Annual Report 2025

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority



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2025 Statistics at a Glance

54

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

95

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

1,966

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

13

centrally authorised human medicines where the HPRA was EU rapporteur or co-rapporteur

473

new human medicines authorised during 2025

6

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

171

medical device economic operators registered with the HPRA

131

free sale certificates issued for cosmetic products

8,565



suspected adverse reaction reports for human medicines received

4,638



medical device vigilance reports received and assessed

108



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

763,027



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

191



market surveillance cases initiated for cosmetic products

564



market surveillance cases undertaken in respect of medical devices

4,762



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

54



medicine recalls consisting of 41 human medicines and 13 veterinary medicines

Foreword from the Chairperson and Chief Executive

As Chair of the Authority and Chief Executive, we present this report confident in the HPRA's contribution to protecting public and animal health and in the organisation's readiness for the demands of a complex and changing regulatory environment.

Our strategic role, patient focus and organisational capabilities are grounded in scientific evidence and in proportionate, risk-based decision-making. They are also shaped by the HPRA's place within an integrated European regulatory system, where effective cooperation, shared standards and strong network participation are essential to achieving the best outcomes for patients, the public and the wider health system. In 2025, the HPRA delivered across a broad and complex remit, and further strengthened the systems, expertise and capacity needed to respond to a dynamic regulatory landscape. In addition, as Ireland's national regulator for medicines, medical devices and other health products, the HPRA helps sustain public trust in health products and their safe use. This role matters more than ever as misinformation grows and unsafe, unauthorised products become easier to access online.

The strategic context now facing the HPRA requires the organisation to deepen capability and remain responsive to national, European and global developments. Global instability continues to shape the context for supply chains and medicines availability. At the same time, the EU regulatory framework is expanding and becoming more complex, while advances in areas such as advanced therapies, digital technologies, data availability and artificial intelligence are reshaping the environment in which regulation operates. In this context, strong scientific capability, organisational agility and active leadership within European regulatory structures and networks are essential to effective coordination, influence and regulatory effectiveness.

Overall, 2025 was marked by strong progress and disciplined execution. It also marked the conclusion of the HPRA's 2021–2025 Strategic Plan, which the organisation delivered successfully in the public interest and against a demanding external backdrop. In addition to core work, the HPRA responded to several complex priorities, including medicines availability and shortages, the Sodium Valproate Inquiry, preparation for Ireland's Presidency of the Council of the European Union in 2026, and development of the new Strategic Plan for 2026–2029. Together these priorities underline the scale of the organisation's role and help to frame the strategic direction outlined in the remainder of this foreword.

Medicines availability and crisis preparedness

Ensuring the availability of safe, effective medicines remains a core HPRA priority. In 2025, supply pressures persisted, driven by manufacturing and quality issues, demand variability, and wider geopolitical and market factors. We advanced several strategic actions relating to medicines availability and shortages, strengthening the systems and partnerships needed to reduce the impact of shortages on patients and healthcare professionals.

At EU level, we played an active role in initiatives of the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) network, including the European Shortages Monitoring Platform (ESMP) and related coordination mechanisms. HPRA experts also contributed to the EMA's Medicines Shortages Steering Group, shaping policy and operational responses where public health impact is greatest.

Together, these initiatives improve our ability to anticipate, prevent and mitigate supply disruption, while strengthening crisis preparedness. Delivering further progress in 2026 will require close collaboration with health system partners in Ireland and across Europe.

Future development of our regulatory systems

At European level, the HPRA played an active role supporting regulatory science, collaboration and innovation in 2025, while also advancing preparations for Ireland's Presidency of the Council of the European Union. Nationally, we progressed a review of regulatory controls for over-the-counter codeine-containing products.

We were a lead contributor to the IncreaseNET Joint Action, a three-year EU4Health initiative to strengthen the capacity and capability of national medicines agencies. Through shared learning and best practice, it supports more effective use of resources, innovation and access to safe, effective medicines.

We also played an active role in the COMBINE initiative to streamline regulation of combination products spanning medicinal and medical device components. Following phase one in 2024, phase two is progressing solutions to support more coherent regulation of modern health technologies.

In veterinary medicines, we made a significant contribution to the HMA Veterinary Strategic Focus Group, helping shape priorities and regulatory approaches in support of animal health, public health, food safety and the EU One Health agenda.

Investment in our people and systems

Our people are central to the HPRA's success. In 2025, we continued to implement the HPRA People Strategy, which sets out how we invest in and support colleagues to deliver our mission and embed our values, while providing a clear framework for capability and organisational development.

Key achievements in 2025 included the launch of HPRA Grow, our dedicated learning and development platform, supporting colleagues to plan and track development through targeted resources and pathways. We also introduced our new Career and Capabilities Framework, providing clearer structures for progression and capability building, and strengthening organisational agility.

In tandem, progress was made on key digital transformation initiatives, including the launch of the redesigned HPRA website in early 2025 to improve accessibility and enhance how information is presented to stakeholders.

European benchmarking exercises

In 2025, the HPRA participated in key European benchmarking and quality assurance processes, including the Benchmarking of European Medicines Agencies (BEMA). Following extensive preparation and self-assessment, an onsite BEMA assessment was carried out in March 2025 by a team of peer assessors from across the European regulatory network. It delivered a very positive outcome, building on the assurance provided by a Joint Audit Programme audit completed in December 2024. These rigorous assessments reflect the strength of our systems and the commitment of our colleagues. They also affirm the HPRA's position as a high-performing regulator and provide useful insight for our continued development.

Looking to the year ahead

Looking ahead, our new Strategic Plan will shape the next phase of the HPRA's development. It builds on strong foundations and successful delivery of the previous strategy, setting clear ambition for how the organisation will respond to a more complex regulatory environment, while reinforcing the HPRA's role nationally and across Europe.

Delivery will require clear focus on scientific and technological change, the growing role of data and digital systems, and the HPRA's expanding contribution within European and international regulatory frameworks. It will also require focused action to strengthen medicines availability, reinforce supply chain resilience and improve preparedness for public health threats.

The HPRA must also continue to deepen engagement with patients, healthcare professionals and the wider health system, supporting transparency, trust and understanding in regulatory decision-making. Achieving this will require continued investment in patient-centred approaches and in the capability, systems and structures needed to sustain a skilled and adaptable workforce.

Acknowledgements

In closing, we acknowledge the contribution of Mr Michael Donnelly, whose tenure as Chair was marked by strong governance, clear oversight and a disciplined approach to the Authority's role. We also thank those Authority members whose terms concluded during the year and welcome those newly appointed, whose experience and judgement will support the organisation in the period ahead. We recognise the transition in governance and oversight during the year and look ahead with confidence to the next phase of the HPRA's development.

We also acknowledge the contribution of colleagues in the HPRA leadership team, particularly Dr Gabriel Beechinor, Ms Elizabeth Stewart and Ms Rita Purcell on their departures. Each made an important contribution to the organisation and to public and animal health. We also welcome Dr David Murphy and Ms Nicola Riggs, who joined the leadership team in 2025 and bring valuable experience to their roles.

We pay particular tribute to Dr Lorraine Nolan, whose 10 years as Chief Executive were marked by strong leadership, strategic development and sustained commitment to the organisation's public health mission. Under her leadership, the HPRA advanced its regulatory impact, organisational capability and standing both nationally and within the European network, leaving the organisation well positioned for the period ahead.

The HPRA's effectiveness is grounded in the expertise, professionalism and commitment of its people. We thank staff across the organisation, whose work underpins the performance reflected in this report, as well as Authority and Committee members for their ongoing support.

We also recognise the support of the Minister for Health and the Minister for Agriculture, Food and the Marine, together with their departments, and the continued engagement of our wider partners across the health and regulatory system.

The HPRA enters the period ahead from a position of capability, credibility and resilience. Its operating environment will continue to evolve, shaped by scientific advancement, system pressures and regulatory change. The foundations are strong, and the organisation is well placed to move forward with confidence and purpose.





Mr Paul Quinn
Chairperson

Ms Grainne Power
Chief Executive

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 2025 were:



Mr Michael Donnelly
Chairperson*



Dr Joe Collins



Mr David Holohan



Mr Brian Jones



Dr Paula Kilbane



Prof Sharon O'Kane*



Prof Richard Reilly



Dr Fiona Kiernan



Dr Suzanne Kelly**

* Term ended 31 December 2025
** Resigned 10 September 2025

Management Committee

The members of the Management Committee as of June 2026:



Ms Grainne Power
Chief Executive



Ms Sinead Curran
Director of Human Products Monitoring



Ms Katherine Morrow
Director of Compliance



Mr Sean d'Art
Director of ICT and Business Services



Mr John Fitzpatrick
Director of Finance, Legal and Corporate Affairs



Dr Finnuala Lonsdale
Director of Human Products Authorisation and Registration



Dr Niall MacAleenan
Director of Medical Devices



Dr David Murphy
Director of Veterinary Sciences



Ms Nicola Riggs
Director Human Resources and Development

Strategic Plan 2021 to 2025 – Key Achievements in 2025

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).

- With an obligation for shortage notification for medical devices introduced by EU Reg 2024/1860, the HPRA 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 where processes have now been implemented and are operational. The HPRA internal process for evaluation of notifications was also developed and implemented.

- Continued work with colleagues from across the national health system to monitor and manage impacts on the supply of medicines and medical devices arising from Brexit and 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 shortages and medical device supply disruptions. 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.

- Continued to lead and participate at EU level to ensure legislative amendments delivered to prevent disruption to supply of essential medical devices for EU citizens, supplemented with measures to promote timely transition by manufacturers to new EU Regulations.

- The Community Pharmacy Implementation Oversight Group (IOG), on which the HPRA participates, ensured that the necessary enablers for pharmacist prescribing as part of the common conditions service were in place to enable the service to commence in 2026.
- Continued as a member of the HSE National Patient Safety Alert Committee to support system-wide responses to health product issues.
- Continued focus on the application of the 3R principles in animal-based research in Ireland, with the aim of enhancing animal welfare. A dedicated 3R event was hosted in 2025. Ongoing promotion of the 3R principles continues through multiple channels.

Goal 2: Progressive regulation

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



- Continued preparations for the EU Presidency which commences in the second half of 2026. During that time, the HPRA will be responsible for hosting the Presidency programme within the European medicines and medical devices regulatory networks.
- Promoted effective application of the EU Medical Device Regulation (MDR) and *In Vitro* Device Regulation (IVDR) at EU and national levels, working to ensure continued supply of essential devices for people in Ireland and collaborating with health institutions in Ireland regulatory compliance.
- 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 Medical Device Coordination Group (MDCG) breakthrough taskforce, which published the first EU guidance on breakthrough designation and clinical evidence requirements, and co-chairing the MDCG Post Market Surveillance and Vigilance (PMSV) Working Group.
- 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 and harmonise regulatory assessments and inspections, to enhance regulatory effectiveness and efficiency through strengthened international collaboration. In 2025, the PQKM project was promoted through multiple public engagements while a sub-group of the ICMRA Executive Committee was convened to develop a proposal for a long-term, sustainable model for collaborative regulatory procedures.
- Negotiation of the draft pharmaceutical legislation in the European Council continued at pace during 2025. The HPRA assisted the Department of Health in providing Irish input as part of the negotiations. A provisional agreement was reached between the Council and the European Parliament at the end of 2025, and it is anticipated that the European legislation will be finalised mid-2026.
- Supported the Department of Health in the negotiations on the Critical Medicines Act for which the Council adopted its position in December 2025 with trilogues expected to take place during the Cypriot presidency in the first half of 2026.

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. The HPRA delivered a patient speaker event focused on rare diseases and progressed the Patient Forum work plan, which included dedicated sessions on interchangeable medicines and on digital health technology in the context of medical devices.
- Continued our engagement with stakeholders through website, social media and newsletter updates.
- Proactive media engagements included enforcement activities, highlighting the risks of illegal GLP-1 medicines, reporting medicines side effects and the safe use of cosmetic products.
- Our digital information campaigns involved raising awareness of the dangers of buying prescription medicines online, promoting the reporting of medicines side effects, highlighting the risks associated with dermal fillers, and the responsible use of over-the-counter medicines.
- The new HPRA website went live in early 2025. The project focused on optimising the design, structure and content of the website, to deliver a more user-friendly, accessible and engaging experience.

Goal 4: Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval



- Continued collaboration in projects at: (1) EU level, through the EU Pharmacovigilance Business Team, and the EU Innovation Network (EU-IN); and (2) national level, through the HPRA Innovation Office and engagement with partners, clinical researchers and sponsors.
- Continued participation in the EU Commission's COMBINE initiative, designed to analyse the challenges encountered by sponsors in conducting clinical research of new medicines in parallel with clinical investigations or performance studies of medical devices and identify possible solutions to ensure applications and reviews are as clear and efficient as possible.
- The HPRA joined the pilot for co-ordinated assessment of multinational studies under MDR and IVDR and supported the commission in launching this initiative in 2025 which is intended to facilitate more medical device trials in the EU.
- The HPRA actively contributes to horizon-scanning initiatives in the EU-IN Reports on new approach methodologies, nanotechnology and engineered living materials were finalised and published. We are also co-leading on a report reviewing the impact of climate change on medicinal products.
- The HPRA continued to actively promote the Innovation Office through engagement with a broad range of stakeholders and organisations.

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 its third year of delivery. This framework continues to guide how we align our people practices with the HPRA's mission and vision. The Career and Capability framework was developed and delivered in 2025.

- Continued our digital transformation activities focusing on integration to EU network systems, improved dataset management and core workflow consolidation. Significant enterprise-wide data quality projects were continued to align with IDMP (Identification of Medicinal Products) standards to aid data transition and integration with European systems. Work also concluded on sharing of medicinal product data with external parties using the HPRA's data API (application programming interface).

- In 2025, the Benchmarking of European Medicines Agencies (BEMA) V assessment was completed with a very positive outcome. From the combination of the self-assessment report and the on-site visit, the external BEMA assessors gave a rating of 4.76 out of 5 for the HPRA. The assessors specifically highlighted the HPRA's contribution to the EU and national networks, our values - specifically our Patient Focus - and the work we do nationally in this area. They noted our clear vision and strategic goals and how we cascade these through the organisation, and our leadership and focus on empowering and developing our staff. They also commended our proactivity in analysing our effectiveness as a regulator and implementing improvements as a result.

- Under the 2021–2030 Energy and Sustainability Project, work was completed on installation of decentralised water heating, the new solar panel system was brought online and all building lighting transitioned to LED supported by PIR motion sensors.

- Building developments in 2025 also included the refurbishment of the ground floor with more efficient HVAC systems to further support our sustainability objectives.

Human Medicines



The HPRA grants licences for medicines subject to a review of their effectiveness, quality and safety 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 473. The 2025 figure incorporates:
  - 6 new national authorisations;
  - 68 parallel import authorisations;
  - 295 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 61 DCP authorisations and 35 MRP authorisations;
  - 13 centralised authorisations completed where the HPRA led the assessment as rapporteur or co-rapporteur for the EU;
  - 91 additional medicines authorised through the centralised procedure for which Ireland was neither rapporteur nor co-rapporteur.

- In addition, a further four rapporteurships and three co-rapporteurships under the centralised procedure were assigned to the HPRA during 2025. It is anticipated some of these assessments will finish in 2026.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2025, we issued 95 authorisations under the EU Clinical Trials Regulation (CTR).

- 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 2025, the HPRA acted as co-ordinator for 54 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 23 such advice procedures (13 standard advice and 10 swift advice).



- Increasing the number of medicines available to patients without a prescription, where appropriate, is an important aspect of improving patient access. Accordingly, 18 medicines were authorised for non-prescription supply, either as pharmacy-only or general sale medicines. In addition, in 2025 one medicine was reclassified from prescription-only status to become available from pharmacies without a prescription.

- 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 192 active substances or combinations of active substances.

- Biosimilar products and assessments is an area of expertise and leadership for the HPRA across the European Medicines Regulatory Network (EMRN) as reflected in our participation on the EMA Biosimilar Medicinal Products Working Party. The HPRA contributed as a drafting group member to the EMA reflection paper on a tailored clinical approach for biosimilar development, shaping future regulatory expectations for biosimilars. We also served on the organising committee for the EMA workshop on tailored clinical approaches, helping to design and deliver a high-impact forum for regulatory–industry dialogue.

- The HPRA is a member of the ICMRA working group responsible for overseeing pilots on collaborative assessment of post-approval variations across global regulatory authorities. We have contributed to the development of a harmonised processes and timetable to enable parallel review of variations submitted simultaneously to multiple regulatory authorities including EMA, US FDA, PMDA Japan, Health Canada, Swissmedic, the UK's MHRA, and others. The HPRA also supported international regulatory convergence by establishing an operational framework that enhances global regulatory collaboration in post-approval lifecycle management.

- 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 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 (MsSG) 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 the European Commission-backed Joint Action on shortages.
  - Work is continuing nationally to strengthen the capacity of the Medicines Shortage Framework (MSF) to prevent and mitigate shortages. This includes seeking the introduction of mandatory notifications of shortages to the HPRA as well as facilitating the introduction of national stock monitoring systems. Such advancements should strengthen response capacity by providing earlier warning of supply risks, allowing timelier action to be taken.
  - In November 2025, the Department of Health established a cross-agency Strategic Medicines Access and Availability Group (SMAAG) to help shape national policy on medicines access and availability. The SMAGG, of which the HPRA is a member, has a stated aim to investigate, examine and pursue all appropriate measures that could improve the availability of medicines in Ireland. This includes strategically addressing medicines shortages and gaps in availability, encouraging increases in the number of authorised and marketed products, and reducing reliance on exempt medicinal products.
  - An internal HPRA medicines availability group has been established to support the workings of the wider national forums focused on medicines access and availability.



- 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). We continued to lead the CMDh Multilingual Packaging Working Group in 2025, 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 195 batch-specific requests.

- In 2025, MAHs began to use the work-sharing procedure for variations to medicines authorisations. A work-sharing variation is the grouping together of a number of variations to one or more authorisations, such as Type IA, IB and/or Type IIs. This is to streamline processes and assessments of variations to the license and considered CMDh best practice. Of the 7,621 variations reported in 2025, 868 relate to worksharing variations. Although the headline number of variation procedures appears lower, this is misleading, as the 868 work-sharing procedures include multiple individual variations.

Authorisation and registration: Key figures	2023	2024	2025
*Classification queries/reviews	72	15*	2*
Scientific advice			
Coordinator EMA scientific advice	93	72	54
National scientific advice	11	12	23
Clinical trial applications under Clinical Trials Directive (CTD)	76	86	113
New medicines applications for marketing authorisations			
National (including new parallel imports)	64	72	74
Mutual recognition and decentralised RMS	34	78	96
Mutual recognition and decentralised CMS	152	224	234
Centralised Rapp/Co-Rapp	12	13	13
Traditional herbal medicinal products under the simplified registration scheme	1	1	0
Homeopathic medicines under the simplified/national rules schemes	0	0	0
Variations to marketing authorisations (Type IA, IB, II)	14,672	11,645	7,621
Articles 45 and 46 - Variations to Update Product Information	13	2	37
Renewals of marketing authorisations	231	201	188
Transfer of marketing authorisation holder	179	236	130
Manufacturers	151	161	156
Manufacturers of investigational medicinal products	82	89	88
Wholesalers	375	381	369
Registrations for active pharmaceutical ingredients			
Manufacturers	22	29	30
Importers	75	74	80
Distributors	98	104	109
Brokers	13	12	12
Export certificates	1,108	1071	1214
Exempt medicine notifications of unauthorised medicine import	69,912 line notifications	78,994 line notifications	80,202 line notifications

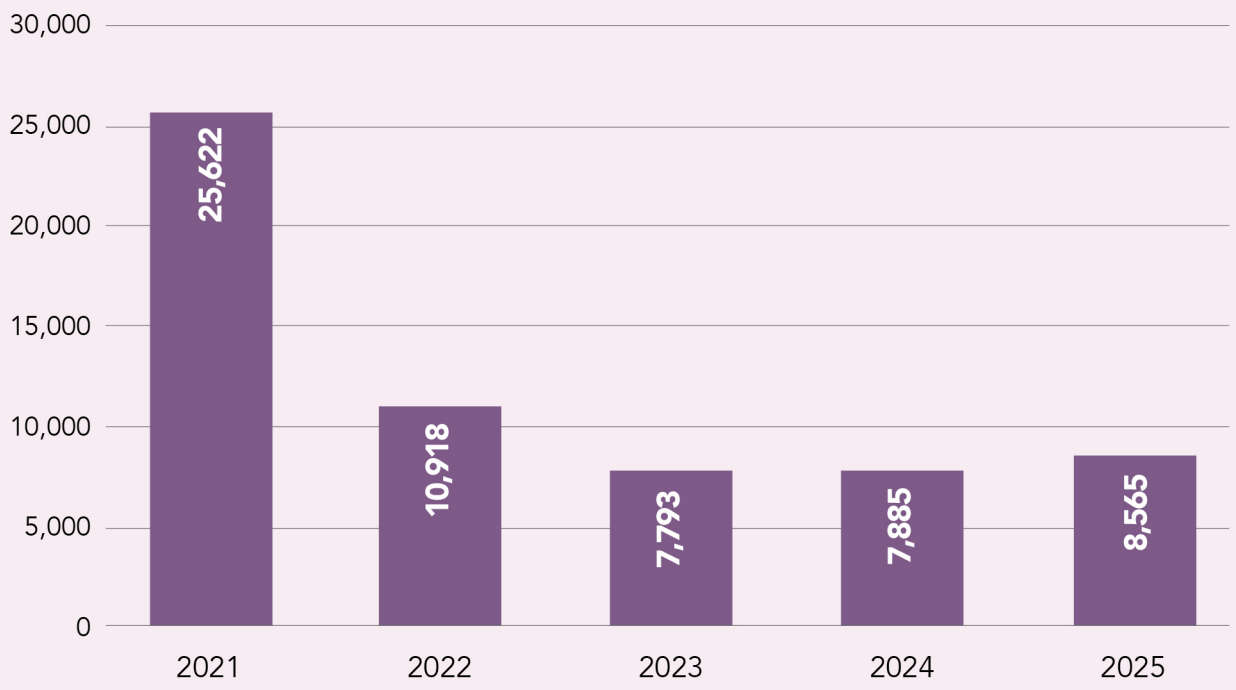
* This figure is not comparable to previous years as it only outlines classification decisions by the Borderline Products Committee, due to a change in the reporting of classification queries.

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 8,565 suspected adverse reaction reports were received associated with the use of human medicines. Although this number is lower than the exceptional volume of reports submitted in 2021 and 2022, which were largely related to COVID-19 immunisation campaigns, the number of reports received in 2025 is greater than received in more recent years.

Suspected Adverse Reaction Reports Received



  – Of the reports received in 2025, 6% were submitted by members of the public, 5% by healthcare professionals and 88% were reported by marketing authorisation holders. A further 1% 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.

– The breakdown of reports submitted directly to the HPRA from 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	10
Nurse	8
Pharmacist	23
Healthcare professional – Other	7

– Medicines subject to additional monitoring (labelled with a black inverted triangle - ▼) accounted for just under 8% of the reports submitted. Reporting of suspected adverse reactions for such medicines is strongly encouraged.

– The HPRA sincerely thanks healthcare professionals and members of the public for their commitment to reporting suspected cases. 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 encourage reporting through the various routes available, including through our online form or via medsafety@hpra.ie

- The medicines most frequently listed as the suspect drug in reports submitted to the HPRA, and which account for approximately 84% of the suspected adverse reaction reports received in 2025, 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	4,424
Medicines for the treatment of Parkinson's Disease	932
Psycholeptic medicines	601
Medicines for the treatment of dermatological conditions	450
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	374
Vaccines	362
Medicines for obstructive airway diseases	330
Medicines for other nervous system conditions/disorders	280
Medicines for the treatment of Diabetes Mellitus	240
Analgesic medicines including medicines for prevention and treatment of migraine	173

* 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 2025, 101 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.
  - It is often the case that 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	56
Psycholeptic medicines	22
Medicines for treating Parkinson's Disease	8
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	6
Perfusion solutions including blood substitutes	6
Vaccines	5
Cardiovascular medicines, including anti-hypertensive, anti-arrhythmic, and lipid lowering medicines	<5**
Genitourinary medicines	<5**
Contrast media used in imaging	<5**
Medicines for the treatment of dermatological conditions	<5**

* Please note that in some cases treatment may have involved more than one medicine from the groups listed, and therefore the total number of reports is more than the total number of patients.

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

- The HPRA 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 2025, 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 69 nationally authorised active substances;
  - Serving as PRAC rapporteur, we were also responsible for the further management of any signals detected in relation to 71 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 922 PSURs and leading the single EU assessment for 34 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 444 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures;
  - Also provided assessment input to 387 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, substantial contributions were made in 2025 to several areas considered of strategic importance. These included:
  - Contributions to the development of new and updated guidance on risk assessment and risk minimisation approaches to support the safe use of medicines during pregnancy;
  - Advancing innovation through engagement on the application of artificial intelligence in pharmacovigilance effectiveness research via active participation in the PRAC Interest Group Impact; and
  - Enhancing regulatory consistency through contributions to a PRAC subgroup tasked with strengthening best practices for PSUR assessments.

  We also contributed to the development of additional 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 2025, we:
  - 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 121 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 four editions of our Drug Safety Newsletter to registered healthcare professionals, which included eleven articles along with product information updates, all of which are also published on the HPRA website. The Drug Safety Newsletter highlights important safety information to healthcare professionals with links 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 2.

- Provided eight articles for inclusion in the monthly MIMS (Ireland) publication in addition to two articles for the Irish Medicines Formulary. The full list of topics covered in these articles is included in Appendix 2.
- The HPRA continued work with the University of Limerick on a Research Ireland-funded project to better understand healthcare professionals' perceptions and use of important medicine-safety information. Through a national survey of doctors and pharmacists, the project is helping us to improve our understanding of what communication methods work best and how we can make safety messages clearer and more effective.
- Highlighted the PRAC monthly agendas, minutes, meeting highlights, notifications of safety reviews and signals via our website.

- The HPRA's inspections programme focuses on ensuring compliance with relevant standards and legislation. This year, there were:
  - 108 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances;
  - 128 good distribution practice (GDP) inspections at wholesalers and distributors;
  - Seven good clinical practice inspections at investigator or sponsor sites;
  - Eight pharmacovigilance inspections;
  - Three 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 2025, 277 cases were initiated under the programme.



- The quality defect and recall programme investigates reports of suspected quality defects in medicines and in their related active substances. It also co-ordinates recalls or other risk-mitigating actions for the Irish market. The number of human medicines quality-defect cases opened in 2025 rose to 1,103, a substantial increase compared with 906 cases in 2024. The risk classifications assigned, along with the corresponding figures for the previous two years, are outlined in the following table:

Risk Classification	2023	2024	2025
High Risk quality defects	332	243	335
Moderate Risk quality defects	291	243	330
Minor Risk quality defects	613	406	427
Number of reports not justified	31	14	11
Total Number Quality Defects	1,267	906*	1,103*

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

The majority (49%) of quality defect reports were submitted by other competent authorities (including the EMA) and by pharmaceutical companies, including manufacturers, distributors and/or marketing authorisation holders (31%). Reports from pharmacists accounted for 15% of cases, while 'others' accounted for 5%.

- In certain instances, it is necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 41 recall actions were taken in relation to human medicines, with the primary causes outlined in the table below:

Cause of recall	Number of recalls
Contamination – Chemical (incl. nitrosamine)	10
Contamination – Microbiological	5
Stability out of specification	5
Unlicensed product on the market	4
Contamination – Particulate	3
Distribution/Storage - Cold chain/temperature excursion	2
Lack of Sterility Assurance	2

- 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 2025, 27 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 2025, 16 cases were investigated, some of which involved multiple products. Of these:
  - 13 cases related to the sale of medicines that did not carry a registration number or authorisation number for the Irish market, resulting in 10 medicines being removed from sale and/or other necessary follow-up actions being taken;
  - Two 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, 32 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, 307 materials were reviewed, and non-compliances, including both major and minor issues, were identified in 113 cases. Additionally, 19 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 38 queries linked to the advertising of human medicines in Ireland were addressed. Three regulatory compliance inspections relating to advertising activities were conducted at MAH offices.

- Under our enforcement programme:

  – We processed the detention of 763,027 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2025, compared to 1,000,984 dosage units in 2024. The products detained included sedatives (27%), erectile dysfunction medicines (14%), anabolic steroids (12%), diabetes/slimming (9%) and analgesics (5%). 13,898 enforcement cases were initiated in 2025, compared to 4,950 in the previous year;

  – The HPRA initiated one criminal prosecution case and issued fourteen 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. The prosecution case taken in 2025 related to the manufacture and distribution of GLP-1 medicines. 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 4,762 websites, e-commerce listings and/or social media pages associated with the sale of falsified or illicit medicinal products;

  – We participated in the Interpol-coordinated Operation Pangea XVII 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 ran from December 2024 to May 2025.

Legislation and Regulation

- Provisions of the Windsor Framework related to medicinal products for human use were applied from 1 January 2025. Throughout the year, the HPRA has closely monitored the impact of these provisions to ensure that there has been no significant impact on the availability of medicinal products in Ireland.

- The following national activities were progressed by the HPRA during 2025 to support clinical research:
  - Continued engagement with the Department of Health and the National Office for Research Ethics Committees regarding the implementation of the Clinical Trials Regulation (CTR) nationally;
  - Updates on training and information on timelines and guidance published on our website, and communicated via news alerts and social media;
  - A clinical trials information day organised in November 2025 with over 170 attendees;
  - Active participation in the Department of Health National Clinical Trials Oversight Group;
  - Ongoing collaboration with the EMA and other Member States to contribute to a harmonised approach to clinical trial authorisation processes under the CTR.

- The HPRA participated in the Community Pharmacy Implementation Oversight Group, established by the Department of Health to facilitate the implementation of recommendations made by the taskforce on the expansion of the role of pharmacists including a common conditions service. By the end of 2025, all necessary enablers to allow pharmacists to prescribe as part of the common conditions service including legislative changes, guidelines, clinical protocols and training had been completed and the service will launch in 2026.



Stakeholders and Partners

- 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.

- Publications and Information:

  – 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 2025 and are available to download from our website. This includes, among others:

    - Guide for national scientific and regulatory advice;
    - Guide to labels and leaflets of human medicines;
    - Guide to good distribution practice of medicinal products for human use;
    - Guide to registration of processes under Article 61(5) of the clinical trial regulation;
    - 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 2025, 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 February 2025 and a separate on-site assessment which involved a European Joint Assessment Team to re-assess and check continued compliance of the notified body with the Medical Devices Regulation (MDR);
  - Contributed a national expert as part of a European Joint Assessment Team for a re-assessment application under the *In Vitro* Device Regulation (IVDR) in the Netherlands;
  - 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.

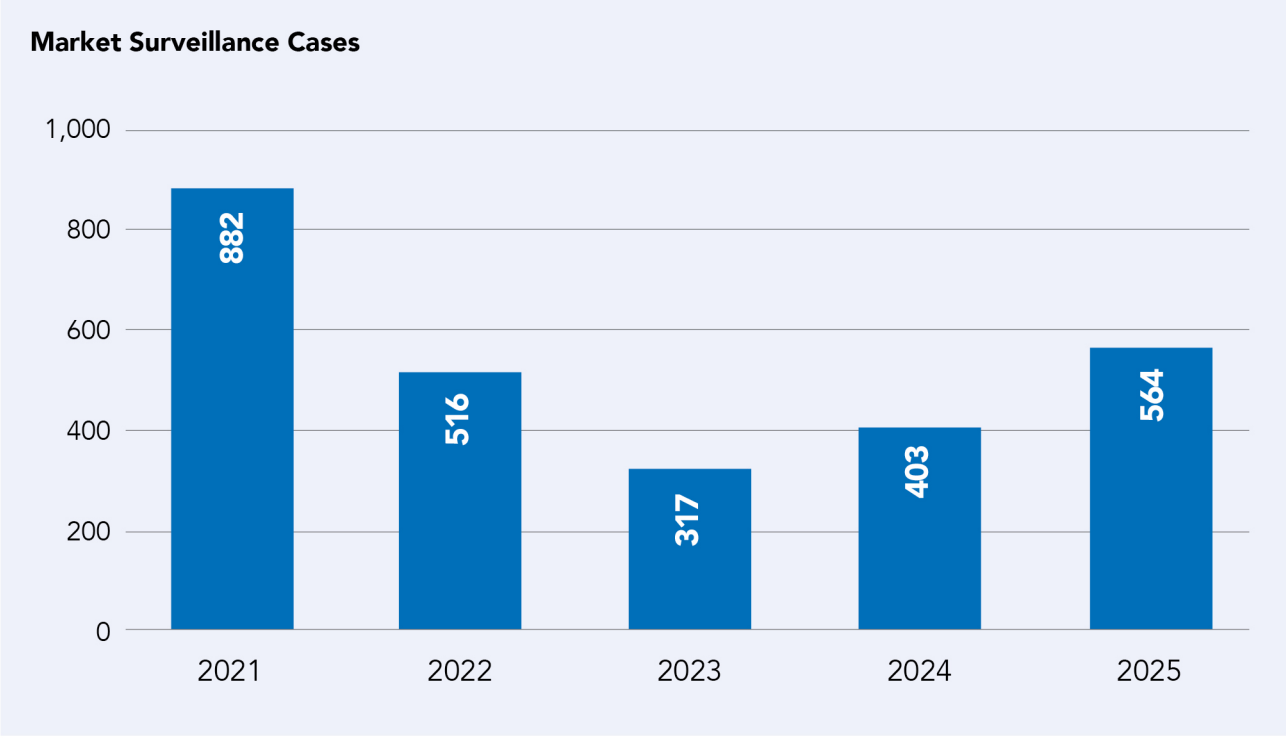
- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2025, this support included:
  - The review of applications to conduct clinical investigations of medical devices in Ireland under the new medical device regulations. We continued to review clinical investigations for innovative devices from both multi-national and academic sponsors with seven new applications, 18 amendments to ongoing investigations and 11 post-marketing clinical investigations. We also reviewed performance studies for new *in vitro* diagnostics (IVDs) under the recently implemented IVDR with seven applications received in 2025;
  - 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 continued in 2025, with 12 meetings with groups of innovators to discuss potential clinical investigation or performance study applications for new medical devices or *in vitro* diagnostic medical devices in 2025. This included the pilot 'hypercare' programme which was initiated in 2024 in collaboration with the Institute of Clinical Trials, Galway. This programme offers additional pre-submission support for sponsors conducting early feasibility studies for high-risk devices and three successful applications were completed in 2025;
  - The provision of technical, clinical and regulatory support in respect of medical devices related queries received by the HPRA Innovation Office;
  - HPRA support for the EU Commission launch of a pilot for coordinated assessment of multinational studies under MDR and IVDR. The HPRA volunteered as one of six competent authorities to act as a reporting member state during the pilot which will run to 2026. This initiative intends to promote harmonisation and consistency of assessments and timelines for sponsors to promote increased device trials in the EU. The HPRA was nominated as RMS for two of the initial eight expressions of interest submitted by sponsors in 2025;

- Continued participation in the COMBINE initiative which in 2025 transitioned to the second phase, known as the COMBINE programme. This led to the establishment of a series of defined projects aimed at developing solutions to address challenges associated with the regulation of clinical trials of medicinal products conducted in parallel with clinical investigations or performance studies of medical devices. The HPRA leads the flagship project piloting an integrated all-in-one coordinated assessment procedure and contributes strategically through its position on the COMBINE Board. During 2025, significant progress was made with the launch of 50% of the projects and the initiation of the first phase of the combined application pilot;
- Appointment as co-chair of the Clinical Investigation and Evaluation, Performance Studies and Evaluation (CIE-PSE) working group in 2025. This followed the expansion of the former Clinical Investigation and Evaluation (CIE) working group, a subgroup of the Medical Device Coordination Group (MDCG), to incorporate performance studies of *in vitro* diagnostic devices (IVDs);
- Participation as advisory board members on the Innovative Health Initiative (IHI) project, Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS). This project is developing best practice methodologies and a harmonised approach for sponsors and competent authorities to promote the conduct of high quality EFS studies for high-risk devices in the EU.

- Manufacturers of certain medical devices and IVDs are required to register with the HPRA via the European medical device database (EUDAMED). In 2025, 171 economic operators were validated on EUDAMED by the HPRA. There is also a requirement for other organisations to register nationally with the HPRA. The HPRA registered 246 new medical device organisations in total.

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 2025:
  - 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 18 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 564 market surveillance cases undertaken in 2025, an increase compared to 403 in 2024.



- We continued to focus our vigilance activities during 2025 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 4,638 medical device vigilance cases, an increase compared to 2024. Of the individual reports received in 2025, manufacturers accounted for 85%, 4% were from users and 11% came from other competent authorities. Of the 3,397 individual serious incident reports notified directly to the HPRA, 5% came from users of medical devices, including members of the public;
  - 15 of the 4,638 medical device vigilance cases received in 2025 relate to periodic summary reports (PSR) provided by manufacturers. These PSRs represent an additional 1,660 incident reports;
  - There were 615 field safety corrective actions (FSCA) associated with the national market;
  - We issued 124 national competent authority reports to other European authorities;
  - We also issued five safety notices in relation to medical devices and 30 direct to healthcare professional communications;
  - Continuous glucose monitoring, insulin infusion pump, *in vitro* diagnostic medical devices, active infusion pump and active cardio device implants together accounted for 49% of the total individual vigilance reports received (see accompanying table).

Vigilance Reports – Most Frequently Reported Product Types	Number of Individual Reports
Continuous glucose monitoring	1,046
Insulin infusion pumps	455
In vitro diagnostic medical devices	327
Active infusion pumps	270
Active cardio device implants (generators)	196

- 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.

- We continued our activities to better understand digital health technologies that are regulated as medical devices. This work is aimed at ensuring that appropriate processes and procedures are in place to effectively regulate emerging device types and support stakeholder engagement.

- 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 2025, 32 such inspections were performed all of which were based on market surveillance projects and notified body surveillance/assessment. Five of these inspections were conducted collaboratively with other EU member state inspections as part of the European Joint Action on Market Surveillance (JAMS) 2.0 project.

Legislation and Regulation

- Our work during 2025 focused on progressing implementation and application of EU device regulations and contributing to the EU Commission's targeted evaluation on the application of the regulations. 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 to support continued progress in transitioning to the regulations as well as raising awareness within health services of the impact of transitional timelines on device availability;
  - 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 participation in workshops to support the EU Commission's targeted evaluation.

- 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 2025, 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. This includes 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, including co-chairing the breakthrough technologies taskforce which published the first EU guidance on breakthrough designation and clinical evidence requirements in Q4 2025;
  - Continued participation in discussions and activities aimed at collaboration between the EU regulatory system and the Medical Device Single Audit Programme (MDSAP).

  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 2025, the HPRA provided a leadership role and participated in the delivery of a workshop of heads of medical device agencies in highlighting challenges with the medical devices regulatory system and called for reform of the regulatory system.

- 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;
  - Participation in the good regulatory review practices 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 2025. We also continued our engagement with health services and healthcare professionals to raise awareness to 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 Medical Devices Regulations. During 2025, we:
  - Hosted webinars for health institutions on medical device regulatory and safety reporting requirements, including the 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 EU regulations;
  - Relaunched 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 2025:

  – An in-person information session for health institutions on regulatory requirements, clinical requirements and safety reporting for medical devices and *in vitro* diagnostic medical devices was delivered for HSE and private hospitals;

  – A number of webinars were delivered to key health service partners (HSE, voluntary hospitals and private hospitals) on the regulatory framework for medical devices;

  – We participated at a number of academic, industry and laboratory conferences on regulatory developments for medical devices and IVDs.

Medical devices: Key figures	**2023**	**2024**	**2025**
Lead Competent Authority role on specific vigilance issues	114	146	124
NCARs and vigilance related communications	140	195	163
Vigilance cases received/opened	3,065	3,672	4,638
Field safety notices uploaded	368	437	384
Medical device safety/information notices	1	5	5
Medical device targeted healthcare professional communications	25	42	30
NCARs managed as IMDRF NCAR secretariat	N/A	N/A	N/A
CEF reports to EU network	8	11	18
Market surveillance cases	312	403	564
Notifications relating to notified body certificates	5#	6	1
Classification requests	18	22	19
Compassionate use applications	27	12	19
Certificates of free sale	5,507	6,527	4,665
Medical device queries received	804	721	693
Clinical investigation (Article 62 MDR)	11	11	7
Clinical investigation (Article 82 MDR)	7	11	11
Performance study (IVDR)	7*	11	7

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	2021	2022	2023	2024	2025
Blood establishments	3	3	3	3	3
Tissue establishments	26	26	27	27	25
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 2025. The report reflected information received by the NHO in 2024 and included 105 serious adverse reactions and 158 serious adverse events that met the mandatory legislative reporting requirements. The EU Commission, on an annual basis, publishes an analysis of the serious adverse reactions and events submitted, which aims to provide insights into haemovigilance trends across Europe.

- We also submitted an annual report on serious adverse reactions and events associated with tissues and cells to the EU Commission during 2025. The report reflected information received in 2024 and encompassed 22 reports, 11 of which met the

legislative reporting requirements. Of the 11 reports, 10 were serious adverse events and one was a serious adverse reaction.

- The EU Commission, on an annual basis, publishes an analysis of the serious adverse reactions and events submitted by the member states for blood and for tissues and cells. These publications aim to provide insights into safety trends in the respective areas across Europe.

- 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 2025, the HPRA received seven 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 2025 included:
  - 11 tissue establishment inspections, the majority of which were routine;
  - Six blood establishments inspections;
  - One inspection 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 on the implementation of revised European legislation for substances of human origin (SoHO) including blood, tissues and cells.

Stakeholders and Partners

- Several HPRA guidance documents were issued and updated during 2025 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;
  - Reporting serious adverse reactions and serious adverse events associated with human tissues and cells.

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

- Prior to a new veterinary 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 benefits outweigh its known risks. Where this is the case, it may be granted a marketing authorisation. The total number of veterinary medicines authorised in Ireland, with authorisations issued by the HPRA, at year-end was 1,966.

- There are several routes 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). 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 2025:

  – The total number of new veterinary medicines authorised by the HPRA was 57. This included three new national (only) authorisations and 54 new veterinary medicines authorised through DCP or MRP routes;

- The HPRA continued to support the authorisation of medicines through European procedures acting as reference (lead) Member State (RMS) for eight DCPs and six MRPs. In addition, the HPRA led a further twenty-one applications as RMS under the Subsequent Recognition Procedure (SRP). While these SRPs did not result in new products on the Irish market, they support the authorisation of products in other EU Member States. Based on the figures presented, the HPRA was a leading national competent authority in the EU for RMS work during 2025;
- Experts from the HPRA acted as rapporteur or co-rapporteur in respect of six medicines that were authorised via the centralised procedure.

- The EMA operates a scientific advice procedure for applicants on the appropriate tests and studies to perform during the development of a veterinary medicine. This is designed to support new product development and innovation for the benefit of animal and public health.

  During 2025, the HPRA acted as co-ordinator for nine 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 2025.

Authorisation and registration: Key figures	**2023**	**2024**	**2025**
Classification enquiries	8	5	5
Clinical trials	7	5	7
New centralised as (co-)rapporteur	10	10	6
New MR/DCP as RMS	42	49	34
New MR/DCP as CMS	52	64	47
New homeopathic applications	5	0	0
New national applications	2	8	3
Variations, national and MR	2,620	2,493	3,092
Manufacturers of veterinary medicines	33	32	34
Export certificates	140	33	34
Registrations for active pharmaceuticals ingredients			
Manufacturers	3	4	5
Importers	0	2	2
Distributors	4	8	9

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. In 2025, a total of 1,042 adverse event reports were recorded on the European Pharmacovigilance Database (UPhD) as occurring in Ireland. Note that, prior to 2022, only adverse event reports classified as 'serious' were required to be reported to the UPhD. However, since 2022, all reports (both 'serious' and 'non-serious') must be recorded in the database and this explains the increase in reports in 2022 compared to the previous year.

Suspected adverse events	2021	2022	2023	2024	2025
Number of reports	426	998	835	883	1,042

We are grateful to veterinary healthcare professionals and animal owners who take the time to report suspected adverse events to either the relevant MAH or the HPRA. 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 an Operational Expert Group for signal detection and management coordinated by the EMA. We processed a total of 192 signal reviews for adverse events as lead authority in 2025.

- 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 2025, we published one safety notice on our website, a caution-in-use notice to communicate important information on the correct and safe use of certain authorised anti-parasitic veterinary medicines.

- During 2025, we 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 which met on five occasions throughout the year.

- Antimicrobial resistance (AMR) affects both human and animal health and has been linked to the inappropriate use of antimicrobials. The HPRA continues to collect and report on the volume of sales of veterinary antimicrobials. Collected from each MAH, this information allows us to monitor national trends in veterinary antimicrobial consumption, and it feeds into an EMA data gathering exercise designed to monitor the EU's progress towards a 50% reduction of overall antimicrobial sales for farmed animals and aquaculture by 2030. Further details can be found in the annual HPRA reports on sales of veterinary antimicrobials in Ireland, as well as in the EMA's European sales and use of antimicrobials for veterinary medicine annual surveillance reports.

  The quantity of veterinary antibiotics (as active substance) sold in Ireland for the years 2020 to 2024 are detailed in the accompanying table.

Veterinary antimicrobial sales	2020	2021	2022	2023	2024
Tonnes sold	103.9	94.2	76.5	75.2	76.0

- The analytical testing and examination of veterinary medicines is a key component of our risk-based sampling and analysis programme. Sixty-eight veterinary medicines cases were included in surveillance programmes in 2025. Of these, 21 samples were sent for analytical testing. The testing carried out was physiochemical in nature with one exception where biological testing was performed. In addition, packaging and labelling checks were performed on 38 veterinary products. Four products were found to have been out-of-specification, and appropriate follow-up actions were taken in each case. Eight cases were cancelled due to sample unavailability on the Irish marketplace during 2025.

- There were 71 veterinary medicine quality defect cases opened in 2025, significantly up from 48 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	2023	2024	2025
High risk quality defects	13	8	7
Moderate risk quality defects	20	19	20
Low risk quality defects	34	21	40
Number of reports not justified	1	0	4
Total number quality defects	68	48*	71*

* These figures are not directly comparable to previous year's figures, due to the introduction of a new workflow system in March 2023.

The majority of reports (55%) were submitted by pharmaceutical companies, including manufacturers, distributors and MAHs. Other competent authorities accounted for 44% of the remaining reports received, and others 1%.

- 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. Thirteen recall actions for veterinary products occurred during 2025, for the following reasons:

Cause of recall	Number of recalls
Particulate contamination	6
Non-compliance with GMP	3
Lack of Sterility Assurance	2
Stability - Out of specification	1
Product mix-up	1
Total	**13**

- Caution in Use Notifications (CIUNs) are issued for medicines with a quality defect, but for which a recall action could not be initiated (e.g. as a recall may cause a stock-out). One such communication was approved during 2025.

- During 2025 a Rapid Alert notification was issued by the HPRA to alert other competent authorities of the potential for particulate contamination in a number of veterinary medicinal products manufactured at an Irish site.

- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2025, there were 11 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, we continued to implement various requirements of the Regulation including:
  - Continued engagement with EMA and stakeholders to improve data quality in the EMA's Union Product Database (UPD) of veterinary medicinal products;
  - Updating of pharmacovigilance contact information in the UPD;
  - Revision of pharmacovigilance processes based on experience and active participation in the centralised management of adverse reaction surveillance at the EMA;
  - Adequately resourcing and streamlining the process for assessing variations submitted to update product labelling to comply with legislative requirements. The changes aim to reduce the amount of text that appears on labels which is expected to facilitate the creation of multilingual labelling which, in turn, is expected to improve product availability in small markets such as Ireland;
  - Engagement with MAHs to create awareness of the deadline for compliance with labelling requirements and to promote the concept of multilingual labelling;
  - Working with stakeholders to develop indicators to measure the impact of changes required by the legislation.

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2025 we:
  - Participated in a series of meetings with representatives of the Department of Agriculture, Food and the Marine (DAFM) and the Veterinary Council of Ireland to discuss issues of mutual interest related to the importation, use, dispensing, control, and prescribing of veterinary medicines in Ireland;
  - Introduced a stakeholder survey on new DCP and MRP applications where the HPRA takes the lead assessment role. This survey will run on an ongoing basis to gauge feedback on the service provided;
  - Engaged with industry stakeholders in relation to an availability initiative for veterinary vaccines in short supply nationally.

- 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:
  - Continued participation in 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 and multiple communications with MAHs to create awareness of year-end expiry of those transitional arrangements;
  - Liaising with stakeholders concerning the availability of veterinary medicinal products on the island of Ireland.

- Throughout 2025, we continued our involvement across the EU regulatory network, which includes active participation at the EMA and the HMA. Of note, a HPRA expert was elected to the position of Chair of the Scientific Advice Working Party of the EMA's Committee for Veterinary Medicinal Products (CVMP) and two other HPRA experts were re-elected to positions of co-opted members of the CVMP.

- As in recent years, we continued to deliver a programme of presentations to veterinary students and veterinary nursing students on the role of the HPRA and the promotion of veterinary pharmacovigilance. We provided training on veterinary pharmacovigilance to DAFM veterinary officers in regional veterinary laboratories. We also presented at a number of industry stakeholder events.

- We also contributed a number of articles to Veterinary Ireland Journal and the It's Your Field publication. Details are included in Appendix 2. In addition, we published two animated short videos on the HPRA website with further dissemination via social media channels – one highlighted the role of the HPRA, the second promoted the reporting of suspected adverse reactions to veterinary medicines.

- Several HPRA guidance documents, which provide stakeholder advice and directions in respect of legislation and regulatory requirements, were issued and updated during 2025 and are available to download from our website. This included, among others:
  - Guide to registration of veterinary medicinal products for pets that qualify for registration under article 5(6) of regulation 2019/6.

Scientific Animal Protection



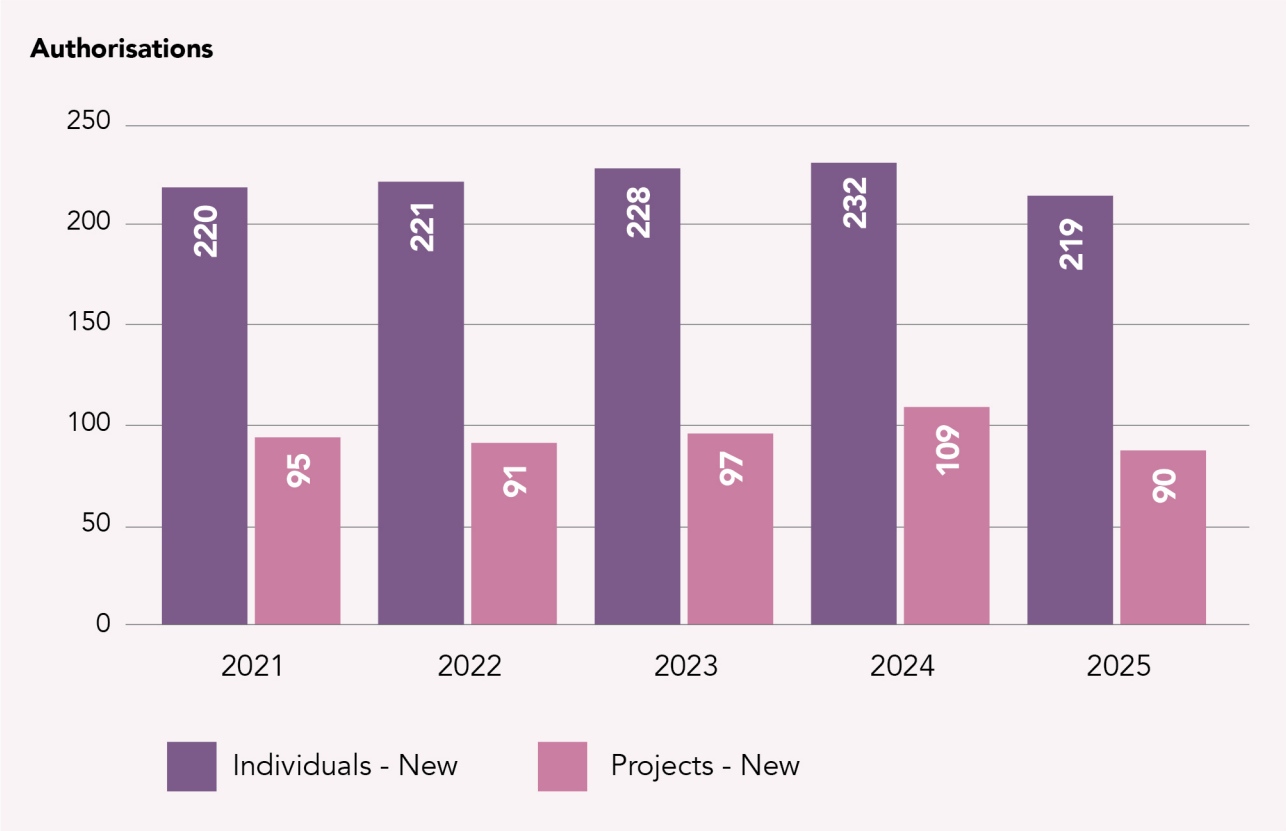
The HPRA is the competent authority in Ireland responsible for the implementation of EU legislation (Directive 2010/63/EU) for the protection of animals used for scientific purposes.

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 2025 figures
Individual authorisations	219
Individual renewals	63
Project authorisations	90
Individual amendments	22
Project amendments	60
Establishment renewals	1
Retrospective assessments	21

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 twelfth 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 2025, there were 39 inspections performed to monitor animal welfare standards and compliance with legislation, 72% of which were conducted as unannounced inspections.

- Of the non-compliances recorded in 2025 under the Scientific Animal Protection inspections and compliance programme, 40% were self-reported to the HPRA by authorised breeder/supplier/user establishment personnel. A further 48% were identified during HPRA inspections, with the remaining 12% detected during HPRA assessment of applications for authorisation or during the analysis of statistical data on animal usage.

- Non-compliances are categorised as Type 1, Type 2 and Type 3, with Type 1 the most serious, and Type 3 the most minor in nature. Of the non-compliances identified in 2025:

  – 20% were Type 1

  – 64% were Type 2

  – 16% were Type 3

  The most frequently recorded reason for non-compliance in 2025 was failure to meet the requirements of Annex III to Directive 2010/63/EU in relation to the care and accommodation of animals. Examples of compliance issues identified included failures to maintain environmental parameters within the required specifications and not performing or documenting routine daily health checks appropriately.

  The second most common reason for non-compliance was failure to comply with the terms and conditions of HPRA project or individual authorisation. This included, for example, failure to adhere to the terms of authorisation, such as inadvertently using more animals than authorised, and failure to follow agreed welfare monitoring arrangements.

Stakeholders and Partners

- In 2025, we supported the National Committee for the Protection of Animals Used for Scientific Purposes (NCPA) in its meetings and in several key activities. This included delivering a successful 3Rs stakeholder training event focused on Replacement. We also supported the NCPA in the developing guidance for Scientific Animal Protection (SAP) stakeholders and in establishing an Irish National Network of Animal Welfare Bodies.

- We disseminated three SAP 'Regulatory Updates' to provide stakeholders with the latest news and guidance from the HPRA. These updates included comprehensive information on best practices relating to the 3Rs and compliance with the legislation, as well as details of 3Rs training opportunities for stakeholders.

- We delivered a presentation to a global biopharmaceutical conference to raise awareness of the 3Rs amongst the biopharmaceutical industry and medicines regulators.

- 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 2025, we continued our involvement and engagement with 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.

- Several HPRA guidance documents, which provide stakeholder advice and directions in respect of legislation and regulatory requirements, were issued and updated during 2025 and are available to download from our website. This included, among others:
  - Guide to new, amendment, renewal and reactivation application for individuals under scientific animal protection legislation;
  - Guide to applications for breeder/supplier/user authorisations under scientific animal protection legislation;
  - Guide to project applications under scientific animal protection legislation;
  - Guide to training, education and competency requirements under scientific animal protection legislation.

Controlled Drugs and Precursor Chemicals

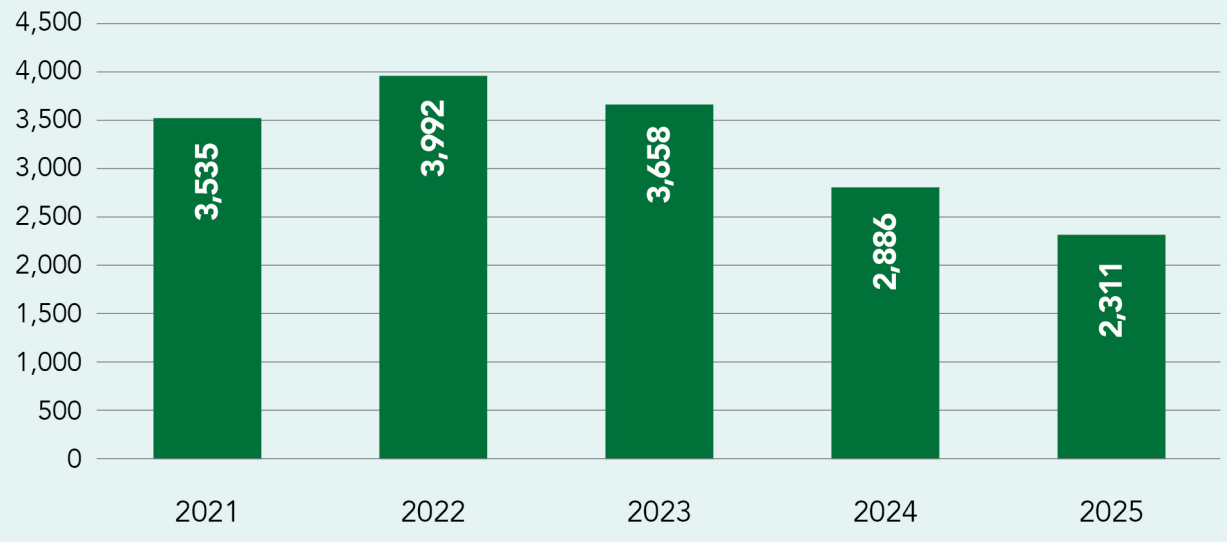


The HPRA is responsible for reviewing the licence application for a controlled drug as listed in the schedule to the Misuse of Drugs Acts 1977 and 1984. Additionally, the HPRA regulates the movement of precursor chemicals used in the manufacture of licensed medicines, certain foodstuffs and for other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

Controlled Drugs Licensing Activity



- The following table shows the licensing activity for precursor chemicals since 2023:

Precursor Chemicals Licensing Activity	2023	2024	2025
Total	19	29	15

- 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	2023	2024	2025
Total	21	30	18

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 2025, 28 inspections were conducted linked solely to the possession and/or supply of controlled drugs. Any non-compliances identified were notified to the operators with requests to implement corrective actions.



Legislation and Regulation

- Throughout 2025, 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 during 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 three new applications in 2025 from potential suppliers seeking to have their products included on the programme. All three are still undergoing assessment at the time of publication.

Three additional applications, one originally submitted in 2023 and two submitted in 2024, are still undergoing assessment at the time of publication. The HPRA recommended one cannabis-based product, the application for which was originally submitted in 2024, for inclusion on the MCAP which was accepted by the Department of Health.

In total, 11 cannabis-based products have been included for use on the MCAP by the Department 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 131 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 includes 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 2025, 191 market surveillance cases were initiated, including both proactive and reactive surveillance of cosmetic products and we received 1,667 Safety Gate alert notifications regarding non-compliant products.

- We also carried out 22 inspections to assess compliance with the EU Cosmetics Regulation in relation to Responsible Person or distributor obligations.

Stakeholders and Partners

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

- In late 2025, we issued a press release to highlight new HPRA research showing that six in ten Irish adults continue to use cosmetic products beyond their expiry date or recommended shelf life. The release urged the public to follow labelling guidance, including the 'open jar' symbol, to reduce the risk of irritation and other adverse reactions.

Other Regulatory Programmes



Inspections and Market Compliance

- Throughout 2025, HPRA contributions at an EU and international level included participation in/leading on:
  - Inspector Working Groups for GMP/GDP, GCP and PV;
  - the Pharmaceutical Inspection Co-operation (PIC/S) Committee of Officials and selected sub-committees;
  - the PIC/S Expert Circles;
  - the EU funded project EU4Health Joint Action on quality of medicines and implementation of pharmaceutical legislation/strategy;
  - 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 2025 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.

- The HPRA co-chaired a multi-stakeholder session on innovation in clinical trials at the DIA Europe conference. We also presented on national supports for innovation at an EMA event marking the 20th anniversary of the small and medium-sized enterprises (SME) Regulation in October.

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.

- Patient engagement:
  - The Patient Forum continued to meet over the course of the year. The forum is a platform for dialogue and exchange between the patient community and the HPRA on issues relevant to the regulation of medicines and medical devices, and aims to give patients in Ireland a voice in the regulatory process.
  - Working collaboratively, forum members and HPRA staff developed a rolling work plan for 2025 that included areas of common interest and aligned with the purpose of the forum. There was engagement on a range of topics including an overview of interchangeable medicines and emerging digital health technologies. Additionally, the Pharmaceutical Society of Ireland hosted a dedicated forum meeting to introduce its role as the regulator for the pharmacy profession in Ireland, its interface with the HPRA, and its approach to engaging with patients.
  - A patient speaker event was also held for HPRA staff, involving guests from different stakeholder perspectives on the topic of rare diseases. The patient speaker programme aims to help HPRA staff incorporate the values and perspectives of patients into HPRA activities by listening to, and understanding, the views of patients and their representative organisations.

- Corporate and digital communications:
  - During the year, we delivered four targeted digital information campaigns, each focused on a distinct public health theme and tailored to raise awareness and understanding of the safe use of health products:
    - We continued our multi-platform digital information campaign to warn of the health risks of sourcing prescription medicines online. First launched in 2022, 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 2025 campaign reached over half a million people, generated seven million impressions and drove over 50,000 clicks to the campaign webpage;
    - For the second year running, we ran a targeted social media-based campaign highlighting the risks associated with dermal fillers. This campaign targets both the public and those who administer dermal fillers and is built on strong, plain English web content giving clear advice to help people make safer choices. The key messages of this campaign are supported by custom-made illustrations designed to capture attention on busy social media feeds across Instagram, Facebook and Pinterest. The campaign was shown on social media feeds over one million times, reached over 100,000 people and drove almost 9,000 clicks to the campaign webpage;
    - In September, we took part in the first-ever Europe-wide campaign to raise awareness of the importance of taking over-the-counter medicines safely. The campaign was coordinated by the Heads of Medicines Agencies (HMA) with an overarching theme of "Medicines are not sweets". Nationally, we supported this theme with the tagline "Don't sugarcoat it. Remember all medicines come with benefits and risks". The campaign highlighted the key message that although some medicines can be bought over the counter, they are still medicines and come with instructions for use. Using them incorrectly can lead to side effects and even health risks. The initial round of this campaign achieved over 100,000 impressions on social media;
    - We again participated in the 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 2025, the campaign

marked its 10th anniversary with the message: we all have the power to make medicines safer. This message came to life through eye-catching superhero visuals and the hashtag #MedSafetyHero. The campaign consisted primarily of short, animated videos, available to view and download from the HPRA website, and shared across our social media accounts. #MedSafetyWeek in 2025 involved more than 100 organisations worldwide while at a national level, 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 campaign achieving over one million impressions (1,012,083) in total across platforms that included Instagram, Facebook, LinkedIn and YouTube.

– In addition to promoting #MedSafetyWeek via our social media channels, we expanded our activity this year by running a proactive public relations campaign to further amplify this important public health message. This featured a press release and engagement with broadcasters to secure a number of media interviews for our HPRA spokesperson. The HPRA delivered several radio interviews across national, regional and community radio including RTÉ, Q102 and LMFM. Coverage from the press release appeared across national, regional and health publications.

– 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 12 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 602 initial and follow-up queries from national, local and specialist media during the year.

– 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. In January 2025, we launched our newly redeveloped site following a two-year project aimed at significantly improving how users interact with HPRA services and information online. While the refreshed look and feel modernised the site, the primary focus of the project was on enhancing functionality, navigation and overall user experience. The redevelopment reflects our commitment to digital-first, accessible and user-centred design across a broad audience, including patients, healthcare professionals and industry stakeholders;
  - 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 2025, following another year of significant growth, our total number of followers had grown to more than 30,000;
  - We also continued to utilise our corporate Instagram account to highlight and promote important public health messages as well as certain activities and events. In 2025, this included #MedSafetyWeek as well as our additional digital-based information campaigns. The HPRA Instagram account now has over 2,500 followers.

- 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. 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 2025.

- European and international contribution:
  - We continued our active participation in all EMA Management Board and HMA Management Group meetings. The HPRA Chief Executive completed her mandate as chair of the EMA Management Board on 21 March 2025;
  - 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 3);
  - The HPRA continued its role as a member of the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee, contributing to a range of significant initiatives. During 2025:
    - We continued as co-lead, alongside the US FDA, on the Pharmaceutical Quality Knowledge Management System (PQ KMS) project, which was promoted through multiple public engagements. These included a virtual workshop held in September, the outputs of which were posted on the ICMRA website. The HPRA also presented an update on the project at the ICMRA Summit in October. As part of the work carried out under the PQ KMS project, a sub-group of the ICMRA Executive Committee was convened to develop a proposal for a long-term, sustainable model for collaborative regulatory procedures. The group's proposal was endorsed in 2025, and the work previously undertaken through the PQ KMS pilot programmes is to be transitioned to a more long-term operating model over the course of 2026 and beyond;
    - We continued to chair the Governance Working Group of ICMRA;
    - The HPRA also co-led the ICMRA innovation project in conjunction with the EMA and Japan's MHLW/PMDA.
  - 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 2025, negotiations on the proposed revision of the EU pharmaceutical legislation continued in the European Council's Working Party on Pharmaceuticals and Medical Devices resulting in a Council position being adopted in June 2025. Trilogues took place during the second half of 2025, and a provisional agreement was reached in December. It is expected that the revised legislation will be finalised by mid-2026. The HPRA continues to support the Department of Health in these discussions;

- A Council position on the Critical Medicines Act was agreed following negotiations during the Danish presidency of the Council of the EU. Trilogues between the Council and European Parliament will take place during the Cypriot presidency in the first half of 2026.

- Protected disclosures:
  - During 2025, 23 reports of relevant wrongdoing were received by the HPRA as a prescribed person;
  - Eleven reports warranted no follow-up, and four reports were transmitted to another appropriate prescribed person;
  - Eleven investigations were opened which involved a breach of legal obligation;
  - Fifteen open investigations were carried over from the previous year, with eight investigations closed during 2025;
  - Fifteen investigations remained open at the end of the calendar year;
  - There was one internal report of relevant wrongdoing received, which remained open at the end of the calendar year.

Key outreach and engagement figures	**2025**
Public consultations held	2
Public consultations responded to	2
Events managed by HPRA events teams	10
Freedom of information (FOI) requests	68
Freedom of information requests answered outside the FOI Act	56
Requests received in accordance with the Data Protection Acts	11
Parliamentary questions	52
Queries from Government departments or members of the Oireachtas	137
Complaints related to standards of service	5
Customer service queries	2,101

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.

Human Resources and Development

The Human Resources and Development (HRD) function continued to deliver both operational and strategic priorities for the organisation through the consistent application of best-practice support, robust policy implementation, and the advancement of key strategic deliverables. All activities were firmly aligned to the four pillars of the People Strategy; 'Purpose, Growth, Belonging, and Wellbeing', ensuring that HRD initiatives not only addressed immediate organisational needs but also strengthened long-term capability and cultural sustainability.

Throughout 2025, we focused on key areas including leadership development, health and wellbeing, diversity and inclusion, recruitment, embedding HPRA values, and supporting personal and career development. Alongside these initiatives, we developed our new Career & Capability Framework, ensuring it underpins how we develop capability, and support meaningful progression in the organisation. These initiatives are helping to foster a more inclusive, resilient, and purpose-driven workplace, ensuring that our people remain central to everything we do.

Leadership and Development

- A major focus for 2025 was the launch of our Career & Capability Framework, establishing a clear, transparent structure for career development and supporting employees in navigating progression pathways. This framework is fully aligned to our People Strategy and performance development process. It also reinforces the delivery of our organisational strategic plan and objectives by ensuring that capability building, development priorities, and progression pathways are directly connected to the skills, behaviours and strategic contributions required across the organisation. Together, these elements ensure consistency in expectations, capability building and stronger development conversations, enabling employees to grow in ways that support both individual and organisational success.

- In 2025, we strengthened leadership capability across the organisation through the launch of our leadership forums, providing a regular space for managers and leaders to share best practice, explore challenges, and deepen alignment with our People Strategy. These forums reinforce our ongoing commitment to building a culture of trust, collaboration and high performance.

- Furthering the reach and impact of the Learning and Development Roadmap, we expanded access to leadership development by adapting our Leadership Identity course and releasing to all employees. This initiative supports greater self-awareness, personal impact and ownership of leadership behaviours at every level - further embedding leadership as a shared organisational responsibility.

- We expanded our psychological safety initiatives by delivering team-based Psychological Safety for High Performance workshops, helping teams and managers build trust, open dialogue and shared behaviours for effective teamwork. The workshops further improved our psychological safety results in our Employee Experience Survey and advanced our People Strategy commitments by strengthening our culture of belonging, growth and high performance.

- To enhance everyday performance and strengthen our feedback culture, we introduced our new Get Great at Feedback course. This programme equips employees and managers with the skills to give and receive feedback constructively, supporting continuous growth and reinforcing expectations within our Performance Development Programme (PDP).

Change Management

- Tailored change-management support was provided at departmental level for a structure review process. The purpose of this support is to help ensure alignment between departmental strategies and organisational priorities, while streamlining and standardising processes, enhancing operational efficiency, and optimising the utilisation of resources. A governance model for change management was designed and developed with implementation planned for 2026.

Gender Pay Gap

- In 2025, we continued our in-depth analysis of the gender pay gap to better understand its drivers and identify meaningful actions to address any imbalances. Our current gender pay gap is 2.51%.

- 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 remained a key priority for the HPRA in 2025. Building on the strong momentum of recent years, we achieved a further 7% increase in our employee engagement score, bringing our overall improvement to 18% since 2022. This progress reflects the collective effort of our employees and managers across departments, supported by HRD and the HPRA leadership team.

Wellbeing

- The HPRA was successfully reaccredited with the KeepWell Mark for 2025-26, 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 reaccreditation was particularly significant as it was conducted under a newly updated framework, which introduced higher requirements and two additional assessment areas: 'Talent Support and Development' and 'Inclusion and Belonging'. We are proud to have received the highest award, Excellence, in both areas. The dedicated and ongoing efforts in this area were also externally recognised, with the organisation being named finalists for the 2025 KeepWell Mark Awards.



- For the fifth 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.

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 partnered with an external company to undertake a detailed assessment approach. A cross organisational group was established, and workshops were conducted to support a comprehensive assessment and subsequent action plan to be developed in early 2026.

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 processes;
- 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 in 2025 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 protecting digital assets, enhancing resilience and improving recovery processes;
- The project to rebuild the organisation's website was also completed with the new website launched in January 2025.

Operational Excellence and Quality Management

- The HPRA is committed to a culture of continuous improvement and application of its quality management system. In 2025, eight internal audits were completed with no major concerns identified.

- The quality management team implemented various improvements to the quality management systems for increased collaboration and efficiencies across the organisation. There was close co-operation 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 and updated legislation.

- Considerable progress has been made in advancing operational excellence at the HPRA. In 2025, organisation-wide lean training was delivered, including the introduction of new, hands-on practical learning sessions to strengthen capability and engagement. The HPRA planning process was comprehensively reviewed, with a redesigned approach successfully piloted during the second half of the year. Progress continued in transitioning the parliamentary queries cross-organisational process to the HPRA case management system, and planning for the 2026 Operational Excellence Awards was initiated.

Finance

- The HPRA is committed to the highest standards of corporate governance. During 2025, 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 2024 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.

- The annual review of regulatory fees for 2026, incorporating a public consultation, was completed followed by the publication of the updated fees.

- One internal audit review took place, and a report was issued on procurement.



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 2025, the HPRA consumed 605.4 MWh of energy consisting of:
  - 378.5MWh of electricity;
  - 226.9 MWh of fossil fuels;
  - 0 MWh of renewable fuels.
- According to the Sustainable Energy Authority of Ireland (SEAI) Annual Report 2024 on Public Sector Energy Efficiency Performance, total energy reduction achieved by the HPRA since baseline was 67.8%* 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 HPRA 2025 annual 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 2025.

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 2025 and considered a number of strategic matters including strategic planning, financial matters, the continued supply of medicines to the Irish market, and the implementation of new Regulations in areas such as medical devices. Financial matters included monthly management accounts, annual budgets and the financial statements for 2024. The Authority also had five closed sessions in 2025.

- 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 2025 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
Prof Richard Reilly	5	5
Prof Sharon O'Kane	5	4
Dr Paula Kilbane	5	5
Dr Fiona Kiernan	5	5
Dr Suzanne Kelly	4*	4

* Resigned September 2025.

  - The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2025. Further details are provided in the HPRA's Financial Statements;
  - The Advisory Committee for Human Medicines met once;
  - The Advisory Committee for Veterinary Medicines met twice;
  - The Advisory Committee for Medical Devices met twice;
  - 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 2025.

- 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 HPRA Leadership Team.

  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 HPRA Leadership Team 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 HPRA Leadership Team 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 2025

Authority Members and Other Information

		Most recent appt date	*Expiry date*
Authority:	Mr. Michael Donnelly (Chairperson)	19/04/2021	31/12/2025
	Mr. Paul Quinn (Chairperson)	10/03/2026	09/03/2031
	Dr. John Byrne	22/04/2026	21/04/2031
	Prof. Deirdre Campion	22/04/2026	21/04/2031
	Mr. Joe Collins	01/01/2025	27/09/2028
	Prof. Peter Doran	10/03/2026	09/03/2031
	Mr. David Holohan	27/01/2021	21/04/2026
	Mr. Brian Jones	27/01/2021	21/04/2026
	Dr. Suzanne Kelly	01/11/2024	10/09/2025
	Dr. Fiona Kiernan	12/09/2022	31/12/2026
	Dr. Paula Kilbane	28/06/2021	31/12/2028
	Dr. Sharon O'Kane	15/07/2021	31/12/2025
	Prof. Richard Reilly	01/01/2025	31/12/2027
	Mr. John Tohill	10/03/2026	09/03/2031

All Authority members are appointed by the Minister for Health.
Attendance at Authority meetings is documented on page 77 of the annual report.

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

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 Members' 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 2025.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2025. 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 2025, the internal auditor carried out internal audit reviews on procurement. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2025, 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 84 to 86.

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, Infrastructure, Public Service Reform and Digitalisation 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.

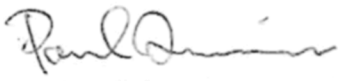
Statement of Compliance

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 2025.

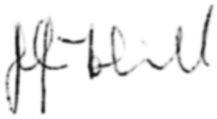
Performance Review

The Authority carried out a self-assessment evaluation of its own performance and its committees for the year ended 31 December 2025.

On behalf of the Authority



Mr. Paul Quinn
Chairperson



Mr. John Tohill
Authority Member

Date: 02 June 2026

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, Infrastructure, Public Service Reform and Digitalisation, has been in place in the HPRA for the year ended 31 December 2025 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 2025.

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 2025 one internal audit review was 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 2025 the HPRA complied with those procedures.

Review of Effectiveness

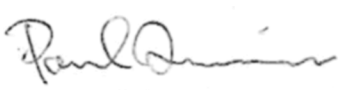
In the post Covid-19 era, the HPRA is operating a hybrid working environment, with a combination of office based and home based days. The controls in place pre-Covid, which continued to apply during the period of remote working, continue to apply during this hybrid working environment.

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 2025. This review was carried out at its meeting on 21 January 2026.

Internal Control Issues

No weaknesses in internal control were identified in relation to 2025 that require disclosure in the financial statements.



Mr. Paul Quinn
Chairperson

Date: 02 June 2026

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 2025 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 2025 and of its income and expenditure for 2025 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 2025 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.

Irena Grzebieniak

Irena Grzebieniak

For and on behalf of the

Comptroller and Auditor General

9 June 2026

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 2025

	Notes	2025	2024
		€	€
Fee Income	3	**41,763,962**	35,861,630
Department of Health Funding	3	**6,665,000**	5,665,000
Other Income	4	**1,655,140**	1,507,055
		50,084,102	43,033,685
Salaries and Wages	5	**37,429,876**	34,476,136
Other Operating Costs	6	**6,564,582**	6,101,162
Depreciation	2	**1,928,637**	1,945,128
		45,923,095	42,522,426
Surplus for the year before write back of Superannuation contributions		**4,161,007**	511,259
Staff Superannuation Contributions		**643,911**	768,134
Surplus for the year		**4,804,918**	1,279,393
Balance brought forward		**43,451,720**	42,172,327
Balance carried forward	12	**48,256,638**	43,451,720

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 94 - 105 form part of the financial statements.

On behalf of the Authority

Mr. Paul Quinn
Chairperson

Mr. John Tohill
Authority Member

Date: 02 June 2026

Statement of Financial Position
As at 31 December 2025

	Notes	2025	2024
		€	€
Fixed Assets			
Property, Plant and Equipment	2	**24,385,925**	24,746,990
Current Assets			
Debtors and Prepayments	7	**1,696,012**	2,006,105
Inventory of Stationery		**4,285**	3,934
Cash and Cash Equivalents	9	**10,265,674**	3,508,149
Short Term Deposits	10	**28,568,128**	29,187,676
		40,534,099	34,705,864
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	**16,663,386**	16,001,134
Mortgage	13	**-**	-
		16,663,386	16,001,134
Net Current Assets		**23,870,713**	18,704,730
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	**-**	-
NET ASSETS		**48,256,638**	43,451,720
Reserves			
Retained Revenue Reserves	12	**24,339,065**	20,178,058
Superannuation Reserve	12	**23,917,573**	23,273,662
		48,256,638	43,451,720

The Statement of Cash Flows and the notes on pages 94 - 105 form part of the financial statements.

On behalf of the Authority

Mr. Paul Quinn
Chairperson

Mr. John Tohill
Authority Member

Date: 02 June 2026

Statement of Cash Flows
For the year ended 31 December 2025

	Notes	2025	2024
		€	€
Cash flows from Operating Activities			
Surplus for financial year		**4,804,918**	1,279,393
Depreciation of property, plant and equipment		**1,928,637**	1,945,128
(Profit)/Loss on Disposal of property, plant and equipment		**(100)**	(50)
(Increase)/Decrease in Debtors		**310,093**	(466,596)
(Increase)/Decrease in Stock		**(351)**	2,214
Increase/(Decrease) in Creditors - amounts falling due within one year		**662,252**	890,655
Deposit Interest		**(461,925)**	(401,952)
Bank Interest		**0**	16,473
Cash from Operations		**7,243,524**	3,265,265
Bank Interest Paid		**0**	(16,473)
Net Cash generated from Operating Activities		**7,243,524**	3,248,792
Cash flows from Investing Activities			
Deposit Interest Received		**461,925**	401,952
(Increase)/Decrease in Bank Deposits		**619,548**	(7,172,468)
Payments to acquire property, plant and equipment		**(1,568,478)**	(2,056,670)
Receipts from sales of property, plant and equipment		**1,006**	50
Net cash from Investing Activities		**(485,999)**	(8,827,136)
Cash flows from Financing Activities			
Repayment of Borrowings		**0**	(168,337)
Net cash used in Financing Activities		**0**	(168,337)
Net increase/(decrease) in Cash and Cash Equivalents		**6,757,525**	(5,746,681)
Cash and Cash Equivalents at beginning of year		**3,508,149**	9,254,830
Cash and Cash Equivalents at end of year	9	**10,265,674**	3,508,149

Notes to the Financial Statements
For the year ended 31 December 2025

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.

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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.
- Oireachtas grants are recognised on an accruals basis.

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, Infrastructure, Public Service Reform and Digitalisation.

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 2025	**1,325,110**	**21,141,751**	**866,055**	**4,871,921**	**23,156,037**	**51,360,874**
Additions for the year	**31,679**	**638,265**	**-**	**898,534**	**-**	**1,568,478**
Disposals for the year	**(172,753)**	**(621,155)**	**(502,445)**	**(35,185)**	**-**	**(1,331,538)**
As at 31 December 2025	**1,184,036**	**21,158,861**	**363,610**	**5,735,270**	**23,156,037**	**51,597,814**
Depreciation						
Balance as at 1 January 2025	**1,239,063**	**19,405,078**	**711,352**	**4,492,149**	**766,242**	**26,613,884**
Charge for the year	**37,453**	**1,330,878**	**36,361**	**140,824**	**383,121**	**1,928,637**
Disposals for the year	**(172,753)**	**(620,249)**	**(502,445)**	**(35,185)**	**-**	**(1,330,632)**
As at 31 December 2025	**1,103,763**	**20,115,707**	**245,268**	**4,597,788**	**1,149,363**	**27,211,889**
Net Book value at 31 December 2025	**80,273**	**1,043,154**	**118,342**	**1,137,482**	**22,006,674**	**24,385,925**
Net Book value at 1 January 2025	**86,047**	**1,736,673**	**154,703**	**379,772**	**22,389,795**	**24,746,990**

3. Income	2025	2024
	€	€
Fee Income		
Human Medicines - National Fees	**13,403,180**	12,287,578
Human Medicines - Centralised Fees	**10,597,663**	8,362,945
Veterinary Sciences - National Fees	**3,434,435**	3,691,575
Veterinary Sciences - Centralised Fees	**2,369,076**	1,178,909
Compliance Department	**8,631,630**	7,223,358
Medical Devices	**3,283,860**	3,395,143
	41,719,844	36,139,508
Movement in deferred revenue	**44,118**	(277,878)
	41,763,962	35,861,630
Dept Of Health Funding (Vote 38 Subhead E1)	**6,665,000**	5,665,000
Other Income (Note 4)	**1,655,140**	1,507,055
Total Income	**50,084,102**	43,033,685

Fees received by the Authority under Section 13 of the Irish Medicines Board Act 1995 totalling €23,204,246 in 2025, shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure, Infrastructure, Public Sector Reform and Digitalisation directs.

4. Other Income	2025	2024
	€	€
Bank Interest	**461,925**	401,952
Joint Action Income	**334,419**	379,893
Conference Income	**17,190**	9,460
IT Income	**841,506**	715,700
Gain On Disposal Of Fixed Assets	**100**	50
	1,655,140	1,507,055

5. Salaries and Wages	2025	2024
	€	€
Basic Pay	**29,375,512**	27,591,972
Overtime	**1,726**	418
Allowances	**115,596**	132,852
Staff Short Term Benefits	**29,492,834**	27,725,242
Retirement Benefit Costs	**2,694,727**	1,849,107
Employer's Contribution to Social Welfare	**3,064,705**	2,854,617
Employer's Contribution to Single Scheme Pension	**2,177,610**	2,047,170
	37,429,876	34,476,136

The average number of staff employed during the year was 418 (2024 - 406).
Payroll numbers at 31 December 2025 can be analysed across the following departments :

Chief Executive	**16**	16
Compliance	**82**	82
Finance, Corporate & International	**32**	32
Human Products Authorisation & Registration	**126**	115
Human Products Monitoring	**42**	41
Human Resources & Development	**11**	11
IT & Business Services	**19**	21
Medical Devices	**55**	53
Veterinary Sciences	**41**	38
Staff	**424**	409
Authority Members	**5**	8
Pensioners	**75**	65
	504	482

No termination or severance payments were made during the year.

Additional superannuation contributions for Public Servants of €955,746 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 €875,984 were deducted from staff during the year and paid over to the Department of Public Expenditure, Infrastructure, Public Sector Reform and Digitalisation ('DPEIPSRD'). In agreement with our parent department and DPEIPSRD, 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:

	2025	2024
Salary Band		
€0 to €60,000	**192**	203
€60,001 to €70,000	**39**	33
€70,001 to €80,000	**63**	62
€80,001 to €90,000	**48**	33
€90,001 to €100,000	**19**	16
€100,001 to €110,000	**16**	18
€110,001 to €120,000	**26**	25
€120,001 to €130,000	**8**	8
€130,001 to €140,000	**7**	6
€140,001 to €150,000	**5**	4
€150,001 to €160,000	**-**	-
€160,001 to €170,000	**-**	-
€170,001 to €180,000	**-**	-
€180,001 to €190,000	**-**	1
€190,001 to €200,000	**1**	-
	424	409
Average Salary	**€67K**	€70K

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	2025	2024
	€	€
Accommodation Costs	**1,738,746**	1,918,602
Travel, Representation and Training	**964,520**	825,876
Bank Charges and Interest	**5,341**	21,978
Legal Fees	**590,697**	104,742
Audit Fees (External and Internal)	**42,112**	38,307
Stationery, Publications, Postage and Communications	**364,325**	300,144
Consultancy	**537,466**	590,402
Sampling and Analysis	**243,062**	255,039
IT Costs	**2,163,086**	1,786,142
Storage Costs	**179,185**	126,751
Telephone and Telecommunications	**19,252**	30,684
Movement on Bad Debt Provision	**(283,210)**	102,495
	6,564,582	6,101,162

Travel costs include an amount of €52,428 related to hospitality and staff wellbeing, and an amount of €392,075 related to travel and subsistence, of which €232,972 is national and €159,103 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 €171,404 related to public relations/marketing, €178,435 related to human resources/ pensions and €187,627 related to other.

7. Debtors (all due within one year)	2025	2024
	€	€
Trade Debtors	**1,215,675**	1,449,361
Prepayments	**423,537**	427,374
Other Debtors	**56,800**	129,370
	1,696,012	2,006,105

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)	2025	2024
	€	€
Trade Creditors	**246,276**	387,334
Credit Balances on Debtor Accounts	**5,504,011**	5,371,858
Accruals	**7,864,596**	7,186,127
Deferred Revenue	**1,988,551**	2,032,669
Revenue Commissioners	**1,059,952**	1,023,146
	16,663,386	16,001,134

9. Cash and Cash Equivalents	2025	2024
	€	€
Cash at Bank and in Hand	**760,064**	2,375,752
Demand Deposits (Convertible to Cash on Demand)	**9,505,610**	1,132,397
	10,265,674	3,508,149

10. Short Term Deposits	2025	2024
	€	€
Short Term Deposits (not immediately convertible to cash)	**28,568,128**	29,187,676
	28,568,128	29,187,676

11. Administration Expenses	2025	2024
	€	€
Surplus for the year was calculated having charged : -		
Auditor's Remuneration	**28,600**	26,600

12. Movement on Income and Expenditure Reserves	As At 01/01/2025	Income & Expenditure	Transfer To Superann Reserve	As At 31/12/2025
	€	€	€	€
Retained Revenue Reserves	**20,178,058**	**4,161,007**	**-**	**24,339,065**
Superannuation Reserve	**23,273,662**	**643,911**	**-**	**23,917,573**
	43,451,720	**4,804,918**	**-**	**48,256,638**

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 :

	2025	2024
	€	€
- within one year	**-**	-
- between one and five years	**-**	-
- after five years	**-**	-
	-	-

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 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 €499,348 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 ran for 3 years to 11 May 2025.

	2025	2024
	€	€
The amounts due under this lease are as follows:		
- within one year	-	128,173
- between one and five years	-	-
- after five years	-	-
	-	128,173

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 2025 this lease had 8 years and 5.5 months remaining.

	2025	2024
	€	€
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	**1,284,496**	1,655,917
	3,141,600	3,513,021

16. Capital Commitments

	2025	2024
	€	€
Contracted For (Contract Signed)	**12,300**	942,750
Contracted For (Contract Not Signed)	-	-
	12,300	942,750

17. Authority Remuneration	Fees	Expenses
	€	€
Michael Donnelly (Chairperson)	**11,970**	**-**
Joe Collins	**7,695**	**603**
David Holohan	**7,695**	**668**
Brian Jones	**7,695**	**785**
Suzanne Kelly	**5,366**	**125**
Fiona Kiernan	**7,695**	**-**
Paula Kilbane	**7,695**	**-**
Sharon O'Kane	**7,695**	**-**
Richard Reilly	**-**	**-**
	63,506	**2,181**

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	2025	2024
	€	€
Chief Executive	**190,606**	184,552
Senior Management	**1,156,872**	1,102,935
	1,347,478	1,287,487

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 2025

19. Related Party Transactions

The HPRA adopts procedures in accordance with the guidelines issued by the Department of Public Expenditure, Infrastructure, Public Service Reform and Digitalisation (DPEIPSRD) covering the personal interests of Authority members. A register of such interests is maintained. In addition to the DPEIPSRD 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 : -

2025 €1 = STG £0.87184

2024 €1 = STG £0.82886

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. Changes in HPRA Leadership Team (HLT)

Since the last financial statements, the following changes have taken place in the HPRA Leadership team:

(i) Lorraine Nolan resigned as Chief Executive on 4th January 2026.

(ii) Grainne Power was appointed Chief Executive on 4th January 2026.

(iii) Gabriel Beechinor retired as Director of Veterinary Sciences on 4th September 2025.

(iv) David Murphy was appointed Director of Veterinary Sciences on 1st September 2025.

(v) Elizabeth Stuart resigned as Director of Human Resources & Development on 30th September 2025.

(vi) Nicola Riggs was appointed Director of Human Resources & Development on 1st October 2025.

(vii) Rita Purcell retired as Deputy Chief Executive on 27th January 2026.

(viii) John Fitzpatrick was appointed as Director of Finance, Legal & Corporate Affairs on 3rd February 2026.

25. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 02 June 2026.

Appendix 1
2025 Committee Members

HPRA Leadership Team

Dr Lorraine Nolan, Chief Executive

Ms Rita Purcell, Deputy Chief Executive

Dr Gabriel Beechinor, Director of Veterinary Sciences *(Retired September 2025)*

Dr David Murphy, Director of Veterinary Sciences *(Appointed September 2025)*

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 *(Resigned September 2025)*

Ms Nicola Riggs, Director Human Resources and Development *(Appointed October 2025)*

Ms Grainne Power, Director of Compliance

Dr Finnuala Lonsdale, Director of Human Products Authorisation and Registration

Authority (Board)

Mr Michael Donnelly – Chairperson *(Term ended 31 December 2025)*

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

Dr Paula Kilbane

Prof Sharon O'Kane *(Term ended 31 December 2025)*

Prof Richard Reilly

Dr Fiona Kiernan

Dr Suzanne Kelly *(Resigned 10 September 2025)*

Audit and Risk Committee

Mr David Holohan – Chair

Mr Brian Jones

Prof Sharon O'Kane *(Term ended 31 December 2025)*

Advisory Committee for Human Medicines

Dr Suzanne Kelly – Chair *(Resigned 10 September 2025)*

Prof Brian Cleary

Prof Paul Gallagher *(Term ended 31 December 2025)*

Ms Fionnuala King *(Term ended 31 December 2025)*

Prof Fionnuala Ní Ainle *(Term ended 31 December 2025)*

Ms Margaret O'Doherty

Dr Michael McCarthy

Ms Lorraine Schwanberg

Professor Peter Greally

Advisory Committee for Veterinary Medicines

Dr Joe Collins – Chair

Dr Patrick Paul Corkery

Dr Abina Crean

Dr Caroline Garvan

Dr John Gilmore *(Term ended 31 December 2025)*

Dr David Graham

Dr Andrew Hillan

Dr Orla Keane

Dr Edward Malone *(Term ended 31 December 2025)*

Dr Bryan Markey *(Term ended 31 December 2025)*

Dr Kevin Murtagh

Dr Emer O'Reilly *(Resigned 11 April 2025)*

Advisory Committee for Medical Devices

Prof Richard Reilly – Chair

Prof Robert Byrne

Dr Ger Flynn *(Term ended 31 December 2025)*

Dr Vida Hamilton

Dr Tanya Mulcahy

Dr Fergal McCaffrey *(Term ended 31 December 2025)*

Prof Ronan Cahill *(Appointed April 2025)*

Ms Lucy Nugent *(Appointed April 2025)*

Prof Richard Greene *(Appointed April 2025)*

Ms Marie Culliton *(Appointed April 2025)*

Prof Alan Fraser *(Appointed April 2025)*

Appendix 2
Publications and Articles 2025

Drug Safety Newsletters

Edition	Articles
March 2025 118th Edition	• Glatiramer acetate: Anaphylactic reactions may occur months up to years after treatment initiation • Medroxyprogesterone acetate: Risk of meningioma and measures to minimise this risk
June 2025 119th Edition	• Finasteride and dutasteride: Outcome of EU review regarding risk of suicidal ideation • Bilastine oral formulations: New warning on the risk of QT prolongation/Torsade de points • Azathioprine: Update to warning on hepatoxicity and monitoring • Mesalazine: New warning regarding the risk of idiopathic intracranial hypertension
August 2025 120th Edition	• Oral retinoids (acitretin and isotretinoin): Psychiatric disorders and pregnancy prevention programme reminder
December 2025 121st Edition	• Fezolinetant: Risk of drug-induced liver injury and new recommendations on monitoring of liver function before and during treatment. • Enzalutamide and digoxin: Laboratory test interference leading to falsely elevated digoxin plasma levels and a reminder of the existing interaction. • Glucagon-like peptide-1 (GLP-1) analogues: Highlight and reminder of certain safety aspects.

Human Medicines Safety Articles – External Publications

Month	Publication	Topic
January	IMF	Fluconazole: Update on pregnancy outcomes following use and new advice for women of childbearing potential
January and February	MIMS	Updated recommendations on the use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) during pregnancy
April	MIMS	Updated recommendations on the use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) during pregnancy
May	MIMS	Glatiramer acetate: Anaphylactic reactions may occur months up to years after treatment initiation
June	IMF	Finasteride and dutasteride: Outcome of EU review regarding risk of suicidal ideation
June	MIMS	Medroxyprogesterone acetate: Risk of meningioma and measures to minimise the risk
July and August	MIMS	Finasteride and dutasteride: Outcome of EU review regarding risk of suicidal ideation
September	MIMS	Finasteride and dutasteride: Outcome of EU review regarding risk of suicidal ideation
October	MIMS	Oral retinoids (acitretin and isotretinoin): Psychiatric disorders and pregnancy prevention programme reminder
November	MIMS	Adverse Reaction Reporting – Reminder

Veterinary Medicines Articles – External Publications

Title	Date	Publication
Controlled drugs: What you need to know	September	Veterinary Ireland Journal
Anthelmintic Residues in Sheep: Understanding the risks	Spring Edition	It's Your Field
Countdown to 31 December 2025 and impact on veterinary medicines	Summer Edition	It's Your Field
Vaccines are different to other veterinary medicines – here is what you need to know	Autumn Edition	It's Your Field
Vaccines and the importance of the cold chain	Winter Edition	It's Your Field

Appendix 3

Standing Committees / Working Groups Participation

Committee/Working Group	Organisation	Meetings in 2025
Quality and Safety Advisory Committee	CAI / RCPI	3
Controlled Drugs Cross Border Group	Care Quality Commission (UK)	3
National Criminal Investigative Forum	CCPC	3
Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED)	EDQM	2
Critical Entities Resilience Directive	Office of Emergency Planning	2
Interdepartmental Chemical Directors Group	Department of Enterprise, Trade and Employment	1
National Market Surveillance Strategy Subgroup	Department of Enterprise, Trade and Employment	4
National Valproate Stakeholder Group	Department of Health	1
Pharmaceutical Strategy Working Group	Department of Health	1
Oversight Committee for Ireland's Public Health Emergency Preparedness Assessment (PHEPA)	Department of Health	1
Strategic Medicines Access and Availability Group	Department of Health	1
Medicines Criticality Assessment Group	Department of Health / HSE	3
SoHO Working Group on Inspections	DG-SANTE	14
Working group on authorisation and assessment of SoHO preparations	DG-SANTE	5
NCA Organs	DG-SANTE	1

Committee/Working Group	Organisation	Meetings in 2025
Development of Implementing acts on Good Manufacturing Practices (Veterinary medicinal products (VMPs) and API used in VMPs)	DG-SANTE	4
Development of Implementing acts on Good Manufacturing Practices (autogenous vaccines)	European Commission (Sante)	3
SoHO Co-Ordination Board	European Commission (DG Sante)	5
Working group on registration of entities and authorisation of establishments	EU Commission DG Sante	17
Regulatory Coherence – SoHO & other legal frameworks workshop	EU Commission DG Sante	1
Platform of European Market Surveillance Activities in Cosmetics (PEMSAC) – Market Surveillance	European Commission DG-Grow	2
PEMSAC Sub-group on Cosmetovigilance	European Commission DG-Grow	2
Extended Producer Responsibility (EPR) scheme sub-group	Department of Housing, Local Government and Heritage	7
Committee for Cosmetics and Consumer Health	EDQM	2
Joint session draft agenda, CD-P-COS and OCCL Network	EDQM	2
Monthly API Telecon with EDQM and other authorities	EDQM	5
Biological Working Party	EMA	11
Biosimilar Working Party	EMA	9
Committee for Advanced Therapies (CAT)	EMA	11
Committee for Medicinal Products for Human Use (CHMP) - Plenary	EMA	12
Committee for Medicinal Products for Human Use (CHMP) - Preparatory and Organisational Matters (PROM)	EMA	11
Good Clinical Practice (GCP) Inspectors' Working Group (IWG)	EMA	4
GCP IWG and CHMP assessors 2025 Joint Virtual EU GCP inspectors-assessors	EMA	1

Committee/Working Group	Organisation	Meetings in 2025
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee on Herbal Medicinal Products (HMPC)	EMA	8
Novel Therapies Working Party	EMA	4
EEA Drafting Group on the Revision of the Quality Defects and Rapid Alert procedures in the Compilation of Union Procedures	EMA	1
Efficacy Working Party - Veterinary	EMA	3
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) (including subgroups and working groups)	EMA	25
European Sales and Use of Antimicrobials for Veterinary Medicine Working Group	EMA	4
GCP IWG Interested Parties'	EMA	1
GCP IWG and CMDh joint meeting	EMA	4
Extraordinary meeting of the GCP IWG CMDh WP on Raptim	EMA	1
GCP IWG re-labelling and re-packaging subgroup	EMA	1
Veterinary medicines GCP ad hoc meeting - virtual	EMA	1
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group	EMA	4
GMDP IWG Drafting group on Inspection of MAHs	EMA	2
GMDP-IWG Sub-group on the revision of EU GMP Guide Annex 15 (Qualification and Validation)	EMA	2
GDP Working Group	EMA	2
Immunologicals Working Pary (vet)	EMA	2
Joint GMDP-IWG/QWP/BWP Meeting	EMA	1
Management Board	EMA	5
Medicine Shortages Single Point of Contact Working Party (including subgroups and working groups)	EMA	24
Methodology Working Party Modelling and Simulation Operational Expert Group	EMA	12
Network ICT Advisory Committee (NICTAC)	EMA	6
Non-Clinical Working Party	EMA	11

Committee/Working Group	Organisation	Meetings in 2025
Paediatric Committee (PDCO)	EMA	11
Pharmacovigilance (PV) Inspectors' Working Group (Human and Veterinary)	EMA	4
PhV IWG Interested Parties	EMA	1
PhV IWG training workshop	EMA	1
Risk Based Planning for Inspection Working Group	EMA	1
Pharmacovigilance Business Team (PhVBT)	EMA	3
Pharmacovigilance Risk Assessment Committee (PRAC) – Plenary	EMA	12
Pharmacovigilance Risk Assessment Committee (PRAC) – Orgam	EMA	5
PRAC Impact Group	EMA	10
Pharmacovigilance Working Party - Veterinary	EMA	9
Quality Review of Documents Working Groups	EMA	3
Quality Working Party (QWP)	EMA	11
Safe-CT Steering Committee	EMA	3
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
Quality Innovation Group (QIG)	EMA	28
BE GCP Collaboration EMA - EU MSs - WHO	EMA	1
EU-FDA Tcon BE GCP Inspections Collaboration	EMA	1
Pharmaceutical Quality System (PQS) Pilot Co-ordination	EMA	2
Incident Review Network (IRN)	EMA	1
AMA EU-Alignment Platform	EMA	1
Quality defect risk categorisation	EMA	3
European Medicines Verification Organisation (EMVO) workshop with NCAs	EMVO	1

Committee/Working Group	Organisation	Meetings in 2025
CHESSMEN Joint Action	EU Member State Consortium	13
Clinical Trials Coordination and Advisory Group (CTAG)	European Commission	4
EU4H11 Project Working Groups (Medicines)	European Commission	10
EU4H11 Follow Up Actions	EU Commission (AGES leading)	2
Group of Experts on Drug Precursors	European Commission	1
Joint Action – GAPP PRO	DG-SANTE	1
MDCG – Medical Device Coordination Group	European Commission	5
MDCG – Borderline and Classification	European Commission	1
MDCG – Clinical Investigation and Evaluation, Performance and Studies Evaluation (CIEPSE)	European Commission	2
MDCG – Eudamed	European Commission	3
MDCG – In Vitro Diagnostic (IVD)	European Commission	2
MDCG – International Matters	European Commission	2
MDCG – Market Surveillance	European Commission	2
MDCG – New Technologies	European Commission	2
MDCG – Notified Body Oversight (NBO)	European Commission	2
MDCG – Orphan Device Task Force	European Commission	2
MDCG – Post Market Surveillance and Vigilance (PMSV)	European Commission	3
MDCG – Standards	European Commission	1
MDCG – Unique Device Identification (UDI)	European Commission	2

Committee/Working Group	Organisation	Meetings in 2025
MDCG – Breakthrough Device Task Force	European Commission	2
COMBINE Project Board	Member State competent authorities and European Commission	11
National AI Act Committee	Department of Enterprise, Trade and Employment	8
National Contact Points for the Implementation of Directive 2010/63/EU	European Commission	2
European Pharmacopoeia Commission	European Commission	3
EC Education and Training Framework Expert Working Group	European Commission	4
Pharmaceutical Committee	European Commission	1
Expert Group on Safety Features	European Commission	1
Competent Authorities for Organ Donation and Transplantation	European Commission	2
Standing Committee on Cosmetic Products	European Commission DG-Grow	3
Standing Committee for Veterinary Medicinal products	European Commission	4
Working Group on Cosmetic Products	European Commission DG-Grow	3
Cosmetic Subgroup on Sunscreen Products	European Commission DG-Grow	3
Cosmetic Subgroup on CPNP Review	European Commission DG-Grow	3
Cosmetic subgroup on borderline products	European Commission	3

Committee/Working Group	Organisation	Meetings in 2025
Critical Medicines Alliance	European Commission	1
Clinical Trials Coordination Group (CTCG)	HMA	10
Clinical Trials Coordination Group Safety Roundtable	HMA	11
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	4
Heads of Agency Meeting	HMA	4
Homeopathic Medicinal Products Working Group	HMA	1
IDMP Community of Experts	HMA/EMA	3
Pharmacovigilance Work-sharing Procedures Working Party	HMA	4
Working Group of Enforcement Officers (WGEO) (including management committee)	HMA	2
Working Party on Pharmacovigilance Procedures Work Sharing	HMA	4
Joint GCP Inspectors Working Party/CMDh working party	HMA	7
Non-Prescription Medicinal Products Task Force	HMA	1
Working Group on the HMA Risk Assessment tool for surveillance testing (including sub-groups)	HMA / EDQM	6
Joint CMDh/CHMP/CMDv/CVMP/EMA/QWP/ EDQM working group on ASMF procedures	HMA/EMA/EDQM	3
Communications Working Group	HMA / EMA	18
EU Innovation Network (EU-IN)	HMA / EMA	11
EU Innovation Network Borderline Classification Group	HMA / EMA	9
Clinical Trials Coordination Group Assessor Roundtable	HMA / EMA	44
Joint CMD/EMA Working Party on variation regulation	HMA/EMA	4
National Patient Safety Alert Committee	HSE	11
Antibiotic Consumption Subgroup	HSE (AMRIC)	1

Committee/Working Group	Organisation	Meetings in 2025
National Cosmetics Surveillance Forum	HSE Environmental Health Service (EHS) and Public Analyst Laboratories	1
ICH Expert Working Group (EWG) : Q3E Guideline on Extractables and Leachables	International Council for Harmonisation (ICH)	30
ICH Q9(R1) Training Group	ICH	3
ICH PQKM (Pharmaceutical Quality Knowledge Management) Task Force	ICH	50
ICMRA Organized Working Group	ICMRA	10th – 12th March 2025
Safety Features Oversight Group	IMVO / PSI / Department of Health	1
CGTV Forum	NIBRT	1
Regulation of Human Milk Banks under SoHO discussion	Northern Ireland Dept of Health and DHSC UK	1
NSAI/TC 42 Cosmetics Advisory	NSAI	2
GVP Expert Circle - Artificial Intelligence and Machine Learning Working Group	Pharmaceutical Inspection Co-operation Scheme (PIC/s)	7
Expert Circle on Quality Risk Management (QRM) (including training seminar and telecons)	PIC/S	5
Sub-committee on Expert Circle	PIC/S	1
Expert Circle Coordinating Committee	PIC/S	1
GDP Expert Circle	PIC/S	10
Sub-Committee on Harmonisation	PIC/S	1
Committee of Officials	PIC/S	2
GCP EC- Risk Proportionate Approaches Working Group	PIC/S	6
GVP Expert Circle Training Event (AI)	PIC/S	1
GCP Expert Circle Training Event	PIC/S	1
SOHO Coordination Board, Subgroup on Vigilance and Traceability	European Commission	6

Committee/Working Group	Organisation	Meetings in 2025
National Immunisation Advisory Committee (NIAC): Observer	HIQA	6
CERD Cross Agency Collaboration	HIQA, Department of Health	1
HTA Scientific Advisory Group	HIQA	1
Finished Dosage Reliance Pilot with FDA and MRA / PIC/S authorities	US FDA	2
Cross-border Interagency	Norther Ireland Medicines Regulatory Group (MRG), PSI, Pharmaceutical Society of Northern Ireland (PSNI)	4
National Clinical Trial Oversight Group (NCTOG)	Department of Health	8
HERA Irish Stakeholder Forum	European Commission	4
Regulatory Agencies Global Network against AMR (RAGNA)		4

HPRA
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