Annual Report 2023

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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36

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1,913

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114

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2,348

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60

The number of centrally authorised human medicines where the HPRA was EU rapporteur for the monitoring of any safety signals

7,793

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302

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317

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3,065

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65

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204

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103

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

874,945

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Chairperson's Statement

I am honoured to present the HPRA's annual report for 2023. The year was marked by significant achievements and challenges across the full spectrum of the HPRA's remit. Yet through collaborative efforts and steadfast dedication, the HPRA has continued to fulfil its vital mission of regulating medicines and devices for the benefit of people and animals.

Mid-term review of HPRA's Strategic Plan

June 2023 marked the midway point for the HPRA's current strategic plan, which covers the period 2021 to 2025. Having reached this important milestone, the Authority, supported by the organisation's senior leadership, took the opportunity to reflect on what had been achieved under the first half of the strategy's tenure. We also took this opportunity to determine what actions may be needed to ensure the strategy continues to meet the changing needs of the organisation and our stakeholders over the remainder of its lifetime.

An in-depth review of the strategic plan was undertaken, which confirmed to the Authority that the strategy continues to accurately reflect the organisation's core mission, vision, and values. The review also confirmed that the strategy's five high-level goals continue to provide structure and purpose to the HPRA's broad range of regulatory activities. A number of opportunities for improvement were identified, including a small number of changes to specific action areas within the strategy. These changes allowed for consolidation of certain actions, while also reflecting the fact that operations relating to COVID-19 had been incorporated into routine HPRA regulatory activities. Additionally, the review identified updates needed to capture planned work on a number of important issues that had emerged since the strategy was first developed. These included the upcoming revision of the European pharmaceutical legislation, impacts of the Windsor Framework, as well as developments and challenges concerning availability of medicines.

A further outcome of the review was the recommendation to consider moving to a shorter strategic planning cycle for future strategies. It was agreed that doing so will enable the HPRA to maintain the progressive and adaptive approach to regulation that is required to meet the fast-paced evolution of the regulatory environment.

As we progress through the second half of the strategic timeframe covered by our current plan, we are assured of the strategy's appropriateness and robustness. This solid strategic framework supports the HPRA in successfully conducting its regulatory activities, while also allowing the necessary agility to respond to developments and advancements in the dynamic sectors regulated by the HPRA.

Strategic development to safeguard medicines supply

For many actors in the Irish health system, the first weeks of 2023 were consumed by the challenges faced in responding to shortages of antibiotics. Similar shortages were seen the world over, having been driven by extraordinarily high levels of demand globally. While challenges associated with antibiotic supply abated, issues surrounding medicines availability persisted throughout the year. These issues highlighted the need for investment in both strategy and infrastructure to safeguard medicines supply. With this in mind, I, along with members of the HPRA's Leadership Team, met with the Minister for Health to discuss strategic developments needed to strengthen the medicines supply chain in Ireland. Among these were revised and enhanced governance, appropriate digital infrastructure, and targeted legislative updates. These pragmatic proposals recognise that the greatest strategic opportunity in relation to medicines availability lies in the ability to take pre-emptive actions to prevent the occurrence of shortages.

Medicines availability remains a key priority for the Authority, and we continue our ardent support of the HPRA executive, working alongside the Department of Health, to progress strategic developments pertaining to medicines availability.

Succession planning and preparing for future change

Throughout 2023, succession planning and preparing for future change was once again of utmost importance to the Authority. As such, succession planning was progressed for the Authority and at all levels of the organisation. In relation to the Authority, the structured and proactive approach to review and planning has supported us in ensuring the optimal mix of strategic and operational skills are represented across the Authority. Additionally, the review and planning process enabled the identification of the full and diverse range of expertise, knowledge, and competencies of Authority members. This in turn is empowering us to maximise use of these attributes in our stewardship of the HPRA. The thorough review completed in 2023 is a welcome foundation on which to build into the future and will form the basis of an annual review of the succession plan going forward.

Looking to the future

As I look to the future, there are a number of significant matters and themes on the horizon for the HPRA. Perhaps principal among these is the upcoming inquiry into historical licensing and use of sodium valproate in women of childbearing potential. The inquiry, which received government approval in July 2023, is an important and welcome opportunity to provide a voice to those affected by sodium valproate. A great deal of work has already been undertaken in preparation for the inquiry and the HPRA is committed to engaging fully with the inquiry to ensure the best possible outcome for patients and their families.

In April 2023, the European Commission published its proposal to revise the European pharmaceutical legislation. Some key objectives of the legislation include better access to innovative and affordable medicines, promotion of innovation and competition, promotion of public health interests, ensuring security of supply, protection of the environment, and tackling antimicrobial resistance. At EU level, the HPRA is actively contributing to a detailed review of the legislative package. The package itself is over 500 pages in length and likely to take several years to progress through the legislative process. Nationally, the HPRA is working closely with the Department of Health and other government stakeholders to develop policy positions in relation to the proposed legislation. This legislative package will shape the future of pharmaceutical regulation, research, development, and manufacturing in Europe for decades to come. As such, it is imperative that we take full advantage of the current opportunity to influence and shape the new legislation. It is only by doing so that we can ensure it works optimally for European patients, healthcare professionals, and health systems.

Also on the horizon for the HPRA is the Irish Presidency of the Council of the European Union. Ireland will hold the Presidency from July to December 2026. This represents an exciting time and opportunity for the HPRA to contribute to key EU legislative and regulatory initiatives across the broad spectrum of health products under its remit. Early-stage preparations and planning are already underway to ensure a successful and productive Presidency.

Acknowledgements

Firstly, and on behalf of the Authority, I would like to thank the Minister for Health, the Minister for Agriculture, Food and the Marine, their advisors, and the staff of their respective departments for their continued engagement and partnership.

I would like to express my gratitude to my fellow Authority members, who gave freely and generously of their time and expertise throughout 2023. Also, to the Chairs and members of the HRPA advisory committees and subcommittees, thank you for your valuable contributions and expert insights.

Lastly, I want to take this opportunity to express my sincere appreciation to the Chief Executive, leadership team, and dedicated employees of the HPRA. Thank you for your outstanding commitment to the protection of public and animal health not just nationally but also through your significant contributions at European and international level. I look forward to seeing what lies ahead for the HPRA and the continued progress we will make over 2024 and beyond.

Michael Donnelly
Chairperson

Authority Members

The Authority of the HPRA is appointed by the Minister for Health in accordance with the powers conferred by subsection 2 of section 7 of the Irish Medicines Board Act, 1995. The members of the Authority during 2023 were:

Mr Michael Donnelly
Chairperson

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

Dr Fiona Kiernan

Dr Paula Kilbane

Prof Sharon O'Kane

Dr Diarmuid Quinlan

Prof Richard Reilly

Management Committee

The members of the HPRA Management Committee in 2023 were:

Dr Lorraine Nolan
Chief Executive

Ms Rita Purcell
Deputy Chief Executive

Dr J.G. Beechinor
Director of Veterinary Sciences

Ms Sinead Curran
Director of Human Products Monitoring

Mr Sean d'Art
Director of ICT and Business Services

Dr Finnuala Lonsdale
Director of Human Products Authorisation and Registration

Dr Niall MacAleenan
Director of Medical Devices

Ms Gráinne Power
Director of Compliance

Ms Elizabeth Stuart
Director of Human Resources and Change

Chief Executive's Report

Embracing the opportunities and challenges of new legal frameworks is fundamental to the role of the regulator. Over the course of 2023, significant progress was made in the implementation of multiple legislative frameworks introduced over the preceding years. As we continued to adapt to those legislative changes, we were also tasked with commencing regulatory preparations for an overhaul of the European pharmaceutical legislation in the years to come. These adaptations and preparations, paired with our routine work and managing a wide variety of emerging issues, made for another exceptionally busy year for the HPRA.

Medicines availability challenges

Throughout 2023, medicines availability continued to be an issue of significant importance and a top priority for the HPRA and partners across the Irish health system. Over the course of the year, we continued to experience an increased prevalence in medicines shortages, an issue that is by no means unique to Ireland. All member states throughout the EU and countries globally reported similar experiences for the year.

The causes of medicines shortages are complex and multi-factorial. However, during 2023, post-pandemic impacts on global supply chains for medicines and geopolitical events were additional factors that contributed to challenges concerning medicines availability. We also saw demand for certain medicines strongly influenced through social factors and media coverage, with a significant resultant impact on supply chains and availability.

We recognise that the experience during the year was challenging and at times frustrating for both patients and healthcare professionals. In our role as coordinator of the national Medicines Shortages Framework, we continued to work with all involved stakeholders to mitigate the impacts of medicines shortages and ensure continued access to appropriate treatment for patients.

Given the complexity of this issue, it is recognised that our national approach to the management of medicines availability needs further strategic development to ensure better capacity to prevent the occurrence of shortages. During 2023, we submitted a proposal to the Minister for Health outlining a number of potential opportunities to build greater resilience in the national supply chain for medicines. Among these are a system to increase visibility and transparency across all stakeholders on the availability of medicines stock nationally. Additionally, it is proposed that a national forum represented by key groups from across the health system be established, to focus on securing sustained availability of medicines essential to healthcare in Ireland. We remain committed to working with colleagues in the Department of Health and supporting them with the progression of policy enhancements in this area.

At an EU level, the HPRA continues to contribute to the European medicines regulatory network's initiatives to combat shortages. In the past year, these included an initiative to ensure adequate supply of antibiotics for EU patients during the 2023/2024 winter season and development of the first Union list of critical medicines. The network also launched a solidarity mechanism through which EU Member States can support each other in the event that an individual Member State is impacted by a critical shortage that cannot be mitigated through other means. These initiatives are a demonstration of the network's commitment to addressing current issues affecting medicines availability, and the HPRA will continue its active involvement in this important work.

Implementation of medical device and *in vitro* diagnostic legislation

During 2023, we continued to experience challenges with the ongoing implementation of the medical device and *in vitro* diagnostics (IVD) Regulations at European level. Indeed, at the end of the 2023, the European Commission announced their intention to propose legislation in January 2024 to defer transition

to the IVD Regulation. The HPRA remains strongly committed to ensuring successful implementation of both Regulations and the vision for these, which is greater capacity to protect and enhance patient safety and promote confidence in the European regulatory system. While challenges undoubtedly remain, we believe that these Regulations, if implemented successfully, provide the framework under which that can be achieved.

Throughout 2023, we continued to advocate for much needed enhancements and developments in the European regulatory approach and have promoted this through our ongoing engagement with medical device agencies in Europe as well as the European Commission. We believe that the regulatory network in Europe, at national and central levels, needs to address how it can more effectively coordinate and oversee the implementation of the Regulations. Areas of focus include the development of approaches for investigation of high-profile safety issues. The provision of significantly enhanced support for innovators across the sector in the areas of clinical evidence generation, orphan devices, digital and combination products is also vitally important. This work remains amongst our highest priorities and will continue throughout 2024 and beyond.

Milestone in the implementation of the Clinical Trials Regulation

The end of January 2023 marked a significant milestone in the implementation of the Clinical Trials Regulation (CTR), with the use of the Clinical Trials Information System (CTIS) becoming mandatory at that time. Initial challenges encountered following the rollout of CTIS continued to be addressed and resolved over 2023, resulting in significant improvements to the system. The HPRA increased resourcing internally to meet the demands of the new regulatory framework and continued to strengthen relationships with the National Office for Research Ethics Committees. We also continued to expand our support offering for external stakeholders. This included additional supports to provide clarity on the appropriate regulatory pathway for trials for combination products composed of drug and device components. Each of these steps will assist us in fully realising the aims of the CTR, including centralisation of key regulatory activities and increased transparency.

HPRA supporting innovation

We were delighted to host the EU-Innovation Network conference in Dublin in November 2023. The event, which focused on the theme of supporting life sciences innovation across Europe, was attended by a wide range of stakeholders. These included regulators, researchers, incubators, and technology transfer offices, representing the diverse nature of the innovation ecosystem.

Attendees explored some of the challenges faced by innovators when navigating regulatory requirements, analysed existing supports, and proposed enhancements to better support innovation. Discussions on the day underscored the need for agile and adaptive approaches to regulation in order to effectively respond to scientific and technological advancements. This has been, and will continue to be, an important focus for the HPRA.

National sales of veterinary antibiotics

In November 2023, the HPRA published the 2022 report on sales of national veterinary antibiotics. The report showed that, in 2022, sales of veterinary antibiotics decreased by 18.8% compared to 2021. Reduced sales were recorded in almost all classes of antimicrobial, and most importantly in the highest priority critically important antibiotics. This reduction, which is thanks to the collective efforts of multiple stakeholders, is a welcome development given the current national and EU focus on reducing use of veterinary antibiotics. It also coincides with a significant change in EU legislation whereby the validity of the duration of a prescription for a veterinary antibiotic was reduced to five days, having previously been one year. These developments, along with further restrictions and initiatives coming into effect over the course of 2024, will make a very real difference in helping us meet the ambitious targets set out under the European Green Deal and Farm to Fork Strategy.

Redevelopment of the HPRA website

Communication and engagement is a key focus area for the HPRA under our current strategic plan. We recognise that our website is one of our most important tools through which we communicate and engage with our stakeholders. As part of our Digital Transformation Strategy, we are undertaking a major cross-organisational project to redevelop the HPRA website to ensure it meets the diverse needs of our broad range of stakeholders. Among the improvements that will be made to the website are modernisation of its layout and enhancements in the readability and accessibility of the site's content. We are also taking steps to improve the interoperability of the website with our internal digital systems, thereby enabling us to streamline and optimise the way information is presented to website users. Teams across the HPRA invested significant time and effort into this project throughout 2023 to ensure it is a success, and that work is continuing throughout 2024 also. It is thanks to the diligence and dedication of everyone contributing to the project that I am confident our new website will better serve the very broad range of stakeholders who use it.

Acknowledgements

I want to take this opportunity to acknowledge the continued support of the Ministers and staff of the Department of Health and the Department of Agriculture, Food and the Marine. We are committed to continuing our close and collaborative partnerships to address challenges in the areas of public and animal health. I would also like to thank the Authority and advisory committees for their invaluable guidance over the course of the year, which has been instrumental in the achievements and growth of the organisation.

Finally, my sincere and heartfelt thanks to the HPRA Leadership Team and to all of my hardworking colleagues across the HPRA. Your professionalism and unwavering commitment have been the cornerstone of our successes throughout 2023. I am immensely proud to be part of an organisation where we continue to work collectively and to the highest standards to achieve the shared goal of protecting patients and animals.

Dr Lorraine Nolan
Chief Executive

Strategic Plan 2021-2025 – Key Achievements in 2023

Goal 1

Health system partnerships

Strengthening our collaborations across all areas of the health system

Extensive work carried out in response to medicines availability issues under the HPRA's medicines shortages framework. This included working with the Department of Health to develop improved systems for coordinated management of high impact shortages and agreement of new measures to be implemented over the coming years which will assist with shortages prevention. Preparatory work was also undertaken to improve availability of veterinary medicines that are subject to shortages or not marketed in Ireland.

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

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

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

Continued as a member of the HSE National Patient Safety Alert Committee to support system-wide responses to health product issues. This included the implementation of a new framework for escalation of key safety issues within the HSE and participation in HSE-led incident management teams.

Continued monitoring of sales of veterinary antibiotics in Ireland. This work is an important component in supporting a continued reduction in use nationally.

Goal 2

Progressive regulation

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

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

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

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

Developed a HPRA policy paper in relation to strengthening controls on the administration and use of dermal fillers in Ireland.

Introduced a new registration system for non-prescription veterinary medicines for exotic pets.

Continued to co-lead an International Coalition of Medicines Regulatory Authorities (ICMRA) project piloting global assessments of post-approval change management protocols for innovative medicines.

1 The Medical Device Coordination Group

2 Co-ordination of Research and Evaluation of Medical Devices

Goal 3

Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Continued collaboration and engagement with the patient community through the Patient Forum, with positive feedback from members. Launched educational modules for HPRA employees and a Patient Speaker Programme.

Continued our engagement with stakeholders through website, social media and newsletter updates. Proactive media engagements included enforcement activities and medicines safety. Our digital awareness campaigns involved raising awareness of the dangers of purchasing prescription medicines online and the importance of reporting side effects to regulators. The development of a new stakeholder engagement plan will ensure our continued focus and development in this area over the next years.

Introduction of a new social media template library to ensure consistency of design approach and to support promotion of brand identity.

Launched a project to redevelop the HPRA website which focuses on optimising the design, structure and content of the website, to enhance information exchange and stakeholder engagement. Web content creation and accessibility training was carried out, as well as user testing with stakeholders for an enhanced website structure.

Goal 4

Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Continued collaboration in projects at: (1) EU level, relating to areas of innovation and research, such as EMA Real-World Evidence rapid data analytics pilot, PRISMA (PRAC Risk Minimisation Alliance), EU Pharmacovigilance Business Team, STARS[3] and the EU-IN Borderline Classification Group; and (2) national level, through the HPRA Innovation Office and engagement with partners, clinical researchers and sponsors.

Adopted a leadership role within the EU Commission's COMBINE project, designed to analyse the challenges encountered by sponsors in conducting combined clinical performance studies and identify possible solutions.

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

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

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

Goal 5

Great people, great processes

Developing our organisation and people to successfully achieve our goals

Launched a People Strategy framework for managing, developing, and supporting HPRA employees to deliver on the HPRA's vision and mission, under four core pillars (Purpose, Growth, Belonging and Wellbeing).

Continued our digital transformation activities focusing on integration to EU network systems, improved dataset management and core workflow consolidation.

Continued the implementation and evaluation of a hybrid model of working to ensure the new model fits the needs of the organisation and its core vision, mission and values.

Continued the focus on a continual improvement and lean management culture at the HPRA through the establishment of an Operational Excellence Team, lean training and a review of strategies and operations of various functions.

Under the 2021-2030 energy and sustainability project, introduced waste reduction and travel-related emissions programmes, sourced sustainable stationary, and installed LED and programmable infrared lighting throughout the premises.

This year marked the half-way point of the HPRA's 2021-2025 Strategic plan. A mid-term review was carried out which confirmed that the five high-level goals and 16 objectives of the plan continue to provide a clear structure and purpose relating to the HPRA's regulatory activities and its mission, vision and values. While the breadth of the plan allows for the continual evolvement of our organisation, adjustments were made to some specific actions to ensure the focus for the remaining tenure of the strategic plan takes into consideration the changing external environment and the HPRA's own internal organisational development.

Human Medicines

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

Authorisation and Registration

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

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

  During the year in review, the total number of new medicines authorised in Ireland was 384. The 2023 figure incorporates:

  – Seven new national authorisations and 57 parallel import authorisations;

  – 32 new authorisations under MRP and 156 new authorisations under DCP. The HPRA acted as reference (lead) Member State for 44 authorisations;

  – Eight rapporteurships and four co-rapporteurships under the centralised procedure;

  – An additional 119 medicines authorised through the centralised procedure for which Ireland was neither rapporteur nor co-rapporteur;

  – One traditional herbal medicinal product under the simplified registration scheme.

- 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 2023, the HPRA acted as co-ordinator for 93 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 13 such advice procedures.

- Overall, for 2023, the HPRA was among the top 10 contributors at EU level for lead assessment of centrally authorised human medicines and EMA scientific advice.

- As the EU/Europe Topic Lead and a member of the ICH Q13 Expert Working Group (EWG), the HPRA continued to support innovation in the chemical manufacturing space. We again represented Ireland and Europe at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in the development of the ICH Q13 guideline on continuous manufacturing of drug substances and drug products. In 2023, the guideline was implemented in Europe and the EWG transitioned into an Implementation Working Group, tasked with developing guideline training materials for ICH.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2023, we issued 19 new clinical trial authorisations under the EU Clinical Trials Directive (CTD) and 36 authorisations under the new EU Clinical Trials Regulation (CTR).

- Reclassification of the legal status of medicines aims to increase the number of medicines available to patients without prescription where it is safe to do so. In 2023, three medicines were authorised for non-prescription, pharmacy-only sale.

- The HPRA publishes and maintains a list of interchangeable medicines to facilitate generic substitution by pharmacists and to allow for reference pricing by the HSE. By year-end, the interchangeable medicines list included 113 active substances or combinations of active substances.

- The Medicine Shortages Framework brings together key players in the health sector with the aim of developing strategies to mitigate the effect of shortages in Ireland when they occur. Shortages are a global issue experienced by all countries regardless of size or economic status. Their incidence is increasing. Taking 2023 as a snapshot, all medicines regulatory agencies at the global level reported sharp increases in reported shortages relative to previous years. The impact of the pandemic on medicines supply chain resilience, geopolitical events and costs are generally accepted as the primary contributory factors behind the challenges observed in 2023.

  The year saw significant engagement with individual stakeholders to mitigate individual shortages, to understand multiple perspectives and to issue relevant communications and updates. In May 2023, a multistakeholder meeting was convened involving all aspects of the supply chain and including representation from patient groups and healthcare professionals, the HSE and the Department of Health. This served to inform agreement on proposed actions and strategies in response to the shortages issue.

  An update to the HPRA web page for shortage notifications was also implemented in 2023 to improve clarity and functionality as well as mobile accessibility.

  The HPRA also 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. The HPRA is also actively involved in the EMA and HMA joint Task Force on the Availability of Authorised Medicines and a European Commission-backed Joint Action on Shortages initiative.

- As the use of multilingual labelling remains an important means of minimising the impact of Brexit and supporting the availability of medicines in Ireland and Europe, the HPRA remains actively involved in progressing this initiative at the HMA level through the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). The HPRA continued to lead the CMDh Multilingual Packaging Working Group, which engaged with interested parties to obtain feedback on their use of multilingual packaging and experiences with the ongoing multilingual packaging pilot, which continued throughout 2023. Responses to queries from Member States and marketing authorisation holders (MAHs) on multilingual packaging and on practical aspects of the pilot were also prepared.

- To aid the continuity of supply to the marketplace in the event of a medicine shortage the HPRA granted 415 temporary 'batch-specific request' authorisations during 2023.

- The HPRA granted five marketing authorisations following the zero-day mutual recognition procedure to ensure the availability of medicinal products deemed important for the Irish market.

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

- On 1 January 2022, the Irish language gained full status as an official language of the European Union. Since then, the HPRA has completed translation of all European Directorate for Quality of Medicines standards terms (over 900 in total) into the Irish language with 15 further standard terms undergoing translation in 2023. The translations are available on the European Directorate for the Quality of Medicines and HealthCare (EDQM) website – Standard Terms Database.

Authorisation and registration: Key figures	2021	2022	2023
Classification queries/reviews	89	100	72
Scientific advice			
Lead in EMA scientific advice	82	109	93
National scientific advice	7	15	11
Clinical trial applications under Clinical Trials Directive (CTD)	107	64	19
Clinical trial applications under Clinical Trials Directive (CTR), implemented 31 January 2022	N/A	3	76
New medicines applications for marketing authorisations			
National (including new parallel imports)	94	92	64
Mutual recognition and decentralised RMS	29	57	34
Mutual recognition and decentralised CMS	220	176	152
Centralised Rapp/Co-Rapp	28	18	12
Traditional herbal medicinal products under the simplified registration scheme	3	2	1
Homeopathic medicines under the simplified/national rules schemes	0	2	0
Variations to marketing authorisations (Type IA, IB, II)	9,665	14,367	14,672
Articles 45 and 46 - Variations to Update Product Information	6	19	13
Renewals of marketing authorisations	305	232	231
Transfer of marketing authorisation holder	468	161	179
Manufacturers	145	149	151
Manufacturers of investigational medicinal products	75	82	82
Wholesalers	391	386	375
Registrations for active pharmaceuticals ingredients			
Manufacturers	23	22	22
Importers	77	75	75
Distributors	99	100	98
Brokers	7	12	13
Export certificates	1,102	1,304	1,108
Exempt medicine notifications of unauthorised medicine import	58,503 line notifications	62,940 line notifications	69,912 line notifications

Safety and Quality

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

  This year:

  – A total of 7,793 suspected adverse reaction reports were received associated with the use of human medicines. This is a decrease on the heightened number of reports received in 2022 and associated with COVID-19 vaccines.

  – Of the reports received in 2023, 400 were associated with the use of COVID-19 vaccines. The remaining 7,393 reports received in 2023 were associated with the use of other human medicines (including other vaccines).

  The HPRA is grateful to healthcare professionals and members of the public who take the time to report suspected adverse reactions and continues to encourage this. Reports of suspected adverse reactions remain a fundamental part of pharmacovigilance and support us in ongoing monitoring of the safety profile of medicines in clinical use.

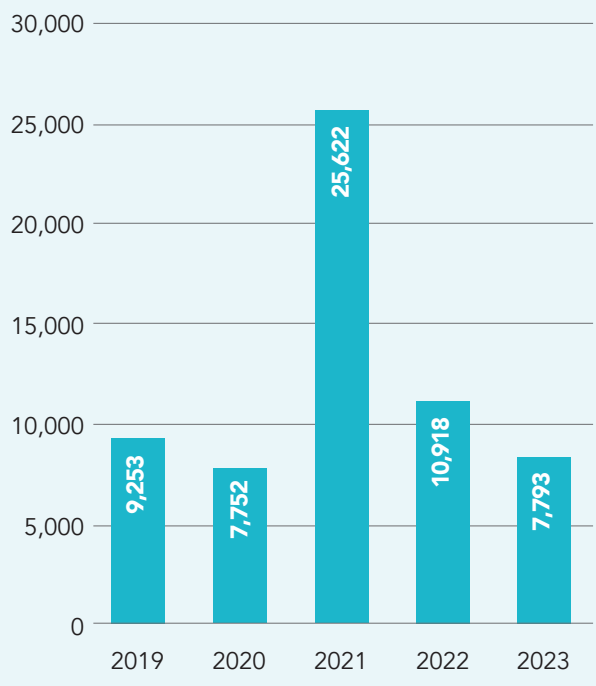
  – Of the reports received in 2023, 8% were submitted by members of the public, 7% by healthcare professionals and 84% were reported by marketing authorisation holders. A further 1% were reported by sponsors in the context of ongoing clinical trials. It is important to note that reports received by marketing authorisation holders will have been initially notified to them by healthcare professionals or members of the public.

  Medicines subject to additional monitoring accounted for 13.5% of the reports submitted of which 5% were related to COVID-19 vaccines.

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

Sources of Suspected New Adverse Reaction Reports	%
Member of the public (patient/carer)	52
Doctor	16.5
Nurse	10
Pharmacist	18
Healthcare professional – Other	3.5

Suspected Adverse Reaction Reports Received



- The medicines most frequently included in reports submitted to the HPRA, and which account for approximately 94% of the suspected adverse reaction reports received in 2023, 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. Further, 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	3,954
Vaccines, including COVID-19 vaccines	607
Psycholeptic medicines	527
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	457
Medicines for obstructive airway diseases	268
Medicines for the treatment of Parkinson's Disease	497
Analgesic medicines including medicines for prevention and treatment of migraine	208
Medicines for the treatment of Diabetes Mellitus	267
Other nervous system medicines	160
Medicines for the treatment of dermatological conditions	186

* 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 2023, 140 patients were reported to have died following treatment with a suspect medicine. The following table outlines the medicines or class of medicines associated with the highest number of 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 are examined, including that from voluntary reporting systems, as well as from literature, epidemiological studies and clinical trials, to reach robust conclusions on causal relationship.
  - In many cases, where a fatality is reported, the patient concerned was described as having significant underlying illness and were treated with multiple medicines and/or surgery.
  - In respect of COVID-19 vaccines, the HPRA continues to closely monitor reports of suspected side effects received particularly those that describe a fatal outcome. Throughout 2023, the HPRA continued to publish on our website summary information on suspected side effects reported in Ireland following COVID-19 vaccination.

Suspect Medicine(s)/ Class of Medicines	Number of Reports*
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	60
Psycholeptic medicines	26
Vaccines including COVID-19 vaccines	16
Antithrombotic medicines including anti-coagulant and anti-platelet medicines	13
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	9
Medicines for treating Parkinsons Disease	6
Antithrombotic medicines including anti-coagulant and anti-platelet medicines	5
Electrolyte solutions and parenteral nutrition preparations	5

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

- The HPRA also plays a key role in monitoring the safety of medicines through benefit-risk reviews and risk management over the lifecycle of products. This incorporates our contribution to the work of the Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA. During 2023, 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 62 nationally authorised active substances;
  - Serving as PRAC rapporteur, we were also responsible for the further management of any signals detected in relation to 60 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 752 PSURs and leading the single EU assessment for 33 active substances or combination of active substances;
  - Participated as a PRAC Member State in four ongoing safety referrals, two of which reached a conclusion during the year;
  - Contributed to the review of 394 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures;
  - Also provided assessment input to 438 post-authorisation safety procedures (including safety study protocols, reports and other post authorisation safety-related measures).

- 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 2023, the HPRA:
  - Approved the content and communication plan for 14 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 92 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, all of which are also published on the HPRA website. The Drug Safety Newsletter highlights important safety information to healthcare professionals with hyperlinks to product information and other relevant documents on the HPRA and EMA websites. A full index of topics covered during the past year is included in Appendix 3.
  - Provided 12 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 3.
  - 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:
  - 103 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances;
  - 134 good distribution practice (GDP) inspections at wholesalers and distributors;
  - 12 good clinical practice inspections at investigator or sponsor sites;
  - Three 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 2023, 334 cases were initiated under the programme.

Quality Defects and Recalls – Human Medicines

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

  The number of human medicines quality defect cases opened during 2023 was 1,267*.

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

Risk Classification	2021	2022	2023
High Risk quality defects	396	361	332
Moderate Risk quality defects	1,381	935	291
Minor Risk quality defects	235	705	613
Number of reports not justified	21	33	31
Total Number Quality Defects	2,033	2,034	1,267

  The majority of quality defect reports were submitted by other competent authorities (37%) and pharmaceutical companies, including manufacturers, distributors and/or marketing authorisation holders (37%). Reports from pharmacists accounted for 22% of cases, and other 4%.

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

- In certain instances, it is necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 59 recall actions were taken in relation to human medicines, with some of the primary causes outlined in the table below:

Cause of Recall	Number of Recalls
Contamination – chemical	6
Distribution/Storage – cold chain/ temperature excursion	6
Product mix-up	5
Product characteristic issues – underfill/ overfill/no. dosage units	5
Product characteristic issues – other	5
Packaging/artwork – secondary packaging	4
Lack of sterility assurance	3
Contamination – microbiological	3
Stability out of specification	3

- 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 2023, 29 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 2023, 22 cases were investigated, some of which involved multiple products. Of these:
  - 17 cases related to the sale of medicines that did not carry a valid registration number or authorisation number for the Irish market, resulting in 17 medicines being removed from sale and/or other necessary follow-up actions being taken;
  - Three cases related to an investigation into non-compliance with the paracetamol regulations as established by the Medicinal Products (Prescription and Control of Supply) Regulations 2003;
  - Two cases related to the classification status of products. One product was removed from sale.

  In addition, 52 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, 302 materials were reviewed, and non-compliances, including both major and minor issues, were identified in 116 cases. Additionally, seven advertising-related complaints were received and investigated by the HPRA. In all cases, we oversaw the necessary corrective and/or preventative actions, where relevant.

- Under our enforcement programme:
  - We processed the detention of 874,945 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2023, compared to 956,263 dosage units in 2022. The products detained included sedatives (34%), anabolic steroids (29%), erectile dysfunction medicines (10%) and analgesics (5%). 4,407 enforcement cases were initiated, compared to 5,171 in the previous year;
  - The HPRA initiated two criminal prosecution cases and issued 14 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 prosecutions taken in 2023 related to the unauthorised supply of anabolic steroids. We also supported prosecutions brought by the Director of Public Prosecutions in relation to the illegal supply of medicines;
  - The Interpol-coordinated Operation Pangea XVI was a year-round operation designed to enhance worldwide cooperation between health products regulators and other government agencies. The continued joint agency cooperation between the HPRA, Revenue's Customs Service and An Garda Síochána was reflected in the HPRA detention figures for 2023;
  - In addition, the monitoring of websites, online marketplace advertisements and social media sites throughout the year resulted in the amendment or shutdown of 2,348 websites, e-commerce listings and/or social media pages associated with the sale of falsified or illicit medicinal products.

Legislation and Regulation

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

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

- Separately, the exemptions granted to Ireland in respect of medicines arising from the Brexit negotiations expire at the end of 2024 and the HPRA commenced a programme of work in 2023 to ensure that marketing authorisation holders bring their products into compliance.

- The new Clinical Trials Regulation, Regulation EU No 536/2014, came into effect on 31 January 2022, after the Clinical Trial Information System (CTIS) developed by the EMA was deemed fully functional by the European Commission. As of 1 Feb 2023, new/initial applications under the Clinical Trials Directive (CTD) are no longer accepted by the HPRA and must be submitted under the Clinical Trials Regulation (CTR), using the Clinical Trials Information System (CTIS).

  The following national activities were progressed by the HPRA during 2023 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 and the development of national legislation;

  – Updates on training information and guidance published on our website, and communicated via social media;

  – Ongoing collaboration with the EMA and other Member States on the implementation of the new legislation, and the development of guidance and training materials.

- Since 9 February 2019, under the Falsified Medicines Directive, the outer packs of prescription medicines must carry safety features in the form of an anti-tamper device and a barcode containing unique identifiers, including a serial number to allow verification of the authenticity of the packs. In 2023, the HPRA worked with partners to ensure:

  – The full implementation of the system;

  – On-going engagement in the national oversight steering group of stakeholders which met regularly to monitor the roll-out both nationally and across the EU;

  – Relevant contributions were made to the EU Expert Group on Safety Features.

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. A full list of all presentations delivered during 2023 relevant to human medicines is provided in Appendix 2.

- Publications and Information

  – The Medicinal Products Newsletter provides regulatory news and updates for those working in the pharmaceutical industry. Three editions were published on our website in 2023 and are available to download from the 'Publications' section.

  – 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 2023 and are available to download from our website. This includes, among others:

    - Guide to registration of processes exempted under Article 61(5) of the Clinical Trials Regulation;

    - Reporting serious adverse reactions (SARs) and serious adverse events (SAEs) associated with human tissues and cells;

    - Guide for national scientific and regulatory advice;

    - Guide to NDSWeb extranet.

Medical Devices

As the national competent authority for medical devices, the HPRA carries out a range of registration, surveillance, assessment and 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.

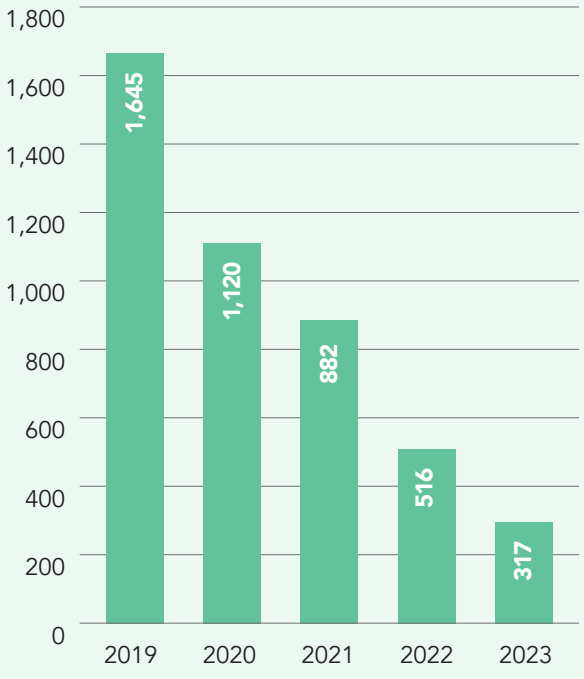
Authorisation and Registration

- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at a national and European level. In 2023, we:
  - Concluded an application for designation under Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) with the completion of the formal designation and notification steps of the process in early 2023;
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits. This included an on-site surveillance assessment in January 2023 and a further on-site assessment in November 2023;
  - Contributed a national expert as part of a European Joint Assessment Team (JAT) for a designation application under the MDR in Sweden;
  - Continued to support the development of EU coordination of notified body designation and oversight through participation in the EU Notified Bodies Oversight (NBO) group and the Medical Device Coordination Group (MDCG);
  - Worked 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 MDR and IVDR.
- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2023, this support included:
  - The review of applications to conduct clinical investigations of medical devices in Ireland under the new medical device regulations. We continued to review clinical investigations for innovative devices from both multi-national and academic sponsors with 11 new applications, 15 amendments to ongoing investigations and seven post-marketing clinical investigations. The HPRA devices team also reviewed performance studies for new IVD devices under the recently implemented IVD regulation with seven applications received in 2023 and anticipates that these numbers will increase further in the future;
  - A continued focus on ensuring regulatory requirements and processes are clear and accessible to potential applicants. As part of our commitment to encourage engagement during product development and innovation of medical technologies, we offer pre-submission meetings. Activity in this area increased again in 2023, with 12 groups of innovators engaging with the HPRA to discuss potential clinical investigation applications in 2023;
  - The provision of technical, clinical and regulatory support in respect of medical devices related queries received by of the HPRA Innovation Office.
- Manufacturers of certain medical devices and *in-vitro* diagnostics (IVDs) are required to register with the HPRA via the European medical device database (EUDAMED). In 2023, the HPRA registered 114 medical device economic operators (for example, manufacturers and authorised representatives) on the national database. 263 economic operators were validated on EUDAMED by the HPRA. This represented a decrease in economic operator registrations when compared to previous years.

Safety and Quality

- We continue to develop and reinforce our market surveillance activities, with a particular emphasis on proactive rather than reactive actions. Of note in 2023:
  - We further developed our lifecycle market surveillance strategy and planning mechanism to allow for more effective management and reporting of these activities;
  - A total of eight 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 317 market surveillance cases undertaken in 2023, a decrease compared to 2022.

Market Surveillance Cases



- We continued to focus our vigilance activities during 2023 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 3,065 medical device vigilance cases, a decrease compared to 2022. Of the reports received in 2023, manufacturers accounted for 80%, 5% were from users and 13% came from other competent authorities. Of the 2,205 incident reports notified directly to the HPRA, 7% came from users of medical devices;
  - There were 391 field safety corrective actions (FSCA) associated with the national market;
  - We issued 114 national competent authority reports to other European authorities;
  - We also issued one safety notice in relation to a medical device and 25 direct to healthcare professional communications;
  - Infusion devices, implants, surgical devices, vital signs monitoring and *in-vitro* diagnostic medical devices together accounted for 70% of the total vigilance reports received (see accompanying table).

Vigilance Report – Top 5 Product Types	Number of Reports
Infusion devices	763
Implants	418
Surgical devices	379
Vital signs monitoring	297
In-vitro diagnostic medical devices	290

- The HPRA also adopted the role of co-chair of the European Working Group on Post-market Surveillance and Vigilance, a subgroup of the Medical Devices Coordination Group (MDCG).
- As part of its market surveillance activities, the HPRA undertakes proactive and 'for-cause' inspections of manufacturers, notified bodies, importers, distributors and authorised representatives with the objective of monitoring compliance of devices emanating from Irish based organisations.

  During 2023, 18 such inspections were performed all of which were based on proactive market surveillance projects and notified body surveillance/assessment.

Legislation and Regulation

- Our work during 2023 focused on progressing implementation and application of EU Device Regulations for both medical devices and *in vitro* diagnostic medical devices at a national and European level particularly with regard to gathering data on the challenges with implementation. This included:
  - Working with the Department of Health on escalating mechanisms, identifying and proposing solutions for the lack of regulatory system readiness;
  - Supporting the Department of Health in preparing for EPSCO interventions calling out the need for focussed solutions to the lack of system readiness and the need for a focussed discussion on the root causes of the longer-term challenges;
  - Engagement with key stakeholders in the sector to ensure awareness of the impact of the regulations incorporating the provision of information, the development of guidance and specific information sessions/ webinars on MDR/ IVDR implementation;
  - Participating and providing input into the EU4Health initiatives on governance and innovation and medical device availability as part of our role as EU Medical Device Coordination Group (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 tasked with developing guidance for specific functional areas including orphan medical devices.

- The HPRA continues to play a significant role in the development of EU regulatory systems and mechanisms to promote co-ordination, co-operation and consistency. In 2023, this included:
  - Continued participation in the Executive Group of the CAMD network;
  - Participation in the MDCG discussions on improving co-ordination and consistency of implementation of the new EU Regulations and prioritisation of implementation activities in the short, medium and long term, including priority areas such as safety and access to critical devices;
  - Continued to take a leading role in a number of taskforces of the MDCG working groups to help identify solutions to key practical challenges with implementation.
- Throughout the year, our focus remained on identifying and promoting discussions and developing practical measures to ensure the regulatory system operates effectively in practice. We were 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 2023, the HPRA chaired a number of meetings of the medical devices core group of the HMA. The focus of the core group during 2023 was to prioritise the capacity challenges for Notified Bodies in the EU network and to work together on identifying solutions to these challenges.
- 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 and Germany);
  - Participation in the clinical evaluation working group of the IMDRF;
  - Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review.

Stakeholders and Partners

- Our work to encourage the direct reporting of incidents and medical devices issues by device users and members of the public continued throughout 2023. We also continued our engagement with health services and healthcare professionals to encourage reporting and raise awareness of the roles and activities of the HPRA.

- The HPRA undertook a number of communication initiatives to raise awareness of the impact and requirements arising from the new EU Device Regulations. During 2023, we:
  - Hosted a webinar for custom made device manufacturers on MDR requirements;
  - Updated the HPRA website and social media channels to provide information and guidance regarding the new EU Regulations;
  - Delivered briefings, advice and workshops on the new 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 talks to a range of external stakeholders. A full list of all presentations related to the regulation of medical devices that were delivered during 2023 is provided in Appendix 2.

- The HPRA are contributing to a Horizon 2020 funded project (Co-ordination of Research and Evaluation of Medical Devices) CORE-MD. The project runs from 2021-2024 and HPRA is leading a work package and is also part of the project board. A number of project deliverables were presented and published in 2023.

Medical devices: Key figures	2021	2022	2023
Lead Competent Authority role on specific vigilance issues	141	93	114
NCARs and vigilance related communications	172	114	140
Vigilance cases received/ opened	1,855	3,935	3,065
Field safety notices uploaded	382	324	368
Medical device safety/ information notices	8	3	1
Medical device targeted healthcare professional communications	22	15	25
NCARs managed as IMDRF NCAR secretariat	4	4	N/A
CEF reports to EU network	11	6	8
Market surveillance cases	621	414	312
Notifications relating to notified body certificates	187	101	5#
Classification requests	40	24	18
Compassionate use applications	23	13	27
Certificates of free sale	4,482	5,361	5,507
Medical device queries received	1,397	1,069	804
Clinical investigation (Article 62 MDR)	N/A	14	11
Clinical investigation (Article 82 MDR)	N/A	17	7
Performance study (IVDR)	N/A	N/A	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	2019	2020	2021	2022	2023
Blood establishments	3	3	3	3	3
Tissue establishments	27	25	26	26	27
Organ procurement/ transplantation	4	4	4	4	4

Safety and Quality

- Following collaboration with the National Haemovigilance Office (NHO), we submitted an annual report of serious adverse reactions and events to the EU Commission during 2023. The report reflected information received by the NHO in 2022 and included information on 83 serious adverse reactions and 154 serious adverse events that met the mandatory legislative reporting requirements.

- We also submitted an annual report on serious adverse reactions and events associated with tissues and cells to the EU Commission during 2023. The report reflected information received in 2022 and encompassed 23 reports, 17 of which met the legislative reporting requirements. Each of the 17 reports were serious adverse events with no serious adverse reactions reported.

- 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 2023, the HPRA received 24 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 2023 included:
  - 13 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 in respect of the revision of European legislation for blood, 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

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

  The total number of veterinary medicines authorised in Ireland at year-end was 1,913. During 2023, there were:

  – Two new national (only) applications;

  – 64 applications made under DCP. The HPRA acted as reference (lead) Member State (RMS) for the assessment of 21 of these DCP applications;

  – Three applications made under the MRP. While the HPRA did not act as RMS for the assessment of the MRP applications, it led a further 20 applications as RMS under the repeat use procedure.

  Based on the figures presented above, the HPRA was the second leading national competent authority in the EU for outgoing work during 2023.

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

- During 2023, the HPRA acted as co-ordinator or joint co-ordinator for five EMA scientific advice procedures.

- To aid the continuity of supply to the marketplace in the event of a medicine shortage following Brexit, the HPRA granted 16 temporary 'batch-specific request' authorisations during 2023.

- Relating to Brexit, the HPRA accepted 23 notifications for veterinary medicines under the Commission Notice on 'Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period'.

Authorisation and registration: Key figures	2021	2022	2023
Classification enquiries	13	11	8
Clinical trials	3	6	7
New centralised as (co-) rapporteur	8	8	10
New MR/DCP as RMS	39	21	42
New MR/DCP as CMS	35	41	52
New homeopathic applications	0	0	5
New national applications	5	3	2
Variations, national and MR	2,362	2,113	2,620
Manufacturers of veterinary medicines	31	34	33
Export certificates	142	144	140
Registrations for active pharmaceuticals ingredients			
Manufacturers	0	2	3
Importers	0	0	0
Distributors	0	2	4

Safety and Quality

- The operation of a national pharmacovigilance system for veterinary medicines is dependent on the submission of reports by veterinarians, pharmacists, licensed merchants and others involved in dispensing or using the medicines concerned. 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 on 28/01/2022, marketing authorisation holders (MAHs) no longer submit adverse event reports directly to the HPRA, instead they are recorded by the MAH in the European Pharmacovigilance Database. However, adverse event reports from veterinarians and animal owners continue to be received directly by the HPRA. The 2023 figure of 852 reports represents the total number of reports received by the HPRA and those recorded in the European Pharmacovigilance Database, whereas the value for 2022 relates only to reports received by the HPRA predominantly from veterinarians or animal owners:

Suspected adverse events	2019	2020	2021	2022	2023
Number of reports	347	391	439	29	852

- We processed a total of 82 signal reviews for adverse events as lead authority as part of the pilot signal management procedure coordinated by the EMA.

- Containing the development of antimicrobial resistance (AMR) is essential for public and animal health. Our work in this area includes the collection of annual information on the sale of veterinary antibiotics from each MAH. This information, which is included in the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC), is important as it allows us to benchmark our usage rate against those of our European neighbours and to follow any developing trends. The quantity of veterinary antibiotics (as active substance) sold in Ireland for the years 2018 to 2022 are detailed in the accompanying table. The 2022 sales data for veterinary antibiotics revealed a significant decline of 18.8% compared to the previous year. This decline extended across all antibiotic classes, including the highest priority critically important antibiotics.

Veterinary antibiotic use	2018	2019	2020	2021	2022
Tonnes sold	99.4	88.8	103.9	94.2	76.5

- The analytical testing and examination of veterinary medicines is a key component of our risk-based sampling and analysis programme. 20 veterinary medicines samples were included in surveillance programme in 2023. Of these, 19 samples were sent for analytical testing. The testing carried out was physiochemical in nature. Two products were analysed at the HPRA's Official Medicines Control Laboratory (OMCL) as part of the EDQM's surveillance programme for centrally authorised veterinary products. An out-of-specification was observed for the deliverable dose test for one of these products. This was reported to the EDQM as per the normal reporting mechanism. Appropriate follow-up actions were carried out by the EDQM. In addition, packaging and labelling checks were performed on one veterinary product. No out-of-specification was observed.

- There was 68 veterinary medicine quality defect cases opened in 2023. (This figure is not directly comparable to previous year's figures, due to the introduction of a new workflow system in March 2023).

  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	2021	2022	2023
Critical (High Risk) quality defects	12	10	13
Major (Moderate Risk) quality defects	35	27	20
Minor (Low Risk) quality defects	37	41	34
Number of reports not justified	1	1	1
Total Number Quality Defects	85	79	68

- The majority of reports (54%) were submitted by pharmaceutical companies, which included manufacturers, distributors and MAHs. Other competent authorities accounted for 44% of the remaining reports received.

- 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. Six recall actions for veterinary products occurred during 2023, for the following reasons:

Category of Defect	Number of Recalls
Stability - Out of specification	2
Pharmacovigilance - Other adverse reaction	2
Contamination - Particulate	1
Non-compliance with GxP - GMP issue	1
Total	6

- Caution in Use Notifications (CIUNs) are issued for medicines with a significant quality defect, but where a recall action should not be initiated. This, for example, includes a scenario 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 than the quality defect itself. During 2023, one such communication was approved for a veterinary medicine.

- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2023, there were three good manufacturing practice (GMP) inspections of manufacturers producing veterinary medicines and one routine pharmacovigilance inspection to determine compliance with pharmacovigilance obligations.

Legislation and Regulation

- While Regulation 2019/6 was applied in the EU on 28 January 2022, a number of associated delegated and implementing acts continued to be elaborated. During 2023, we continued to meet and engage with the Department of Agriculture, Food and the Marine in respect of the development of new national legislation, including the Veterinary Medicinal Product, Medicated Feed and Fertilisers Regulation Act 2023. Furthermore, the HPRA continued to implement various requirements of Regulation 2019/6 including:
  - Uploading of product data to the EMA's Union Product Database (UPD) of veterinary medicinal products;
  - Engagement with EMA and stakeholders to improve data quality in the UPD;
  - Implementation of updated best practice guidelines developed by the Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv);
  - Participation in a pilot work-sharing procedure for the centralised management of signal detection of adverse reactions at the EMA;
  - Input into the development of changes to EMA procedures required by the legislation.

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2023 we:
  - Hosted a webinar to keep stakeholders up-to-date and informed as regards developments with the new veterinary medicines Regulation;
  - Published a periodic blog on HPRA implementation activities, as well as those of the wider EU network, on the HPRA website;
  - Participated in the Department stakeholder group on antiparasitic resistance control measures.
- With regard to Brexit, we focused 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:
  - Exploring an initiative with Spain, Portugal and France regarding medicines for unmet needs;
  - Reached agreement 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;
  - Publication of a guide to joint labelling for veterinary medicinal products for use in Ireland and the UK;
  - Providing an update to the EU Commission in respect of transitional arrangements regarding products being imported into Ireland from Great Britain;
  - Liaising with stakeholders concerning the availability of veterinary medicinal products on the island of Ireland.
- Throughout 2023, we continued our involvement across the EU regulatory network, which includes active participation at the EMA and the HMA.
- As in recent years, we continued to deliver a programme of presentations to veterinarian students and veterinary nursing students on the role of the HPRA and the promotion of veterinary pharmacovigilance. We also presented at a number of industry stakeholder events. A full list of presentations for 2023, many of which were delivered remotely, is provided in Appendix 2.
- Our Medicinal Products Newsletter provides updates for those working in the veterinary medicines sector on Irish and European legislation, new/revised HPRA regulatory publications and stakeholder events such as information days. Three editions were published in 2023 and are available to download from the 'Publications' section on our website.

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

Scientific Animal Protection

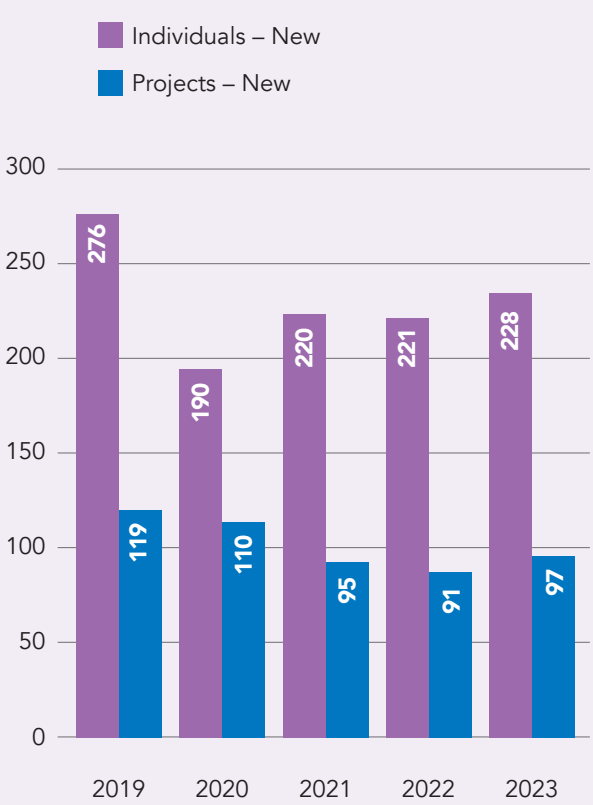
The HPRA is the competent authority in Ireland responsible for the implementation of EU legislation (Directive 2010/63/EU) for the protection of animals used for scientific purposes.

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 2023 figures	
Individual authorisations	228
Individual renewals	154
Project authorisations	97
Individual amendments	30
Project amendments	56
Establishment renewals	19
Retrospective assessments	12

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 tenth 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 2023, there were 32 inspections performed to monitor animal welfare standards and compliance with legislation. This total incorporated 23 breeder, supplier or user establishment renewal inspections (announced) and nine compliance inspections. Of the compliance inspections completed, 78% were carried out as unannounced inspections.

- Of the non-compliances recorded in 2023 under the Scientific Animal Protection inspections and compliance programme, 44% were self-reported to the HPRA by authorised breeder/supplier/user establishment personnel, 48% were identified during the course of HPRA inspections, and the remaining 8% were detected during the HPRA assessment of applications for individual authorisation.

- Non-compliances are categorised as Type 1, Type 2 and Type 3, with Type 1 being the most serious and Type 3 being more minor in nature. Of the non-compliances identified in 2023:

  – 17% were Type 1

  – 54% were Type 2

  – 29% were Type 3

  The most common reason recorded for non-compliance was failure to comply with the terms and conditions of HPRA project or individual authorisation, for example due to the performance of procedures after authorisation had expired. The second most common reason recorded was a failure to comply with the requirements of Annex III to Directive 2010/63/EU in relation to the care and accommodation of animals. Non-compliances in relation to Annex III requirements related to, for example, failures to log daily health checks and failures to maintain environmental parameters within the required specifications.

Stakeholders and Partners

- We supported the National Committee for the Protection of Animals Used for Scientific Purposes in its meetings and activities throughout 2023.

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

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

- Throughout 2023, we continued our active involvement in the EU regulatory network, which includes active participation at National Contact Point meetings for the Implementation of Directive 2010/63/EU.

Controlled Drugs and Precursor Chemicals

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

Authorisation and Registration

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

- The following table shows the licensing activity for precursor chemicals since 2021:

Precursor Chemicals Licensing Activity	2021	2022	2023
Total	14	9	19

- 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	2021	2022	2023
Total	78	56	21

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 2023, 23 inspections were conducted linked solely to the possession and/or supply of controlled drugs. Operators were informed of any non-compliances identified and requested to implement corrective actions.

Legislation and Regulation

- Throughout 2023, 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 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 two new applications in 2023 from potential suppliers seeking to have their products included in the programme. From these applications, one application was withdrawn with the second application still undergoing assessment at time of publication.

  In 2023, one product application for consideration for inclusion on the MCAP, which was originally submitted in 2022, was cancelled.

  Three products for which applications were submitted in 2022 were subsequently placed on the MCAP programme by the Department of Health during 2023.

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

Stakeholders and Partners

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

Cosmetic Products

The role of the HPRA is to regulate the manufacture, sale and supply of cosmetic products in Ireland. We identify and address cosmetic product quality and safety issues, in conjunction with the HSE, so that a cosmetic product will not compromise the health and safety of the consumer or the person applying the product.

Authorisation and Registration

- We issued 68 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 2023, 204 market surveillance cases were initiated, including both proactive and reactive surveillance of cosmetic products and we received 1,103 Safety Gate alert notifications regarding non-compliant products.

  We also carried out 13 on-site inspections to assess compliance with the EU Cosmetics Regulation in relation to Responsible Person or distributor obligations.

Stakeholders and Partners

- The cosmetic team presented at the Irish Cosmetics and Detergents Association workshop in September 2023.
- We contributed to European meetings, both at the European Commission and the Council of Europe, throughout the year.

Other Regulatory Programmes

Inspections and Market Compliance

- Throughout 2023, HPRA contributions to the EU included participation in/leading on:
  - the Pharmaceutical Inspection Co-operation (PIC/S) drafting group for revision of the GMP guide for the manufacture of veterinary medicines;
  - the EU funded GAPP project to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments;
  - the EU funded project EU4Health Joint Action on quality of medicines and implementation of pharmaceutical legislation/strategy;
  - the development of a new risk assessment tool for the selection of medicinal products and active substances for surveillance testing;
  - the development of a communication toolkit for the OMCL Network.

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.
  - In November 2023, the HPRA hosted a conference focused on strengthening life-sciences innovation across Europe. This event was organised in conjunction with the EMA and the EU Innovation Network. It took place in a hybrid format and was attended by over 200 participants from Ireland and across the EU including funders, support bodies, university technology transfer offices and other European competent authorities. A focussed medical devices information day was also held in the latter half of 2023;
  - The HPRA's Innovation Office continues to offer regulatory advice to anyone developing an innovative heath product or technology. Approximately 70% of queries received by the innovation office came from small and medium enterprises, and academia;
  - The HPRA continues to co-chair the EU-Innovation Network. 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. We also continue to offer advice to stakeholders on the borderline between different regulatory frameworks including medicines, medical devices, cosmetics and other products via our borderline classification service at national level.

Outreach and Engagement

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

- In our outreach activities to support education and innovation developments in Ireland:
  - The HPRA continued to meet and interact with a number of other state agencies and organisations who seek to support innovation in Ireland as well as representatives from third level institutions. During 2023 engagement took place with Enterprise Ireland, the National Clinical Trials Office, the Science Foundation Ireland Research Centre for Pharmaceuticals (SSPC) and others to promote the innovation office and other available regulatory supports.
  - 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 2023 with training provided to a biochemistry graduate with an MSc in Regulatory Affairs and Toxicology as part of this initiative.
- Stakeholder communications and engagement:
  - We further developed our multi-platform digital information campaign to warn of the health risks of sourcing prescription medicines online. First launched in 2022 and incorporating both social media and display advertising, the campaign targets members of the general 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 2023 campaign consisted of two separate advertising bursts in June and December, and featured a number of updates:

    - Launch of a new landing page to complement the creative approach in the digital adverts.
    - Launch of Irish language versions of both the landing page and a number of the adverts.
    - Change in campaign objective from awareness building to website traffic. This resulted in a significant increase in the number of click-throughs to the campaign landing page.
    - Refinement of target audience across key platforms to focus on consumers interested in health, sports, beauty and fitness.

    In total, incorporating the two advertising bursts and our ads in both English and Irish, the campaign achieved almost 19 million impressions suggesting high visibility of the campaign. It also secured close to 40,000 visits to the new landing page.
  - 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 approximately 20 press releases and website statements concerning safety and regulatory matters to ensure consumers, healthcare professionals and other stakeholders received timely and accurate information and advice. In a number of instances, these communications resulted in national and regional media interviews with a HPRA spokesperson. In addition, we responded to more than 360 initial and follow-up queries from national, local and specialist media during the year.
  - The Patient Forum was developed to provide a platform for dialogue and exchange between patients and the HPRA on issues relevant to the regulation of medicines and medical devices,

and to give patients in Ireland a voice in the regulatory process. Forum members and HPRA staff collaboratively developed a rolling work plan for 2023 that included areas of common interest and aligned with the purpose of the forum. Work was progressed on a range of topics including fostering a patient focused culture and raising awareness of reporting of suspected side effects. Forum members also provided valuable feedback on a range of topics, including, the importance of patient-focused approaches to communication. Additionally, members of the forum reported having a greater understanding and appreciation of the HPRA's work, while the forum itself was seen as an important avenue for patients to provide feedback on a diverse range of issues and to stay up to date with latest developments in the regulation of medicines and medical devices.

– The HPRA participated in the eight annual #MedSafetyWeek, an international social media campaign designed to raise awareness of the importance of reporting side effects from medicines. With the theme 'Who can report?', the 2023 campaign focused on the key role of every patient, pharmacist, doctor and nurse who reports a side effect and contributes to using medicines safely. #MedSafetyWeek is a global initiative led by the Uppsala Monitoring Centre (UMC), the World Health Organisation Collaborating Centre for International Drug Monitoring. This year's campaign involved more than 80 countries working together to improve the safety of medicines globally. The campaign consisted primarily of short animated videos, available to view and download from the HPRA website, and shared across our Twitter, LinkedIn and Instagram accounts. Following a request for support from the HPRA in advance of the launch, a large number of national patient and consumer organisations, health agencies and other public bodies promoted the campaign's important public health message on social media. For the first time, working in partnership with UMC, the HPRA produced a selection of the campaign materials in Irish. For the second year running, 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 compared to earlier campaigns with over two and a half million impressions for 2023. Additionally, a press release promoting the HPRA's involvement in #MedSafetyWeek was issued and alerted to website subscribers.

– All of our communications activities 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. As outlined in our Strategic Plan for 2021 – 2025, the HPRA is committed to the redevelopment of our current site. A public procurement process to appoint a website agency to partner with the HPRA in the redevelopment of the website commenced in late 2022 and was completed in March 2023. This followed a detailed assessment of tenders received. Work commenced with the successful agency in the second quarter of 2023 and continued throughout the year with involvement of nominated representatives from across the organisation. The planned launch date for the new site is Q4 2024. The overall objective of modernising the website is to provide a richer, tailored experience and information source for a range of stakeholders. It is envisaged that the redesigned website will enable easy and speedy access to information and services for all users from any device. There will be a focus on improving the quality, accessibility and effectiveness of digital interaction while reducing the process complexity for the organisation.
  - 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 2023, following another year of significant growth, our total number of followers had grown to more than 20,000.
  - The @TheHPRA Twitter account supports our communications activities and helps to direct additional traffic to the HPRA website. We continued to develop our Twitter activity during 2023 and by year-end we had grown our number of followers to more than 4,300.
  - We also continued to utilise our corporate Instagram account to highlight and promote certain activities and events including #MedSafetyWeek.
  - Of note in 2023, we also developed a new suite of HPRA branded social media templates for use across all of our social media accounts. The templates support the HPRA's brand identify and will ensure a consistency of style and branding across all our social posts.

- European and international contribution:
  - During 2023, many of the European COVID-19 working groups were stepped down and the regulatory network's focus switched from lessons learned to addressing future public health emergencies. The HPRA again contributed to the work of the EU Executive Steering Group on Shortages of Medicines (MMSG) which continued to meet and provide strategic oversight of EU activities relating to monitoring, management and mitigation of critical shortages. This included a joint exercise with the European Commission to monitor supply and availability of key antibiotics used to treat respiratory infections during autumn and winter 2023-24. In October 2023, the MSSG published a toolkit of recommendations for tackling shortages of medicinal products, which included a new solidarity mechanism. The solidarity mechanism enables a coordinated approach through which a European member state can seek support from other member states in the event of a critical shortage that cannot be mitigated through other means. The MSSG also contributed to the development of the first Union list of critical medicines, which was published in December 2023 and identified medicines considered essential to ensure provision and continuity of quality healthcare.
  - We continued our active participation in all EMA and all HMA management board/group meetings and the HMA Management Group. Dr Lorraine Nolan continued to act as Chair of the EMA Management Board and Ms Rita Purcell joined the EMA Management Board Audit and Risk Group.
  - The EMA Management Board was updated on a number of significant issues, including the implement of the Clinical Trials Regulation and related Clinical Trials Information Systems (CTIS), the implementation of the New Veterinary Regulation and the Union Product Database, DARWIN EU and the use of Real World Evidence. There was further consideration of the lessons learned from the COVID-19 pandemic as well as implementation of the new EMA powers for crisis preparedness under Regulation 2022/123 including its expansion to medical devices.
  - Additionally, as part of our ongoing contribution to the European regulatory system, HPRA scientific and technical staff participated in a broad range of committees and working parties at the European Commission, EMA, HMA, CAMD and other fora (see Appendix 4).
  - The HPRA continued its role as a member of the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee. At the ICMRA Summit in 2023, the HPRA co-led with Health Canada on a session on innovative clinical trial designs, while other sessions were held on the use of AI in medicines regulation and on advanced therapies. The HPRA actively participated in a range of initiatives and co-led with FDA on the Pharmaceutical Quality Knowledge Management System (PQ KMS) and the Governance project.
  - Throughout 2023, the EU Commission continued its work in developing the new pharmaceutical strategy and related pharma package to include a revision of the orphans, paediatric and human medicines pharmaceutical legislation. The HPRA continues to participate in the development of that strategy.

- Protected disclosures:
  - During 2023, eleven external protected disclosures were received by the HPRA as a prescribed person, of which one was transmitted to the Protected Disclosures Commissioner, and one warranted no further follow-up.
  - Nine investigations were opened which involved a breach of legal obligation.
  - Seventeen open investigations were carried over from the previous year with eleven investigations closed during 2023.
  - Seventeen investigations remained open at the end of the calendar year.
  - There were no internal protected disclosures received.

Key outreach and engagement figures	2023
Public consultations held: – Proposed regulatory fees for human medicines, compliance activities, blood, tissue establishments, organs and medical devices – Proposed regulatory fees for veterinary medicines – Draft guide for health institutions who manufacture and use in-house *in vitro* diagnostic medical devices in Ireland	3
Public consultations responded to: – Included Department of Health and the Medical Council	3
Events managed by HPRA events teams	3
Freedom of information requests	61
Freedom of information requests answered outside the FOI Act	5
Requests received in accordance with the Data Protection Acts	3
Parliamentary questions	55
Queries from Government departments or members of the Oireachtas	205
Complaints	4
Customer service queries	2,335

HPRA digital information campaign

Organisational Development

The HPRA is committed to having the necessary corporate functions, systems and supports in place to deliver on our public health mission. We must ensure that our organisational capabilities continue to expand and evolve in line with regulatory and scientific developments and that we adapt to other changes in our operating environment.

Change Programmes

2023 saw the commencement of a number of organisational development change programmes. These included initiatives across human and veterinary medicines, the establishment of a new function to meet emerging stakeholder needs, and the formation of a cross-organisational operational excellence working group. These change programmes have been undertaken to align departmental strategic objectives with the HPRA Strategic Plan, streamline and standardise activities, deliver process improvements and optimize application of the organisation's resources.

Human Resources and Change

The HR and Change team delivered across a number of operational and strategic priority areas throughout 2023. The primary focus continued to be on developing the organisation and providing effective, best practice advice and support.

People Strategy

- Our new People Strategy was launched in 2023 and there was a subsequent focus on embedding the strategy into our everyday work. Developed through a consultative process to elicit employee views, the People Strategy underpins Goal 5 of the HPRA Strategic Plan – great people, great processes. The purpose of this strategy is to outline how we invest in and support our people to deliver on our vision and mission, further embed our values, and enable organisational success. The People Strategy is arranged into four pillars: Purpose, Growth, Belonging and Wellbeing. These pillars provide the framework for our People Strategy and encapsulate the essence of what everyone in the organisation should experience while working here. They enable the identification of areas around which organisational activities will be prioritised to ensure that as an organisation we deliver on our strategic objectives.

Gender Pay Gap

- Analysis was undertaken to understand what drives our pay gap and how we can work to address any imbalance as a result. We are proud to report that our gender pay gap for 2023 has reduced from 3.65% to 1.22%. Transparency around any gender pay gap is core to our values and we strive to ensure we have a diverse and equitable gender balance across the organisation. Further details can be found in the full report on our website.

Engagement

- Employee engagement is an ongoing priority for the HPRA. In 2023, we further embedded the use of a new software tool within the organisation delivering insights into what it means to work within the HPRA. We are proud of the fact that due to these insights, the support given through Human Resources and Change and the HPRA Leadership team, and the work completed at department level by all employees and their managers, our engagement score rose by 10 points year on year.

Wellbeing

- The HPRA continues to invest in employee wellbeing. For the third year in a row, the HPRA was honoured to be listed in the Top 100 Leading in Wellbeing Index by IBEC and Business and Finance. This index recognises those organisations who are leading the way in workplace wellbeing. It commends their commitment to instilling a best practice approach to wellbeing and to creating a lasting impact on their employees and on the business community.

Management and Employee Capabilities

- Management and employee capabilities were developed this year through our management development and new manager training. In line with the People Strategy, these concentrated on the themes of psychological safety for high performance, and growth mindset for leaders, managers and their teams. Our in-demand collaboration training and 'Plan Prioritise Be Productive' workshops continued across the whole organisation in addition to being integrated as core elements in the new manager training programme.

- To support the 2023 organisational focus competencies of 'Organisational Motivation and Development' and 'Continued Focus on Results', eLearning resources were released to the organisation to help develop skills relevant to these two competencies. Supplementary courses were supported and arranged to assist with technical skill development needs.

- Aligned with the organisational approach of continuous improvement within the HPRA core values of 'Innovation' and 'Excellence', Lean Six Sigma Green and Yellow Belt training was made available in collaboration with the Operational Excellence function.

Public Sector Equality and Human Rights Duty

The HPRA seeks to meet obligations under Section 42 of the Irish Human Rights and Equality Act 2014 and actively contributes to public consultations in this area. As an organisation, we strive to ensure that consideration is given to human rights and equality in the development of policies, procedures and engagement with stakeholders as we fulfil our mission to regulate medicines and medical devices for the benefit of people and animals.

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 a performant and secure technology platform and to enhance the efficiency and effectiveness of the organisation.

The strategy is constructed around six core themes:

– Optimising Transaction Applications: providing efficient core transaction capability to support day to day process.

– Enhancing Digital Integration: automating the transfer of data between systems and across the organisation boundary without the need for manual intervention.

– Improving Data Management and Decision Support: ensuring availability, integrity and security of data to enable efficient organisation processes.

– Enhancing Client Computing: provide facilities and user productivity applications to enable staff fulfil their roles and collaborate effectively.

– Enhancing Technology Infrastructure: provide a performant and resilient technology infrastructure and connectivity to distributed workforce.

– Improving Governance: provide oversight and control over information technology activities to ensure alignment with the business strategy.

Delivery of the strategy proceeded with a focus on optimising transaction applications, enhancing digital integration and enhancing the technology infrastructure. Consolidation of processes and data onto a core suite of applications progressed, as did enhancing the capabilities of the applications to support improved organisational processes. Work continued to progress on the adoption of the IDMP (Identification of Medicinal Products) data standards in conjunction with other European regulators. Information technology security capabilities and controls continued to be upgraded with a particular focus on enhancing resilience and recovery processes. The project to rebuild the organisation's website was mobilised with a number of prerequisite technology upgrades completed to provide data integration with enterprise applications.

Operational Excellence and Quality Management

- The HPRA is committed to a culture of continuous improvement and application of its quality management system. In 2023, 11 internal audits were completed with no major concerns identified.
- The quality management team worked closely with departments to support various lean improvement projects and the HPRAs Digital Transformation Strategy, as well as the continued implementation of new legislation.
- The Operational Excellence and Quality department carried out a week of special training and information sessions, promoting quality standards, continuous improvement and lean management throughout the HPRA.
- The HPRA has introduced the role of Operational Excellence Manager within the organisation, with a specific mandate to cultivate an operational excellence culture and focus throughout the entire HPRA while aligning with the pursuit of its strategic objectives. Throughout the year, a series of initiatives were successfully undertaken. These included:
  - The transition of the Medical Devices department to a new case management platform and the migration of the freedom of information (FOI) process to a case management platform.
  - Establishment of a cross-organisational operational excellence team and completion of a review of organisational performance metrics.
  - A dedicated emphasis on the ongoing training and development of personnel in the principles of Lean Six Sigma. To ensure sustained progress, a comprehensive multi-year roadmap was created at the end of 2023. This roadmap serves as a guiding framework, steering the organisation through its ongoing Operational Excellence journey.

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Finance

- The HPRA is committed to the highest standards of corporate governance. During 2023, 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 2022 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.
- The annual review of regulatory fees for 2024, incorporating a public consultation, was completed followed by the publication of the updated fees.
- Two internal audit reviews took place and reports were issued on the system of internal financial controls and ICT disaster recovery.

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 2023, the HPRA consumed 624.5MWh of energy consisting of:
  - 370.3 MWh of electricity;
  - 2254.2 MWh of fossil fuels;
  - 0 MWh of renewable fuels.

  According to the Sustainable Energy Authority of Ireland (SEAI) Annual Report 2023 on Public Sector Energy Efficiency Performance, total energy reduction achieved by the HPRA since baseline was 65%* 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 2023 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 2023.

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 2023 and considered a number of strategic matters including the continued supply of medicines to the Irish market, strategic planning, website development, the implementation of new Regulation in the areas of medical devices and veterinary, and financial matters. The latter included monthly management accounts, annual budgets and the financial statements for 2022.

  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 2023 was as follows:

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

- The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2023. Further details are provided in the HPRA's Financial Statements.
- The Advisory Committee for Human Medicines did not meet in 2023. The Clinical Trials Sub-Committee is a sub-committee to the Advisory Committee for Human Medicines. The Clinical Trials Sub-Committee held its last meeting in January 2023 before it was disbanded in line with changes stemming from the Clinical Trials Regulation (Regulation (EU) No 536/2014).
- The Advisory Committee for Veterinary Medicines met three times.
- The Advisory Committee for Medical Devices met twice.
- The National Committee for the Protection of Animals Used for Scientific Purposes, a statutory committee to provide guidance to the regulator and those working in this area, met once in 2023.

- Decisions of the Authority:

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

  The following decisions are reserved functions of the Authority:

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

Financial Statements

for the Year Ended 31 December 2023

Authority Members and Other Information

Authority:	*Most recent appointment date*	*Expiry date*
Mr. Michael Donnelly (Chairperson)	19/04/2021	31/12/2025
Mr. Joe Collins	28/09/2020	31/12/2024
Mr. David Holohan	27/01/2021	26/01/2026
Mr. Brian Jones	27/01/2021	26/01/2026
Dr. Fiona Kiernan	12/09/2022	31/12/2026
Dr. Paula Kilbane	28/06/2021	31/12/2025
Dr. Sharon O'Kane	15/07/2021	31/12/2025
Dr. Diarmuid Quinlan	22/05/2019	21/05/2024
Prof. Richard Reilly	01/01/2020	31/12/2024

All Authority members are appointed by the Minister for Health.

Bankers:

Allied Irish Bank
1-3 Lower Baggot Street
Dublin 2

Bank of Ireland Corporate
2 Burlington Plaza
Burlington Road
Dublin 4

National Treasury Management Agency
North Wall Quay
Dublin 1

Solicitors:

Addleshaw Goddard
Temple Chambers
3 Burlington Road
Dublin 4

Byrne Wallace
88 Harcourt Street
Dublin 2

Head Office:

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Auditors:

Comptroller and Auditor General
3A Mayor Street Upper
Dublin 1

Governance Statement and Authority Member's Report

Governance

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

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

Authority Responsibilities

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

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

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

In preparing those statements the Authority is required to:

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

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

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

The Authority considers that, except for the non-compliance with the requirements of FRS102 in relation to retirement benefits, the financial statements of the HPRA give a true and fair view of the financial performance and the financial position of the HPRA at 31 December 2023.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2023. 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 2023, the internal auditor carried out internal audit reviews on the system of internal financial controls and ICT disaster recovery. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2023, 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 49 to 50.

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

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

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

Statement of Compliance

The Authority has adopted the Code of Practice for the Governance of State Bodies (2016) and has put procedures in place to ensure compliance with the Code. The HPRA was in full compliance with the Code of Practice for the Governance of State Bodies for 2023.

Performance Review

The Authority were subject to an external evaluation of their own performance and its committees during the year ended 31 December 2023.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 06 June 2024

Statement on Internal Control

Scope of Responsibility

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

Purpose of the System of Internal Control

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

The system of internal control, which accords with guidance issued by the Department of Public Expenditure, National Development Plan Delivery and Reform, has been in place in the HPRA for the year ended 31 December 2023 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 2023.

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 2023 two internal audit reviews were conducted.

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

Risk and Control Framework

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

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

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

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

Ongoing Monitoring and Review

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

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

Procurement

I confirm that the HPRA has procedures in place to ensure compliance with current procurement rules and guidelines, and that during 2023 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 2023. This review was carried out at its meeting on 27 March 2024.

Internal Control Issues

No weaknesses in internal control were identified in relation to 2023 that require disclosure in the financial statements.

Mr. Michael Donnelly
Chairperson

Date: 06 June 2024

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 2023 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 2023 and of its income and expenditure for 2023 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 2023 has not been quantified.

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

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

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

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

I have nothing to report in that regard.

John Crean

For and on behalf of the
Comptroller and Auditor General

10 June 2024

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 judgment 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 2023

	Note	2023	2022
		€	€
Fee Income	3	33,049,885	31,099,071
Department of Health Funding	3	5,560,000	4,900,000
Other Income	4	1,019,691	813,244
		39,629,576	36,812,315
Salaries and Wages	5	30,531,250	28,423,991
Other Operating Costs	6	6,237,802	5,905,143
Depreciation	2	1,581,427	1,009,375
		38,350,479	35,338,509
Surplus for the year before write back of Superannuation contributions		1,279,097	1,473,806
Staff Superannuation Contributions		597,819	658,600
Surplus for the year		1,876,916	2,132,406
Balance brought forward		40,295,411	38,163,005
Balance carried forward	12	42,172,327	40,295,411

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 57 to 67 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 06 June 2024

Statement of Financial Position
As at 31 December 2023

	Note	2023	2022
		€	€
Fixed Assets			
Property, Plant and Equipment	2	**24,635,448**	24,677,887
Current Assets			
Debtors and Prepayments	7	**1,539,509**	2,044,475
Inventory of Stationery		**6,148**	5,308
Cash and Cash Equivalents	9	**9,254,830**	17,198,418
Short Term Deposits	10	**22,015,208**	10,000,000
		32,815,695	29,248,201
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	**15,110,479**	13,294,003
Mortgage	13	**168,337**	168,337
		15,278,816	13,462,340
Net Current Assets		**17,536,879**	15,785,861
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	**–**	168,337
NET ASSETS		**42,172,327**	40,295,411
Reserves			
Retained Revenue Reserves	12	**19,666,799**	20,387,702
Superannuation Reserve	12	**22,505,528**	19,907,709
		42,172,327	40,295,411

The Statement of Cash Flows and the notes on pages 57 to 67 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 06 June 2024

Statement of Cash Flows
For the year ended 31 December 2023

	Note	2023	2022
		€	€
Cash flows from Operating Activities			
Surplus for financial year		1,876,916	2,132,406
Depreciation of property, plant and equipment		1,581,427	1,009,375
(Profit)/Loss on Disposal of property, plant and equipment		0	0
(Increase)/Decrease in Debtors		504,966	(402,414)
(Increase)/Decrease in Stock		(840)	(209)
Increase/(Decrease) in Creditors - amounts falling due within one year		1,816,476	718,284
Deposit Interest		(120,240)	(8,000)
Bank Interest		21,184	89,064
Cash from Operations		5,679,889	3,538,506
Bank Interest Paid		(21,184)	(89,064)
Net Cash generated from Operating Activities		5,658,705	3,449,442
Cash flows from Investing Activities			
Deposit Interest Received		120,240	8,000
(Increase)/Decrease in Bank Deposits		(12,015,208)	(10,000,000)
Payments to acquire property, plant and equipment		(1,538,988)	(1,326,792)
Receipts fom sales of property, plant and equipment		0	0
Net cash from Investing Activities		(13,433,956)	(11,318,792)
Cash flows from Financing Activities			
Repayment of Borrowings		(168,337)	(168,337)
Net cash used in Financing Activities		(168,337)	(168,337)
Net increase/(decrease) in Cash and Cash Equivalents		(7,943,588)	(8,037,687)
Cash and Cash Equivalents at beginning of year		17,198,418	25,236,105
Cash and Cash Equivalents at end of year	9	9,254,830	17,198,418

1. Accounting Policies

A. General information

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

B. Compliance with FRS 102

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

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

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

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

C. Basis of preparation

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

D. Critical accounting estimates and judgements

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

(a) Provisions

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

(b) Bad and Doubtful Debts

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

E. Revenue recognition

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

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

F. Expenditure recognition

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

G. Reporting currency and currency translation

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

H. Property, plant and equipment

Plant and equipment excluding Premises

Plant and equipment excluding premises are stated at cost less accumulated depreciation. Depreciation is calculated in order to write off the cost of property, plant and equipment to their estimated residual values over their estimated useful lives by equal annual instalments.

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

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

Premises

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

No depreciation had been calculated on the value of premises, as the useful economic life was estimated to be greater than 50 years. In 2023, the HPRA Authority decided to commence charging depreciation on premises, over a period of 50 years.

I. Taxation

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

J. Debtors

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

K. Superannuation

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

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

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

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

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

L. Provisions

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

M. Library

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

N. Leases

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

O. Loans

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

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

2. Property, plant and equipment	Fixtures and Fittings	Computer Equipment	Leasehold Improvements	Improvements To Premises	Premises	Total
	€	€	€	€	€	€
Cost						
Balance as at 1 January 2023	1,329,270	18,049,011	866,055	4,721,147	23,156,037	48,121,520
Additions for the year	30,518	1,500,706	-	7,764	-	1,538,988
Disposals for the year	(1,867)	(261,607)	-	-	-	(263,474)
As at 31 December 2023	1,357,921	19,288,110	866,055	4,728,911	23,156,037	49,397,034
Depreciation						
Balance as at 1 January 2023	1,252,299	17,157,660	638,630	4,395,044	-	23,443,633
Charge for the year	42,933	1,077,610	36,361	41,402	383,121	1,581,427
Disposals for the year	(1,867)	(261,607)	-	-	-	(263,474)
As at 31 December 2023	1,293,365	17,973,663	674,991	4,436,446	383,121	24,761,586
Net Book value at 31 December 2023	64,556	1,314,447	191,064	292,465	22,772,916	24,635,448
Net Book value at 1 January 2023	76,971	891,351	227,425	326,103	23,156,037	24,677,887

3. Income	2023	2022
	€	€
Fee Income		
Human Medicine - National Fees	11,669,627	10,951,292
Human Medicines - Centralised Fees	7,280,716	6,572,322
Veterinary Sciences - National Fees	3,605,164	2,756,928
Veterinary Sciences - Centralised Fees	989,280	1,119,484
Compliance Department	6,581,665	6,682,641
Medical Devices	3,177,401	2,923,278
	33,303,853	31,005,945
Movement in deferred revenue	(253,968)	93,126
	33,049,885	31,099,071
Dept Of Health Funding (Vote 38 Subhead E1)	5,560,000	4,900,000
Other Income (Note 4)	1,019,691	813,244
Total Income	39,629,576	36,812,315

Fees received by the Authority under Section 13 of the Irish Medicines Board Act 1995 and Section 29 of the Animal Remedies Act 1993, totalling €24,052,096 in 2023, shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure, National Development Plan Delivery and Reform directs.

4. Other Income

	2023	2022
	€	€
Bank Interest	120,240	8,000
Joint Action Income	273,812	-
Conference Income	-	74,055
IT Income	625,639	731,189
	1,019,691	813,244

5. Salaries and Wages

Basic Pay	24,517,352	22,601,049
Overtime	125	10,258
Allowances	152,589	160,145
Staff Short Term Benefits	24,670,066	22,771,452
Retirement Benefit Costs	1,550,042	1,656,223
Employer's Contribution to Social Welfare	2,541,435	2,383,856
Employer's Contribution to Single Scheme Pension	1,769,707	1,612,460
	30,531,250	28,423,991

The average number of staff employed during the year was 383 (2022 - 364).
Payroll numbers at 31 December 2023 can be analysed across the following departments:

Chief Executive	11	7
Compliance	76	69
Finance, Corporate & International	31	28
Human Products Authorisation & Registration	118	105
Human Products Monitoring	43	40
Human Resources & Development	11	10
IT & Business Services	19	17
Medical Devices	48	46
Organisational Excellence & Quality	6	7
Veterinary Sciences	35	32
Staff	398	361
Authority Members	8	8
Pensioners	62	58
	468	427

No termination or severance payments were made during the year.

Additional superannuation contributions for Public Servants of €813,889 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 €632,603 were deducted from staff during the year and paid over to the Department of Public Expenditure, National Development Plan Delivery and Reform. In agreement with our parent department and DPENDPDR, the HPRA have also paid over Single Scheme employer contributions since January 2019 for employees not employed in exchequer funded areas.

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

Salary Band	2023	2022
€0 to €60,000	207	186
€60,001 to €70,000	40	46
€70,001 to €80,000	61	57
€80,001 to €90,000	18	8
€90,001 to €100,000	23	20
€100,001 to €110,000	14	26
€110,001 to €120,000	23	8
€120,001 to €130,000	5	5
€130,001 to €140,000	5	4
€140,001 to €150,000	1	-
€150,001 to €160,000	-	-
€160,001 to €170,000	-	-
€170,001 to €180,000	1	1
	398	361
Average Salary	€60K	€59K

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

	2023	2022
	€	€
Accommodation Costs	2,348,359	1,812,724
Travel, Representation and Training	915,362	801,907
Bank Charges and Interest	26,130	95,128
Legal Fees	135,088	303,514
Audit Fees (External and Internal)	44,028	24,200
Stationery, Publications, Postage and Communications	321,713	395,833
Consultancy	288,204	379,514
Sampling and Analysis	249,234	235,995
IT Costs	1,643,778	1,638,029
Storage Costs	180,837	126,983
Telephone and Telecommunications	79,734	84,934
Movement on Bad Debt Provision	5,335	6,382
	6,237,802	5,905,143

Travel costs include an amount of €49,656 related to hospitality and staff welbeing, and an amount of €387,303 related to travel and subsistence, of which €201,815 is national and €185,488 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 €137,121 related to public relations/marketing, €102,056 related to human resources/ pensions and €49,027 related to other.

7. Debtors (all due within one year)	2023	2022
	€	€
Trade Debtors	1,337,000	1,938,886
Prepayments	86,372	41,422
Other Debtors	116,137	64,167
	1,539,509	2,044,475

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)		
Trade Creditors	363,009	383,580
Credit Balances on Debtor Accounts	5,421,998	4,647,643
Accruals	6,680,240	5,937,114
Deferred Revenue	1,754,792	1,500,823
Revenue Commissioners	890,440	824,843
	15,110,479	13,294,003

9. Cash and Cash Equivalents		
Cash at Bank and in Hand	3,187,595	5,131,670
Demand Deposits (Convertible to Cash on Demand)	6,067,235	12,066,748
	9,254,830	17,198,418

10. Short Term Deposits		
Short Term Deposits (not immediately convertible to cash)	22,015,208	10,000,000
	22,015,208	10,000,000

11. Administration Expenses		
Surplus for the year was calculated having charged:		
Auditor's Remuneration	24,200	24,200

12. Movement on Income and Expenditure Reserves

	As At 01/01/2023 €	Income & Expenditure €	Transfer to Superann Reserve €	As At 31/12/2023 €
Retained Revenue Reserves	20,387,702	1,279,097	(2,000,000)	19,666,799
Superannuation Reserve	19,907,709	597,819	2,000,000	22,505,528
	40,295,411	1,876,916	0	42,172,327

Our Authority recommended the transfer of a further €2,000,000 in 2023 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.

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 :

	2023 €	2022 €
- within one year	168,337	168,337
- between one and five years	-	168,337
- after five years	-	-
	168,337	336,674

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. This will result in lower quarterly repayment amounts over the remaining years of the mortgage.

14. Interest Rate Exposure

The HPRA have taken all necessary steps to minimise its interest rate exposure by fixing 2/3s of the borrowings for the mortgage duration. The balance of the borrowings are fully offset by cash reserves. As the mortgage is at a fixed rate, the Authority has no interest rate exposure.

15. Financial Commitments

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

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

	2023	2022
	€	€
The amounts due under this lease are as follows:		
- within one year	353,070	353,070
- between one and five years	128,173	481,243
- after five years	-	-
	481,243	834,313

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 2023 this lease had 10 years and 5.5 months remaining.

The amounts due under this lease are as follows:		
- within one year	371,421	371,241
- between one and five years	1,485,683	1,485,683
- after five years	2,027,338	2,398,758
	3,884,442	4,255,682

16. Capital Commitments

Contracted For (Contract Signed)	127,367	284,499
Contracted For (Contract Not Signed)	789,702	-
	917,069	284,499

17. Authority Remuneration

	Fees	Expenses
	€	€
Michael Donnelly (Chairperson)	11,970	-
Joe Collins	7,695	2,048
David Holohan	7,695	-
Brian Jones	7,695	511
Fiona Kiernan	7,695	-
Paula Kilbane	7,695	11
Sharon O'Kane	7,695	-
Diarmuid Quinlan	7,695	-
Richard Reilly	-	-
	65,835	2,570

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

	2023	2022
	€	€
Chief Executive	176,435	171,056
Senior Management	1,051,279	973,216
	1,227,714	1,144,272

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.

19. Related Party Transactions

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

20. Prompt Payment of Accounts

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

21. Exchange Rates

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

2023 €1 = STG £0.86680

2022 €1 = STG £0.88519

22. Provisions

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

23. Going Concern

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

24. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 04 June 2024.

Appendix 1

2023 Committee Members

HPRA Management Committee

Dr Lorraine Nolan – Chief Executive

Ms Rita Purcell
Deputy Chief Executive

Dr Gabriel Beechinor
Director of Veterinary Sciences

Ms Sinead Curran
Director of Human Products Monitoring

Mr Sean d'Art
Director of ICT and Business Services

Dr Niall MacAleenan
Director of Medical Devices

Ms Elizabeth Stuart
Director Human Resources and Change

Ms Gráinne Power
Director of Compliance

Dr Finnuala Lonsdale
Director of Human Products Authorisation and Registration

Authority (Board)

Mr Michael Donnelly – Chairperson

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

Dr Paula Kilbane

Prof Sharon O'Kane

Dr Diarmuid Quinlan

Prof Richard Reilly

Dr Fiona Kiernan

Audit and Risk Committee

Mr David Holohan – Chair

Mr Brian Jones

Prof Sharon O'Kane

Advisory Committee for Human Medicines

Dr Diarmuid Quinlan – Chair

Prof Brian Cleary

Prof Desmond Corrigan

Prof Paul Gallagher

Ms Fionnuala King

Prof Fionnuala Ní Ainle

Dr Brian O'Connell

Ms Margaret O'Doherty

Dr Patrick Sullivan
(Resigned January 2023)

Advisory Committee for Veterinary Medicines

Dr Joe Collins – Chair

Dr Patrick Paul Corkery

Dr Abina Crean

Dr Caroline Garvan

Dr John Gilmore

Dr David Graham

Dr Andrew Hillan

Dr Orla Keane

Dr Edward Malone

Dr Bryan Markey

Dr Christina Tlustos
(Resigned July 2023)

Advisory Committee for Medical Devices

Prof Richard Reilly – Chair

Prof Robert Byrne

Dr Ger Flynn

Dr Vida Hamilton

Dr Tanya Mulcahy

Dr Fergal McCaffrey

Ms Margaret O'Donnell

Prof Pat Twomey

Appendix 2

Presentations 2023

Educational/Professional Development Presentations and Training

Institution	Course / Subject	Presentation Title
Atlantic Technological University	Veterinary Nursing	The Regulation of Veterinary Medicinal Products in Ireland
DCU	MSc in course in Bioprocess Engineering	Medicines Regulation (General) and Regulation of Biological Medicines
IPPOSI	IPPOSI Patient Education Programme	Quality Defect and Recall Programme
National Office for Research Ethics Committees	GCP in Regulated Studies	Good Clinical Practice Inspections
RCSI	Nursing/Midwifery (Medicinal Product Prescribing)	The Role of the HPRA and Safety Monitoring of Medicines
RCSI	RCSI Research Summer School	The Role of the HPRA and Safety Monitoring of Medicines
St John's College	Veterinary Nursing	The Regulation of Veterinary Medicinal Products in Ireland
TCD	M.Sc. in Hospital Pharmacy	Pharmacovigilance and Risk Management
TCD	MSc in Immunotherapeutics	Medicines Regulation (General) and Regulation of Biological Medicines
TCD	MSc in Pharmaceutical Manufacturing Technology	The HPRA and the Role of the Pharmacopoeia in the Regulation of Medicines
TCD	MSc in Regulatory Affairs for Medical Devices	HPRA Perspective on Clinical Investigations
TCD	QP Forum Committee	HPRA Regulatory Update
TCD	QP Forum Committee	Technical Agreements & PQRs - the EMA Reflection Paper on GMP and MAHs
TOPRA	Introduction to Pharmaceutical Regulatory Affairs	Module 3: An Agency Perspective
TU Dublin	ICH Q9 (R1) Seminar	ICH Guideline Q9 (R1) on Quality Risk Management
TU Dublin	Medical Device Decontamination	Medical Devices Legislation

Institution	Course / Subject	Presentation Title
TU Dublin	Medical Device Decontamination	Practical Aspects of Medical Device Regulation
TUS	MSc in MedTech Regulatory Affairs	Clinical Evaluation
UCD	Nurse and Midwife Medicinal Product Prescribing	The Role of the HPRA and Safety Monitoring of Medicines
University of Galway	MSc (Medical Technology Regulatory Affairs)	Med Tech Clinical Evaluation
University of Limerick	Professional Diploma in Regulatory Affairs (Bio) Pharmaceuticals	Fundamentals of Pharmaceutical Development: A Regulatory Perspective

Regulatory Presentations

Event/Organiser	Presentation Title
Animal and Plant Health Association	Update on the Implementation of the New Veterinary Medicines Regulation
Biomedical Alliance	The Use of Registries to Facilitate the Evaluation of Medical Devices: Enhancing Clinical Evidence
BioPharmaChem Conference	Regulatory Innovation
BioPharmaChem Skillnet	Quality Defect Reporting and Investigation – Updated Guidance Document
BioPharmaChem Skillnet	Risk-based Considerations for Quality Defect Investigations
Combatting Antimicrobial Resistance –Strategies and Challenges (BVL Germany)	Global Response to AMR
CORE-MD (EU Horizon 2020 Project)	Clinical Evaluation and Investigation Working Group: Role in the European Medical Device Regulatory System
DIA (Drug Information Association)	The 2023 Revision of ICH Q9
Dublin Airport Customs / HPRA	Enforcement of Medicines Legislation: Training to Dublin Airport Customs Staff
European Innovation Network / HPRA	National Regulatory Supports for Innovation
GIRP (European Healthcare Distribution Association)	Implementation of the Falsified Medicines Directive
Grafton Medical – Centric Health	PRAC: Role in Promoting and Protecting Public Health of EU Citizens
HRB National Clinical Trials Office	Clinical Investigations and Performance Studies under MDR and IVDR / Transition of Existing Clinical Trials to the CTR

Event/Organiser	Presentation Title
HRB National Clinical Trials Office	Clinical Investigations and Innovative Medical Devices
IABS (International Alliance for Biological Standardization)	Specifications - Too Wide or Too Narrow? The Age-old Debate between Regulators and Industry
IMDRF (International Medical Device Regulators Forum)	Orphan Medical Devices Challenges and Tools
Irish College of General Practitioners	Medicine Shortages: A Multistakeholder Approach
Irish Cosmetics and Detergent Association	Overview of Cosmetics within the HPRA, Borderline Claims and EU Working Group Overview
Irish Institute of Pharmacy	Medicines Shortages: A Multistakeholder Framework Approach to Shortages
Irish Medication Safety Network	Medicine Shortages: A Multistakeholder Approach
Irish Medicines in Pregnancy Service	Use of Medicines in Pregnancy: A Medicines Regulator Perspective
Irish Pharmaceutical Healthcare Association	HPRA's Regulatory Compliance Inspection and Other Activities: Key Findings 2021-2023
Irish Pharmaceutical Healthcare Association	An Overview of the HPRA's Advertising Compliance Programme
ISPE (International Society for Pharmaceutical Engineering)	ICH Guideline Q9 (R1) on Quality Risk Management
Klifovet (Veterinary Contract Research Organisation)	VICH Good Clinical Practice and Field Efficacy Studies - A Regulatory View
Klifovet (Veterinary Contract Research Organisation)	Benefit/Risk Balance
NIBRT Biopharma Focus on the Future Conference	Focus on the Future: A Regulatory Perspective
NIBRT Biopharma Focus on the Future Conference	Supporting Innovation Through Regulation and Science
PEACe Conference	Guidance for Quality of Biopharmaceuticals
PPAR (Pharmaceutical Process Analytics Roundtable)	Process Analytical Technology and Models
Sir Peter Freyer Memorial Lecture and Surgical Symposium	Clinical Investigations with Medical Devices – Considerations for Surgical Research and Trials

Appendix 3

Publications and Articles 2023

Drug Safety Newsletters

Edition	Articles
March 111th Edition	• Levothyroxine: Biotin interference with thyroid function tests, and drug-drug interaction between levothyroxine and St. John's Wort and proton-pump inhibitors (PPIs) • Levonorgestrel-containing products: Factors associated with increased risk of expulsion and update on risks associated with intrauterine exposure • IMBRUVICA® (ibrutinib): New risk minimisation measures, including dose modification recommendations, due to increased risk of serious cardiac events • Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC): - Donepezil: Potential risk of QTc prolongation and Torsade de Pointes in patients prescribed donepezil-containing medicines - Guanfacine (Intuniv): Updated warnings concerning potential for suicide-related events and aggressive behaviour - Lisdexamphetamine: Risk of QTc interval prolongation
June 112th Edition	• Fluoroquinolone antibiotics: Reminder about restrictions of use and risk of rare but serious long-lasting adverse reactions • Hydroxychloroquine: Risk of drug-induced liver injury • Tramadol-containing medicines: New warnings and precautions for use regarding sleep-related breathing disorders, adrenal insufficiency and serotonin syndrome • Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC): - Flucloxacillin-containing medicines: Addition of a warning regarding hypokalaemia - Ceftriaxone-containing medicines: Addition of a warning regarding risk of encephalopathy - Teicoplanin-containing medicines: Updated warning on nephrotoxicity - Xeljanz (tofacitinib): Addition of warnings on the risks of hypoglycaemia in patients treated for diabetes and the risk of retinal venous thrombosis
November 113th Edition	• Topiramate: Introduction of a pregnancy prevention programme and new restrictions on use • Valproate (Epilim): Ongoing review of potential risk of neurodevelopmental disorders in children of fathers treated with valproate in the three months prior to conception

Edition	Articles
December 114th Edition	• Montelukast: New boxed warning to raise further awareness of the risk of neuropsychiatric events • Paracetamol: Monitoring risk factors for hepatotoxicity in patients during treatment • Ustekinumab: New warning regarding lupus-related conditions and updated advice regarding infections • Venlafaxine: Updated warning and advice on complex cases involving overdose and severe poisoning

Human Medicines Safety Articles – External Publications

Month	Publication	Topic
January/ February	MIMS	Janus Kinase inhibitors (JAKi) – Recommendations to mitigate risks of malignancy, major adverse cardiovascular events, serious infections, venous thromboembolism and mortality when used in the treatment of chronic inflammatory disorders
	MIMS	Amoxicillin – Drug-induced enterocolitis syndrome (DIES)
March	IMF	Janus Kinase inhibitors (JAKi) – Recommendations to mitigate risks of malignancy, major adverse cardiovascular events, serious infections, venous thromboembolism and mortality when used in the treatment of chronic inflammatory disorders
March	MIMS	Gabapentin and Pregabalin - Expanded warnings regarding the potential for abuse, dependence, and withdrawal symptoms
	MIMS	Nurofen Plus (codeine/ibuprofen) – Serious clinical harms, including renal tubular acidosis and severe hypokalaemia, following prolonged use of codeine/ibuprofen at higher than recommended doses
April	MIMS	Valproate (Epilim) – Reminder about the contraindications, warnings and measures to prevent exposure during pregnancy
	MIMS	Imbruvica (ibrutinib) – New risk minimisation measures, including dose modification recommendations, due to increased risk of serious cardiac events
June	MIMS	Optimising the safe and effective use of medicines in clinical practice through proactive risk management
	MIMS	Adverse Reaction Reporting to Vaccines – Reminder
September	IMF	Fluoroquinolone antibiotics: Reminder about restrictions of use and risk of rare but serious long-lasting adverse reactions
September	MIMS	Product Information for Medicines
October	MIMS	Topiramate: Introduction of a pregnancy prevention programme in the EU

Month	Publication	Topic
November	MIMS	Montelukast: New boxed warning to raise further awareness of the risk of neuropsychiatric events
	MIMS	Paracetamol – Monitoring risk factors for hepatotoxicity in patients during treatment
December	MIMS	Topiramate: Introduction of a pregnancy prevention programme and new restrictions on use

Veterinary Medicines Articles – External Publications

Month	Publication	Topic
March	It's your Field	Using veterinary medicines
June	It's your Field	Homeopathic veterinary medicines and the role of the HPRA
August	It's your Field	Enhancing information about veterinary medicines
September	It's your Field	Tips in managing veterinary medicines
December	It's your Field	Update on regulatory developments in control of antimicrobial resistance

Appendix 4

Standing Committee/ Working Group Participation

Committee/Working Group	Organisation	Meetings in 2023
Quality and Safety Advisory Committee	CAI / RCPI	4
Controlled Drugs Cross Border Group	Care Quality Commission (UK)	2
National Criminal Investigative Forum Workshop	Competition and Consumer Protection Commission	1
Counterfeiting of Medical Products (CMED)	Council of Europe	4
Market Surveillance Forum	Department of Enterprise, Trade and Employment	3
Early Warning and Emerging Trends Group	Department of Health	3
National Valproate Stakeholder Group	Department of Health	2
Pharmaceutical Strategy Working Group	Department of Health	4
Medicines Criticality Assessment Group	Department of Health / HSE	8
Connecting for Life Strategy	Department of Health / National Office of Suicide Prevention / National Suicide Research Foundation	4
Medicine Shortages Stakeholder Event	DOH	1
Revision of SoHO regulations	DOH / Health Attaché	1
Committee for Cosmetics and Consumer Health	EDQM	1
European Network of Official Cosmetics Control Laboratories (OCCL)	EDQM	2
General OMCL Network Advisory Group (AdG-GEON)	EDQM	3
OMCL Network General Annual Meeting	EDQM	1
OMCL Network MRP/DCP/CAP Annual Meeting	EDQM	1
PAT Working Party	EDQM	3
Biological Working Party	EMA	11
Biosimilar Working Party	EMA	3
Committee for Advanced Therapies (CAT)	EMA	11

Committee/Working Group	Organisation	Meetings in 2023
Committee for Medicinal Products for Human Use (CHMP) - Plenary	EMA	11
Committee for Medicinal Products for Human Use (CHMP) - Preparatory and Organisational Matters (PROM)	EMA	11
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee on Herbal Medicinal Products (HMPC)	EMA	3
EEA Rapid Alert Network meeting	EMA	1
Efficacy Working Party - Veterinary	EMA	2
European Medicines Verification Organisation (EMVO) workshop with NCAs	EMA	1
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	EMA	7
Expert group - Implementing measures under Article 93(2) of Regulation (EU) 20196	EMA	14
GCP inspection procedures and guidelines (sub-groups of GCP-IWG)	EMA	5
Good Clinical Practice (GCP) Inspectors' Working Group	EMA	4
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group	EMA	4
Infectious Diseases Working Party	EMA	11
Joint Meeting between the GMDP-IWG and the QWP to discuss the implementation of ICH Q12 in the EU	EMA	1
Management Board	EMA	4
Medicine Shortages Single Point of Contact Working Party	EMA	24
Modelling and Simulation Operational Expert Group	EMA	11
Non-Clinical Working Party	EMA	11
Paediatric Committee (PDCO)	EMA	11
Pharmacovigilance (PV) Inspectors' Working Group (Human and Veterinary)	EMA	3
Pharmacovigilance Business Team	EMA	4
Pharmacovigilance Risk Assessment Committee (PRAC) – Plenary	EMA	11
Pharmacovigilance Working Party - Veterinary	EMA	6
Quality Innovation Group (QIG) Listen and Learn Focus Groups	EMA	2
Quality Review of Documents Working Groups	EMA	3
Quality Working Party	EMA	7
Safe-CT Steering Committee Meeting	EMA	4
Safety Working Party – Veterinary	EMA	2
Scientific Advice Working Party - Human	EMA	11
Scientific Advice Working Party – Veterinary	EMA	11

Committee/Working Group	Organisation	Meetings in 2023
Signal Management Review Technical (SMART) Working Group: Methods	EMA	4
Signal Management Review Technical (SMART) Working Group: Processes	EMA	1
Vaccines Working Party	EMA	11
Revision of GMP Annex 4	EMA / PIC/S	3
Joint GCP IWG / CMDh Working Party	EMA / HMA	4
Health Advisory Committee	Environmental Protection Agency	2
National Persistent Organic Pollutants Forum	Environmental Protection Agency	1
CHESSMEN Joint Action	EU Member State Consortium	17
Clinical Trials Coordination and Advisory Group (CTAG)	European Commission	4
Competent Authorities for Organ Donation and Transplantation	European Commission	2
Cosmetic Meeting on new Cosmetic Product Notification Portal (CPNP)	European Commission	1
EU4H11 Project Working Group (Medicines)	European Commission	2
Expert group on clinical trials (CTEG)	European Commission	2
Expert Group on Precursor Chemicals	European Commission	2
Expert Group on Safety Features	European Commission	1
Expert Sub-Group on Vigilance for Blood, Tissues and Cells, and Organs (VES)	European Commission	9
Joint Action – GAPP PRO	European Commission	1
MDCG – Annex XVI	European Commission	2
MDCG – Borderline and Classification	European Commission	1
MDCG – Clinical Investigation and Evaluation (CIE)	European Commission	2
MDCG – Eudamed	European Commission	5
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 – Nomenclature	European Commission	1
MDCG – Notified Body Oversight (NBO)	European Commission	3
MDCG – Orphan Device Task Force	European Commission	3
MDCG – Post Market Surveillance and Vigilance (PMSV)	European Commission	3
MDCG – Standards	European Commission	2
MDCG – Unique Device Identification (UDI)	European Commission	2

Committee/Working Group	Organisation	Meetings in 2023
National Contact Points for the Implementation of Directive 2010/63/EU	European Commission	2
PEMSAC Sub-group on Cosmetovigilance	European Commission	2
Pharmaceutical Committee	European Commission	1
Platform of European Market Surveillance Activities in Cosmetics (PEMSAC)	European Commission	4
SoHO Competent Authorities	European Commission	4
Standing Committee on Cosmetic Products	European Commission	4
UNICOM WP3 (Digital Forms) Working Group	European Commission	16
UNICOM WP4 (IDMP Adoption) Working Group	European Commission	18
Working Group on Cosmetic Products	European Commission	4
Clinical Trials Coordination Group (CTCG)	HMA	10
Clinical Trials Coordination Group Safety Roundtable	HMA	9
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
Heads of Agency Meeting	HMA	4
Homeopathic Medicinal Products Working Group	HMA	2
Pharmacovigilance Work-sharing Procedures Working Party	HMA	4
Working Group of Communications Professionals (EU Presidency)	HMA	2
Working Group of Enforcement Officers (WGEO)	HMA	6
Working Group of Quality Managers	HMA	2
Risk Assessment Tool for Surveillance Testing	HMA / EDQM	8
Communications Working Group Meetings	HMA / EMA	22
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	34
Task Force on the Availability of Authorised Medicines	HMA / EMA	14
Annual compliance meeting	HPRA / National Office for Research Ethics / NCTO	1
National Patient Safety Alert Committee	HSE	12
National Vaginal Mesh Implant Oversight Group	HSE	4
National Cosmetics Surveillance Forum	HSE Environmental Health Service (EHS)	1
ICH Expert Working Group: Revision of the ICH Q9 Guideline on Quality Risk Management (and other Sub-groups)	ICH	6
ICH Q13 (Continuous Manufacturing) EWG	ICH	2

Committee/Working Group	Organisation	Meetings in 2023
ICH Q9(R1) Implementation Working Group on Quality Risk Management	ICH	2
ICMRA Real-World Evidence Meeting	ICMRA	1
Brexit/Windsor Framework and safety features	IMVO	1
Safety Features Oversight Group	IMVO / PSI / Department of Health	3
Safety Features Meetings	IMVO, European Commission, and other Stakeholders	4
Unique Identifiers Working Group	International Coalition of Medicines Regulatory Authorities (ICMRA)	2
Operation Pangea XVI Management Committee Meeting	Interpol	1
Operation Pangea XVI Pre-Operational Briefing	Interpol	1
Revision of ICH Q9 Guideline	ISPE	1
Overprescribing Working Group	Medical Council	4
HPRA Medicines Shortages Framework	Multiple Stakeholders	1
CGTV Forum	NIBRT	1
Meeting of Organs Competent Authorities	Organ Donation and Transplant Ireland	3
Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Executive Bureau	PIC/S	2
PIC/S Artificial Intelligence and Machine Learning Working Group	PIC/S	3
PIC/S Expert Circle on Quality Risk Management	PIC/S	2
PIC/S Sub-Committee on Harmonisation	PIC/S	1
PIC/S Sub-Committee on Training	PIC/S	1
PIC/S Working Group on Inspectors' Travel Safety	PIC/S	1
National Immunisation Advisory Committee (NIAC): Observer	Royal College of Physicians of Ireland (RCPI)	6
Internet Working Group	WHO	1

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