HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Annual Report 2022

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199

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58

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240

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516

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60

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956,263

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Chairperson's Statement

2022 was largely characterised by the relaxation of COVID-19 restrictions. We saw society begin to return to pre-pandemic ways, as we moved to living with COVID-19 in the community. Notwithstanding this, the pandemic response remained a central area of focus for the HPRA, particularly for the first few months of the year. This was both nationally and also in terms of the organisations' contribution at the European level.

I would like to take this opportunity to commend HPRA colleagues for the apparent seamless nature in which they have worked to address the challenges presented by the pandemic, while also ensuring that the vital work undertaken by the organisation in the protection of public and animal health continued. COVID-19 was a truly unique experience that required, and received, a truly unique response across all sectors of society. I wish to acknowledge the HPRA's contribution throughout all stages of the pandemic and note, in particular, the key role played as part of a coordinated multi-agency approach to provide timely and trustworthy information, facilitate vaccine take-up and support the needs of the health system. The pandemic further underlined the need for, and importance of, collaboration, co-operation, and transparency in all walks of life, and no more so than within our public health system. The HPRA remains committed to maintaining and expanding upon this co-operation nationally to ensure that collectively we continue to deliver benefits on behalf of the Irish public.

As COVID-19 restrictions began to come to an end, the organisational focus shifted back towards business as normal. 2022 represented the second year of the HPRA's five-year Strategic Plan. Under this plan, five key goals have been identified as areas of renewed and increased effort for the organisation over the coming years. Expanding on the success of year one, the organisational focus remained on aligning everyday activities with these goals to ensure value-driven regulation and partnerships. Considerable progress was made under each goal throughout the year.

The HPRA continued to focus on developing and expanding health system partnerships and strengthening our collaboration across all areas of the health system. As part of this work, the organisation continued its role in the coordination of the management of medicines shortages in partnership with other stakeholders under the National Shortages Framework. As Chair of the Authority, I recognise medicines availability and shortages management as one of the key priorities for both the HPRA and all medicines agencies globally. This is set to continue given the complexity of the issue and the multiple factors which contribute to the occurrence of shortages. The Authority is committed to supporting the HPRA in its work in the area given the importance of both medicines and medical device availability to continuity of care and the ongoing protection of patients.

The expansion of our current partnerships with national, European and international agencies, professional bodies and patient groups remains a key priority for the coming year. I look forward to the future progress that the organisation will make in this area and the positive impact this will have on stakeholders. The HPRA recognises that regulation cannot and should not occur within a vacuum and remains fully supportive of the 'One Health' approach which seeks to unify and integrate the health of people, animals, plants and the environment.

Further contributing to the organisations' ongoing efforts to improve and expand upon our models of engagement with the public, was the valuable and progressive work undertaken by the HPRA's Patient Forum throughout the year. The HPRA acknowledges the unique breadth of experience and knowledge possessed by patients and the positive impact their involvement can have on the regulation of medicines and medical devices in Ireland. The forum provides an opportunity for patients to engage directly with the regulatory system and ensures that we continue to place the patient and patient needs at the heart of everything we do as an organisation. The Authority fully supports the HPRA's commitment to

expanding and deepening its engagement with patients and patient organisations. This enable a greater understanding of patient perspectives and experiences in the context of health products regulation.

In March 2022, Dr Lorraine Nolan was appointed as Chair of the European Medicines Agency (EMA) Board. Dr Nolan's appointment is a reflection not only of her exemplary contribution to the protection of human and animal health and safety in Ireland but also of the emphasis the organisation places on co-operation and collaboration across the wider regulatory network.

During the year, a number of regulations became fully applicable in the areas of *in-vitro* diagnostic medical devices (IVDR), veterinary medicines, and clinical trials. To better understand the implications of these regulations for stakeholders, and to assist in transposing them into Irish law, colleagues worked closely with the Department of Health, the Department of Agriculture, Food and the Marine, and other relevant partner organisations. To foster increased awareness and preparedness amongst stakeholders, the HPRA conducted numerous webinars on the new regulations. These webinars provided an overview of the regulations and their possible impact for Ireland and Irish patients, giving practical guidance on the next steps for stakeholders. The various webinars, guides and resources produced regarding the new regulations represent one facet of the HPRA's ongoing commitment to open and proactive interaction and engagement.

Another focus for the organisation throughout the year was the ongoing support of innovation. The HPRA's Innovation Office continued to provide support to the national sector through regulatory advice to stakeholders wishing to explore the development of innovative health products and technologies. At a European level, the HPRA again served as co-chair of the EU Innovation Network which is a collaboration between national medicines agencies and the EMA on regulatory matters relating to emerging therapies and technologies. The HPRA recognises the importance that supporting innovation has to the protection of Irish patients as well as positioning Ireland and Irish patients at the forefront of improvements and advancements in the area.

The organisation continued its efforts with respect to horizon scanning. This related not only to innovation but also to the future challenges and opportunities of health product regulation which may impact or benefit the needs of our stakeholders. To this end, the HPRA will continue to assist stakeholders in understanding and transitioning to the new regulations for clinical trials, medical devices, and veterinary medicines as well as the proposed revision of the pharmaceutical legislation for human medicines.

Looking forward, on behalf of the Authority, I wish to emphasise the ongoing focus and commitment to the successful delivery of the HPRA's strategic goals. I am confident that through the dedication of colleagues across the organisation we will continue to progress our vision of excellence in health product regulation through science, collaboration and innovation for the betterment of all our stakeholders.

Acknowledgments

I would like to start by thanking both the Minister for Health and the Minister for Agriculture, Food, and the Marine for their support and collaboration as well as that of their advisors and staff within their departments.

I am very grateful to my fellow Authority members for their continued support throughout my first full year as Chairperson of the HPRA. The role of Chair has been a truly enlightening experience and the guidance, insight, and experience offered by my fellow Authority members has been invaluable. The commitment shown by the Authority members to the ongoing successful and thorough governance of the organisation is greatly appreciated.

My thanks and appreciation are also extended to Dr Elizabeth Keane who departed the Authority in May 2022 after many years serving as a highly valued and committed Authority member.

The HPRA remains dedicated to successful succession planning at all levels throughout the organisation. At Authority level, planning centred on three main areas for improvement in line with the key areas of priority identified for the organisation over the upcoming year. These areas related to horizon scanning, innovation and a continued focus on public health. In view of the Authority's commitment to expand its expertise in these areas, I am delighted to extend a very warm welcome to our newest Authority member,

Dr Fiona Kiernan, who joined in 2022. Dr Kiernan brings considerable direct experience not only in the area of public health but also innovation, having founded a digital health startup and I have no doubts she will prove a valuable addition to the Authority over the coming years.

The various advisory committees, and by extension the members of these committees, remain a key pillar of support for the organisation. My thanks to all the dedicated members for their valued contribution and to my fellow Authority members who serve as committee chairs.

The introduction of the Clinical Trials Regulation saw the Clinical Trials Directive begin to be phased out and with it, the remit of the Clinical Trial Subcommittee. The steadfast advice and guidance provided by the Subcommittee over the years has been invaluable to the organisation and the clinical network throughout the country. The work undertaken by the Committee contributed immensely to patient safety in Ireland and sincere thanks are extended to the Chair and members for their dedicated work down through the years.

Finally, as I end my reflections on 2022 and attention turns to the upcoming year, I would like to thank the Chief Executive, management and all the staff of the HPRA for their continued and steadfast commitment to the protection of public and animal health in Ireland. The past year has once again highlighted the importance of collaboration with our patient, health system and regulatory partners, and I look forward to even further progress in this area into 2023.

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 2022 were:

Mr Michael Donnelly
Chairperson

Dr Joe Collins

Mr David Holohan

Mr Brian Jones

Dr Elizabeth Keane
Term ended 21 May 2022

Dr Fiona Kiernan
Appointed 12 September 2022

Dr Paula Kilbane

Prof Sharon O'Kane

Dr Diarmuid Quinlan

Prof Richard Reilly

Management Committee

The members of the HPRA Management Committee in 2022 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
Appointed 1 March 2022

Dr Niall MacAleenan
Director of Medical Devices

Ms Gráinne Power
Director of Compliance
Appointed 1 January 2022

Ms Elizabeth Stuart
Director of Human Resources and Change

Chief Executive's Report

For the HPRA, 2022 was another busy but exciting year. We continued our contribution to public health efforts to tackle the ongoing COVID-19 pandemic while also dealing with new challenges that presented as restrictions relaxed and society reopened.

Implementation of legislation

The year saw significant changes in the legislative landscape, with the implementation of the New Veterinary Regulation, Clinical Trials Regulation, Medical Devices Regulation, and *In-Vitro* Diagnostics Regulation. The organisation worked hard in recent years to prepare for implementation of the new regulations, and this work continued as we adjusted to the new regulatory frameworks. It is essential that we continue to work closely with key stakeholders to ensure the transition is as smooth as possible for all involved.

The New Veterinary Regulation modernises the rules for the authorisation and use of veterinary medicines in the EU. It contains new measures for increasing the availability and safety of veterinary medicines, with the objective of simplifying the regulatory environment and reducing administrative burden for those developing veterinary medicines. In doing so, the aim is to stimulate the development of innovative veterinary medicines. Additionally, the Regulation aims to strengthen EU action to fight antimicrobial resistance and keep antimicrobial medicines working effectively for animals and humans alike. In many ways, the New Veterinary Regulation paves the way for the reform of the EU pharmaceutical legislation for human medicines, with common focuses on efficiency, promotion of availability, and use of a One Health approach to medicines regulation.

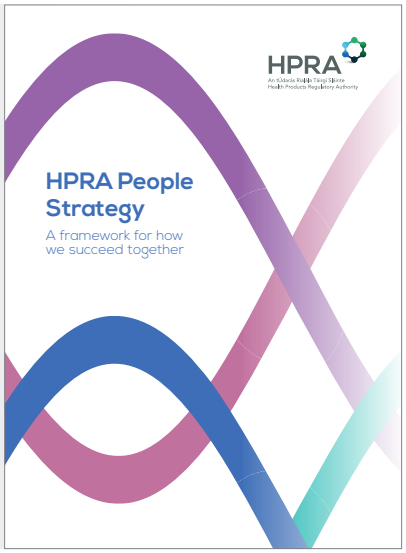
The Clinical Trials Regulation (CTR) brings with it a streamlining and centralisation of key regulatory procedures relating to clinical trials. This includes a single submission for applications, as well as simplification of certain reporting requirements. The CTR focuses on creating an environment in Europe that is better able to support the conduct of clinical research. Through the support of EU initiatives, it aims to systematically grow the numbers of clinical trials conducted here. The introduction of the CTR strengthened the collaboration between the HPRA and the National Research Ethics Committee for Clinical Trials, as we worked together to integrate our systems to support the timely approval of clinical trial applications received under the regulation. Another change brought about by the implementation of the CTR was the fact that in January 2023 the HPRA's Clinical Trials Subcommittee met for the last time. For many years, the Subcommittee was an integral part of clinical trial authorisation in Ireland, and I would like to extend my sincere thanks to its members for the significant contribution they have made to clinical research and public health.

The introduction of the Medical Devices Regulation (MDR) and *In-Vitro* Diagnostics Regulation (IVDR) represents a significant enhancement to how medical devices are regulated in Europe. We as an organisation have undertaken a great deal of work in preparing for the implementation of this new regulatory framework, including the restructuring of our medical devices department and enhancement of resources, skills, and expertise. We commit to continuing these efforts, and to working closely with regulators, policymakers, industry, healthcare professionals, and patients to support the successful implementation of the MDR and IVDR. Only then can we deliver on the objectives of the Regulations to create a robust, transparent, and sustainable regulatory framework, which improves clinical safety and ensures availability of state-of-the-art technologies and diagnostics for EU citizens.

Medicines shortages

As a key contributor to the mitigation and management of medicines shortages, the HPRA is a strong proponent of work, at both a national and European level, to address this ongoing issue. This has involved the establishment and strengthening of infrastructures to proactively monitor, anticipate, and manage shortages of human medicines. What we have seen in recent years is an increasing level of focus on the area of shortages, both across the health system and from the general public. This emphasises the importance of the work undertaken at a national level by the multi-stakeholder medicines shortages framework, which is coordinated by the HPRA. Effective management of shortages requires cooperative and coordinated efforts from all key stakeholders. The framework provides a platform through which we can work together to develop and implement long-term strategies to address this complex issue.

At an EU level, the European Medicines Agency's (EMA) extended mandate relating to crisis preparedness and management of the availability of medicines and medical devices, came into effect in 2022. This brought with it the establishment of the Executive Steering Group on Shortages and Safety of Medicinal Products. The Agency also updated the role of the EU Single Point of Contact (SPOC) network, a system that the EMA and national competent authorities use to exchange information on shortages. The HPRA is an active participant in both groups, which have important roles in coordinating the monitoring and management of medicines shortages across Europe.



Internal development

Over the course of the year, we continued to progress the implementation of the HPRA's Digital Transformation Strategy, which aims to establish technological capabilities that will support the organisation in effectively and efficiently achieving its objectives into the future. An organisation-wide project to redevelop the HPRA website was launched, while we also undertook preparatory work to support regulation of digital health products. With initiatives such as DARWIN EU beginning to explore and demonstrate the uses of real-world evidence in health product regulation, alongside the significant advancements and innovation happening in the area of digital health, it is vital that we keep pace and are well positioned to face the exciting developments that lie ahead.

The way we work as an organisation has changed dramatically in recent years and these changes continued as we successfully transitioned to a model of hybrid working in early 2022. Having spent almost two years working fully remotely as a result of the COVID-19 pandemic, it was important that we reflected on that experience, assessing both the benefits and the challenges presented by a new way of working. We want to make sure that colleagues from across the organisation can contribute to this ongoing review process and that everyone has a voice in shaping our future working arrangements. Since our return to the office, through a combination of experience, observations, and feedback, we have continued to adapt and refine our hybrid working model to create an environment that supports us to continue to meet the needs of the organisation, as well as our strategic objectives.

The success of any organisation is dependent on the people who work there. For this reason, throughout 2022 we focused on the development of the HPRA's first dedicated People Strategy, capturing our commitment to maintaining and nurturing the positive culture within the organisation. The People Strategy is designed to work in tandem with the HPRA's overall strategic plan and is underpinned by the HPRA values. The People Strategy outlines how we develop, invest in, and encourage our staff, so that everyone within the organisation feels empowered and supported to do their best work. This strategy recognises that we are more effective together and acknowledges the importance of creating an environment that helps us to achieve our best as a team and succeed together.

Looking forward

As we enter a time where COVID-19 is no longer classified as a public health emergency, it is important to reflect on what we have learnt over the past three years, so that we can use our experiences to help inform our decisions and practices going forward. The pandemic demonstrated the speed with which the scientific world is capable of reacting, with numerous treatments developed at a pace never seen before.

As the world of science rapidly evolves, in turn so must the way in which we regulate health products. The new legislative frameworks present an opportunity for us to grow to meet the demands of a changing regulatory environment. Coupled with the commitment outlined in our new People Strategy to support, invest in, and upskill our employees, and further empowered through enhanced digitalisation and technology, I am confident that the HPRA is ready to navigate the opportunities and challenges ahead.

Acknowledgements

There were a number of changes to the make-up of the HPRA Management Committee in 2022, with Gráinne Power stepping into the role of director of our Compliance department and Finnuala Lonsdale joining as director of the Human Products Authorisation and Registration department. Both Gráinne and Finnuala bring a breadth of experience and wealth of knowledge to their respective roles. Their input is already proving invaluable and I look forward to continuing to work alongside them.

I would like to acknowledge the Ministers and staff of the Department of Health and of the Department of Agriculture, Food and the Marine for the support, cooperation, and collaboration with the HPRA on a wide variety of topics throughout the year. On behalf of the leadership team and the wider organisation, I wish to thank the Authority and advisory committees, whose contributions are a significant and valued support to the work of the HPRA.

Finally, I cannot emphasise strongly enough my gratitude to, and my appreciation of, my colleagues throughout the HPRA. I am continually impressed and humbled by the ability of everyone in our organisation to adapt to meet new challenges, with public and animal health acting as the driving force for everything we do. I am immensely proud to be part of the HPRA team and I know that we all can continue to succeed together.

Dr Lorraine Nolan
Chief Executive

Strategic Plan 2021-2025 – Key Achievements in 2022

Goal 1

Health system partnerships

Strengthening our collaborations across all areas of the health system

Extensive work undertaken on the HPRA's medicines shortages framework. At an EU level, served as work package lead in the Joint Action CHESSMEN[1] project carried out in response to increasing medicines supply issues.

Continued to work with national and international partners to manage the public health impact from COVID-19 and the high volume of regulatory and communication activities relating to vaccines and therapies.

With the Department of Health and HSE, continued to monitor and manage impacts on the supply of medicines and medical devices arising from the end of the Brexit transition period.

Became a member of the HSE National Patient Safety Alert Committee to support system-wide responses to health product issues.

Published guidance and instructional videos relating to good pharmacovigilance practices and signal management supporting the implementation of the New Veterinary Regulations.

1 Coordination and Harmonisation of the Existing Systems against Shortages of Medicines, European Network

Goal 2

Progressive regulation

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

Continued to collaborate with the Department of Health and national partners to implement national legislation for the EU Clinical Trials Regulation, the EU Medical Device Regulation and *In-Vitro* Diagnostic Regulation, and the national research ethics committees.

Supported the Department of Agriculture, Food and the Marine on developing national legislation to implement the new EU Regulations for veterinary medicines.

Developed a cyber security strategy to target the illegal online sales of medicines.

Introduced a registration scheme for hospital manufactured investigational medicinal products and an associated inspection programme.

Co-led an International Coalition of Medicines Regulatory Authorities (ICMRA) project, which included the design of pilots to assess international regulatory collaboration on post-approval change management for innovative medicines.

Goal 3

Communication and engagement

Improving our models of engagement to strengthen public trust and confidence

Continued the Patient Forum work plan, increasing the level of engagement with members.

Continued engagement with stakeholders through our contributions to the national pandemic response, providing extensive website and newsletter updates, and significant engagement with national media to explain the regulatory processes and outcomes to the general public.

Made a significant contribution to the EU STARS[2] project focused on the training of healthcare professionals on medicines regulation, linking in Irish healthcare professionals and institutions.

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

Goal 4

Enabling innovation

Enhancing our supports for innovation from discovery through to regulatory approval

Ensured the establishment of the EU-IN Borderline Classification Group as chair of the EU-Innovation Network, to contribute to the revision of the pharmaceutical legislation.

Contributed to several horizon-scanning initiatives, including the finalisation of the EU-Innovation Network's report on faecal microbiota transplantation and consideration of regulatory science-based approaches for gene editing products.

Provided guidance to academic and clinical sponsors on the EU Clinical Trials Regulation and encouraged continual engagement with STARS[2] outputs.

Continued collaboration in projects at EU level to identify areas of innovation, such as the EMA Real-World Evidence rapid data analytics pilot, PRISMA (PRAC Risk Minimisation Alliance) and the EU Pharmacovigilance Business Team.

Goal 5

Great people, great processes

Developing our organisation and people to successfully achieve our goals

Developed a People Strategy focusing on the management, development and support of our employees to deliver on the HPRA's vision and mission.

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

Established and implemented our hybrid model of working and a testing and learning process to ensure the new model fit the needs of the organisation and its core vision, mission and values.

Introduced operational excellence into the overall strategy of the organisation to focus on continual improvement and lean management of the HPRA's processes.

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

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 route is co-ordinated by the EMA and results in an authorisation that is granted by the European Commission and is valid across Europe. The assessment is carried out by Member States appointed as lead assessor (rapporteur), joint lead assessor (co-rapporteur) and peer reviewer, with input also from all other Member States.

  During the year in review, the total number of new medicines authorised in Ireland was 529. The 2022 figure incorporates:

  – 92 new national applications including 64 parallel import applications;

  – 31 applications made under the MRP and 202 applications made under DCP. The HPRA acted as reference (lead) Member State for the assessment of 57 of these applications;

  – 10 rapporteurships and eight co-rapporteurships under the centralised route;

  – An additional 182 medicines authorised through the centralised route where the HPRA was neither rapporteur nor co-rapporteur;

  – Two traditional herbal medicinal products under the simplified registration scheme and two homeopathic registrations.

- The EMA operates a scientific advice and protocol assistance procedure system to applicants on the appropriate tests and studies in 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 2022, the HPRA acted as co-ordinator for 109 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 authorisation or marketing authorisations. This service complements advice that we provide on earlier stage product development through our Innovation Office. During the year, we completed 15 requests under this procedure.

- Overall for 2022, the HPRA was among the top 10 contributors at EU level for lead assessment of centrally authorised human medicines and scientific advice.

- As the EU/Europe Topic Lead and a member of the ICHQ13 Expert Working Group, 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 2022, this guideline achieved Step 3 and Step 4 at the November ICH meeting and was adopted by the CHMP in December.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2022, we issued 64 new clinical trial authorisations under the EU Clinical Trials Directive (CTD) and three 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 2022, two 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 119 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. A review of the first two full calendar years of the operation of the framework has shown its effectiveness in addressing shortages and identifying opportunities to further improve the prevention and management of shortages. A multistakeholder meeting, involving all aspects of the supply chain and including representation from patient groups and healthcare professionals, the HSE and the Department of Health, was convened in October 2022 and agreed on the proposed actions and strategies in this regard. The review document, including the recommendations, is published on the HPRA shortages webpage.

  The HPRA also continues to take a prominent role in European and international initiatives to address medicines shortages including the human medicine shortages single point of contact working group which was given a legal basis due to new legislation expanding the EMA's remit in 2022. The HPRA is also actively involved in the EMA and Heads of Medicines Agencies (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 2022. Responses to queries from Member States and marketing authorisation holders on multilingual packaging and on practical aspects of the pilot were also prepared.

  The HPRA continues to actively contribute at the EMA QRD (Quality Review of Documents) group to agree labelling flexibilities for COVID-19 vaccines and labelling exemption requests to maintain availability of small volume medicines.

- To aid the continuity of supply to the marketplace in the event of a medicine shortage following Brexit, the HPRA granted 214 temporary 'batch-specific request' authorisations during 2022.

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

- Relating to Brexit, the HPRA accepted 421 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 Cyprus, Ireland and Malta. As per the requirements of this directive, the HPRA notified the EU 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. The translations are available on the European Directorate for the Quality of Medicines & HealthCare (EDQM) web site – Standard Terms Database.

Authorisation and registration: Key figures	2020	2021	2022
Classification queries/reviews	88	89	100
Scientific advice			
Lead in EMA scientific advice	119	82	109
National scientific advice	11	7	15
Clinical trial applications under Clinical Trials Directive (CTD)	73	107	64
Clinical trial applications under Clinical Trials Regulation (CTR), implemented 31 January 2022	N/A	N/A	3
New medicines applications for marketing authorisations			
National (including new parallel imports)	61	94	92
Mutual recognition and decentralised RMS	23	29	57
Mutual recognition and decentralised CMS	163	220	176
Centralised Rapp/Co-Rapp/Peer reviewer	18	28	18
Traditional herbal medicinal products under the simplified registration scheme	2	3	2
Homeopathic medicines under the simplified/national rules schemes	2	0	2
Variations to marketing authorisations (Type IA, IB, II)	12,026	9,665	14,367
Articles 45 and 46 - Variations to Update Product Information	1	6	19
Renewals of marketing authorisations	390	305	232
Transfer of marketing authorisation holder	202	468	161
Manufacturers	138	145	149
Manufacturers of investigational medicinal products	76	75	82
Wholesalers	379	391	386
Registrations for active pharmaceuticals ingredients			
Manufacturers	29	23	22
Importers	75	77	75
Distributors	102	99	100
Brokers	9	7	12
Export certificates	1,019	1,102	1,304
Exempt medicine notifications of unauthorised medicine import	45,664 line notifications	58,503 line notifications	62,940 line notifications

Safety and Quality

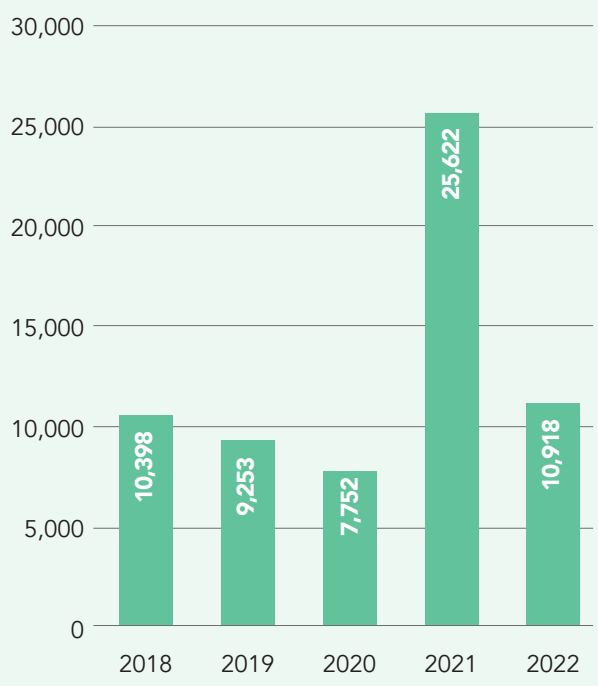
- Adverse reaction reporting assists the HPRA, in co-operation with pharmacovigilance professionals in Europe and further afield, to further characterise the safety profile of authorised medicines when in clinical use. Reports submitted to the HPRA in many instances arise from concerns due to an observation 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 10,918 suspected adverse reaction reports were received associated with the use of human medicines. This is a decrease on the number of reports received in 2021 and during the initial mass immunisation campaigns against COVID-19.

  – Of the reports received in 2022, 2,852 were associated with the use of COVID-19 vaccines. The HPRA has and continues to encourage healthcare professionals and the public to report any suspected adverse reactions to the HPRA following vaccination. The remaining 8,066 reports received in 2022 were associated with the use of other human medicines (including other vaccines).

Suspected Adverse Reaction Reports



  – Of the reports received in 2022, 21.5% were submitted by members of the public, 9% by healthcare professionals and 69% were reported by marketing authorisation holders. A further 0.5% were reported by sponsors in the context of ongoing clinical trials. It is important to note that reports received by companies will have been initially notified to them by healthcare professionals or members of the public.

  Medicines subject to additional monitoring accounted for 32% of the reports submitted of which 26% 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	%
Doctor	11
Patient/Consumer	70
Nurse	8
Pharmacist	8
Healthcare professional - Other	3

- The medicines most frequently included in reports to the HPRA, and which account for approximately 84% of the suspected adverse reaction reports received in 2022, 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. The number of reports received cannot be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using a medicine, is known.

Suspect Medicine(s)/ Class of Medicines	Number of Reports*
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	4,468
Vaccines, including COVID-19 vaccines	3,092
Psycholeptic medicines	558
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	500
Medicines for obstructive airway diseases	426
Medicines for the treatment of Parkinson's Disease	401
Medicines for the treatment of bone diseases	249
Medicines for the treatment of Diabetes Mellitus	210
Medicines for the treatment of gastrointestinal conditions	191
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 2022, 157 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 continued to closely monitor reports of suspected side effects received particularly those that described a fatal outcome. The HPRA also continued to provide regular safety updates on the national reporting experience with COVID-19 vaccines throughout 2022 with updates published on our website.

Suspect Medicine(s)/ Class of Medicines	Number of Reports*
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	69
Psycholeptic medicines	47
Vaccines including COVID-19 vaccines	20
Antithrombotic medicines including anti-coagulant and anti-platelet medicines	11
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	8
Analgesic medicines	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 on the Irish market via our vigilance assessment and risk management activities. This incorporates our contribution to the work of the Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA. During 2022, 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, was also responsible for the further management of any signals detected in relation to 58 centrally authorised medicines (containing 42 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 805 PSURs and leading the single EU assessment for 35 active substances or combination of active substances;
  - Serving as a PRAC Member State, participated in the assessment of 18 monthly safety summary reports as part of close safety monitoring of COVID-19 vaccines;
  - Participated as a PRAC Member State in six ongoing safety referrals, five of which reached a conclusion during the year;
  - Contributed to the review of 415 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures;
  - Also provided assessment input to 419 post-authorisation safety procedures (including safety study protocols, reports and other post authorisation safety-related measures).
- The HPRA continues to communicate important safety information to facilitate clinical readiness at national level for new recommendations on the safe and rational use of medicines following EU benefit-risk reviews. During 2022, the HPRA:
  - Approved the content and communication plan for 15 Direct Healthcare Professional Communications (DHPCs), containing important new information on authorised medicines and highlighting 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 110 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.
  - Published and distributed five issues of the HPRA's Drug Safety Newsletter to registered healthcare professionals, all of which are accessible from the HPRA website. The 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 15 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:
  - 114 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances;
  - 111 good distribution practice (GDP) inspections at wholesalers and distributors;
  - Nine good clinical practice inspections at investigator or sponsor sites;
  - Nine pharmacovigilance inspections;
  - Two 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 2022, 422 cases were initiated under the programme which relate to analytical testing, and the examination of packaging and labelling.

- 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 reported quality defects has increased substantially in recent years. Quality defects pertaining to 2,034 medicines for human use were reported or identified in 2022. Consistent with the number of reports in 2021 (2,033), this is a large increase over the number of reports received in 2020 (1,048) and 2019 (948).

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

Year	2020	2021	2022
Critical quality defects	312	396	361
Major quality defects	701	1,381	935
Minor quality defects	378	235	705
Number of reports not justified	17	21	33
Total Number Quality Defects	**1,408**	**2,033**	**2,034**

The majority of quality defect reports (34%) were submitted by pharmacists, and mainly through the HPRA online reporting portal. Reports from other competent authorities accounted for 33% of reports received, while reports from pharmaceutical companies, including manufacturers, distributors and/or marketing authorisation holders accounted for 30% of cases.

- In certain instances, it is necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 58 human medicines were recalled for reasons outlined in the table below:

Cause of Recall	Number of Products
Contamination – chemical	19
Distribution – cold chain/temperature excursions	13
Stability out of specification	4
Product mix-up	3
FMD – anti-tampering device	3
Product preparation/administration issues	3
Product characteristic out of specification	3
Contamination – particulate	2
Non-compliance with MA - artwork/ packaging	2
Erroneous distribution	1
Change in risk-benefit ratio	1
Other miscellaneous issues	4

- Caution in Use Notifications (CIUNs), and Dear Doctor/Healthcare Professional Communications (DDLs/DHPCs) are issued for medicines with a significant quality defect, but where a recall action should not be initiated. For example, where an out-of-stock situation for the medicine in question might arise as a result of a recall action and this may pose more risk to patients than the quality defect issue. During 2022, 28 such communications were approved.

- One Rapid Alert was issued during 2022 to share relevant information with other competent authorities.

- The HPRA monitors the sale of certain consumer health products in outlets such as grocery shops, health food shops and, where necessary, pharmacies. During 2022, 21 cases were investigated, some of which involved multiple products. Of these:
  - 15 cases related to the sale of medicines that did not carry a valid registration number or authorisation number for the Irish market, resulting in six 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;
  - Three cases related to the classification status of products.

  In addition, 41 queries linked to the sale of health products in Ireland were addressed.

- The advertising compliance programme monitors and reviews the compliance of advertising and promotional activities carried out by the industry in relation to human medicines. In total, 240 advertisements were reviewed, and non-compliances, including both major and minor issues, were identified in 120 cases. 12 advertising-related complaints were also received. In all cases, we oversaw the necessary corrective and/or preventative actions, where relevant.

- Under our enforcement programme:
  - We processed the detention of 956,263 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2022, compared to 1,604,589 dosage units in 2021. The products detained included sedatives (26%), anabolic steroids (23%), erectile dysfunction medicines (9%) and analgesics (7%). 5,171 enforcement cases were initiated, compared to 10,596 in the previous year;
  - The HPRA initiated one criminal prosecution case and issued seven voluntary formal cautions. Prosecutions are taken where the HPRA considers that there is a significant risk to public health or where there are persistent non-compliances. The prosecution taken in 2022 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 XV 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 2022;
- In addition, the monitoring of websites, online marketplace advertisements and social media sites throughout the year resulted in the amendment or shutdown of 639 websites, e-commerce listings and/or social media pages associated with the sale of falsified or illicit medicinal products.

Legislation and Regulation

- 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.

  The following national activities were progressed by the HPRA during 2022 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 2022, the HPRA worked with partners to ensure:
  - The full implementation of the system in the first quarter of 2022;
  - Oversight of the national implementation continued in conjunction with the Irish Medicines Verification Organisation (IMVO), which is responsible for managing the repository and software systems;
  - 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

- Further engagement continued with public health partners in respect of COVID-19 and the regulation of health products.

- January 2021 marked a fundamental change to the EU's and Ireland's relationship with the UK as the transition period ended and full impact of Brexit applied. However, in relation to medicines, a Commission communication allowed for certain derogations/exemptions for medicines impacted by Brexit for Ireland (IE) Northern Ireland (NI), Malta (MT) and Cyprus (CY). In December 2021, the Commission put forward legislation to extend those exemptions for human medicines until the end of 2024. Veterinary medicines were still covered by the Commission Communication until the end of 2022 and following negotiations, this was extended to the end of 2025. Consequently, the impact of Brexit was managed by companies that had made the necessary regulatory changes and those that availed of the exemptions. The HPRA continues to encourage companies to make the necessary changes and is required to report to the Commission on those products that are still availing of the exemptions.

- On 3-5 May 2022, the HPRA hosted in-person good distribution practice (GDP) and good manufacturing practice (GMP) conferences for relevant industry stakeholders. These covered a range of current GDP and GMP topics and regulatory updates, including those relating to Brexit impacts.

- 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 2022 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 2022 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 2022 and are available to download from our website. This includes, among others:
    - Guide to clinical trials conducted under the CTR in Ireland;
    - Guide for marketing authorisation holders on direct healthcare professional communications;
    - Guide to labels and leaflets of human medicines.

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.

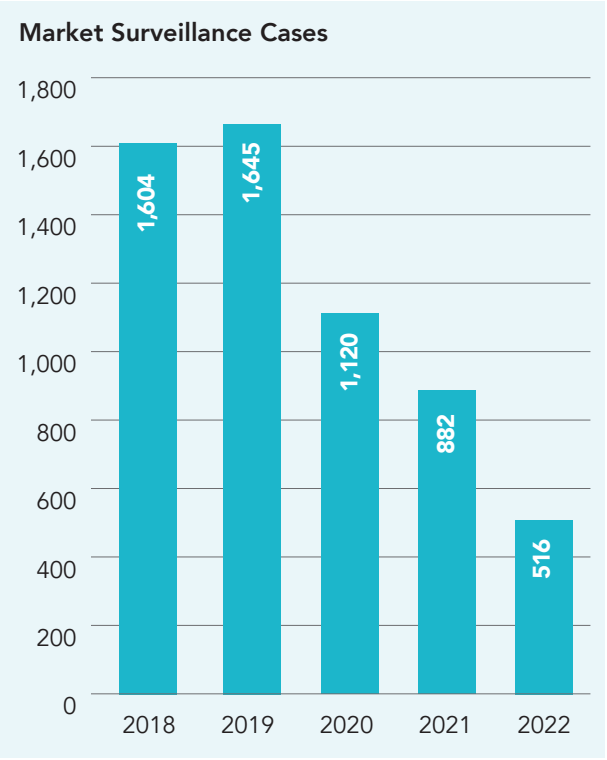
Authorisation and Registration

- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at a national and European level. In 2022, we:
  - Concluded our review of an application for designation under Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR). During the year, we reviewed actions taken following the implementation of a corrective and preventive action (CAPA) plan, ensured open questions from the European joint assessment team were addressed and tabled the application to the HPRA Management Committee and the Medical Devices Coordination Group (MDCG) for approval. The formal designation and notification steps of the process will conclude in early 2023;
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits. This included a surveillance assessment under Regulation (EU) 2017/745 on medical devices (MDR) in January 2022;
  - Contributed as national experts as part of two European Joint Assessment Teams (JATs) for reassessment and designation applications under the MDR and IVDR at bodies located in Germany and Finland. Two other joint assessments could not be fulfilled due to staff availability and proposed changes by the Commission to reassessment frequency which affected assessments scheduled later in 2022;
  - 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 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 2022, this support included:
  - The review of applications to conduct clinical investigations of medical devices in Ireland under the new medical device regulations. The number of clinical investigations for innovative devices increased with 14 new applications,13 amendments to ongoing investigations and 17 post-marketing clinical investigations. The HPRA 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 in 2022, with eight groups of innovators engaging with the HPRA to discuss potential clinical investigation applications;
  - The provision of technical, clinical and regulatory support in respect of medical devices related queries received by the HPRA Innovation Office.

- Manufacturers of certain medical devices and *in-vitro* diagnostics (IVDs) are required to register with the HPRA via the European medical device database (EUDAMED). In 2022, the HPRA registered 199 medical device economic operators (for example manufacturers, authorised representatives) on the national database. 290 economic operators were validated on EUDAMED by the HPRA. A total of 1,838 medical devices were also registered. This represented a decrease in economic operator registrations when compared to previous years. During 2022, the HPRA estimates that around 19% of the economic operators registering in Ireland were due to Brexit.

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 2022:
  - 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 six 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 lead on an initiative to develop common evaluation principles for market surveillance;
  - There were 516 market surveillance cases undertaken in 2022, a decrease compared to 2021.



- We continued to focus our vigilance activities during 2022 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 3,935 medical device vigilance cases, an increase compared to 2021. This increase is attributable to significant number of reports received in relation to a specific SARS-CoV-2 Antigen test. Of the reports received in 2022, manufacturers accounted for 50%, users for 41% while 9% came from other competent authorities. Of the 3,180 incident reports notified directly to the HPRA, 51% came from users of medical devices;
  - There were 323 field safety corrective actions (FSCA) associated with the national market including 99 product removals conducted in Ireland during 2022;
  - We issued 93 national competent authority reports and two vigilance enquiry forms to other European authorities;
  - We also issued three safety notices in relation to medical device issues and 15 direct to healthcare professional communications;
  - Virology devices, infusion devices and implants accounted for 66% of the total vigilance reports (see next page for accompanying graph). Reports continue to be received relating to *in-vitro* diagnostic devices in the area of clinical

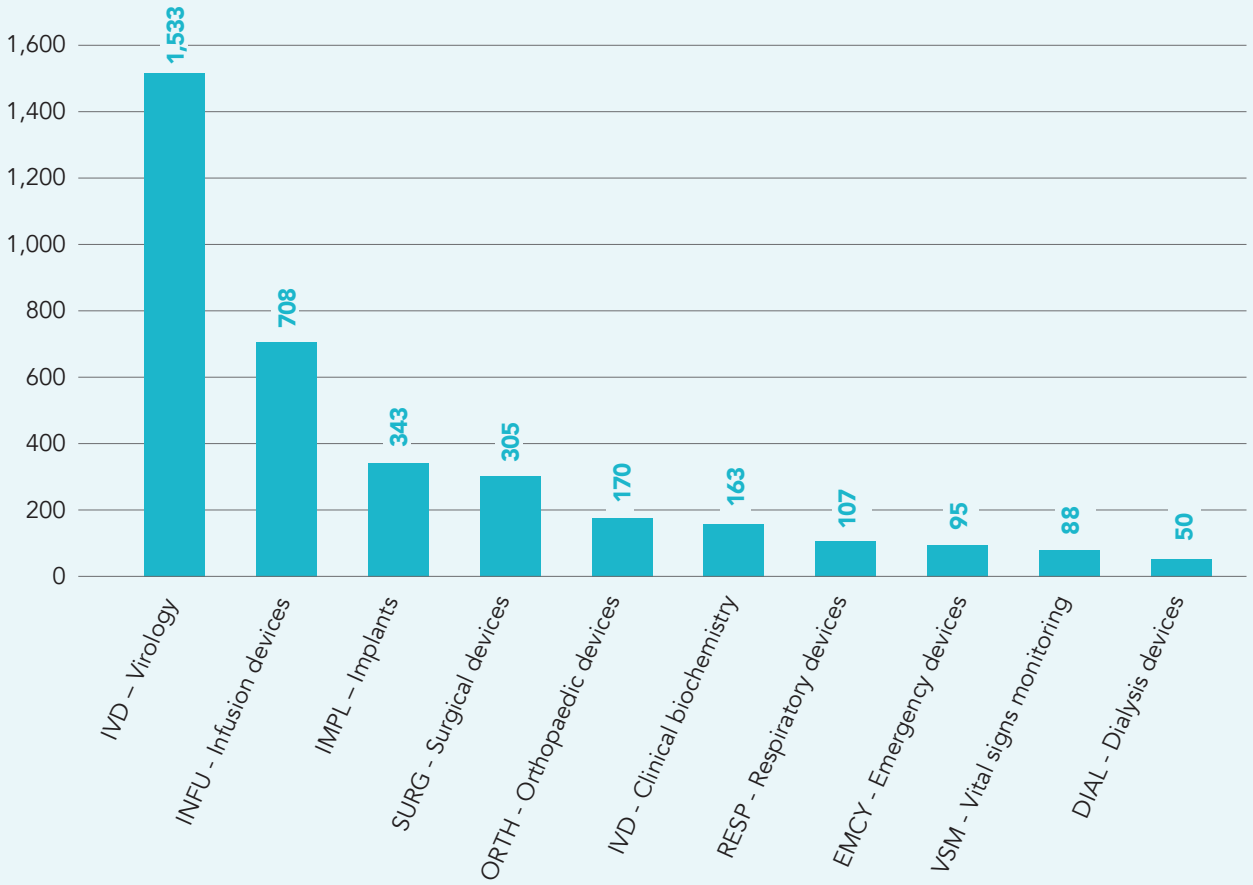
biochemistry (4% of reports), medical devices in the areas of surgical devices (8% of reports), orthopaedic devices (4% of reports), and respiratory devices (5% of reports).

- 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.

- 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 2022, 20 such inspections were performed all of which were based on proactive market surveillance projects and notified body surveillance/ assessment.

Vigilance Reports Received – Top 10 Product Types



Legislation and Regulation

- Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR) became fully applicable in May 2022. Our work during 2022, continued to help ensure an effective and timely implementation of both EU device regulations for medical devices and *in-vitro* diagnostic medical devices at a national and European level particularly with regard to gathering data on the notified body capacity challenges. This included:
  - Working with the Department of Health on escalating mechanisms, identifying and proposing solutions for the lack of regulatory system readiness. This included drafting a non-paper with France and Germany calling out some proposed mechanisms to resolve the short-term immediate challenges;
  - Supported the Department of Health in preparing for two EPSCO interventions calling out the need for focused solutions to the lack of system readiness and the need for a focused 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 on MDR/IVDR implementation;
  - Working with the Department of Health and relevant stakeholders on national policy and national provisions to ensure transposition of the national requirements into Irish law;
  - Contributing to the European Commission's development of the secondary legislation relating to implementation of both regulations;
  - Participating in the EU MDCG. Chaired by the EU Commission, this group 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.
- 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 2022, 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;
  - Continuing to take a lead role in a number of taskforces of the MDCG working groups to help identify solutions to key practical challenges with implementation.
- Throughout the year, our focus remained on identifying and promoting discussions and developing practical measures to ensure the regulatory system operates effectively in practice. Addressing the short term notified body capacity issues was a particular focus for the HPRA. 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 effective implementation of the regulations.
- The HPRA chaired a number of meetings of the medical devices core group of the HMA. The focus of the core group during 2022 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);
  - Continuing to act as the IMDRF secretariat for the National Competent Authority Report (NCAR) Exchange programme and providing training to the incoming Secretariat;
  - 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 2022. 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 2022, we:
  - Hosted a webinar for stakeholders on IVDR implementation, including the impact of new timelines adopted for staggered transition;
  - 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 and talks to a range of external stakeholders. A list of presentations related to the regulation of medical devices that were delivered during 2022 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 the HPRA is leading a work package and is also part of the project board. The mid-term technical report was completed and submitted to the Commission in 2022.

Medical devices: Key figures	2020	2021	2022
Lead Competent Authority role on specific vigilance issues	106	141	93
NCARs and vigilance related communications	142	172	114
Vigilance cases received/ opened	1,668	1,855	3,935
Field safety notices uploaded	362	382	324
Medical device safety/ information notices	18	8	3
Medical device targeted healthcare professional communications	17	22	15
NCARs managed as IMDRF NCAR secretariat	10	4	4
CEF reports to EU network	18	11	6
Market surveillance cases	469	621	414
Notifications relating to notified body certificates	561	187	101
Classification requests	38	40	24
Compassionate use applications	34	23	13
Certificates of free sale	2,520	4,482	5,361
Medical device queries received	1,928	1,397	1,069
Clinical Investigation (Article 62 MDR)	N/A	N/A	14*
Clinical Investigation (Article 82 MDR)	N/A	N/A	17*

* Please note introduced in 2022 under the new 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	2018	2019	2020	2021	2022
Blood establishments	3	3	3	3	3
Tissue establishments	26	27	25	26	26
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 2022. The report reflected information received by the NHO in 2021 and included information on 78 serious adverse reactions and 133 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 2022. The report reflected information received in 2021 and consisted of 24 reports, 17 of which met the legislative reporting requirements, including six serious adverse reactions and 11 serious adverse events.
- The HPRA is participating in the European SoHO Vigilance Expert Sub-Group (VES). The sub-group is considering updates to the common approach for defining reportable serious adverse reactions and events and other vigilance activities in Europe.
- We continued to liaise with the HSE lead and colleagues from Organ Donation and Transplant Ireland (ODTI) in relation to our respective roles under EU and national legislation on the Quality and Safety of Human Organs intended for Transplantation. During the past year, this included:
  - The exchange of relevant information on serious adverse reactions and events. In 2022, the HPRA received 22 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 2022 included:
  - 15 tissue establishment inspections, the majority of which were routine;
  - Nine blood establishments inspections;
  - Two inspections at organ procurement organisations/transplant centres.

Legislation and Regulation

- We worked with the Department of Health on 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 1,925.

  The 2022 figure incorporates:

  – Three new national (only) applications;

  – 52 applications made under DCP. The HPRA acted as reference (lead) Member State (RMS) for the assessment of 12 of these DCP applications;

  – 16 applications made under the MRP. The HPRA acted as RMS for the assessment of one of these MRP applications and also led a further eight applications as RMS under the repeat use procedure.

  Based on the figures presented above, the HPRA was the third leading national competent authority in the EU for outgoing work during 2022.

- 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 by this route.

- During 2022, the HPRA acted as co-ordinator or joint co-ordinator for nine 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 2022.

- Relating to Brexit, the HPRA accepted 87 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	2020	2021	2022
Classification enquiries	11	13	11
Clinical trials	5	3	6
New centralised as (co-) rapporteur	3	8	8
New MR/DCP as RMS	10	39	21
New MR/DCP as CMS	34	35	41
New homeopathic applications	0	0	0
New national applications	5	5	3
Renewals, national and MR	71	102	454
Variations, national and MR	789	2,362	2,113
Manufacturers of veterinary medicines	23	31	34
Export certificates	106	142	144
Registrations for active pharmaceuticals ingredients			
Manufacturers	0	0	2
Importers	0	0	0
Distributors	0	0	2

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. Consequently, the figure of 29 listed in the table below represents reports received by the HPRA from all sources including MAHs up until 28 January 2022 and from veterinarians or animals owners for the remainder of the year:

Suspected adverse events	2018	2019	2020	2021	2022
Number of reports	394	347	391	439	29

- We processed 4,321 periodic safety update reports (PSURs). This incorporated the assessment of individual medicines on the market in Ireland as well as a work-sharing initiative where we led, or contributed to, the assessment of a class of veterinary medicines for the European Union.

- 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 marketing authorisation holder. 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. As can be seen from the data below, sales of veterinary antibiotics fluctuate annually. For 2021, the sales of veterinary antibiotics decreased by 9.3% compared to 2020.

Veterinary antibiotic use	2017	2018	2019	2020	2021
Tonnes sold	99.7	99.4	88.8	103.9	94.2

- The analytical testing and examination of veterinary medicines is a key component of our risk-based sampling and analysis programme. 21 veterinary medicines samples were included in surveillance programme in 2022. Of these, 16 products were sent for analytical testing at various laboratories. The testing carried out was physiochemical in nature. One product was analysed at the HPRA's Official Medicines Control Laboratory (OMCL) as part of the EDQM's surveillance programme for centrally authorised veterinary products. There were no out-of-specification test results obtained for any analytical tests completed and reported during 2022. In addition, packaging and labelling checks were performed on five veterinary products. Two non-compliances were observed on a single product. Firstly, the product name detailed on the package leaflet did not conform exactly to the product name as listed on the product SPC. Secondly, the distribution category was not detailed on the small immediate packaging which is a mandatory requirement for veterinary products. Appropriate follow-up actions were taken.

- Quality defects pertaining to 79 veterinary medicines were reported or identified in 2022. This represented a slight decrease from the 2021 figure (85). The risk classifications assigned, along with the corresponding figures for the previous two years, are outlined in the following table:

Year	2020	2021	2022
Critical quality defects	12	12	10
Major quality defects	36	35	27
Minor quality defects	29	37	41
Number of reports not justified	1	1	1
Total Number Quality Defects	78	85	79

- The majority of reports (76%) were submitted by pharmaceutical companies, which included manufacturers, distributors and marketing authorisation holders, while 24% of the reports were received from other competent authorities.

- 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.
  - Two such recalls occurred during 2022.
  - One recall related to product stability and one to a particulate contamination.
- One Rapid Alert was issued during 2022 to share relevant information with other competent authorities.
- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2022, there were ten good manufacturing practice (GMP) inspections of manufacturers producing veterinary medicines and one routine pharmacovigilance inspection to determine compliance with pharmacovigilance obligations.

Legislation and Regulation

- The new veterinary regulation (Regulation 2019/6) was applied in the EU on 28 January 2022. During 2022, we continued to meet and engage with the Department of Agriculture, Food and the Marine in respect of the development of new national legislation that is needed to support the new Regulation. Furthermore, the HPRA continued to engage with network preparations, including the following:
  - Uploading of national product data to the EMA's Union Product Database (UPD) of veterinary medicinal products;
  - 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.
- Additionally, a project to modify internal IT systems to interface and communicate with the UPD was undertaken. The goal is to develop an automated system to upload changes in the national product database to the UPD.
- Concerning Brexit, the production and supply of medicines for animals remained a key focus in 2022 and the HPRA engaged in extensive discussions with stakeholders and the European Commission to manage the outcome and facilitate continued supply of essential veterinary medicines. On 19 December 2022, the EU Commission published a notice on the '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'. Applying to Ireland, Malta, Cyprus and Northern Ireland, and taking into account the special characteristics of these markets for medicines supply, the notice facilitated a further time extension to the derogations for those medicines which had not made some of the necessary regulatory changes to stay on the market for a final period of three years (to 31 December 2025).

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2022 we:
  - Held a webinar to keep stakeholders abreast of developments with the new veterinary Regulation;
  - Provided a periodic blog on HPRA implementation activities as well as those of the wider EU network on the HPRA website;
  - Participated in a number of seminars held by stakeholders in respect of the implications of the new legislation on the availability of veterinary medicinal products in Ireland;
  - Participated in the Department stakeholder group on antiparasitic resistance control measures.
- Concerning 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:
  - Continued engagement with industry to identify potentially vulnerable products;
  - Continued dialogue with the UK's Veterinary Medicines Directorate regarding maintenance of common labelling for medicines post Brexit;
  - Engagement with the EU Commission in respect of the need for a further extension to the transitional arrangements regarding products being imported onto the island of Ireland from Great Britain;
  - Liaising with stakeholders concerning the availability of veterinary medicinal products on the island of Ireland.
- Throughout 2022, 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 list of presentations for 2022, 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 2022 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 or to conduct procedures or euthanasia of animals.

Authorisation and registration – Key 2022 figures	
Individual authorisations	221
Individual renewals	45
Project authorisations	91
Individual amendments	19
Project amendments	57
Establishment renewals	62
Retrospective assessments	21

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

- In December, we published the ninth 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 2022 there were 23 inspections completed to monitor animal welfare standards and compliance with legislation. 48% of these were performed as unannounced inspections, with 52% performed on an announced basis.

- Of the 40 non-compliances recorded in 2022 under the Scientific Animal Protection inspections and compliance programme, 27.5% were self-reported to the HPRA by authorised breeder/supplier/user establishment personnel. 62.5% were identified during the course of HPRA inspections, with the remaining 10% detected as a result of other HPRA activities including, for example, the review of end-of-project reports.

- 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 2022:

  - 17.5% were Type 1
  - 62.5% were Type 2
  - 20% were Type 3

  The most common reason recorded for non-compliance 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 adhere to stocking density requirements or to log daily health checks. The next most common reason recorded for non-compliance was a breach of the terms and conditions of HPRA project authorisation, for example, due to failure to comply with agreed animal monitoring arrangements.

Stakeholders and Partners

- We supported the National Committee for the Protection of Animals Used for Scientific Purposes in hosting a national 3Rs training event that was widely attended by representatives from the research community in Ireland.

- We published and disseminated three '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.

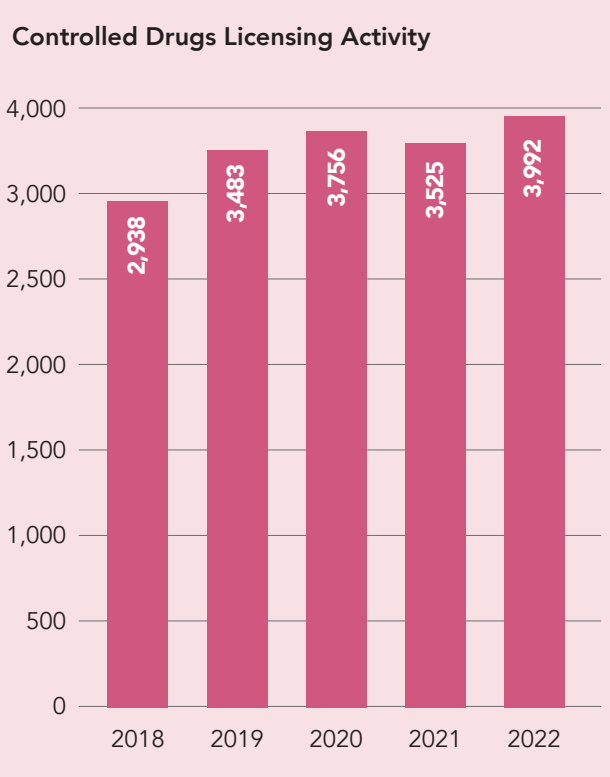
- Throughout 2022, we continued our active involvement in EU regulatory network, which includes active participation at National Contact Point meetings for the Implementation of Directive 2010/63/EU.

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 2020:

Precursor Chemicals Licensing Activity	2020	2021	2022
Total	14	14	9

- 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	2020	2021	2022
Total	94	78	56

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 2022, 12 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 2022, the HPRA provided 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.
- The HPRA received four applications from potential suppliers seeking to have their products included in the programme. From these applications, two cannabis products were considered to meet the specified requirements and were proposed to the Department of Health for inclusion on the programme, one was cancelled and one was still undergoing assessment at time of publication.

  In total, seven cannabis products have been accepted for use on the MCAP to date.

Further information is available on the Department of Health website.

Stakeholders and Partners

- The HPRA continues to review and 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 64 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);
  - serious risk alerts received from other countries (Safety Gate RAPEX rapid alerts);
  - importation of potentially non-compliant unsafe products.

  During 2022, 416 market surveillance cases were initiated, including both proactive and reactive surveillance of cosmetic products, encompassing over 500 different products. This reflects an increased resource applied to the oversight of this area in 2022 arising from the relocation of Responsible Persons for cosmetic products to Ireland following Brexit.

  We also carried out one inspection of a distribution site to assess compliance with the EU Cosmetics Regulation.

Stakeholders and Partners

- The cosmetic products team attended the Irish Cosmetics and Detergents Association workshop in December 2022.
- 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 2022, 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 ICMRA digital transformation of inspections working group which produced a reflection paper on the regulatory experience of digital approaches to GCP and GCP oversights during the COVID-19 pandemic;
  - 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 development of a new risk assessment tool for the selection of medicinal products and active substances for surveillance testing;
  - a new risk-based tool to support inspection and surveillance relating to heparin manufacturers and their related products;
  - 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.

  Our actions in 2022 included the following:

  - The conclusion of the 'Strengthening regulatory sciences and supporting regulatory scientific advice' (STARS) project was marked by a global conference held in Brussels. This Horizon 2020 project aimed to facilitate translation of academic medical research into approved health products by increasing regulatory knowledge and tailoring regulatory supports to academic researchers. A representative from an Irish research centre presented at the global conference which included a session that was moderated by the HPRA. A number of other representatives from Irish research centres also attended;
  - The HPRA's Innovation Office continues to offer regulatory advice to anyone developing an innovative health product or technology. 45% of queries received by the Innovation Office related to medical devices with just under 30% relating to medicines. The majority of queries to the innovation office come from academia or small and medium enterprises;
  - As co-chair of the EU-Innovation Network, the HPRA continued to play a lead role in progressing and promoting supports for innovation at European level. Phase 2 of the simultaneous national scientific advice pilot project was launched in November 2022 with a specific focus on advice relating to clinical trials. The HPRA is participating in this pilot which has also developed links with the Accelerating Clinical Trials in the EU (ACT EU) initiative. We also continue to support horizon scanning at EU level and June 2022 saw the publication of the EU-IN horizon scanning report on faecal microbiota transplantation for which the HPRA was the lead member state;
  - Our national classification process continued to offer advice to stakeholders on the borderline between different regulatory frameworks including medicines, medical devices, cosmetics and other products. The HPRA continues to participate in a subgroup of the EU Innovation Network to facilitate discussions on borderline product classification at an EU level. This is to ensure consistency across the different regulatory frameworks that apply to borderline innovative products.

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. In November 2022, we participated in a venture build programme event organised by Enterprise Ireland during which we provided information on the available regulatory supports for the development of innovative medicines and medical devices. We also met with individuals and organisations who are seeking to develop innovative health products and technologies to provide guidance on the regulatory requirements that will apply to their products.
  - The HPRA continues to contribute to education programmes at both undergraduate and postgraduate levels. During 2022, we continued to implement a new policy related to our involvement in third level educational programmes.
  - The HPRA's graduate training programme for medical devices continued throughout 2022 with training provided to a pharmacy graduate with an MSc in Regulatory Affairs and Toxicology as part of this initiative.
- Stakeholder communications and engagement:
  - We launched a new multi-platform digital information campaign to warn of the health risks of sourcing prescription medicines online. Incorporating both social media and display advertising, the campaign targets members of the general public and highlights to them 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 online. Given the fact that so many transactions take place online, it is particularly important and appropriate to highlight those risks through online channels and, where possible, to influence the decision of the buyer prior to purchase. The first phase of the campaign took place in September following development of the creative approach during the summer. In total, there are four complementary adverts which highlight several key messages including:
    - Consumers have no guarantees about the safety or quality of prescription medicines they buy outside of the regulated pharmacy setting;
    - Consumers may risk more than their health when they buy prescription medicines online. They could also lose their money or their personal data when they buy from online criminal enterprises.

    The campaign ran on Twitter, Facebook, Instagram, TikTok, YouTube, and Google Search as well as through display ads on a range of websites. The campaign featured each of the four adverts in various formats suited to different social media platforms, including stories, reels, regular videos, static images and carousels. Over the four-week period, the campaign achieved over 10 million impressions, and reached close to two million people, suggesting high visibility of the campaign across Ireland. The campaign ads link

to a consumer advice page on the HPRA website: Dangers of buying prescription medicines online. The webpage text is written in plain English to ensure it is accessible to readers of all abilities.

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

– We continued to proactively communicate updates relating to COVID-19 with a particular focus on the key role of the HPRA in monitoring the safety and quality of medicines, including vaccines, and medical devices. This included the publication of a further four vaccine safety update reports in addition to the provision of summary high-level data published throughout the second half of the year. Also, in January, we issued updates and advice to raise awareness of a product recall of two batches of a SARS-CoV-2 Rapid Antigen Self-Test.

HPRA digital information campaign

– 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 Irish patients a voice in the regulatory process. Forum members and HPRA staff collaboratively developed a rolling work plan for 2022 that included areas of common interest and aligned with the goals of the forum. Work on organisational culture and values, in addition to adverse event reporting, were identified as core workplan topics. There was significant progress on all work topics throughout the year, including, the co-creation of a new induction module focusing on the HPRA's value of being patient focused, establishment of a pilot patient speaker programme, and development of an accessible notice outlining key information on the reporting of adverse events associated medicines or medical devices. Forum members also provided valuable feedback on a range of issues, including, the importance of patient-focused approaches to communication. Direct benefits of forum activities will help ensure staff maintain an outward focus and foster a deeper understanding of patient needs. In addition to the direct impact and obvious benefits of forum activities to the HPRA, over 80% of members who responded to an online survey either agreed or strongly agreed that the patient forum met their expectations. Members felt they had a greater understanding and appreciation of the work done by the HPRA. In addition, the forum itself was seen as an important mechanism for patients to provide feedback on a 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 seventh annual #MedSafetyWeek, an international social media campaign designed to raise awareness of the importance of reporting side effects from medicines. In 2022, the campaign focused on the key role played by every healthcare professional, patient, and carer who reports a suspected side effect. Every report received can help to improve the safety of medicines for all patients. The campaign 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 medicines regulators from 82 countries. While UMC led the campaign, a planning committee comprising representatives from several medicines agencies, including for the

second year running, the HPRA, met regularly to develop the campaign materials. The campaign consisted primarily of short animated videos, available to view and download on our website, which were shared on 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, the HPRA purchased advertising across social media to maximise visibility of the campaign. As a result, we significantly increased engagement with the campaign materials compared to previous years. The number of impressions rose from less than 100,000 in 2021 to more than two million in the 2022 campaign. 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. There was significant preparatory work and planning during the past year in advance of a 2023 public procurement process to appoint a website agency.

  - 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 2022 and by year-end we had grown our number of followers to more than 4,000.

  - Our LinkedIn account continues to support the growth of our employer brand. In addition, it facilitates the dissemination of important regulatory and safety information to industry and health professionals. By end 2022, our total number of followers had grown to more than 17,500.

  - Also, during 2022, we continued to utilise our corporate Instagram account to highlight and promote certain activities and events including #MedSafetyWeek.

• European and international contribution:

  – Throughout the year, the HPRA participated in a significant number of initiatives and working groups in respect of COVID-19, which included the EMA Pandemic Task Force and the EU Executive Steering Group on Shortages of Medicines caused by Major Events. The latter part of the year saw a focus on medicines shortages arising from increased respiratory illnesses combined with global supply issues.

  – We continued our participation in all EMA and all HMA management board/group meetings with in person meetings recommencing in 2022. In March 2022, Dr Lorraine Nolan was elected as Chair of the EMA Management Board.

  – While the Management Board continued to be updated on new vaccines and therapeutics, the focus moved to lessons learned and future planning. Other ongoing issues considered at its quarterly meetings included the new veterinary legislation and Clinical Trials Regulation implementation, including the new Clinical Trials Information Systems (CTIS) which became compulsory from January 2023.

  – We continued our role as a member of the HMA Management Group, which contributes to the direction and oversight of the European regulatory network.

  – The HPRA hosted the PIC/S 50th anniversary symposium in Dublin on 4 October 2022. The symposium titled "Thriving at 50 and Striving Forward" promoted and highlighted PIC/S' contributions to international collaboration and co-operation while looking to the future.

    - The programme comprised a wide range of presentations and panel discussions on inspection-related topics, which included participation from the HMA, Heads of GMDP Inspectorates and official PIC/S representatives. Ms. Emer Cooke, Executive Director of the EMA, addressed how to strive for better international relationships and collaboration. The programme can be located on the PIC/S website.

    - Over 200 participants from all continents participated in the event, including most of PIC/S 54 Participating Authorities and 7 (Pre-) Applicant Authorities and PIC/S Associated Partner Organisations.

    - The HPRA also hosted the PIC/S Committee meetings and the 2022 Annual Training Seminar.

– 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 forums (see Appendix 4).

– The HPRA continued its role as a member of the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee. Real world evidence, pharmacovigilance and safety monitoring, vaccine updates for both COVID-19 and Monkey Pox were important topics. The HPRA actively participated in a range of initiatives and co-led on the Pharmaceutical Quality Knowledge Management System (PQ KMS) project and the Governance project. In November 2022, the HPRA hosted the 17th ICMRA summit and welcomed over 80 delegates from over 30 countries. The theme of the Summit was "The Future of Medicines – How working together as regulators supports innovation and patients" and the key focus was on pharmacovigilance, innovation and public health emergencies.

– Throughout 2022, 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.

Key outreach and engagement figures	**2022**
Public consultations held: - Proposed regulatory fees for human products - Proposed regulatory fees for veterinary medicines - Registration of processes exempted under Article 61(5) and applicable requirements under Article 61 (6) of the CTR	3
Public consultations responded to: - Included Department of Health, European Commission and Health Information and Quality Authority (HIQA)	5
Events managed by HPRA events teams	3
Freedom of information requests	48
Freedom of information requests answered outside the FOI Act	4
Requests received in accordance with the Data Protection Acts	6
Parliamentary questions	37
Queries from Government departments or members of the Oireachtas	122
Protected disclosures received by external persons under section 7(2) of the protected Disclosures Act, of which investigation is: - Concluded - Ongoing	 7 2
Complaints	3
Customer service queries	2,340

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.

Human Resources and Change

The HR and Change team delivered across a number of operational and strategic priority areas throughout 2022. Our primary focus continued to be on developing the organisation and providing effective, best practice advice and support.

The HR and Change team were central to the organisation wide initiative to return to the office with an emphasis on developing management capabilities, change management support and the delivery of collaboration training across the organisation.

In support of the delivery of the organisational Strategic Plan, 2022 also marked the development of our People Strategy.

People Strategy

- The development of our People Strategy, a first for the organisation, was a key deliverable for the HR and Change department in 2022, underpinning goal 5 of the HPRA Strategic Plan. 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 output of extensive research conducted by the HR and Change team, along with extensive consultation with the HPRA Management Committee and across the wider organisation, resulted in the identification of four interconnected people 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

- Our inaugural Gender Pay Gap report, developed in collaboration with our colleagues in Finance, presented a gender pay gap of 3.65%. Being transparent about 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. As such, analysis was undertaken to understand what drives our pay gap and how we can work to address any imbalance. Further details can be found in the full report on our website.

Engagement

- Employee engagement is an ongoing priority for the HPRA. In 2022, we implemented a new software tool to support and evolve our approach to engagement activities. A series of engagement surveys were delivered using this platform, better assisting us to identify both departmental and centralised actions. The implementation of the platform enables a deep dive into analytics and demographics to appropriately understand concerns/patterns and therefore identify bespoke solutions in a more timely and effective manner. Results are driven across both the organisation and within departments and underpinned by targeted support from the HR and Change teams.

Keep Well Mark

- In October, the HPRA were awarded reaccreditation with the Keep Well Mark, a national workplace wellbeing accreditation. We originally received accreditation in 2018 with reaccreditation in 2020 and again in 2022. Achieving the KeepWell Mark demonstrates the HPRA's continuous commitment to improving the health and wellbeing of our employees. It is an evidence-based accreditation that recognises and celebrates the work we are doing to improve health and wellbeing and includes benchmarking the organisation across a number of key areas. The award provides recommendations and insight to help us enhance our work in the area. In addition to this, our Learning and Development Manager was invited to speak as a panellist on behalf of HPRA at the 2022 IBEC Keep Well Summit on the topic 'Minding your Mind'.

Management and Employee Capabilities

- In the first quarter of 2022, the HPRA began the return to office following the pandemic, a significant transition for the organisation. As a result, specific resources were curated, created and released across the organisation for managers and employees to ensure they were supported across a broad and relevant range of topics from managing remotely, to communication in a hybrid workplace.
- To support the 2022 organisational focus competencies of 'Effective Team Work' and 'Openness to Change', as well as reinforcing the HPRA core values of 'Collaboration' and 'Inclusion', the collaboration training, Tetramap, was run internally. A growth mindset programme was also rolled out.
- Aligned with the organisational approach of continuous improvement within the core values of 'Innovation' and 'Excellence', Lean Six Sigma Green and Yellow Belt training was made available.

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. In 2022, analysis was progressed to understand where gaps may exist 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 in fulfilling 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.

Delivering on the strategy objectives proceeded with improvements in the technology infrastructure, extension of organisation's collaborative working capabilities, and transitioning telecommunication services to government networks. Information technology security capabilities and controls continued to be upgraded with the introduction of security services to improve protection of the organisation assets. Consolidation of processes and data on to a standard suite of capable enterprise applications continued, as did integration with systems hosted by the EMA on behalf of the regulatory network.

Operational Excellence and Quality Management

- The HPRA's quality management team was responsible for the continued implementation of policies and procedures relating to the General Data Protection Regulation (GDPR). There were six data subject requests received in 2022. All requests were managed within the required timelines.

- In the HPRA's continued commitment to the quality management system and continuous improvement, 12 internal audits were completed in 2022 throughout various departments. No major concerns were highlighted during these internal audits.

- The quality management team worked closely with various departments to support the implementation of the new veterinary medicines, clinical trials regulations and medical device and *in-vitro* device regulations.

- In the latter half of 2022, the HPRA introduced an Operational Excellence Manager role to the organisation tasked with enhancing an operational excellence culture and focus across the HPRA to support the achievement of its strategic goals. The work will involve development, enhancement and implementation of a number of organisational systems and standards across the HPRA. It will focus on driving operational excellence and operations development by achieving enhanced business process uniformity, strengthened capacity management, and focus on continuous improvement. Work has already commenced in several areas including the transition of the Medical Devices department to a new case management platform, using lean project management tools and business process reengineering to manage the work.

Finance

- The HPRA is committed to the highest standards of corporate governance. During 2022, 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 2021 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.

- The annual review of regulatory fees for 2023, incorporating a public consultation, was completed followed by the publication of the updated fees.

- One internal audit review took place and a report was issued on the risk management framework.

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 2022, the HPRA consumed 525.9MWh of energy consisting of:

  – 303.7 MWh of electricity;

  – 222.2 MWh of fossil fuels;

  – 0 MWh of renewable fuels.

  According to the Sustainable Energy Authority of Ireland (SEAI) Annual Report 2021 on Public Sector Energy Efficiency Performance, total energy reduction achieved by the HPRA since baseline was 62.4%* exceeding the public sector target of 33% by 2020.

* Please note data in the 2022 report should not be compared on a like for like basis to the data for previous years due to the impact of COVID-19.

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 six times in 2022 and considered a number of strategic matters including the response to COVID-19, the continued supply of medicines to the Irish market, strategic planning, the implementation of new Regulation in the areas of medical devices, veterinary, and clinical trials and financial matters. The latter included monthly management accounts, annual budgets and the financial statements for 2021.

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 2022 was as follows:

Authority Member	Number of meetings held during the period the member was on the Authority	Number of meetings attended during the period the member was on the Authority
Mr Michael Donnelly (Chairperson)	6	6
Dr Joe Collins	6	6
Mr David Holohan	6	6
Mr Brian Jones	6	5
Dr Elizabeth Keane	3	3
Dr Diarmuid Quinlan	6	5
Prof Richard Reilly	6	6
Prof Sharon O'Kane	6	6
Dr Paula Kilbane	6	6
Dr Fiona Kiernan	2	2

- The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2022. Further details are provided in the HPRA's Financial Statements.
- The Advisory Committee for Human Medicines met once in 2022. The Clinical Trials Sub-Committee is a sub-committee to the Advisory Committee for Human Medicines and it met twelve times in the past year. The Clinical Trials Regulation (Regulation (EU) No 536/2014) came into effect on a phased basis on 31 January 2022. Following the requirement for new clinical trials to be submitted under the Regulation from 31 January 2023, the Clinical Trials Sub-Committee met for the last time in early 2023.
- The Advisory Committee for Veterinary Medicines met twice.
- The Advisory Committee for Medical Devices met three times.
- The National Committee for the Protection of Animals Used for Scientific Purposes, a statutory committee to provide guidance to the regulator and those working in this area, met twice in 2022.

- 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 2022

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

KBC Bank Ireland
Sandwith Street
Dublin 2

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 2022.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2022. 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 2022, the internal auditor carried out an internal audit review on the risk management framework. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2022, 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 51 to 52.

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 2022.

Performance Review

The Authority carried out a self-assessment evaluation of its own performance and its committees for the year ended 31 December 2022.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. Brian Jones
Authority Member

Date: 24 May 2023

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 2022 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 2022.

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 2022 one internal audit review was conducted.

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

Risk and Control Framework

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

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

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

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

Ongoing Monitoring and Review

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

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

Procurement

I confirm that the HPRA has procedures in place to ensure compliance with current procurement rules and guidelines, and that during 2022 the HPRA complied with those procedures.

Review of Effectiveness

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 2022. This review was carried out at its meeting on 05 April 2023. Prior to this meeting, a document outlining the effectiveness of the internal controls in the HPRA for 2022 was circulated to the Authority members by e-mail. This document was circulated on 09 March 2023.

Internal Control Issues

No weaknesses in internal control were identified in relation to 2022 that require disclosure in the financial statements.

COVID-19 Pandemic

Due to the impact of Covid-19, the HPRA carried out a review of its control environment, based on a guidance document issued by the Office of the Comptroller and Auditor General. Many of the controls in place pre-Covid continue to apply in the current environment. This review document was considered by the Audit and Risk Committee at its December 2020 meeting, who were happy with the content. These controls continued to apply during the year ended 31 December 2022.

During 2022 HPRA staff returned to the office on a phased basis, and the HPRA is currently 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.

Mr. Michael Donnelly
Chairperson to the Authority

Date: 24 May 2023

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 2022 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 2022 and of its income and expenditure for 2022 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 2022 has not been quantified.

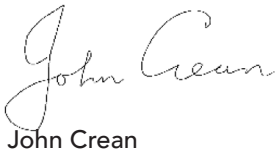
I conducted my audit of the financial statements in accordance with the International Standards on Auditing (ISAs) as promulgated by the International Organisation of Supreme Audit Institutions. My responsibilities under those standards are described in the appendix to this report. I am independent of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

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

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

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

I have nothing to report in that regard.



John Crean

For and on behalf of the
Comptroller and Auditor General

9 June 2023

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 it is not a guarantee that an audit conducted in accordance with the ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

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

- I identify and assess the risks of material misstatement of the financial statements whether due to fraud or error; design and perform audit procedures responsive to those risks; and obtain audit evidence that is sufficient and appropriate to provide a basis for my opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- I obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal controls.
- I evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures.
- I conclude on the appropriateness of the use of the going concern basis of accounting and, based on the audit evidence obtained, on whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If I conclude that a material uncertainty exists, I am required to draw attention in my report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify my opinion. My conclusions are based on the audit evidence obtained up to the date of my report. However, future events or conditions may cause the Authority to cease to continue as a going concern.
- I evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

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

I report by exception if, in my opinion,

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

Information other than the financial statements

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

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

Reporting on other matters

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

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

Statement of Income and Expenditure and Retained Revenue Reserves
For the year ended 31 December 2022

	Note	2022	2021
		€	€
Fee Income	3	**31,099,071**	30,035,513
Department of Health Funding	3	**4,900,000**	5,200,000
Other Income	4	**813,244**	648,438
		36,812,315	35,883,951
Salaries and Wages	5	**28,423,991**	27,291,731
Other Operating Costs	6	**5,905,143**	5,609,084
Depreciation	2	**1,009,375**	1,122,662
		35,338,509	34,023,477
Surplus for the year before write back of Superannuation contributions		**1,473,806**	1,860,474
Staff Superannuation Contributions		**658,600**	643,824
Surplus for the year		**2,132,406**	2,504,298
Balance brought forward		**38,163,005**	35,658,707
Balance carried forward	12	**40,295,411**	38,163,005

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 59 to 69 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. Brian Jones
Authority Member

Date: 24 May 2023

Statement of Financial Position
As at 31 December 2022

	Note	2022	2021
		€	€
Fixed Assets			
Property, Plant and Equipment	2	24,677,887	24,360,470
Current Assets			
Debtors and Prepayments	7	2,044,475	1,642,061
Inventory of Stationery		5,308	5,099
Cash and Cash Equivalents	9	17,198,418	25,236,105
Short Term Deposits	10	10,000,000	-
		29,248,201	26,883,265
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	13,294,003	12,575,719
Mortgage	13	168,337	168,337
		13,462,340	12,744,056
Net Current Assets		15,785,861	14,139,209
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	168,337	336,674
NET ASSETS		40,295,411	38,163,005
Reserves			
Retained Revenue Reserves	12	20,387,702	20,913,896
Superannuation Reserve	12	19,907,709	17,249,109
		40,295,411	38,163,005

The Statement of Cash Flows and the notes on pages 59 to 69 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. Brian Jones
Authority Member

Date: 24 May 2023

Statement of Cash Flows
For the year ended 31 December 2022

	Note	2022	2021
		€	€
Cash flows from Operating Activities			
Surplus for financial year		2,132,406	2,504,298
Depreciation of property, plant and equipment		1,009,375	1,122,662
(Profit)/Loss on Disposal of property, plant and equipment		0	0
(Increase)/Decrease in Debtors		(402,414)	1,204,200
(Increase)/Decrease in Stock		(209)	(163)
Increase/(Decrease) in Creditors - amounts falling due within one year		718,284	(1,238,706)
Deposit Interest		(8,000)	0
Bank Interest		89,064	146,739
Cash from Operations		3,538,506	3,739,030
Bank Interest Paid		(89,064)	(146,739)
Net Cash generated from Operating Activities		3,449,442	3,592,291
Cash flows from Investing Activities			
Deposit Interest Received		8,000	0
(Increase)/Decrease in Bank Deposits		(10,000,000)	0
Payments to acquire property, plant and equipment		(1,326,792)	(817,291)
Receipts fom sales of property, plant and equipment		0	0
Net cash from Investing Activities		(11,318,792)	(817,291)
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		(8,037,687)	2,606,663
Cash and Cash Equivalents at beginning of year		25,236,105	22,629,442
Cash and Cash Equivalents at end of year	9	17,198,418	25,236,105

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

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 has been calculated on the value of premises, as the remaining useful economic life is estimated to be greater than 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 2022	1,331,358	17,663,753	866,055	4,374,608	23,156,037	47,391,811
Additions for the year	38,389	941,864	-	346,539	-	1,326,792
Disposals for the year	(40,477)	(556,606)	-	-	-	(597,083)
As at 31 December 2022	1,329,270	18,049,011	866,055	4,721,147	23,156,037	48,121,520
Depreciation						
Balance as at 1 January 2022	1,253,642	16,895,046	602,268	4,280,385	-	23,031,341
Charge for the year	39,134	819,220	36,362	114,659	-	1,009,375
Disposals for the year	(40,477)	(556,606)	-	-	-	(597,083)
As at 31 December 2022	1,252,299	17,157,660	638,630	4,395,044	-	23,443,633
Net Book value at 31 December 2022	76,971	891,351	227,425	326,103	23,156,037	24,677,887
Net Book value at 1 January 2022	77,716	768,707	263,787	94,223	23,156,037	24,360,470

3. Income	2022	2021
	€	€
Fee Income		
Human Medicine - National Fees	10,951,292	11,690,298
Human Medicines - Centralised Fees	6,572,322	6,563,095
Veterinary Sciences - National Fees	2,756,928	3,316,202
Veterinary Sciences - Centralised Fees	1,119,484	502,203
Compliance Department	6,682,641	5,525,818
Medical Devices	2,923,278	2,393,218
	31,005,945	29,990,834
Movement in deferred revenue	93,126	44,679
	31,099,071	30,035,513
Dept Of Health Funding (Vote 38 Subhead E1)	4,900,000	5,200,000
Other Income (Note 4)	813,244	648,438
Total Income	36,812,315	35,883,951

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 €21,920,032 in 2022, 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

	2022	2021
	€	€
Bank Interest	8,000	-
Conference Income	74,055	-
IT Income	731,189	648,438
	813,244	648,438

5. Salaries and Wages

Basic Pay	22,601,049	21,765,662
Overtime	10,258	33,563
Allowances	160,145	172,045
Staff Short Term Benefits	22,771,452	21,971,270
Retirement Benefit Costs	1,656,223	1,636,878
Employer's Contribution to Social Welfare	2,383,856	2,300,829
Employer's Contribution to Single Scheme Pension	1,612,460	1,382,754
	28,423,991	27,291,731

The average number of staff employed during the year was 364 (2021 - 370).
Payroll numbers at 31 December 2022 can be analysed across the following departments :

Chief Executive	7	7
Compliance	69	67
Finance, Corporate & International	28	31
Human Products Authorisation & Registration	105	101
Human Products Monitoring	40	44
Human Resources & Change	10	8
IT & Business Services	17	18
Medical Devices	46	44
Organisational Excellence & Quality	7	7
Veterinary Sciences	32	36
Staff	361	363
Authority Members	8	8
Pensioners	58	51
	427	422

No termination or severance payments were made during the year.

Additional superannuation contributions for Public Servants of €757,464 were deducted from staff during the year and paid over to the Department of Health. On 1 January 2019, in accordance with DPER circular 21/2018, the pension related deduction (PRD) was replaced by an additional superannuation contribution (ASC).

Pension deductions for Public Servants who are members of the Single Public Service Pension Scheme of €567,599 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	2022	2021
€0 to €60,000	186	206
€60,001 to €70,000	46	64
€70,001 to €80,000	57	25
€80,001 to €90,000	8	15
€90,001 to €100,000	20	20
€100,001 to €110,000	26	20
€110,001 to €120,000	8	8
€120,001 to €130,000	5	3
€130,001 to €140,000	4	1
€140,001 to €150,000	-	-
€150,001 to €160,000	-	-
€160,001 to €170,000	-	1
€170,001 to €180,000	1	-
	361	363
Average Salary	€59K	€56K

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

	2022	2021
	€	€
Accommodation Costs	1,812,724	1,470,181
Travel, Representation and Training	801,907	513,945
Bank Charges and Interest	95,128	151,424
Legal Fees	303,514	171,302
Audit Fees (External and Internal)	24,200	35,481
Stationery, Publications, Postage and Communications	395,833	400,713
Consultancy	379,514	555,654
Sampling and Analysis	235,995	250,482
IT Costs	1,638,029	1,812,010
Document Storage	126,983	137,087
Telephone and Telecommunications	84,934	90,445
Movement on Bad Debt Provision	6,382	20,360
	5,905,143	5,609,084

Travel costs include an amount of €31,055 related to hospitality, and an amount of €326,190 related to travel and subsistence, of which €151,513 is national and €174,677 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 €161,151 related to public relations/marketing, €155,137 related to human resources/pensions and €63,226 related to other.

7. Debtors (all due within one year)	2022	2021
	€	€
Trade Debtors	1,938,886	1,341,833
Prepayments	41,422	228,775
Other Debtors	64,167	71,453
	2,044,475	1,642,061

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)		
Trade Creditors	383,580	118,175
Credit Balances on Debtor Accounts	4,647,643	4,515,049
Accruals	5,937,114	5,596,816
Deferred Revenue	1,500,823	1,593,950
Revenue Commissioners	824,843	751,729
	13,294,003	12,575,719

9. Cash and Cash Equivalents		
Cash at Bank and in Hand	5,131,670	13,134,899
Demand Deposits (Convertible to Cash on Demand)	12,066,748	12,101,206
	17,198,418	25,236,105

10. Short Term Deposits		
Short Term Deposits (not immediately convertible to cash)	10,000,000	-
	10,000,000	-

11. Administration Expenses		
Surplus for the year was calculated having charged:		
Auditor's Remuneration	24,200	22,000

12. Movement on Income and Expenditure Reserves

	As At 01/01/2022 €	Income & Expenditure €	Transfer to Superann Reserve €	As At 31/12/2022 €
Retained Revenue Reserves	20,913,896	1,473,806	(2,000,000)	20,387,702
Superannuation Reserve	17,249,109	658,600	2,000,000	19,907,709
	38,163,005	2,132,406	0	40,295,411

Our Audit and Risk Committee recommended the transfer of a further €2,000,000 in 2022 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:

	2022 €	2021 €
- within one year	168,337	168,337
- between one and five years	168,337	336,674
- after five years	-	-
	336,674	505,011

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 €702,825 in relation to operating leases. On 28 January 2005 the HPRA signed a leasehold interest in respect of the 5th floor, 6 Earlsfort Terrace, Dublin 2. This lease expired on 11 May 2022.

	2022	2021
	€	€
The amounts due under this lease are as follows:		
- within one year	-	103,620
- between one and five years	-	-
- after five years	-	-
	-	103,620

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.

The amounts due under this lease are as follows:		
- within one year	**353,070**	226,353
- between one and five years	**481,243**	832,862
- after five years	-	-
	834,313	1,059,215

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 2022 this lease had 11 years and 5.5 months remaining.

The amounts due under this lease are as follows:		
- within one year	**371,421**	371,421
- between one and five years	**1,485,683**	1,485,683
- after five years	**2,398,758**	2,770,179
	4,255,862	4,627,283

16. Capital Commitments

	2022	2021
	€	€
Contracted For (Contract Signed)	**284,499**	479,002
Contracted For (Contract Not Signed)	-	-
	284,499	479,002

17. Authority Remuneration

	Fees	Expenses
	€	€
Michael Donnelly (Chairperson)	11,970	-
Joe Collins	7,695	1,691
David Holohan	7,695	-
Brian Jones	7,695	699
Elizabeth Keane	3,018	-
Fiona Kiernan	2,366	-
Paula Kilbane	7,695	28
Sharon O'Kane	7,695	-
Diarmuid Quinlan	7,695	-
Richard Reilly	-	-
	63,524	2,418

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

	2022	2021
	€	€
Chief Executive	171,056	163,327
Senior Management	973,216	1,072,759
	1,144,272	1,236,086

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:

2022 €1 = STG £0.88519

2021 €1 = STG £0.83939

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.

The Covid-19 pandemic has impacted how the HPRA operates, with all staff substantially moved offsite since March 2020. From March 2022, staff have begun to return to the office on a phased basis, and the HPRA is moving towards a hybrid working model.

24. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 24 May 2023.

Appendix 1

2022 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
(Appointed January 2022)

Dr Finnuala Lonsdale
Director of Human Products Authorisation and Registration
(Appointed March 2022)

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 Elizabeth Keane
(Term ended May 2022)

Dr Fiona Kiernan
(Appointed September 2022)

Audit and Risk Committee

Dr Elizabeth Keane
Chair
(Term ended May 2022)

Mr David Holohan
Chair
(Appointed May 2022)

Mr Brian Jones

Prof Sharon O'Kane
(Appointed June 2022)

Advisory Committee for Human Medicines

Dr Diarmuid Quinlan
Chair

Prof Brian Cleary

Prof Desmond Corrigan

Dr Paul Gallagher

Ms Fionnuala King

Dr Fionnuala Ní Ainle

Dr Brian O'Connell

Ms Margaret O'Doherty

Ms Siobhan O'Sullivan
(Resigned July 2022)

Dr Patrick Sullivan

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 Robert Shiel
(Resigned April 2022)

Dr Christina Tlustos

Advisory Committee for Medical Devices

Prof Richard Reilly Chair
Prof Robert Byrne
Mr Ger Flynn
Dr Vida Hamilton
Dr Tanya Mulcahy
Dr Fergal McCaffrey
Ms Margaret O'Donnell
Prof Sean Tierney (Resigned November 2022)
Prof Pat Twomey

Clinical Trial Sub-Committee of Advisory Committee for Human Medicines

Dr Patrick Sullivan Chair
Dr Liam Bannan
Dr Patrick Morris
Dr Thomas Peirce (Resigned December 2022)
Prof Catherine McHugh
Dr Amjad Hayat

Advisory Sub-Committee for Herbal Medicines

Prof Des Corrigan Chair
Dr James Barlow
Mrs Ingrid Hook
Ms Claudine Hughes
Ms Anna-Maria Keaveney
Dr Celine Leonard
Dr Donal O'Mathuna
Dr Camillus Power
Dr Helen Sheridan
Dr Emma Wallace

Appendix 2

Presentations 2022

Educational/Professional Development Presentations and Training

Institution	Course / Subject	Presentation Title
ANVSA, Brazil	PIC/S Expert Circle Training	Critique of an FMEA Risk Assessment in a PAT Change Control
BPCI CMC Regulatory Affairs Training Programme	Common Deficiencies in CMC part of Application	BPCI CMC Regulatory Affairs Training Programme
BPCI CMC Regulatory Affairs Training Programme	Common Issues with Variations and Batch Specific Requests	BPCI CMC Regulatory Affairs Training Programme
EMA	Pharmacovigilance Inspectors Working Group Training Course	Remote inspections experience
EMA	Pharmacovigilance Inspectors Working Group Training Course	Inspections of Additional Risk Minimisation Measures
EU Network Training Centre	EU NTC Training	Limited markets: Approach to Determining Eligibility for Authorisation under Article 23
HRB Trials Methodology Research Network	Independent Data Monitoring Committee Course	What do the Regulations and Guidelines Say?
LAST	LAST Ireland - Laboratory Animal Science Training	Implementation of Scientific Animal Protection Legislation in Ireland
RCSI	Pharmacy	Introduction to Pharmacovigilance
RCSI	Pharmacy	Investigation of Quality Defects in Medicinal Products
RCSI	Undergraduate (3rd Year)	Regulation of Biological Medicines
St. John's College	Veterinary Nursing	The Regulation of Veterinary Medicinal Products in Ireland
TCD	ImmunoTherapeutics	Regulation of Biological Medicines
TCD	Regulation of Medicines	Regulation of Medicines - A Regulators Perspective
TCD	Pharmaceutical Medicine	Communication of Drug safety data
TCD	Pharmaceutical Medicine	Non-clinical Drug Development
TCD	Pharmaceutical Medicine	Overview of GCP Inspection Programme at HPRA
TCD	Pharmacy	Overview of Pharmacovigilance

Institution	Course / Subject	Presentation Title
TCD	Regulation of Biologicals	Regulation of Biologicals - A Regulators Perspective
TCD	Pharmacy	Quality Defects and Recalls in Medicines
TOPRA	An Introduction to Regulatory Affairs	Module 3: An Agency Perspective
TUD	Clinical Laboratory Science	European and National Legislation on Substances of Human Origin
UCC	Pharmacy	Quality Defect Investigations and Product Recalls
UCD	Module on Regulatory Affairs in Science	Regulation of Biological Medicines

Regulatory Presentations

Event/Organiser	Presentation Title
Animal Health Division Meeting, Animal and Plant Health Association	HPRA Veterinary Medicines Presentation
ANVISA, Brazil	PIC/S Recommendation on How to Evaluate and Demonstrate PQS Effectiveness with regard to Risk-based Change Management
CASS Meeting	Models in Module 3
Co-op Animal Health Group	Addressing Availability Challenges in Ireland
DIA Europe	CMC Flexibilities for Early Patient Access
DIA Europe	Regulatory Agility for the 21st Century
Enterprise Ireland: Cosmetic Products Regulatory Requirements	Borderline Products and the Definition of a Cosmetic Product
EMA Vet Information Day	CVMP Update on Activities relating to Regulation 2019/6
EMA/HMA Big Data Stakeholder Forum	Collaboration on International Initiatives
European Commission Workshop on EU Cosmetics Regulation	Cosmetic Product Market Surveillance in Ireland
European Society Cardiology – Roundtable Meeting	The Regulator's Perspective from Europe
Europol	Challenges Encountered with Cosmetic Products on the Irish Market
Expert FORUM Labelling, FORUM Institute	Multilingual Packaging in a Digitalised World
GIRP Annual Conference	Medicine Shortages: Where are we after Two Years?
Global Impact of the New EU MDR Regulations on Congenital Interventional Cardiology (Webinar)	Regulation and Innovation: Challenges and Tools

Event/Organiser	Presentation Title
HSE	Safety Monitoring of Medicines in Clinical Use, a Regulatory Perspective
ICH Meeting	Expert Working Group Update on the revision of ICH Q9
InPharma Open Symposium, UCC	Advancing an Integrated, Animal-free, End-to-end Modelling Approach to Oral Drug Product Development
PDA Ireland Seminar on ICH Q12	ICH Q12 and Demonstrating PQS Effectiveness: Risk-based Change Management
PDA Quality and Regulations Conference	How Regulators are Using Data to Drive Better Products and Patient Outcomes
Pharmaceutical Regulatory Science Meeting, Technological University Dublin	Quality Risk Management – Ongoing ICH Q9 Revision Update
Pharmaceutical Regulatory Science Meeting – QRM, Tokyo University of Science	An Update on the Ongoing ICH Q9 Revision
PIC/S Conference	Medicine Shortages and Prevention
PIC/S Expert Circle Seminar on Quality Risk Management, MHRA	Evaluating and Demonstrating the Effectiveness of the Pharmaceutical Quality System: Risk-based Change Management
PIC/S Expert Circle Seminar on Quality Risk Management, MHRA	The Ongoing Revision of ICH Q9 on Quality Risk Management
Tipperary Veterinary Practitioners Meeting	HPRA Veterinary Medicines Presentation
QP Forum Steering Committee	General Regulatory Update
3rd International CCPMJ conference	EU Experience with CM
7th Supply Chain Conference, GIRP, the European Healthcare Distribution Association	Implementation of Falsified Medicines Directive in Ireland

Appendix 3

Publications and Articles 2022

Drug Safety Newsletters

Edition	Articles
February 106th Edition	Review of latest evidence on risks associated with in-utero exposure to phenytoin, phenobarbital, carbamazepine, pregabalin and valproate: - Phenytoin, phenobarbital, carbamazepine - Pregabalin - Valproate (Epilim)
April 107th Edition	- Paxlovid – interactions between ritonavir component and other medicines leading to clinically significant reactions - Transmucosal fentanyl – labelling update to mitigate the risks of off-label use, accidental ingestion or unintentional exposure - Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)
August 108th Edition	- Topiramate – commencement of EU review regarding potential risk of neurodevelopmental disorders in children exposed in utero - Mavenclad® (cladribine) – new liver monitoring requirements to minimise risk of serious liver injury - Pregabalin – expanded warning regarding drug dependence and withdrawal symptoms - Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)
November 109th Edition	- 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 - Leuprorelin-containing depot medicines – risk of idiopathic intracranial hypertension (pseudotumor cerebri) - Pholcodine-containing medicinal products – review of risk of developing anaphylactic reactions to neuromuscular blocking agents (NMBA) - Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

Edition	Articles
December 110th Edition	- 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 - Gabapentin – expanded warnings around abuse potential, dependence, and withdrawal - Amoxicillin – Drug-induced enterocolitis syndrome (DIES) - Product information updates recommended by the EMA's Pharmacovigilance Risk assessment Committee (PRAC)

Human Medicines Safety Articles – External Publications

Month	Publication	Topic
January	MIMS	IL-17 inhibitiors – PI updates on IBD
March	IMF	Ibuprofen-containing medicines – Potential risk of acute generalised Exanthematous pustulosis (AGEP)
	MIMS	Paxlovid – oral antiviral medicine containing ritonavir and PF-07321332
April	MIMS CV Supplement	Direct oral anticoagulants
May	MIMS	Transmucosal Fentanyl
June	MIMS	Product Information for Medicines
	MIMS Diabetes Supplement	Product information updates recommended by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)
July/August	MIMS	Paxlovid – Interactions between ritonavir component and other medicines leading to clinically significant reactions
	MIMS Respiratory Supplement	Optimising the safe and effective use of medicines in clinical practice through proactive risk management
September	IMF	Optimising the safe and effective use of medicines in clinical practice through proactive risk management
	MIMS	Pregabalin – expanded warning regarding drug dependence and withdrawal symptoms
	MIMS General Supplement	Adverse Reaction Reporting – Reminder
October	MIMS	Adverse reaction reporting for vaccines
	MIMS CV Supplement	Methylphenidate
November	MIMS	Mavenclad (cladribine) – new liver monitoring requirement to minimise risk of serious liver injury

Month	Publication	Topic
December	MIMS	SGLT2 inhibitors – reminder of the associated risk of diabetic ketoacidosis
	MIMS Compendium	Nurofen Plus – serious clinical harms including RTA and severe hypokalaemia following prolonged use of codeine/ ibuprofen at higher than recommended doses

Veterinary Medicines Articles – External Publications

Month	Publication	Topic
March	It's Your Field	Implementation of Regulation 2019/6 – implications for the use of veterinary medicines that are given orally in feed and water/milk
July	Veterinary Ireland Journal	Future challenges to the availability of veterinary antibiotics in the EU
	It is Your Field	Future direction regarding controls on the supply of veterinary medicinal products
September	It is Your Field	Changes to withdrawal periods for veterinary medicines
November	Veterinary Ireland Journal	Best practice protocols for use of antiparasitic drugs on farms in Ireland
December	Veterinary Ireland Journal	The environmental impact assessment of veterinary medicines
	It's Your Field	Challenges in availability of veterinary medicines in Ireland

Appendix 4

Standing Committee/ Working Group Participation

Committee/Working Group	Organisation	Meetings in 2022
Controlled Drugs Cross Border Group	Care Quality Commission (UK)	3
National Criminal Investigative Forum Workshop	Competition and Consumer Protection Commission	2
Annual Meeting of the International Network on the Control of Precursors Diversion	Council of Europe	1
Counterfeiting of Medical Products (CMED)	Council of Europe	6
Pharmacare Stakeholder Day (EDQM)	Council of Europe	1
iNAP (Ireland's National Action Plan on AMR) Animal Health Implementation Committee	Department of Agriculture, Food and the Marine	1
Market Surveillance Forum	Department of Enterprise, Trade and Employment	4
Early Warning and Emerging Trends Group	Department of Health	3
National Clinical Effectiveness Team	Department of Health	3
National Public Health Emergency Team – COVID-19	Department of Health	3
National Valproate Stakeholder Group	Department of Health	1
Medicines Criticality Assessment Group	Department of Health / HSE	5
Connecting for Life Strategy	Department of Health / National Office of Suicide Prevention / National Suicide Research Foundation	3
Committee for Cosmetics and Consumer Health	EDQM	1
European Network of Official Cosmetics Control Laboratories (OCCL)	EDQM	2
General OMCL Network Advisory Group	EDQM	3
OMCL Network General Annual Meeting	EDQM	1
OMCL Network MRP/DCP/CAP Annual Meeting	EDQM	1
Biological Working Party	EMA	11
Clinical Trials Information System (CTIS) – Member State Training	EMA	26

Committee/Working Group	Organisation	Meetings in 2022
Committee for Advanced Therapies (CAT)	EMA	11
Committee for Medicinal Products for Human Use (CHMP)	EMA	11
Committee for Medicinal Products for Veterinary Use (CVMP)	EMA	11
Committee for Orphan Medicinal Products (COMP)	EMA	12
Committee on Herbal Medicinal Products (HMPC)	EMA	6
COVID-19 EMA Pandemic Task Force	EMA	2 per week
Efficacy Working Party - Veterinary	EMA	3
ESVAC (European Surveillance of Veterinary Antimicrobial Consumption) Annual Network meeting	EMA	1
EU Industry Standing Group	EMA	1
European Shortages Monitoring Platform	EMA	1
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	EMA	3
GCP inspection procedures and guidelines (sub-groups of GCP-IWG)	EMA	11
GCP IWG / CMDh Joint Meeting	EMA	1
Good Clinical Practice (GCP) Inspectors' Working Group	EMA	2
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group	EMA	4
IRIS Change Champions Group	EMA	1
Management Board	EMA	4
Medicine Shortages Single Point of Contact Working Party	EMA	27
Network ICT Advisory Committee	EMA	4
New EU Veterinary Regulation 2019/6 (GMDP-IWG sub-group)	EMA	3
New Veterinary Regulation Expert Group-		
Drafting of GMP for VMPs and Actives	EMA	9
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) - Organisational, Regulatory and Methodological Matters (ORGAM)	EMA	7
Pharmacovigilance Risk Assessment Committee (PRAC) – Plenary	EMA	11
Pharmacovigilance Working Party - Veterinary	EMA	6
PV Inspectors Working Group – Training Group	EMA	1
Quality Review of Documents Working Groups	EMA	3
Quality Working Party	EMA	4
Safety Working Party – Veterinary	EMA	2
Scientific Advice Working Party - Human	EMA	11

Committee/Working Group	Organisation	Meetings in 2022
Scientific Advice Working Party – Veterinary	EMA	11
Signal Management Review Technical Working Group (Methods) – PRAC	EMA	4
Signal Management Review Technical Working Group (SMART) Processes – PRAC	EMA	4
Subgroup of the ICH Expert Working Group for the Revision of the ICH Q9 Guideline	EMA	5
EMA/IWG/EDQM Sartans Sub-group	EMA / EDQM	3
Eudralex Volume 4, Annex 21 Working Group	EMA / National Competent Authorities	1
Health Advisory Committee	Environmental Protection Agency	1
National Persistent Organic Pollutants Forum	Environmental Protection Agency	1
Clinical Trials Coordination and Advisory Group (CTAG)	European Commission	4
Competent Authorities for Organ Donation and Transplantation	European Commission	2
Essential Use Workshop Plenary (Cosmetic Products)	European Commission	1
EU4H11 Project Working Group (Medicines)	European Commission	2
European Product Compliance Network (EUPCN) – Market Surveillance	European Commission	7
Expert group on clinical trials (CTEG)	European Commission	3
Expert Group on Precursor Chemicals	European Commission	2
Expert Sub-Group on Vigilance for Blood, Tissues and Cells, and Organs (VES)	European Commission	7
Information Session (EC Chemical Strategy Impact on Cosmetic Products)	European Commission	1
Joint Action (JA07) – Pilot: Novel Blood, Tissues and Cells Preparation Processes	European Commission	3
MDCG – Annex XVI	European Commission	3
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 – Post Market Surveillance and Vigilance (PMSV)	European Commission	3
MDCG – Standards	European Commission	2

Committee/Working Group	Organisation	Meetings in 2022
MDCG – Unique Device Identification (UDI)	European Commission	1
Medical Device Coordination Group (MDCG) (MDR / IVDR)	European Commission	5
National Contact Points for the Implementation of Directive 2010/63/EU	European Commission	2
Pharmaceutical Committee	European Commission	3
Platform of European Market Surveillance Activities in Cosmetics (PEMSAC)	European Commission	2
Standing Committee on Cosmetic Products	European Commission	3
Standing Committee on Veterinary Medicinal Products	European Commission	3
UNICOM WP3 (Digital Forms) Working Group	European Commission	4
UNICOM WP4 (IDMP Adoption) Working Group	European Commission	4
Working Group on Cosmetic Products	European Commission	3
Workshop on the Application of the EU Cosmetics Regulation (1223/2009)	European Commission	1
Workshop on the revision of the Cosmetic Regulation	European Commission	1
Food Fraud Task Force	Food Safety Authority of Ireland (FSAI)	1
Clinical Trials Coordination Group (CTCG)	HMA	6
Clinical Trials Coordination Group Safety Roundtable	HMA	11
Clinical Trials Facilitation and Coordination Group (CTFG)	HMA	1
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
EU-IN Borderline Products Classification Subgroup	HMA	8
EU NTC Training Steering Group meeting	HMA	1
Heads of Agency Meeting	HMA	4
Homeopathic Medicinal Products Working Group	HMA	1
Joint GCP IWD/ CMDh Working Party	HMA	4
Pharmacovigilance Work-sharing Procedures Working Party	HMA	4
Working Group of Communications Professionals (EU Presidency)	HMA	2
Working Group of Enforcement Officers (WGEO)	HMA	10
Working Group of Quality Managers	HMA	2
Risk Assessment Tool for Surveillance Testing	HMA / EDQM	12
Communications Working Group Meetings	HMA / EMA	40+
EU Innovation Network (EU-IN)	HMA / EMA	10
EU Innovation Network Borderline Classification Group	HMA / EMA	7
Clinical Trials Coordination Group Assessor Roundtable	HMA/EMA	21
Task Force on the Availability of Authorised Medicines	HMA/EMA	15

Committee/Working Group	Organisation	Meetings in 2022
National Patient Safety Alert Committee	HSE	2
National Cosmetics Surveillance Forum	HSE Environmental Health Service (EHS)	2
ICH Expert Working Group: Revision of the ICH Q9 Guideline on Quality Risk Management (and other Sub-groups)	ICH	20
ICH Q13 (Continuous Manufacturing) EWG	ICH	2
ICMRA COVID-19 Vaccine Pharmacovigilance Network	ICMRA	10
ICMRA Real-World Evidence Meeting	ICMRA	1
Safety Features Oversight Group	IMVO / PSI / Department of Health	5
Safety Features Meetings	IMVO, European Commission, and other Stakeholders	11
Operation Pangea	Interpol	4
Revision of ICH Q9 Guideline	ISPE	1
Overprescribing Working Group	Medical Council	3
HPRA Medicines Shortages Framework	Multiple Stakeholders	1
Consultation by National Cancer Control Programme: Contingency Manufacture of Compounded Products	NCCP & PSI	2
CGTV Forum	NIBRT	1
Expert Group on Pharmaceuticals and Medical Devices	OECD	1
Meeting of Organs Competent Authorities	Organ Donation and Transplant Ireland	3
PFIPC Liaison Meetings	Permanent forum on International Pharmaceutical Crime (PFIPC)	2
Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Executive Bureau	PIC/S	1
PIC/S 50th Anniversary Organising Committee	PIC/S	9
PIC/S Expert Circle on Quality Risk Management	PIC/S	18
PIC/S Secretariat	PIC/S	1
PIC/S Sub-Committee on Harmonisation	PIC/S	2
PIC/S Sub-Committee on Training	PIC/S	4
Shortages: Information Sharing across International Inspectorates	PIC/S	1
NIAC COVID-19 Working Group	RCPI	21
National Immunisation Advisory Committee (NIAC)	Royal College of Physicians of Ireland (RCPI)	6
Anti-Doping Committee	Sports Council	1
Internet Working Group	WHO	5

HPRA
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