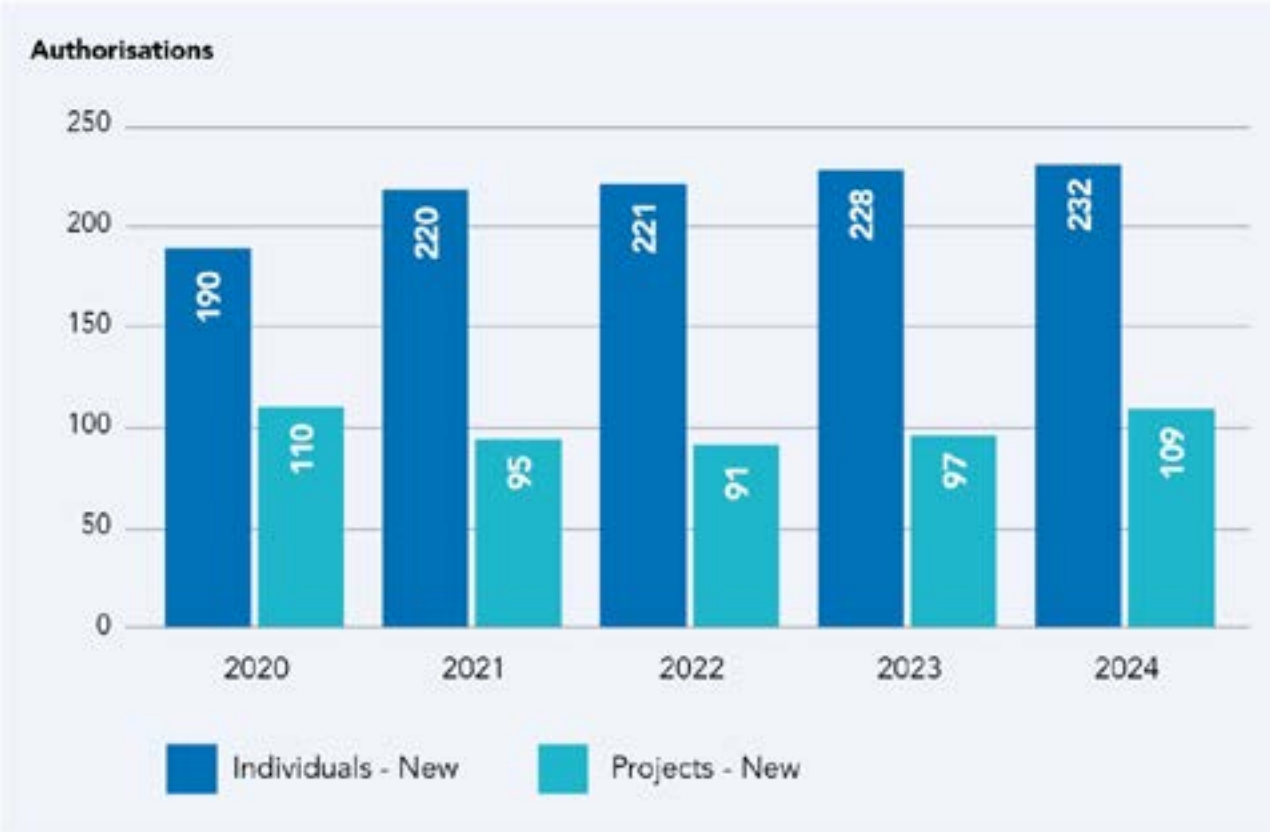
The HPRA is the competent authority in Ireland responsible for the implementation of EU legislation (Directive 2010/63/EU) for the protection of animals used for scientific purposes.

Authorisation and Registration

- The HPRA carries out evaluations of applications for the authorisation of research establishments and projects. In addition, we assess applications from individuals to allow them to manage projects, to conduct procedures, or to euthanise animals.

Authorisation and registration	Key 2024 figures
Individual authorisations	232
Individual renewals	109
Project authorisations	109
Individual amendments	46
Project amendments	63
Establishment renewals	5
Retrospective assessments	17

The number of new individual and project authorisations issued during the past five years are outlined in the following graph.



- In December, we published the eleventh annual statistical report on the use of animals for scientific purposes in Ireland. The HPRA is required to collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures.

Inspections and Compliance

- During 2024, there were 40 inspections performed to monitor animal welfare standards and compliance with legislation. 63% of these inspections were conducted as unannounced compliance inspections.

- Of the non-compliances recorded in 2024 under the Scientific Animal Protection inspections and compliance programme, 21% were self-reported to the HPRA by authorised breeder/supplier/user establishment personnel. 78% were identified during the course of HPRA inspections, with the remaining 1% detected during the HPRA assessment of applications for authorisation.

- Non-compliances are categorised as Type 1, Type 2 and Type 3, with Type 1 being the most serious and Type 3 being more minor in nature. Of the non-compliances identified in 2024:

  – 36% were Type 1

  – 54% were Type 2

  – 10% were Type 3

  The most frequently recorded reason for non-compliance in 2024 was failure to meet the requirements of Annex III to Directive 2010/63/EU in relation to the care and accommodation of animals. Compliance issues identified included, for example, failures to maintain environmental parameters within the required specifications or to perform and log routine daily health checks appropriately.

  The second most common reason for non-compliance was failure to comply with the terms and conditions of the HPRA project or individual authorization. This included, for example, non-adherence to agreed animal welfare monitoring arrangements or failure to have the appropriate authorisations in place to perform certain regulated activities.

Stakeholders and Partners

- We supported the National Committee for the Protection of Animals Used for Scientific Purposes in its meetings and activities throughout 2024, including in the development of guidance resources aimed at supporting the vital work of Animal Welfare Bodies within Irish research establishments.

- We published and disseminated four 'Regulatory Updates' to provide stakeholders with the latest news and guidance from the HPRA including information on best practices in respect of the 3Rs and compliance with the legislation.

- We delivered a number of Laboratory Animal Science and Training (LAST) lectures in relation to the legislative and regulatory aspects of scientific animal protection.

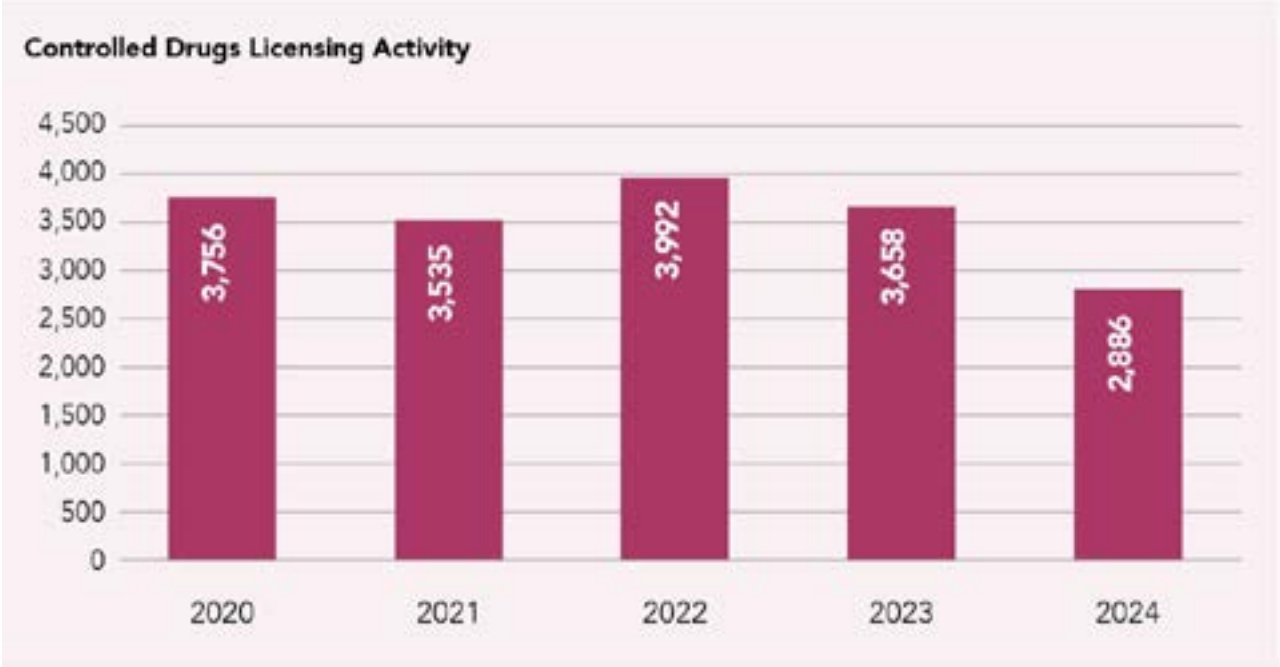
- Throughout 2024, we continued our active involvement in the EU regulatory network, which includes active participation at National Contact Point meetings for the Implementation of Directive 2010/63/EU and in EU Expert Working Groups.

Controlled Drugs and Precursor Chemicals

The HPRA is responsible for reviewing the licence application for a controlled drug as listed in the schedule to the Misuse of Drugs Acts 1977 and 1984. Additionally, the HPRA regulates the movement of precursor chemicals used in the manufacture of licensed medicines, certain foodstuffs and for other scientific or laboratory uses.

Authorisation and Registration

- Import, export and holding of controlled drugs (for legitimate purposes) are subject to licensing. The Department of Health is the licensing authority while the HPRA handles the administrative aspects of the application and licensing process. Licensing activity consists primarily of export and import licences, and letters of no objection. Data for the past five years are outlined in the accompanying graph:



- The following table shows the licensing activity for precursor chemicals since 2022:

Precursor Chemicals Licensing Activity	2022	2023	2024
Total	9	19	29

- We process applications for licences to cultivate hemp on behalf of the Department of Health. A cultivation licence is valid for a period of one year from the date it is granted. The below table shows the number of licences issued during the past three years:

Hemp Cultivation Licensing Activity	2022	2023	2024
Total	56	21	30

Safety and Quality

- We carry out inspections of manufacturers and distributors of controlled drugs, as well as some other operators, as necessary, to monitor compliance with the relevant requirements.

  In 2024, 11 inspections were conducted linked solely to the possession and/or supply of controlled drugs. Operators were informed of any non-compliances identified and requested to implement corrective actions.

Legislation and Regulation

- Throughout 2024, the HPRA continued to provide support to the Department of Health in the implementation and progression of the Medical Cannabis Access Programme (MCAP). The programme became fully operational in 2021, with consultants on the specialist medical register able to prescribe a cannabis-based treatment for patients with any of the following three specified conditions:
  - Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions;
  - Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes;
  - Severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications.

Further information is available on the Department's website.

The HPRA received four new applications in 2024 from potential suppliers seeking to have their products included on the programme. From these applications, one application was withdrawn, and two applications are still undergoing assessment at the time of publication. The assessment of the fourth application has been completed and the HPRA's final recommendation submitted to the Department of Health for consideration for inclusion on the MCAP. The final outcome of this recommendation is pending at the time of publication.

One additional application, originally submitted in 2023, is still undergoing assessment at the time of publication.

In total, 10 cannabis-based products have been included for use on the MCAP by the Department of Health to date.

Stakeholders and Partners

- Throughout the year, the HPRA continued to review applications and to respond to all relevant stakeholder queries.

Cosmetic Products

The role of the HPRA is to regulate the manufacture, sale and supply of cosmetic products in Ireland.

We identify and address cosmetic product quality and safety issues, in conjunction with the HSE, so that a cosmetic product will not compromise the health and safety of the consumer or the person applying the product.

Authorisation and Registration

- We issued 88 cosmetics free sale certificates, requested by companies intending to export products to non-European Economic Area countries.

Safety and Quality

- Cosmetic product market surveillance includes both proactive and reactive approaches. Proactive market surveillance incorporates use of an annual sampling plan of cosmetics on the Irish market, both in retailers and via online supply. Our reactive market surveillance includes investigation of:
  - quality-related complaints (compliance cases);
  - reports of adverse events relating to the use of cosmetics (vigilance cases);
  - product risk alerts received from EEA countries (Safety Gate rapid alert notifications) and;
  - importation of potentially non-compliant unsafe products.

During 2024, 176 market surveillance cases were initiated, including both proactive and reactive surveillance of cosmetic products and we received 1,557 Safety Gate alert notifications regarding non-compliant products.

- We also carried out two on-site inspections to assess compliance with the EU Cosmetics Regulation in relation to Responsible Person or distributor obligations.

Stakeholders and Partners

- The cosmetics team presented at the NCCP SunSmart Campaign webinar which was held in May 2024.

- We contributed to European meetings, both at the European Commission and the Council of Europe, throughout the year.

Other Regulatory Programmes

Inspections and Market Compliance

- Throughout 2024, HPRA contributions at an EU level included participation in/leading on:
  - the Pharmaceutical Inspection Co-operation (PIC/S) drafting group for revision of the GMP guide for the manufacture of veterinary medicines;
  - the PIC/S Expert Circle on Quality Risk Management;
  - the EU funded GAPP project to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments;
  - the EU funded project EU4Health Joint Action on quality of medicines and implementation of pharmaceutical legislation/strategy;
  - the development of a new risk assessment tool for the selection of medicinal products and active substances for surveillance testing;
  - The development of training materials for the International Council on Harmonisation (ICH) to support the ICH Q9 (R1) Guideline on Quality Risk Management.

Innovation Support

- The HPRA continues to focus on supporting innovation as one of our five strategic goals. Our supports for innovation aim to facilitate safe and timely access to innovative health products and to increase and improve treatment options for patients. They also benefit the HPRA by helping to inform our future development and allowing us to identify novel product types and technologies that require new or adapted regulatory science approaches.
  - The HPRA's Innovation Office offers regulatory advice to anyone developing an innovative heath product or technology. Approximately 70% of queries received by the innovation office in 2024 came from small and medium enterprises, and academia;
  - Through our innovation office, we continue to co-chair the EU-Innovation Network (EU-IN). As part of this group, we play a prominent role in activities such as horizon scanning, simultaneous national scientific advice, the Accelerating Clinical Trials in the EU (ACT EU) initiative, and discussions relating to the classification of borderline products. In November, the EU-IN helped to organise a workshop on access to ATMPs in Europe, which was hosted by the Italian agency AIFA. The HPRA participated in the organisation committee and chaired a session during this workshop;
  - In December 2024, the International Coalition of Medicines Regulatory Authorities (ICMRA) organised a workshop for regulatory authorities on decentralised manufacturing. The HPRA co-chaired a session during this workshop and led on the drafting of the workshop report.

Outreach and Engagement

The HPRA is committed to a strategic focus on outreach and engagement with key partners and stakeholders to enhance and maximise the effectiveness of the regulatory system.

- In our outreach activities to support education and innovation developments in Ireland:
  - The HPRA continued to meet and interact with a number of other state agencies and organisations who seek to support innovation in Ireland as well as representatives from third level institutions. During 2024, engagement took place with the Science Foundation Ireland Research Centre for Pharmaceuticals (SSPC), RCSI, UCD and others to promote the innovation office and other available regulatory supports. We also contributed to an event organised by Enterprise Ireland as part of their venture build programme for life sciences;
  - We continued to contribute to education programmes at both undergraduate and postgraduate levels in line with our policy on involvement in third level educational programmes;
  - The HPRA's graduate training programme for medical devices continued throughout 2024.

- Stakeholder communications and engagement:
  - We continued our multi-platform digital information campaign to warn of the health risks of sourcing prescription medicines online. First launched in 2022 and incorporating both social media and display advertising, the campaign targets members of the public and highlights the very real dangers presented when buying prescription medicines online. The goals of the campaign are to increase public awareness and understanding of the safe supply routes for medicines and the associated dangers of buying prescription medicines from unregulated sources.

The 2024 campaign consisted of two separate advertising bursts in August and December. In total, incorporating the two advertising bursts and our ads in both English and Irish, the campaign achieved almost nine million impressions suggesting high visibility of the campaign. It also secured close to 47,000 visits to the dedicated landing page on the dangers of buying prescription medicines online;

– In June, we ran a targeted social media-based campaign to promote our website content on the risks associated with dermal fillers. Several key themes were identified including:

  - The risks of getting dermal fillers and our advice to consult a qualified and experienced healthcare professional;
  - Highlighting the need to have expertise to carry out this procedure;
  - Sourcing genuine products;
  - Reporting side effects to help the HPRA monitor safety.

  These key messages formed the content basis for eight separate visuals for use across Instagram, Facebook and Pinterest. After a month of organic (non-paid promotion) we allocated a modest budget to promote the posts and boost visibility across each of the platforms. This enabled us to select target groups across social media users including by age and by topic of interest such as health and beauty, and cosmetics. The campaign performed extremely well, with the two separate bursts resulting in over half a million impressions and close to 2,000 webpage visits;

- Throughout the year, we continued our media communications programme to proactively communicate important safety messages and to build awareness of the role of the HPRA. We issued more than 10 press releases and statements concerning safety and regulatory matters to ensure consumers, healthcare professionals and other stakeholders received timely and accurate information and advice. In several instances, these communications resulted in national and regional media interviews with a HPRA spokesperson. In addition, we responded to more than 513 initial and follow-up queries from national, local and specialist media during the year;

- The Patient Forum, developed to provide a platform for dialogue and exchange between patients and the HPRA on issues relevant to the regulation of medicines and medical devices, and to give patients in Ireland a voice in the regulatory process, continued to meet over the course of the year. Forum members and HPRA staff collaboratively developed a rolling work plan for 2024 that included areas of common interest and aligned with the purpose of the forum. There was engagement on a range of topics including diversity and inclusion, medical devices, clinical trials, online sale of medicines and educational materials for medicines. A patient speaker event was also held for HPRA staff, involving guests from Cancer Trials Ireland's Patient Consultants Committee. The patient speaker event aims to help HPRA staff incorporate the values and perspectives of patients into HPRA activities by listening to and understanding patients' and representative organisations' views;

- The HPRA participated in the ninth annual #MedSafetyWeek, a global initiative led by the Uppsala Monitoring Centre (UMC), the World Health Organisation Collaborating Centre for International Drug Monitoring, designed to raise awareness of the importance of reporting side effects from medicines. For 2024, the theme was preventing side effects by using medicines correctly. The campaign encouraged patients to take their medicines properly (correct dose, time, and method). Healthcare professionals were also reminded to evaluate whether a medicine is suitable for the patient, considering any underlying conditions and other medicines or herbal remedies being taken by the patient. #MedSafetyWeek involved more than 100 organisations worldwide in 2024. The campaign consisted primarily of short, animated videos, available to view and download from the HPRA website, and shared across our Twitter, LinkedIn and Instagram accounts. Following a request for support from the HPRA in advance of the launch, a large number of national patient and consumer organisations, health agencies and other public bodies promoted the campaign's important public health message on social media. We also purchased advertising across social media to maximise visibility of the campaign. As a result, we again secured significant profile for this important public health message with the social media posts gaining more than 840,000 impressions. Additionally, a press release promoting the HPRA's involvement in #MedSafetyWeek was issued and alerted to website subscribers;

- All of our communications activities throughout the year were supported by social media content and through the publication of relevant updates on our website:
  - Our website – www.hpra.ie – is a key communications channel facilitating timely publication and dissemination of regulatory, safety and corporate information. Work continued in 2024 on the redevelopment of the website, as outlined in our Strategic Plan for 2021 – 2025. The overall objective of modernising the website, which subsequently launched in early 2025, is to provide a richer, tailored experience and information source for a range of stakeholders. The new site is designed to enable easy and speedy access to information and services for all users from any device. There was a clear focus on improving the quality, accessibility and effectiveness of digital interaction while reducing the process complexity for the organisation. Throughout 2024, colleagues from every department across the organisation worked collaboratively to support and deliver key milestones including final design approval, content migration, content management system (CMS) training, and initial functionality and user testing. Significant work also took place to ensure integration and compatibility with internal HPRA systems including our national medicines database;
  - Our LinkedIn account continues to support the growth of our employer brand. In addition, it has become the primary social media platform for the dissemination of important regulatory and safety information to industry and health professionals. By end 2024, following another year of significant growth, our total number of followers had grown to more than 25,000;
  - The @TheHPRA X (Twitter) account supports our communications activities and helps to direct additional traffic to the HPRA website. We continued to publish targeted communications during 2024 and by year-end we had grown our number of X followers to more than 4,500;
  - We also continued to utilise our corporate Instagram account to highlight and promote certain activities and events including #MedSafetyWeek. The HPRA Instagram account now has over 1,800 followers.

- European and international contribution:
  - We continued our active participation in all EMA and all HMA management board/group meetings and the HMA Management Group. The HPRA Chief Executive continued to act as Chair of the EMA Management Board while our deputy Chief Executive is a member of the EMA Management Board Audit and Risk Group;
  - The HPRA Chief Executive co-chaired a workshop of a number of heads of medical device agencies, hosted by the French regulator, ANSM, in collaboration with the EU Commission and CAMD. The workshop was focussed on discussion and agreement of key priorities for the development of the medical device regulatory system. The agencies present identified a range of measures to help secure and develop the functioning of the regulatory system under the MDR and the IVDR focussing on specific themes including enhancing safety, supporting innovation, access and availability and governance/coordination;
  - Additionally, as part of our ongoing contribution to the European regulatory system, HPRA scientific and technical staff participated in a broad range of committees and working parties at the European Commission, EMA, HMA, CAMD and other fora (see Appendix 4);
  - The HPRA continued its role as a member of the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee. The HPRA actively participated in a range of initiatives, including acting as co-lead alongside the US FDA on the Pharmaceutical Quality Knowledge Management System (PQ KMS) project. The HPRA also co-led the ICMRA Innovation project in conjunction with the EMA and MHLW/PMDA. At the ICMRA Summit in 2024, the HPRA presented on the PQ KMS project during a session on lessons learned from the COVID-19 pandemic and future preparedness for the next global health emergency. The HPRA also chairs the Governance Working Group of ICMRA and presented at the plenary session;
  - The HPRA continued to participate in the International Medical Devices Regulators Forum (IMDRF), as part of the EU Management Committee as well as co-chairing the adverse event terminology working group;
  - During 2024, negotiations on the proposed revision of the EU pharmaceutical legislation continued in the European Council's Working Party on Pharmaceuticals and Medical Devices. The HPRA continues to support the Department of Health in these discussions.

- Protected disclosures:
  - During 2024, 16 external protected disclosures were received by the HPRA as a prescribed person, of which two were transmitted to the Protected Disclosures Commissioner, and two warranted no further follow-up;
  - Nine investigations were opened which involved a breach of legal obligation;
  - 11 open investigations were carried over from the previous year, with 18 investigations closed during 2024;
  - 14 investigations remained open at the end of the calendar year;
  - There were no internal protected disclosures received.

Key outreach and engagement figures	**2024**
Public consultations held: - Proposed regulatory fees for human medicines, compliance activities, blood, tissue establishments, organs and medical devices - Proposed regulatory fees for veterinary medicines - Draft guide for health institutions who manufacture and use in-house in vitro diagnostic medical devices in Ireland	3
Public consultations responded to: - Included Department of Health, Medical Council, HSE, IMVO and EU4Health	6
Events managed by HPRA events teams	5
Freedom of information (FOI) requests	53
Freedom of information requests answered outside the FOI Act	10
Requests received in accordance with the Data Protection Acts	16
Parliamentary questions	30
Queries from Government departments or members of the Oireachtas	257
Complaints	2
Customer service queries	2,217

Organisational Development

The HPRA is committed to maintaining robust corporate functions, systems, and supports that enable us to effectively deliver on our public health mission. As the regulatory and scientific landscape continues to evolve, we are proactively strengthening our organisational capabilities to ensure we remain agile, forward-looking, and well-positioned to meet emerging challenges in our operating environment.

Change Programmes

In 2024, the HPRA launched a series of organisational development change programmes aimed at enhancing operational effectiveness and aligning with our Strategic Plan. These initiatives span both our human and veterinary medicines departments as well as key technology-driven projects designed to modernise systems and improve service delivery.

The programmes are focused on aligning departmental strategies with organisational priorities, streamlining and standardising processes, enhancing efficiency, and optimising resource utilisation. These efforts support our commitment to continuous improvement and ensure we remain responsive to evolving regulatory and organisational needs.

Human Resources and Development

In 2024, the Human Resources and Development (HRD) team played a central role in advancing both operational and strategic priorities across the organisation. Our focus remained on strengthening organisational capability through best-practice HR support, policy guidance, and the delivery of targeted development initiatives. These efforts supported the organisation's ongoing growth, adaptability, and alignment with our People Strategy.

People Strategy

- Implementation of our People Strategy continued for a second year following its launch in 2023. Built around four core pillars – Purpose, Growth, Belonging and Wellbeing – the strategy defines the experience we aim to create for everyone in our organisation. These pillars form the foundation for prioritising initiatives that align with our strategic objectives.

- Throughout 2024, we focused on key areas including leadership development, health and wellbeing, diversity and inclusion, recruitment, embedding HPRA values, and supporting personal and career development. These initiatives are helping to foster a more inclusive, resilient, and purpose-driven workplace, ensuring that our people remain central to everything we do.

Gender Pay Gap

- In 2024, we continued our in-depth analysis of the gender pay gap to better understand its drivers and identify meaningful actions to address any imbalances. We are pleased to report that our gender pay gap shifted from 1.22% in 2023 to -1.91%*.

- Transparency around any gender pay gap is central to our values, and we remain committed to fostering a diverse, equitable and inclusive workplace. Our efforts in this area are ongoing, and we will continue to monitor and refine our approach to ensure long-term progress. Further details are available in the full report on our website.

Employee Experience

- Enhancing the employee experience remains a core priority for the HPRA. In 2024, we sustained the momentum built on the previous year maintaining the significant 10% increase in employee engagement and achieving a further 1% increase. This progress reflects the collective effort of our employees and managers across departments, supported by the HRD team and the HPRA leadership team.

- Central to this achievement was the continued integration of a dedicated employee experience platform, which provided valuable insights into what it means to work at the HPRA. These insights enabled more targeted and responsive actions to support our people and culture.

*This figure was updated in September 2025 to correct a textual error

Wellbeing

- In 2024, the HPRA was successfully reaccredited with the Keep Well Mark, a national workplace wellbeing standard that acknowledges organisations demonstrating excellence in health and wellbeing. First accredited in 2018, we have consistently maintained this recognition through biennial reviews. This year's reaccreditation was particularly significant as it was conducted under a newly updated framework, which introduced two additional assessment areas: 'Talent Support and Development' and 'Inclusion and Belonging'. We are proud to receive the highest award, excellence, in both areas. Furthermore, despite increased expectations across the original assessment categories, we sustained our high level of scoring.

- For the fourth consecutive year, the HPRA was also recognised in the Top 100 Leading in Wellbeing Index by IBEC and Business and Finance. This recognition highlights our continued commitment to embedding best-practice wellbeing initiatives and creating a supportive and inclusive workplace that positively impacts our employees and the broader business community.

Leadership and Employee Capabilities

- In 2024, we continued to build management and employee capabilities through targeted development initiatives aligned with our People Strategy. Our management and new manager training programmes focused on fostering psychological safety for high performance and cultivating a growth mindset across leaders, mangers and their teams.

- Our popular 'Collaboration' and 'Plan, Prioritise, Be Productive' workshops remained in high demand across the organisation and are also embedded as core components of the new manager training programme. In addition, we introduced a 'Leadership Identity' workshop for managers and leaders, aimed at strengthening self-awareness and authentic leadership practices.

- To reinforce our cultural focus on empowerment and innovation, we identified two organisation-wide focus competencies for 2024: 'Leadership and Role Modelling', which encourages leadership behaviours at all levels, and 'Creativity and Innovation', which supports continuous improvement through learning and adaptability. To support development in these areas, we delivered dedicated workshops and released new e-learning resources accessible to all staff.

- Aligned with our core values 'Innovation' and 'Excellence', and our commitment to continuous improvement, we also offered Lean Six Sigma Green and Yellow Belt training in collaboration with the Operational Excellence function.

Public Sector Equality and Human Rights Duty

As part of our ongoing commitment to equality, inclusion, and compliance with Section 42 of the Irish Human Rights and Equality Act 2014, the HPRA conducted a comprehensive assessment in 2024. This work reflects our dedication to embedding human rights and equality principles across all aspects of our organisation.

The key areas of focus included reviewing and updating policies, promoting an inclusive culture, collecting and analysing demographic data, implementing new policies, delivering training, and strengthening transparency through communication and engagement.

A detailed report outlining our findings, actions taken, and future commitments will be published on our website, reinforcing our accountability and continued focus on building a fair and inclusive workplace.

IT Developments

The HPRA's Digital Transformation Strategy (2021-2025) was launched at the beginning of 2021 establishing an application and technology direction to support the organisation in achieving its objectives in the coming years. The strategy focuses on building existing capabilities, while also introducing innovative technologies that will support new ways of working. It integrates a series of objectives to ensure an efficient and secure technology platform and to enhance the efficiency and effectiveness of the organisation.

The strategy is constructed around six core themes:

- Optimising transaction applications: providing efficient core transaction capability to support day to day process;
- Enhancing digital integration: automating the transfer of data between systems and across the organisation boundary without the need for manual intervention;
- Improving data management and decision support: ensuring availability, integrity and security of data to enable efficient organisation processes;
- Enhancing client computing: provide facilities and user productivity applications to enable staff fulfil their roles and collaborate effectively;
- Enhancing technology infrastructure: provide a performant and resilient technology infrastructure and connectivity to distributed workforce;
- Improving governance: provide oversight and control over information technology activities to ensure alignment with the business strategy.

Delivery of the strategy proceeded with a focus on optimising transaction applications, enhancing digital integration and enhancing the technology infrastructure. Consolidation of processes and data onto a core suite of applications progressed, as did enhancing the capabilities of the applications to support improved organisational processes. Work continued to progress on the adoption of the IDMP (Identification of Medicinal Products) data standards in conjunction with other European regulators with the HPRA being a member of the European Commission's UNICOM consortium. Information technology security capabilities and controls continued to be upgraded with a particular focus on enhancing resilience and recovery processes. The project to rebuild the organisation's website progressed with systems and process changes being made to provide the necessary data feeds for the new website.

Operational Excellence and Quality Management

- The HPRA is committed to a culture of continuous improvement and application of its quality management system. In 2024, 11 internal audits were completed with no major concerns identified.

- The quality management team worked closely with departments across the organisation to support various lean improvement projects and the HPRA's Digital Transformation Strategy, as well as the continued implementation of new legislation.

- Considerable progress has been made in advancing operational excellence at the HPRA. In 2024, the launch of the internal Operational Excellence Awards encouraged innovation, generating project submissions from across the organisation. This initiative contributed to the HPRA being shortlisted for two national awards for Innovation in Operations. Additional efforts in this area have included process mapping workshops, expanded Lean Six Sigma training, and the pilot implementation of a structured change control process.

Finance

- The HPRA is committed to the highest standards of corporate governance. During 2024, the financial statements for the previous year were prepared and submitted for audit to the Comptroller and Auditor General and subsequently published in the HPRA's 2023 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.

- The annual review of regulatory fees for 2025, incorporating a public consultation, was completed followed by the publication of the updated fees.

- Two internal audit reviews took place, and reports were issued on corporate governance compliance and payroll.

Energy Usage

- The HPRA, as a public sector body, is required to report annually on its energy usage and actions taken to reduce consumption in accordance with the European Union (Energy Efficiency) Regulations 2014 (S.I. No. 426 of 2014). As an organisation, we use electricity for lighting, air conditioning or heating as required and the provision of hot water. Natural gas is used for central heating. In 2024, the HPRA consumed 496.9 MWh of energy consisting of:
  - 323.3 MWh of electricity;
  - 173.6 MWh of fossil fuels;
  - 0 MWh of renewable fuels.
- According to the Sustainable Energy Authority of Ireland (SEAI) Annual Report 2023 on Public Sector Energy Efficiency Performance, total energy reduction achieved by the HPRA since baseline was 68.4%* exceeding the public sector target of 50% energy efficiency improvement and 51% reduction in energy related greenhouse gas emissions (divided between thermal and electrical use) by 2030.

* Data in the 2024 report should not be compared on a like-for-like basis to the data for previous years due to the impact of COVID-19, and changes in the data source from 2024.

Authority and Committees

The Authority (Board) of the HPRA is appointed by the Minister for Health in accordance with the powers conferred by subsection 2 of section 7 of the Irish Medicines Board Act, 1995. In addition to the Authority, there are three advisory committees: The Advisory Committee for Human Medicines, the Advisory Committee for Veterinary Medicines and the Advisory Committee for Medical Devices.

- The Authority of the HPRA met five times in 2024 and considered a number of strategic matters including the continued supply of medicines to the Irish market, strategic planning, website development, the implementation of new Regulation in the areas of medical devices and veterinary, and financial matters. The latter included monthly management accounts, annual budgets and the financial statements for 2023. The Authority also had five closed sessions in 2024.

- The Authority also reviewed update reports from the Statutory Advisory Committees and the Audit and Risk Committee.

- The number of meetings attended by each Authority member during 2024 was as follows:

Authority Member	Number of meetings held	Number of meetings attended
Mr Michael Donnelly (Chairperson)	5	5
Dr Joe Collins	5	5
Mr David Holohan	5	4
Mr Brian Jones	5	4
Dr Diarmuid Quinlan	4*	4
Prof Richard Reilly	5	4
Prof Sharon O'Kane	5	5
Dr Paula Kilbane	5	4
Dr Fiona Kiernan	5	5
Dr Suzanne Kelly	1*	1

* Number of meetings held during the period the member was on the Authority.

  - The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2024. Further details are provided in the HPRA's Financial Statements;
  - The Advisory Committee for Human Medicines met three times;
  - The Advisory Committee for Veterinary Medicines met twice;
  - The Advisory Committee for Medical Devices met three times;
  - The National Committee for the Protection of Animals Used for Scientific Purposes, a statutory committee providing guidance to the regulator and those working in this area, met twice in 2024.

- Decisions of the Authority:

  The terms of reference of the Authority, which are published on the HPRA website, include an overview of how the Authority operates, an overview of all decisions taken by the Authority and those devolved to the Management Committee.

  The following decisions are reserved functions of the Authority:

  - The Authority takes decisions relating to very significant and serious public and/or animal health matters except in circumstances where a meeting of the Authority cannot be convened, in which case the Management Committee takes the decision and informs the Chairperson at the earliest opportunity and the Authority as soon as is practical.

- The Authority refuses applications, or suspends, revokes or terminates authorisations as set out in legislation except in circumstances where:
  (a) the urgency is such that a meeting of the Authority cannot be convened, or
  (b) the application or authorisation is subject to a binding European decision, or
  (c) the application or authorisation is for a clinical trial or clinical investigation; in which case the Management Committee takes the decision and informs the Authority.
- Through its Audit and Risk Committee, the Authority approves the internal financial controls and the financial audit function and satisfies itself that the financial controls and systems of risk management are robust and defensible. The Authority appoints the internal financial auditor.
- The Authority approves the investment policy, major investments, capital projects and the terms of major contracts.
- Significant acquisitions and the disposal or retirement of assets above a threshold set by the Authority are subject to Authority approval.
- The Authority approves treasury policy and risk management policies. The Authority approves corporate plans as required.
- The Authority approves significant amendments to the pension benefits of the Chief Executive and staff.
- The Authority approves the annual budget, monitors expenditure and supervises the preparation and submission of the annual statutory accounts.
- The Authority makes an annual report on the activities of the HPRA, including a financial statement, to the Minister for Health. This report is then published.
- The Authority selects and appoints the Chief Executive, with the consent of the Minister for Health. The terms of office and the remuneration of the Chief Executive are determined by the Minister for Health, after consultation with the Authority and with the consent of the Minister for Finance. The Authority, through its Performance Review Committee, conducts a process of annual performance appraisal of the Chief Executive. Succession planning for the role of Chief Executive is also undertaken by the Authority.

Financial Statements

for the year ended 31 December 2024

Authority Members and Other Information

		Most recent appt date	*Expiry date*
Authority:	Mr. Michael Donnelly (Chairperson)	19/04/2021	31/12/2025
	Mr. Joe Collins	01/01/2025	27/09/2028
	Mr. David Holohan	27/01/2021	26/01/2026
	Mr. Brian Jones	27/01/2021	26/01/2026
	Dr. Suzanne Kelly	01/11/2024	31/10/2029
	Dr. Fiona Kiernan	12/09/2022	31/12/2026
	Dr. Paula Kilbane	28/06/2021	31/12/2025
	Dr. Sharon O'Kane	15/07/2021	31/12/2025
	Dr. Diarmuid Quinlan	22/05/2024	31/10/2024
	Prof. Richard Reilly	01/01/2025	31/12/2027

All Authority members are appointed by the Minister for Health.

Bankers:
Allied Irish Bank
1-3 Lower Baggot Street
Dublin 2

Bank of Ireland Corporate
2 Burlington Plaza
Burlington Road
Dublin 4

Solicitors:
Addleshaw Goddard
Temple Chambers
3 Burlington Road
Dublin 4

Byrne Wallace
88 Harcourt Street
Dublin 2

Head Office:
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Auditors:
Comptroller and Auditor General
3A Mayor Street Upper
Dublin 1

Governance Statement and Authority Member's Report

Governance

The Health Products Regulatory Authority (the HPRA) was established under the terms of the Irish Medicines Board Act, 1995 (as amended), and is governed by an Authority which was appointed by the Minister for Health. The Authority of the HPRA (the Authority) consists of a chairperson and eight non-executive members. The Authority is accountable to the Minister for Health and is responsible for ensuring good governance and performs this task by setting strategic objectives and targets and taking strategic decisions on all key business issues. The regular day-to-day management, control and direction of the HPRA are the responsibility of the Chief Executive and the Management Committee. The Chief Executive and the Management Committee must follow the broad strategic direction set by the Authority and must ensure that all Authority members have a clear understanding of the key activities and decisions related to the HPRA, and of any significant risks likely to arise. The Chief Executive acts as a direct liaison between the Authority and management of the HPRA.

On 1 July 2014 the organisation changed its name from the Irish Medicines Board, as provided for in Section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013 and SI (205/2014) Health (Pricing and Supply of Medical Goods) Act 2013 (Commencement) order 2014.

Authority Responsibilities

The work and responsibilities of the Authority are set out in the Irish Medicines Board Act, 1995 (as amended), as well as in the 'Terms of Reference and Rules of Procedure' of the HPRA, which also contains the matters specifically reserved for Authority decision. Standing items considered by the Authority include:

- declaration of interests,
- reports from committees,
- financial reports / management accounts,
- performance reports, and
- reserved matters.

The Authority is required by the Irish Medicines Board Act, 1995 to prepare financial statements for each financial year which give a true and fair view of the financial position of the HPRA and of its surplus or deficit for that period.

In preparing those statements the Authority is required to:

- select suitable accounting policies and apply them consistently,
- make judgements and estimates that are reasonable and prudent,
- prepare the financial statements on a going concern basis unless it is inappropriate to presume that the HPRA will continue in existence, and
- state whether applicable accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements.

The Authority is responsible for keeping adequate accounting records which disclose, with reasonable accuracy at any time, the financial position of the HPRA and which enable it to ensure that the financial statements comply with the Irish Medicines Board Act, with accounting standards generally accepted in Ireland and with accounting directions issued by the Minister for Health. The maintenance and integrity of the corporate and financial information on the HPRA's website is the responsibility of the Authority.

The Authority is responsible for approving the annual plan and budget. It is also responsible for safeguarding the assets of the HPRA and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Authority considers that, except for the non-compliance with the requirements of FRS102 in relation to retirement benefits, the financial statements of the HPRA give a true and fair view of the financial performance and the financial position of the HPRA at 31 December 2024.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2024. This committee is responsible for reviewing internal control matters, together with any other issues raised by the external auditors, the Authority or management. The external auditor is invited annually to meet with the audit and risk committee to brief them on the outcome of the external audit, and the audit and risk committee also meets annually with the internal auditor. During 2024, the internal auditor carried out internal audit reviews on corporate governance compliance and payroll. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2024, the finance section of the HPRA continued the process of implementing and reviewing standard operating procedures (SOPs) under the quality management system. This process involved a critical review and analysis of internal controls and processes throughout the section with particular emphasis on risk management. This system now underpins the internal control environment and feeds into the internal audit process and ultimately into the audit and risk committee.

Remuneration Policy - Authority Members and Executive Directors

Remuneration and travel expenses paid to Authority members are disclosed in note 17 to the Financial Statements. The Chairperson receives remuneration as directed by the Minister for Health in accordance with the Irish Medicines Board Act, 1995. Other Authority members receive remuneration under the terms of the Health (Miscellaneous Provisions) Act 2017. All Authority members are entitled to receive travel expenses in accordance with circulars issued by the Department of Health. The Chief Executive is remunerated in accordance with guidelines issued from Government and other Executive Directors are paid in accordance with Department of Health pay scales. The remuneration of the Chief Executive and Executive Directors are disclosed in note 18 to the Financial Statements.

Internal Control

The Authority is responsible for the HPRA's systems of internal control. Such systems can only provide reasonable and not absolute assurance against material misstatement or loss. The systems of internal controls in use in the HPRA are described more fully in the Chairperson's report on pages 86 to 88.

Disclosures Required by Code of Practice for the Governance of State Bodies (2016)

The Authority is responsible for ensuring that the HPRA has complied with the requirements of the Code of Practice for the Governance of State Bodies, as published by the Department of Public Expenditure, National Development Plan Delivery and Reform in August 2016. The following disclosures are required by the Code, and are contained in the notes to the financial statements:

- employee short term benefits breakdown,
- consultancy costs,
- legal costs and settlements,
- travel and subsistence expenditure, and
- hospitality expenditure.

Statement of Compliance

The Authority has adopted the Code of Practice for the Governance of State Bodies (2016) and has put procedures in place to ensure compliance with the Code. The HPRA was in full compliance with the Code of Practice for the Governance of State Bodies for 2024.

Performance Review

The Authority carried out a self-assessment evaluation of its own performance and its committees for the year ended 31 December 2024.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 29 May 2025

Statement on Internal Control

Scope of Responsibility

I, as Chairperson, acknowledge the Authority's responsibility for ensuring that an effective system of internal control is maintained and operated. This responsibility takes account of the requirements of the Code of Practice for the Governance of State Bodies (2016).

Purpose of the System of Internal Control

The system of internal control is designed to manage risk to a tolerable level rather than to eliminate it. The system can therefore only provide reasonable and not absolute assurance that assets are safeguarded, transactions authorised and properly recorded, and that material errors or irregularities are either prevented or detected in a timely way.

The system of internal control, which accords with guidance issued by the Department of Public Expenditure, National Development Plan Delivery and Reform, has been in place in the HPRA for the year ended 31 December 2024 and up to the date of approval of the financial statements.

Capacity to Handle Risk

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2024.

The HPRA has outsourced the internal audit function to an independent professional firm, who conduct a programme of work as agreed with the audit and risk committee. During 2024 two internal audit reviews were conducted.

The HPRA have developed a risk management framework, which sets out its risk appetite, the risk management processes in place and details the roles and responsibilities of staff in relation to risk. This framework has been made available to all staff, who are expected to work within the HPRA's risk management policies, to alert management on emerging risks and control weaknesses, and assume responsibility for risks and controls within their own area of work.

Risk and Control Framework

The HPRA has implemented a risk management system which identifies and reports key risks and the management actions being taken to address, and to the extent possible, to mitigate those risks.

A risk register is in place which identifies the key risks facing the HPRA, and these have been identified, evaluated and graded according to their significance. The register is reviewed and updated by management, considered by the audit and risk committee twice per year and presented to the Authority. The outcome of these assessments is used to plan and allocate resources to ensure risks are managed to an acceptable level.

The risk register details the controls and actions needed to mitigate risks and responsibility for operation of controls assigned to specific staff. I confirm that a control environment containing the following elements is in place:

- procedures for all key business processes have been documented,
- financial responsibilities have been assigned at management level with corresponding accountability,
- there is an appropriate budgeting system with an annual budget, which is kept under review by senior management,
- there are systems aimed at ensuring the security of the information and communication technology systems, and
- there are systems in place to safeguard the assets.

Ongoing Monitoring and Review

Formal procedures have been established for monitoring control processes, and any control deficiencies are communicated to those responsible for taking corrective action, and to management and the Authority, where relevant, in a timely manner. I confirm that the following ongoing monitoring systems are in place:

- key risks and related controls have been identified, and processes have been put in place to monitor the operation of those key controls and report any identified deficiencies,
- reporting arrangements have been established at all levels where responsibility for financial management has been assigned, and
- there are regular reviews by senior management of periodic and annual performance and financial reports, which indicate performance against budgets.

Procurement

I confirm that the HPRA has procedures in place to ensure compliance with current procurement rules and guidelines, and that during 2024 the HPRA complied with those procedures.

Review of Effectiveness

In the post Covid-19 era, the HPRA is operating a hybrid working environment, with a combination of office based and home based days. The controls in place pre-Covid, which continued to apply during the period of remote working, continue to apply during this hybrid working environment.

I confirm that the HPRA has procedures to monitor the effectiveness of its risk management and control procedures. The HPRA's monitoring and review of the effectiveness of the system of internal control is informed by the work of the internal and external auditors, the audit and risk committee which oversees their work, and the senior management within the HPRA, responsible for the development and maintenance of the internal control framework.

I confirm that the Authority conducted an annual review of the effectiveness of the internal controls for 2024. This review was carried out at its meeting on 26 March 2025.

Internal Control Issues

No weaknesses in internal control were identified in relation to 2024 that require disclosure in the financial statements.

Mr. Michael Donnelly
Chairperson

Date: 29 May 2025

Comptroller and Auditor General

Report for presentation to the Houses of the Oireachtas

Qualified opinion on the financial statements

I have audited the financial statements of the Health Products Regulatory Authority (the Authority) for the year ended 31 December 2024 as required under the provisions of section 18 of the Irish Medicines Board Act, 1995. The financial statements have been prepared in accordance with Financial Reporting Standard (FRS) 102 – *The Financial Reporting Standard applicable in the UK and the Republic of Ireland* and comprise

- The statement of income and expenditure and retained revenue reserves
- The statement of financial position
- The statement of cash flows and
- The related notes, including a summary of significant accounting policies.

In my opinion, except for the non-compliance with the requirements of FRS 102 in relation to retirement benefit entitlements referred to below, the financial statements give a true and fair view of the assets, liabilities and financial position of the Authority at 31 December 2024 and of its income and expenditure for 2024 in accordance with FRS 102.

Basis for qualified opinion on financial statements

In compliance with the directions of the Minister for Health, the Authority accounts for the costs of retirement benefit entitlements only as they become payable. This does not comply with FRS 102 which requires that the financial statements recognise the full cost of retirement benefit entitlements earned in the period and the accrued liability at the reporting date. The effect of the non-compliance on the Authority's financial statements for 2024 has not been quantified.

I conducted my audit of the financial statements in accordance with the International Standards on Auditing (ISAs) as promulgated by the International Organisation of Supreme Audit Institutions. My responsibilities under those standards are described in the appendix to this report. I am independent of the Authority and have fulfilled my other ethical responsibilities in accordance with the standards.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Report on information other than the financial statements, and on other matters

The Authority has presented certain other information together with the financial statements. This comprises the annual report, the governance statement and Authority members' report, and the statement on internal control. My responsibilities to report in relation to such information, and on certain other matters upon which I report by exception, are described in the appendix to this report.

I have nothing to report in that regard.

John Crean

For and on behalf of the

Comptroller and Auditor General

9 June 2025

Appendix to the report

Responsibilities of Authority Members

As detailed in the governance statement and Authority members' report, the Authority members are responsible for

- The preparation of annual financial statements in the form prescribed under section 18 of the Irish Medicines Board Act 1995
- Ensuring that the financial statements give a true and fair view in accordance with FRS 102
- Ensuring the regularity of transactions
- Assessing whether the use of the going concern basis of accounting is appropriate, and
- Such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Responsibilities of the Comptroller and Auditor General

I am required under section 18 of the Irish Medicines Board Act 1995 to audit the financial statements of the Authority and to report thereon to the Houses of the Oireachtas.

My objective in carrying out the audit is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement due to fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with the ISAs, I exercise professional judgement and maintain professional scepticism throughout the audit. In doing so,

- I identify and assess the risks of material misstatement of the financial statements whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- I obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal controls.
- I evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures.

- I conclude on the appropriateness of the use of the going concern basis of accounting and, based on the audit evidence obtained, on whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my report. However, future events or conditions may cause the Authority to cease to continue as a going concern.
- I evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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

I report by exception if, in my opinion,

- I have not received all the information and explanations I required for my audit, or
- The accounting records were not sufficient to permit the financial statements to be readily and properly audited, or
- The financial statements are not in agreement with the accounting records.

Information other than the financial statements

My opinion on the financial statements does not cover the other information presented with those statements, and I do not express any form of assurance conclusion thereon.

In connection with my audit of the financial statements, I am required under the ISAs to read the other information presented and, in doing so, consider whether the other information is materially inconsistent with the financial statements or with knowledge obtained during the audit, or if it otherwise appears to be materially misstated. If, based on the work I have performed, I conclude that there is a material misstatement of this other information, I am required to report that fact.

Reporting on other matters

My audit is conducted by reference to the special considerations which attach to State bodies in relation to their management and operation. I report if I identify material matters relating to the manner in which public business has been conducted.

I seek to obtain evidence about the regularity of financial transactions in the course of audit. I report if I identify any material instance where public money has not been applied for the purposes intended or where transactions did not conform to the authorities governing them.

Statement of Income and Expenditure and Retained Revenue Reserves
For the year ended 31 December 2024

	Notes	2024	2023
		€	€
Fee Income	3	**35,861,630**	33,049,885
Department of Health Funding	3	**5,665,000**	5,560,000
Other Income	4	**1,507,055**	1,019,691
		43,033,685	39,629,576
Salaries and Wages	5	**34,476,136**	30,531,250
Other Operating Costs	6	**6,101,162**	6,237,802
Depreciation	2	**1,945,128**	1,581,427
		42,522,426	38,350,479
Surplus for the year before write back of Superannuation contributions		**511,259**	1,279,097
Staff Superannuation Contributions		**768,134**	597,819
Surplus for the year		**1,279,393**	1,876,916
Balance brought forward		**42,172,327**	40,295,411
Balance carried forward	12	**43,451,720**	42,172,327

The Statement of Income and Expenditure and Retained Revenue Reserves includes all gains and losses recognised in the year. The Statement of Cash Flows and the notes on pages 96 - 107 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 29 May 2025

Statement of Financial Position
As at 31 December 2024

	Notes	2024	2023
		€	€
Fixed Assets			
Property, Plant and Equipment	2	**24,746,990**	24,635,448
Current Assets			
Debtors and Prepayments	7	**2,006,105**	1,539,509
Inventory of Stationery		**3,934**	6,148
Cash and Cash Equivalents	9	**3,508,149**	9,254,830
Short Term Deposits	10	**29,187,676**	22,015,208
		34,705,864	32,815,695
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	**16,001,134**	15,110,479
Mortgage	13	**-**	168,337
		16,001,134	15,278,816
Net Current Assets		**18,704,730**	17,536,879
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	**-**	-
NET ASSETS		**43,451,720**	42,172,327
Reserves			
Retained Revenue Reserves	12	**20,178,058**	19,666,799
Superannuation Reserve	12	**23,273,662**	22,505,528
		43,451,720	42,172,327

The Statement of Cash Flows and the notes on pages 96 - 107 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 29 May 2025

Statement of Cash Flows
For the year ended 31 December 2024

	Notes	2024	2023
		€	€
Cash flows from Operating Activities			
Surplus for financial year		**1,279,393**	1,876,916
Depreciation of property, plant and equipment		**1,945,128**	1,581,427
(Profit)/Loss on Disposal of property, plant and equipment		**(50)**	0
(Increase)/Decrease in Debtors		**(466,596)**	504,966
(Increase)/Decrease in Stock		**2,214**	(840)
Increase/(Decrease) in Creditors - amounts falling due within one year		**890,655**	1,816,476
Deposit Interest		**(401,952)**	(120,240)
Bank Interest		**16,473**	21,184
Cash from Operations		**3,265,265**	5,679,889
Bank Interest Paid		**(16,473)**	(21,184)
Net Cash generated from Operating Activities		**3,248,792**	5,658,705
Cash flows from Investing Activities			
Deposit Interest Received		**401,952**	120,240
(Increase)/Decrease in Bank Deposits		**(7,172,468)**	(12,015,208)
Payments to acquire property, plant and equipment		**(2,056,670)**	(1,538,988)
Receipts from sales of property, plant and equipment		**50**	0
Net cash from Investing Activities		**(8,827,136)**	(13,433,956)
Cash flows from Financing Activities			
Repayment of Borrowings		**(168,337)**	(168,337)
Net cash used in Financing Activities		**(168,337)**	(168,337)
Net increase/(decrease) in Cash and Cash Equivalents		**(5,746,681)**	(7,943,588)
Cash and Cash Equivalents at beginning of year		**9,254,830**	17,198,418
Cash and Cash Equivalents at end of year	9	**3,508,149**	9,254,830

Notes to the Financial Statements
For the year ended 31 December 2024

1. Accounting Policies

A. General information

The Health Products Regulatory Authority (HPRA) is a public statutory body established under the Irish Medicines Board Act 1995 (as amended). The principal place of business is at Earlsfort Centre, Earlsfort Terrace, Dublin 2. The Health Products Regulatory Authority is the competent Authority for the regulation of medicines, medical devices and other health products in Ireland.

B. Compliance with FRS 102

The financial statements have been prepared in compliance with the applicable legislation, and with FRS 102 (the Financial Reporting Standard applicable in the UK and the Republic of Ireland), issued by the Financial Reporting Council in the UK, as modified by the directions of the Minister for Health in relation to superannuation.

In compliance with the directions of the Minister for Health, HPRA accounts for the costs of superannuation entitlements only as they become payable (see K). This basis of accounting does not comply with FRS102, which requires such costs to be recognised in the year in which the entitlement is earned.

On the advice of its solicitors, the HPRA is not disclosing the specific amounts of the legal provisions provided for by it, as disclosure of such amounts might prejudice seriously its position in relation to disputes with other parties on the subject matter of the provision.

In all other respects, the financial statements comply with FRS 102.

C. Basis of preparation

The financial statements have been prepared under the historical cost convention. The following accounting policies have been applied consistently in dealing with items which are considered material in relation to the Health Products Regulatory Authority's financial statements.

D. Critical accounting estimates and judgements

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the amounts reported for assets and liabilities as at the reporting date and the amounts reported for revenues and expenses during the year. However, the nature of estimation means that actual outcomes could differ from those estimates. The following may involve a higher degree of judgement and complexity:

(a) Provisions

Provisions for legal obligations which it knows to be outstanding at the period-end date. These provisions are generally made based on historical or other pertinent information, adjusted for recent trends where relevant. However, they are estimates of the financial costs of events that may not occur for some years. As a result of this and the level of uncertainty attaching to the final outcomes, the actual outturn may differ significantly from that estimated.

(b) Bad and Doubtful Debts

The HPRA makes an estimate of the recoverable value of trade and other receivables. The HPRA uses estimates based on historical experience in determining the level of bad debts, which the Authority believes will not be collected. These estimates include such factors as the current credit rating, the ageing profile, historical experience of the particular trade receivable and objective evidence of impairment of the asset. Any significant reduction in the level of bad debt provision would have a positive impact on the annual surplus/deficit. The level of provisioning required is reviewed on an on-going basis and has been disclosed in the notes to the financial statements.

E. Revenue recognition

Revenue is measured at the fair value of the consideration received.

- In the case of applications for marketing authorisations (new applications, variations to existing authorisations, or transfers) and clinical trial applications, income is recognised on a straight line basis over the specified timeline for the processing of the application by the Authority.
- In the case of wholesale and manufacturing licences and maintenance of marketing authorisations, fees are payable annually and a full year's income is accrued in each financial year.

F. Expenditure recognition

Expenditure is recognised in the financial statements on an accruals basis.

G. Reporting currency and currency translation

The financial statements are prepared in euros. Transactions in currencies other than euro are recorded at the rates ruling at the date of the transactions or at a contracted date. Monetary assets and liabilities are translated into euro at the reporting date or at a contracted date. Exchange differences are dealt with in the statement of income and expenditure and retained revenue reserves.

H. Property, plant and equipment

Plant and equipment excluding Premises

Plant and equipment excluding premises are stated at cost less accumulated depreciation.

Depreciation is calculated in order to write off the cost of property, plant and equipment to their estimated residual values over their estimated useful lives by equal annual instalments.

The estimated useful lives of property, plant and equipment by reference to which depreciation has been calculated are as follows:

Fixtures and Fittings :	5 years
Computer Equipment :	3 years
Improvements to Premises :	10 years
Premises :	50 years

Premises

The HPRA purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 on 22 December 2004. The value capitalised was equal to the purchase price plus those costs directly attributable to bringing the asset into use.

In 2023 the HPRA Authority decided to commence charging depreciation on premises, over a period of 50 years.

I. Taxation

The HPRA is exempt from liability to Corporation Tax under Section 227 of the Taxes Consolidation Act, 1997.

J. Debtors

Known bad debts are written off and specific provision is made for any amount the collection of which is considered doubtful.

K. Superannuation

The superannuation scheme operated by the HPRA is in accordance with the Local Government (Superannuation Revision) (Consolidation) Scheme, 1986. It is an unfunded statutory scheme and benefits are met from current income as they arise.

The scheme is a defined benefit scheme for employees. No provision has been made in respect of benefits payable. Pension payments under the scheme are charged to the statement of income and expenditure when paid. Contributions from employees who are members of the scheme are credited to the statement of income and expenditure when received. The surplus/(deficit) for the year is shown both before and after superannuation deductions.

HPRA also operate the Single Public Service Pension Scheme. All new entrants into the public sector with effect from 1 January 2013 are members of this scheme, where all employee pension deductions are paid to the Department of Public Expenditure, National Development Plan Delivery and Reform.

By direction of the Minister for Health, no provision has been made in respect of benefits payable in future years in relation to the Local Government (Superannuation Revision) (Consolidation) Scheme 1986 or the Single Public Service Pension Scheme.

In order to help meet the cost of benefits payable in future years, reserves have been split between retained reserves and superannuation reserves, which consist of employee superannuation contributions. Since 2018 the HPRA Audit and Risk Committee have also recommended further transfers from retained revenue reserves to the superannuation reserve, as a result of a number of recent and upcoming retirements, where the costs are quite significant. This split is shown in note 12 - Movement on Income and Expenditure Reserves.

L. Provisions

A provision is recognised when the HPRA has a present obligation as a result of a past event, it is probable that this will be settled at a cost to the HPRA and a reliable estimate can be made of the amount of the obligation.

M. Library

No value has been placed on the books, audio-visual resources and electronic databases in the library. Expenditure on these items is written off in the year in which it is incurred.

N. Leases

All leases are treated as operating leases and the rentals thereunder are charged to the Statement of Income and Expenditure and Retained Revenue Reserves on a straight line basis over the lease period.

O. Loans

Loans are recognised initially at the transaction price (present value of cash payable, including transaction costs). Loans are subsequently stated at amortised costs. Interest expense is recognised on the basis of the effective interest method and is included in finance costs.

Loans are classified as current liabilities unless there is a right to defer settlement of the loan for at least 12 months from the reporting date.

2. Property, plant and equipment	Fixtures and Fittings	Computer Equipment	Leasehold Improvements	Improvements To Premises	Premises	Total
	€	€	€	€	€	€
Cost						
Balance as at 1 January 2024	**1,357,921**	**19,288,110**	**866,055**	**4,728,911**	**23,156,037**	**49,397,034**
Additions for the year	**59,035**	**1,854,625**	**-**	**143,010**	**-**	**2,056,670**
Disposals for the year	**(91,846)**	**(984)**	**-**	**-**	**-**	**(92,830)**
As at 31 December 2024	**1,325,110**	**21,141,751**	**866,055**	**4,871,921**	**23,156,037**	**51,360,874**
Depreciation						
Balance as at 1 January 2024	**1,293,365**	**17,973,663**	**674,991**	**4,436,446**	**383,121**	**24,761,586**
Charge for the year	**37,544**	**1,432,399**	**36,361**	**55,703**	**383,121**	**1,945,128**
Disposals for the year	**(91,846)**	**(984)**	**-**	**-**	**-**	**(92,830)**
As at 31 December 2024	**1,239,063**	**19,405,078**	**711,352**	**4,492,149**	**766,242**	**26,613,884**
Net Book value at 31 December 2024	**86,047**	**1,736,673**	**154,703**	**379,772**	**22,389,795**	**24,746,990**
Net Book value at 1 January 2024	**64,556**	**1,314,447**	**191,064**	**292,465**	**22,772,916**	**24,635,448**

3. Income	2024	2023
	€	€
Fee Income		
Human Medicines - National Fees	**12,287,578**	11,669,627
Human Medicines - Centralised Fees	**8,362,945**	7,280,716
Veterinary Sciences - National Fees	**3,691,575**	3,605,164
Veterinary Sciences - Centralised Fees	**1,178,909**	989,280
Compliance Department	**7,223,358**	6,581,665
Medical Devices	**3,395,143**	3,177,401
	36,139,508	33,303,853
Movement in deferred revenue	**(277,878)**	(253,968)
	35,861,630	33,049,885
Dept Of Health Funding (Vote 38 Subhead E1)	**5,665,000**	5,560,000
Other Income (Note 4)	**1,507,055**	1,019,691
Total Income	**43,033,685**	39,629,576

Fees received by the Authority under Section 13 of the Irish Medicines Board Act 1995 totalling €21,736,654 in 2024, shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure, National Development Plan Delivery and Reform directs.

4. Other Income	2024	2023
	€	€
Bank Interest	**401,952**	120,240
Joint Action Income	**379,893**	273,812
Conference Income	**9,460**	-
IT Income	**715,700**	625,639
Gain On Disposal Of Fixed Assets	**50**	-
	1,507,055	1,019,691

5. Salaries and Wages	2024	2023
	€	€
Basic Pay	**27,591,972**	24,517,352
Overtime	**418**	125
Allowances	**132,852**	152,589
Staff Short Term Benefits	**27,725,242**	24,670,066
Retirement Benefit Costs	**1,849,107**	1,550,042
Employer's Contribution to Social Welfare	**2,854,617**	2,541,435
Employer's Contribution to Single Scheme Pension	**2,047,170**	1,769,707
	34,476,136	30,531,250

The average number of staff employed during the year was 406 (2023 - 383).
Payroll numbers at 31 December 2024 can be analysed across the following departments :

Chief Executive	**16**	11
Compliance	**82**	76
Finance, Corporate & International	**32**	31
Human Products Authorisation & Registration	**115**	118
Human Products Monitoring	**41**	43
Human Resources & Development	**11**	11
IT & Business Services	**21**	19
Medical Devices	**53**	48
Organisational Excellence & Quality	**-**	6
Veterinary Sciences	**38**	35
Staff	**409**	398
Authority Members	**8**	8
Pensioners	**65**	62
	482	468

No termination or severance payments were made during the year.

Additional superannuation contributions for Public Servants of €901,309 were deducted from staff during the year and paid over to the Department of Health.

Pension deductions for Public Servants who are members of the Single Public Service Pension Scheme of €747,182 were deducted from staff during the year and paid over to the Department of Public Expenditure, National Development Plan Delivery and Reform. In agreement with our parent department and DPENDPDR, the HPRA have also paid over Single Scheme employer contributions since January 2019 for employees not employed in exchequer funded areas.

Employee's short term benefits are categorised into the following bands:

	2024	2023
Salary Band		
€0 to €60,000	**203**	207
€60,001 to €70,000	**33**	40
€70,001 to €80,000	**62**	61
€80,001 to €90,000	**33**	18
€90,001 to €100,000	**16**	23
€100,001 to €110,000	**18**	14
€110,001 to €120,000	**25**	23
€120,001 to €130,000	**8**	5
€130,001 to €140,000	**6**	5
€140,001 to €150,000	**4**	1
€150,001 to €160,000	**-**	-
€160,001 to €170,000	**-**	-
€170,001 to €180,000	**-**	1
€180,001 to €190,000	**1**	-
	409	398
Average Salary	**€70K**	€60K

Higher salaries relate primarily to scientific and other professional staff e.g. clinicians, pharmacists, veterinarians, lawyers etc and are in accordance with Department of Health salary scales.

For the purposes of this disclosure, short-term employee benefits in relation to services rendered during the reporting period include salary, overtime, allowances and other payments made on behalf of the employee, but exclude employer's PRSI.

6. Operating Costs	2024	2023
	€	€
Accommodation Costs	**1,918,602**	2,348,359
Travel, Representation and Training	**825,876**	915,362
Bank Charges and Interest	**21,978**	26,130
Legal Fees	**104,742**	135,088
Audit Fees (External and Internal)	**38,307**	44,028
Stationery, Publications, Postage and Communications	**300,144**	321,713
Consultancy	**590,402**	288,204
Sampling and Analysis	**255,039**	249,234
IT Costs	**1,786,142**	1,643,778
Storage Costs	**126,751**	180,837
Telephone and Telecommunications	**30,684**	79,734
Movement on Bad Debt Provision	**102,495**	5,335
	6,101,162	6,237,802

Travel costs include an amount of €38,868 related to hospitality and staff wellbeing, and an amount of €454,500 related to travel and subsistence, of which €226,628 is national and €227,872 is foreign.

No costs were incurred in relation to client hospitality.

Legal fees are in relation to ongoing legal proceedings, and do not include any amounts in relation to conciliation, arbitration or settlement payments.

Consultancy costs comprise €146,461 related to public relations/marketing, €52,551 related to human resources/ pensions and €391,390 related to other.

7. Debtors (all due within one year)	2024	2023
	€	€
Trade Debtors	**1,449,361**	1,337,000
Prepayments	**427,374**	86,372
Other Debtors	**129,370**	116,137
	2,006,105	1,539,509

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)	2024	2023
	€	€
Trade Creditors	**387,334**	363,009
Credit Balances on Debtor Accounts	**5,371,858**	5,421,998
Accruals	**7,186,127**	6,680,240
Deferred Revenue	**2,032,669**	1,754,792
Revenue Commissioners	**1,023,146**	890,440
	16,001,134	15,110,479

9. Cash and Cash Equivalents	2024	2023
	€	€
Cash at Bank and in Hand	**2,375,752**	3,187,595
Demand Deposits (Convertible to Cash on Demand)	**1,132,397**	6,067,235
	3,508,149	9,254,830

10. Short Term Deposits	2024	2023
	€	€
Short Term Deposits (not immediately convertible to cash)	**29,187,676**	22,015,208
	29,187,676	22,015,208

11. Administration Expenses	2024	2023
	€	€
Surplus for the year was calculated having charged : -		
Auditor's Remuneration	**26,600**	24,200

12. Movement on Income and Expenditure Reserves	As At 01/01/2024	Income & Expenditure	Transfer To Superann Reserve	As At 31/12/2024
	€	€	€	€
Retained Revenue Reserves	**19,666,799**	**511,259**	**-**	**20,178,058**
Superannuation Reserve	**22,505,528**	**768,134**	**-**	**23,273,662**
	42,172,327	**1,279,393**	**-**	**43,451,720**

13. Long Term Liabilities

Mortgage

On 22 December 2004 the HPRA purchased its premises at Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2. The purchase was financed by way of a mortgage, secured on the premises of €20,400,000 over 20 years from Bank of Ireland Corporate Lending. The HPRA is committed to making the following capital repayments on its mortgage :

	2024	2023
	€	€
- within one year	**-**	168,337
- between one and five years	**-**	-
- after five years	**-**	-
	-	168,337

On 30 December 2020 the HPRA made a partial redemption of its mortgage with Bank of Ireland, paying €2,500,000 off the outstanding balance.

The HPRA's final capital repayment on the mortgage was made on 22 December 2024.

14. Interest Rate Exposure

As the mortgage is now finished, the Authority has no interest rate exposure.

15. Financial Commitments

Accommodation Costs (Note 6) includes expenditure of €724,491 in relation to operating leases.

On 12 May 2022 the HPRA signed a lease renewal in respect of the 5th floor, 6 Earlsfort Terrace, Dublin 2. This renewal will run for 3 years to 11 May 2025.

	2024	2023
	€	€
The amounts due under this lease are as follows:		
- within one year	**128,173**	353,070
- between one and five years	**-**	128,173
- after five years	**-**	-
	128,173	481,243

On 11 June 2019 the HPRA signed a leasehold interest in respect of the 4th floor, 6 Earlsfort Terrace, Dublin 2. The lease included a 7 month rent free period to 10 January 2020.

At 31 December 2024 this lease had 9 years and 5.5 months remaining.

	2024	2023
	€	€
The amounts due under this lease are as follows:		
- within one year	**371,421**	371,421
- between one and five years	**1,485,683**	1,485,683
- after five years	**1,655,917**	2,027,338
	3,513,021	3,884,442

16. Capital Commitments

	2024	2023
	€	€
Contracted For (Contract Signed)	**942,750**	127,367
Contracted For (Contract Not Signed)	**-**	789,702
	942,750	917,069

17. Authority Remuneration	Fees	Expenses
	€	€
Michael Donnelly (Chairperson)	**11,970**	**-**
Joe Collins	**7,695**	**2,806**
David Holohan	**7,695**	**-**
Brian Jones	**7,695**	**2,045**
Suzanne Kelly	**1,283**	**-**
Fiona Kiernan	**7,695**	**-**
Paula Kilbane	**7,695**	**18**
Sharon O'Kane	**7,695**	**-**
Diarmuid Quinlan	**6,413**	**-**
Richard Reilly	**-**	**-**
	65,835	**4,869**

Under the 'one person one salary' principle of the Health (Miscellaneous Provisions) Act 2017, one member of the HPRA Authority does not receive a fee for their role as an Authority member.

18. Key Management Personnel Remuneration	2024	2023
	€	€
Chief Executive	**184,552**	176,435
Senior Management	**1,102,935**	1,051,279
	1,287,487	1,227,714

All payments to key management personnel were in respect of salaries and short term employee benefits. No post-employment benefits or termination benefits were paid.

The Chief Executive's and senior management's pension entitlements do not extend beyond the standard entitlements in the model public sector defined benefit superannuation scheme.

Notes to the Financial Statements
For the year ended 31 December 2024

19. Related Party Transactions

The HPRA adopts procedures in accordance with the guidelines issued by the Department of Public Expenditure, National Development Plan Delivery and Reform (DPENDPDR) covering the personal interests of Authority members. A register of such interests is maintained. In addition to the DPENDPDR guidelines, as a regulator the HPRA has strict conflict of interest and disclosure requirements in relation to any interactions with a regulated body, which are updated annually. There have been no transactions with related parties which require disclosure under Financial Reporting Standard 102.

20. Prompt Payment Of Accounts

The Health Products Regulatory Authority (HPRA) confirms that it is complying with EU law in relation to prompt payment of accounts.

21. Exchange Rates

The exchange rates used in preparing these financial statements were as follows : -

2024 €1 = STG £0.82886

2023 €1 = STG £0.86680

22. Provisions

The HPRA has been notified of a number of legal proceedings or potential proceedings. The Authority has provided in full for its 'best estimate' of the expenditure it is likely to incur in relation to those cases. On the advice of its solicitors, the HPRA is not disclosing the specific amounts of the legal provisions provided for by it, as disclosure of such amounts might prejudice seriously its position in relation to disputes with other parties on the subject matter of the provision.

23. Going Concern

The HPRA has a reasonable expectation, at the time of approving the financial statements, that the HPRA has adequate resources to continue its operations. For this reason, the HPRA continues to adopt the going concern basis in preparing the financial statements.

24. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 29 May 2025.

Appendix 1
2024 Committee Members

HPRA Leadership Team

Dr Lorraine Nolan, Chief Executive

Ms Rita Purcell, Deputy Chief Executive

Dr Gabriel Beechinor, Director of Veterinary Sciences

Ms Sinead Curran, Director of Human Products Monitoring

Mr Sean d'Art, Director of ICT and Business Services

Dr Niall MacAleenan, Director of Medical Devices

Ms Elizabeth Stuart, Director Human Resources and Development

Ms Grainne Power, Director of Compliance

Dr Finnuala Lonsdale, Director of Human Products Authorisation and Registration

Authority (Board)

Mr Michael Donnelly – Chairperson

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

Dr Paula Kilbane

Prof Sharon O'Kane

Dr Diarmuid Quinlan *(Term ended October 2024)*

Prof Richard Reilly

Dr Fiona Kiernan

Dr Suzanne Kelly *(Appointed November 2024)*

Audit Committee

Mr David Holohan – Chair

Mr Brian Jones

Prof Sharon O'Kane

Advisory Committee for Human Medicines

Dr Diarmuid Quinlan – Chair *(Term ended October 2024)*

Dr Suzanne Kelly *(Appointed November 2024)*

Prof Brian Cleary

Prof Desmond Corrigan *(Resigned April 2024)*

Prof Paul Gallagher

Ms Fionnuala King

Prof Fionnuala Ní Ainle

Dr Brian O'Connell *(Resigned April 2024)*

Ms Margaret O'Doherty

Dr Michael McCarthy *(Appointed March 2024)*

Ms Lorraine Schwanberg *(Appointed March 2024)*

Professor Peter Greally *(Appointed March 2024)*

Advisory Committee for Veterinary Medicines

Dr Joe Collins – Chair

Dr Patrick Paul Corkery

Dr Abina Crean

Dr Caroline Garvan

Dr John Gilmore

Dr David Graham

Dr Andrew Hillan

Dr Orla Keane

Dr Edward Malone

Dr Bryan Markey

Dr Kevin Murtagh *(Appointed January 2024)*

Dr Emer O'Reilly *(Appointed January 2024)*

Advisory Committee for Medical Devices

Prof Richard Reilly – Chair

Prof Robert Byrne

Dr Ger Flynn

Dr Vida Hamilton

Dr Tanya Mulcahy

Dr Fergal McCaffrey

Ms Margaret O'Donnell *(Resigned February 2024)*

Prof Pat Twomey *(Resigned May 2024)*

Appendix 2
Presentations 2024

Educational / Professional Development Presentations and Training

Institution / Organiser	Course / Subject	Presentation Title
Athlone Technical University	MSc in MedTech Reg Affairs	Clinical Evaluation of Medical Devices
Trinity College Dublin	MSc Clinical Chemistry	Medical Device Management - Regulatory Perspective
Trinity College Dublin	MSc Medical Device Regulatory Affairs	Regulatory policy, a HPRA perspective
Atlantic Technological University	Lecture to veterinary nursing students	Regulation of veterinary medicines in Ireland
Technological University Dublin	MSc Transfusion Transplantation Science Specialist Module	European and National Legislation on Substances of Human Origin: The HPRA's Perspective
UCD	Nurse and midwife prescribing course	The Role of the HPRA & Safety Monitoring of Medicines
RCSI	Nurse and midwife prescribing course	The Role of the HPRA & Safety Monitoring of Medicines

Regulatory Presentations

Event / Organiser	Presentation Title
Global Access: Irish MedTech, Galway	Clinical Investigations in Ireland: Snapshot of activity, supports and developments
RAPS European Clinical, Risk and Post market Surveillance Conference, Barcelona	Clinical Evaluation of High-Risk Implantable Devices: current state of play, including paediatric devices
EMA webinar on Orphan Medical Devices	Clinical Evaluation of Orphan Medical Devices
MedTech Forum, Vienna	Global Clinical evidence: challenges and opportunities of RWE sources
HRB NCTO International Clinical Trials Day, UCD	Clinical Trials Landscape for Medicines and Devices In Ireland: The Regulators Perspective
European Society of Cardiology, Cardiovascular Roundtable, Brussels	Criteria for Orphan Device Status
European Society of Cardiology, Cardiovascular Roundtable, Brussels	Clinical Evaluation of Orphan Devices
CORE-MD Final Conference: "Regulatory science for high-risk medical devices: CORE–MD and beyond, Brussels	Global regulatory convergence – priorities for development
DIA Europe, Brussels	COMBINE: mapping EU landscape
GIRP - European Healthcare Distribution Association	Windsor Framework - How to Ensure EU and UK Regulation Work in Harmony
TCD	Common "quality" Deficiencies in MA Applications - An Agency Perspective
BioPharmChem	Common Deficiencies in Variations
BioPharmChem	Msc In Pharmaceutical Manufacturing technology
CMC Strategy Forum Europe	Navigating the Evolving ICH Regulatory Landscape: A Regulator's Perspective
CMC Strategy Forum Europe	Rethinking Biosimilar Approval: A Future Without Phase 3 Trials?
Meeting with Revenue Customs re 'Precursor Control'	HPRA's role in control of Precursor Chemicals
BioPharmaChem Skillnet	HPRA GMP Webinar
Hospital Exemption Workshop, Maynooth University	ATMP's: Hospital Exemption Route: Regulatory Context
SSPC Annual Symposium	Supporting Innovation: A Regulatory focus

Event / Organiser	Presentation Title
Military Police Drug Investigator Course Defence Forces Military Police	HPRA enforcement activities
Officers of Revenues Customs Service Information Day Officers of Revenues Customs Service	HPRA enforcement activities
Officers of Revenues Customs Service Port Training services Officers of Revenues Customs Service	HPRA enforcement activities
Revenues Customs Service Management team	HPRA enforcement activities
Irish Institute of Pharmacy (IIOP)	Medicine Shortages: An update on the multistakeholder framework
Pharmaceuticals Managers Institute	Medicine Shortages: An update on the multi-stakeholder framework
NCCP SunSmart Campaign	HPRA Sunscreen Presentation
NCCP	HPRA Sunscreen Presentation
St John's College - The role of the HPRA in licensing veterinary medicines in Ireland should be in a seperate line	The role of the HPRA in licensing veterinary medicines in Ireland
Veterinary Ireland, One Health, One Welfare	One health in action: HPRA role in safeguarding veterinary medicines and future challenges
Veterinary Ireland, Annual General meeting and conference 2024	Navigating Regulation 2019/6; Balancing marketing authorisations with veterinary practice realities
EMA / EU Commission	Sterilisation by heat and steam
QP Forum Organising Committee	HPRA Update
Biopharmachem	Regulatory Update
EMA	Sterilisation as a filtration method
Pharmig Annual Conference 2024, Pharmig (Pharmaceutical Microbiology Organisation)	Sterilisation
Parenteral Drug Association (PDA)	Two years on Progress and Insights on the Application of Annex 1
International Society for Pharmaceutical Engineering (ISPE) Annual Conference	Supply chain of medicines a regulators perspective

Event / Organiser	Presentation Title
International Society for Pharmaceutical Engineering (ISPE)	A regulator's perspective on revision of Annex 1 and impact on Irish Industry
International Society for Pharmaceutical Engineering (ISPE)	A regulator's perspective on GMP for computerised systems and opportunities in manufacturing
PIC/s	Inspection experience: MAH planning on implementing AI system for PV activity
HPRA Compliance Meeting	National Clinical Trial Office - Quality Working Group Compliance Meeting
HPRA & Bio Pharma Chem Skillnet	Good Distribution Practice (GDP) in GMP
LAST Ireland Laboratory Animal Science Training Courses	Implementation of scientific animal protection legislation in Ireland
Trinity College Dublin CMU Stakeholder workshop	HPRA Role in the implementation of the SAP legislation
Veterinary Ireland Future of Veterinary - One Health, One Welfare 2024 -	HPRA Role in Promoting the 3Rs and Culture of Care in Research
TOPRA Ireland, hosted at HPRA Office	Clinical Trials in Ireland 2024: HPRA Perspective
TOPRA /EU, London	The SmPC: Regulator's Perspective
TOPRA Ireland, hosted at HPRA Office	EU Legislative Reform Package in a Nutshell

Appendix 3
Publications and Articles 2024

Drug Safety Newsletters

Edition	Articles
April 2024 115th Edition	• Valproate (Epilim): New precautionary measures regarding the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the three months before conception • NSAIDs: Updated recommendations on the use of non-steroidal anti-inflammatory drugs (NSAIDs) during pregnancy • Cystic Fibrosis transmembrane conductance regulators (CFTRs): New warning on the risk of depression and related events associated with Kalydeco, Orkambi, Symkevi and Kaftrio • Product information updates recommended by the EMA's Pharmacovigilance Risk assessment Committee (PRAC)
September 2024 116th Edition	• Chlorhexidine: Inadvertent ocular exposure during surgical site preparation • Availability of Educational Materials for Valproate (Epilim) and Topiramate (Topamax) • The Importance of Reports of Suspected Adverse Reactions to Pharmacovigilance
November 2024 117th Edition	• Fluconazole: Update on pregnancy outcomes following use and new advice for women of childbearing potential • Finasteride and dutasteride: Commencement of EU review regarding association with suicidal ideation and behaviours • Omega-3-acid ethyl ester medicines: Dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or risk factors • Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). (Prampexole, Rotigotine, and Paxlovid)

Human Medicines Safety Articles – External Publications

Month	Publication	Topic
January 2024	IMF	Topiramate: Introduction of a pregnancy prevention programme and new restrictions on use
Jan/Feb 2024	MIMS	New warning on the risk of depression and related events associated with Kalydeco, Orkambi, Symkevi and Kaftrio
April 2024	MIMS	Valproate (Epilim ▼): New precautionary measures regarding the potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the three months before conception
June/July 2024	MIMS	Adverse Reaction Reporting - Reminder
June 2024	IMF	Updated Recommendations on the Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) During Pregnancy
September 2024	MIMS	Adverse Reaction Reporting - Reminder
October 2024	MIMS	Optimising the safe and effective use of medicines in clinical practice through proactive risk management
November 2024	MIMS	Ustekinumab: Warning regarding lupus-related conditions and updated advice regarding infections
December 2024	MIMS	Fluconazole: Update on pregnancy outcomes following use and new advice for women of childbearing potential

Veterinary Medicines Articles – External Publications

Title	Date	Publication
Update on changes in the regulatory framework for antimicrobials	January 2024	It is your Field
Safeguarding availability of VMPs	March 2024	It is your Field
Leadership in regulating veterinary medicines	July 2024	It is your Field
Reducing antibiotic use in Ireland: Are we there yet?	August 2024	Veterinary Ireland Journal
The role of Pharmacovigilance in veterinary medicine	September 2024	It is your Field

Appendix 4

Standing Committees / Working Groups Participation

Committee/Working Group	Organisation	Meetings in 2024
Quality and Safety Advisory Committee	CAI / RCPI	4
Controlled Drugs Cross Border Group	Care Quality Commission (UK)	2
National Clinical Trial Oversight Group	Ministerial Taskforce	5
Counterfeiting of Medical Products (CMED)	Council of Europe	1
CER Directive transposition meeting	Office Of Emergency Planning	3
CER Information Session in NECC	Office Of Emergency Planning	1
Market Surveillance Forum	Department of Enterprise, Trade and Employment	4
Meeting on proposals 779 and 783 One Substance, One Assessment	Department of Enterprise, Trade and Employment	1
CER Directive	Department of Health	3
Early Warning and Emerging Trends Group	Department of Health	4
National Valproate Stakeholder Group	Department of Health	2
Pharmaceutical Strategy Working Group	Department of Health	3
Medicines Criticality Assessment Group	Department of Health / HSE	14
Development of Implementing acts on Good Manufacturing Practices (Veterinary medicinal products (VMPs) and API used in VMPs)	European Commission	4
SoHO Inspection Experts Subgroup (in person)	European Commission	1

Committee/Working Group	Organisation	Meetings in 2024
DoH/ ODTI /HPRA Tripartite meeting	Department of Health	1
Extended Producer Responsibility (EPR) scheme sub-group meeting	Department of Housing, Local Government and Heritage	1
Committee for Cosmetics and Consumer Health	EDQM	1
European Network of Official Cosmetics Control Laboratories (OCCL)	EDQM	2
OMCL Network General Annual Meeting	EDQM	1
PAT Working Party	EDQM	1
Monthly API Telecon with EDQM and other authorities	EDQM	6
Biological Working Party	EMA	11
Biosimilar Working Party	EMA	8
Committee for Advanced Therapies (CAT)	EMA	11
Committee for Medicinal Products for Human Use (CHMP) - Plenary	EMA	11
Committee for Medicinal Products for Human Use (CHMP) - Preparatory and Organisational Matters (PROM)	EMA	11
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee on Herbal Medicinal Products (HMPC)	EMA	5
EEA Rapid Alert Network meeting	EMA	1
Efficacy Working Party - Veterinary	EMA	3
Emergency Task Force (ETF)	EMA	44
European IT Director's Meeting	EMA	2
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	EMA	8
European Sales and Use of Antimicrobials for Veterinary Medicine Working Group	EMA	3
Good Clinical Practice (GCP) Inspectors' Working Group	EMA	5
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group	EMA	4

Committee/Working Group	Organisation	Meetings in 2024
IWG GDP drafting group	EMA	1
Infectious Diseases Working Party	EMA	11
Immunologicals Working Pary (vet)	EMA	2
Joint GMDP-IWG/QWP/BWP Meeting	EMA	1
Management Board	EMA	4
Medicine Shortages Single Point of Contact Working Party	EMA	13
Methodology Working Party Modelling and Simulation Operational Expert Group	EMA	11
Network ICT Advisory Committee	EMA	6
Non-Clinical Working Party	EMA	11
Paediatric Committee (PDCO)	EMA	11
Pharmacovigilance (PV) Inspectors' Working Group (Human and Veterinary)	EMA	4
Pharmacovigilance Business Team	EMA	4
Pharmacovigilance Risk Assessment Committee (PRAC) – Plenary	EMA	11
PRAC Impact Group	EMA	1
Pharmacovigilance Working Party – Veterinary	EMA	11
Quality Review of Documents Working Groups	EMA	3
Quality Working Party	EMA	11
Safe-CT Steering Committee Meeting	EMA	4
Safety Working Party – Veterinary	EMA	3
Scientific Advice Working Party – Human	EMA	11
Scientific Advice Working Party – Veterinary	EMA	11
Signal Management Review Technical (SMART) Working Group: Methods	EMA	4
Signal Management Review Technical (SMART) Working Group: Processes	EMA	2
Vaccines Working Party	EMA	8
Multi-stakeholder workshop on GLP-1 Receptor Agonists	EMA	1
Quality Innovation Group (QIG)	EMA	18

Committee/Working Group	Organisation	Meetings in 2024
Joint GCP IWG / CMDh Working Party	EMA / HMA	3
National Persistent Organic Pollutants Forum	Environmental Protection Agency	1
CHESSMEN Joint Action	EU Member State Consortium	13
40th Meeting of the Expert Group on the Delegated Act on Safety Features for Medicinal Products for Human Use	EU COM/EMA/EU Member States	1
Clinical Trials Coordination and Advisory Group (CTAG)	European Commission	8
EU4H11 Project Working Group (Medicines)	European Commission	5
Group of Experts on Drug Precursors	European Commission	1
Expert Sub-Group on Vigilance for Blood, Tissues and Cells, and Organs (VES)	European Commission	5
Joint Action – GAPP PRO	European Commission	1
Joint Action on Market Surveillance (JAMS 2.0) medical devices	HaDEA funded	47
MDCG – Annex XVI	European Commission	2
MDCG – Borderline and Classification	European Commission	1
MDCG – Clinical Investigation and Evaluation (CIE)	European Commission	2
MDCG – Eudamed	European Commission	4
MDCG – In Vitro Diagnostic (IVD)	European Commission	2
MDCG – International Matters	European Commission	1
MDCG – Market Surveillance	European Commission	1
MDCG – New Technologies	European Commission	2
MDCG – Notified Body Oversight (NBO)	European Commission	2

Committee/Working Group	Organisation	Meetings in 2024
MDCG – Orphan Device Task Force	European Commission	3
MDCG – Post Market Surveillance and Vigilance (PMSV)	European Commission	3
MDCG – Standards	European Commission	2
MDCG – Unique Device Identification (UDI)	European Commission	2
National Contact Points for the Implementation of Directive 2010/63/EU	European Commission	3
EC Education and Training Framework Expert Working Group	European Commission	5
Pharmaceutical Committee	European Commission	2
SoHO Competent Authorities	European Commission	5
Standing Committee on Cosmetic Products	European Commission	3
UNICOM WP4 (IDMP Adoption) Working Group	European Commission	5
Standing Committee for Veterinary Medicinal products	European Commission	2
Development of Implementing acts on Good Manufacturing Practices (autogenous vaccines)	European Commission	1
Working Group on Cosmetic Products	European Commission	3
Cosmetic Subgroup on Nanomaterials	European Commission	2
Cosmetic Subgroup on Sunscreen Products	European Commission	2
Cosmetic subgroup on borderline products	European Commission	2
Critical Medicines Alliance	European Commission	1
Regulation of Faecal Microbiota Transplants (FMT) and FMT-derived medicinal products in the EU webinar	EMA & European Commission	1
Clinical Trials Coordination Group (CTCG)	HMA	9

Committee/Working Group	Organisation	Meetings in 2024
Clinical Trials Coordination Group Safety Roundtable	HMA	13
Co-ordination Group for Mutual Recognition and Decentralised procedures – Human (CMDh)	HMA	11
Co-ordination Group for Mutual Recognition and Decentralised procedures – Veterinary (CMDv)	HMA	11
Veterinary Strategic Focus Group	HMA	5
Heads of Agency Meeting	HMA	4
Homeopathic Medicinal Products Working Group	HMA	2
Pharmacovigilance Work-sharing Procedures Working Party	HMA	5
Working Group of Communications Professionals (EU Presidency)	HMA	2
Working Group of Enforcement Officers (WGEO)	HMA	4
Working Group of Quality Managers	HMA	2
Risk Assessment Tool for Surveillance Testing	HMA / EDQM	5
Communications Working Group Meetings	HMA / EMA	2
EU Innovation Network (EU-IN)	HMA / EMA	11
EU Innovation Network Borderline Classification Group	HMA / EMA	8
Clinical Trials Coordination Group Assessor Roundtable	HMA / EMA	43
Task Force on the Availability of Authorised Medicines	HMA / EMA	7
National Patient Safety Alert Committee	HSE	12
Irish Breast Implant Registry Steering Committee	HSE	3
National Cosmetics Surveillance Forum	HSE Environmental Health Service (EHS)	2
ICH Expert Working Group: Q3E Guideline on Extractables and Leachables	ICH	1 in person (plus weekly call)
ICH Q13 (Continuous Manufacturing) EWG	ICH	1
ICH Q9(R1) Implementation Working Group on Quality Risk Management	ICH	5

Committee/Working Group	Organisation	Meetings in 2024
ICH PQKM (Pharmaceutical Quality Knowledge Management) Task Force	ICH	16
ICMRA Real-World Evidence Meeting	ICMRA	2
Brexit/Windsor Framework and safety features	IMVO	2
Safety Features Oversight Group	IMVO / PSI / Department of Health	3
Overprescribing Working Group	Medical Council	1
CGTV Forum	NIBRT	2
Decentralised clinical trials kick off meeting	National Office for Research Ethics Committees (NREC) / HPRA	3
Inter-regulatory Medication Management Project	Nursing and Midwifery Board of Ireland (NMBI)	1
NSAI/TC 42 Cosmetics Advisory	NSAI	2
Meeting of Organs Competent Authorities	Organ Donation and Transplant Ireland (ODTI)	1
PIC/S Artificial Intelligence and Machine Learning Working Group	PIC/S	9
PIC/S Expert Circle on Quality Risk Management	PIC/S	4
PIC/S Sub-committee on Expert Circle	PIC/S	2
PIC/S GDP Expert Circle	PIC/S	3
PIC/S Sub-Committee on Budget TC (SCB)	PIC/S	2
PIC/S Sub-Committee on Harmonisation	PIC/S	2
PIC/S Committee of Officials (virtual)	PIC/S	2
PIC/S GCP EC- Risk Proportionate Approaches Working Group	PIC/S	1
Bilateral	Pharmaceutical Society of Ireland (PSI)	2
Vigilance Expert Subgroup (VES) Blood Tissues & Cells SAE reporting meeting	SANTE - SoHO	2

Committee/Working Group	Organisation	Meetings in 2024
National Immunisation Advisory Committee (NIAC): Observer	Royal College of Physicians of Ireland (RCPI)	14
Countering Falsified Medical Products And Its Related Crimes In West Africa	WHO	1
National Clinical Effectiveness Committee	Department of Health	1
HTA Expert Advisory Group	HIQA	1

HPRA
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