Annual Report 2020

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Contents

2020 Statistics at a Glance	2
Chairperson's Statement	4
Authority Members	6
Management Committee	7
Chief Executive's Report	8
COVID-19 Response	11
Preparing for Brexit	15
Human Medicines	18
Medical Devices	26
Blood, Tissues and Organs	31
Veterinary Medicines	33
Scientific Animal Protection	36
Controlled Drugs and Precursor Chemicals	38
Cosmetic Products	40
Other Regulatory Programmes	41
Outreach and Engagement	43
Organisational Development	46
Authority and Committees	49
Financial Statements	51
Appendices	73

2020 Statistics at a Glance

Top 10

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

119

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

183

medical device economic operators registered with the HPRA – a significant increase on previous years

424

new human medicines authorised during 2020

73

applications issued for clinical trials of human medicines

10

MRP/DCP lead member state roles for the assessment of veterinary medicines

562,397

regulatory submissions made through the Common Electronic Submission Portal (CESP) managed by the HPRA

3,539

export certificates issued – 1,019 certificates for medicines and 2,520 free sale certificates for medical devices

56

the number of centrally authorised human medicines where the HPRA was EU rapporteur for aspects of safety monitoring and risk management

7,752

suspected adverse reaction reports for human medicines received

391

reports of suspected adverse reactions associated with the use of veterinary medicines

1,668

medical device vigilance reports received and assessed

1,120

market surveillance cases undertaken in respect of medical devices

85

medicine recalls consisting of 72 human medicines and 13 veterinary medicines

63

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

300

reactive surveillance cases initiated for cosmetic products

1,610,295

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

620,000+

website users during the past 12 months

Chairperson's Statement

It gives me great pleasure to introduce the 2020 Annual Report, which outlines the extensive work of the HPRA during what was a remarkably busy and challenging year for many reasons.

COVID-19 and Brexit Response

In February 2020, Ireland saw its first official cases of COVID-19. As we know, the first nationwide lockdown soon followed in March and for the remainder of the year, Government would implement restrictions in a cyclical manner to protect public health as levels of disease in our communities continued to fluctuate. To complement the necessary public health guidelines, it was soon apparent safe and effective vaccines would be required to ultimately control the pandemic and limit the threat to public health. Within a year of the first reported cases of COVID-19, this had been achieved, enabling the initiation of national vaccination campaigns across Europe before year-end.

To move from the discovery of such a deadly virus to the development of safe and effective vaccines providing such significant levels of protection, within a year, is an incredible achievement. While it became possible due to a range of significant scientific developments and interventions, we must also recognise the importance of the adapted regulatory procedures to safely accelerate the authorisation of emergent vaccines. Committed experts from across the HPRA provided an exceptionally important public service through their contributions to both the national, and indeed European, COVID-19 pandemic response. During the first wave of the pandemic at a national level, the HPRA worked tirelessly in partnership with the Department of Health, the Health Service Executive (HSE), healthcare professionals and industry stakeholders to minimise and proactively address any risks posed to the supply of medicines and medical devices to Irish patients. This partnership approach, developed in preparation for Brexit, delivered as intended and helped to ensure continued access to health products across the health system during a time of unprecedented demand internationally.

I would like to acknowledge as well the success of the cohesive and strategic approach taken by the agency in response to the UK's decision to leave the EU. Thanks to the very significant efforts of the HPRA at national and EU level, Ireland was able to maintain supplies of critical human and veterinary medicines, and medical devices into the country and avoiding the very real potential for disruption to supply presented by Brexit. Again, the HPRA's engagement with key public health stakeholders demonstrates the importance of an integrated health system to deal with threats posed by significant external changes in our operating environment.

Strategic Plan

Following the successful implementation and completion of the organisation's last strategy from 2016-2020, we look forward to the next period in development and advancement of the HPRA. Our new strategic plan sets out our ambition for the next five years beginning 2021 to deliver better outcomes for people and animals through value-driven regulation and partnerships.

Building on our partnerships with others is a key theme of this five-year strategy. Significant and meaningful engagement with the broader health sector, and indeed patients, is central to our future effectiveness. Working with national agencies, professional bodies and patient groups can help us regulate more effectively taking into account the needs of the health system, while our input into relevant parts of the system can influence the safe use and availability of health products in clinical practice. The twin challenges of Brexit and COVID-19 have also demonstrated the need for, and value of, working collaboratively at a regional and global level.

The strategy was progressed in a highly collaborative way, with development overseen by the Authority and the CE, but also involving staff, the statutory advisory committees and the organisation's network of experts. External consultation also provided important feedback from many stakeholders, which helped guide the development of the plan. I believe the new strategy is suitably ambitious, comprehensive and representative of the needs of the many stakeholders served by the HPRA in its role as the national regulator of health products.

Changes within the Authority

Our commitment to succession planning aims to ensure the ongoing availability of the necessary knowledge, skills and technical competencies required at Authority level. We have seen the benefits of this work as we welcomed two new Authority members, Prof. Richard Reilly and Dr. Joe Collins. Both Richard and Joe are already contributing effectively to the Authority and have taken on the roles of chair to the advisory committees for medical devices and veterinary medicines, respectively. I believe the HPRA is well positioned to leverage from their vast knowledge and experience, which will complement the deep expertise of the current Authority members.

As my own term came to an end in December 2020, so too did those of Profs. Caitriona O'Driscoll and David Kerins. Caitriona and I both joined the Authority in 2011 and I wish to pay tribute to her dedicated and expert service during this lengthy period. David joined the Authority in 2019 and immediately agreed to take the role of Chair of the Advisory Committee for Human Medicines, having already been an active contributor to the Committee for over 10 years. Both Caitriona and David gave generously of their vast knowledge and experience and I wish to thank them both for their huge contributions as valued members of the Authority.

In addition, I would like to take this opportunity to wish Mr. Michael Donnelly the very best of luck as he begins his tenure as Chairperson. It is an exciting period of growth and development for the organisation as the HPRA management team and staff, supported by the Authority, commences implementation of year one of the new strategy.

Acknowledgements

On behalf of the Authority, I would like to thank the Minister for Health, the Minister for Agriculture, Food and the Marine, their advisors and the staff of their departments for their ongoing support of the HPRA and its activities.

I would also like to express my gratitude to the Chief Executive, the Management Committee and everyone from across the organisation for their continued commitment to protect and enhance both public and animal health. I am certain that their unflinching dedication to this goal, as shown so clearly during a year of unprecedented challenge, will ensure the HPRA continues to deliver for patients and animals alike.

Personal Reflections

I would like to thank all of my fellow members of the Authority, both past and present, for their dedication, support and solidarity. I also wish to acknowledge the contributions of the many experts, including the Chairs and members of the HPRA advisory committees and sub-committees, whose advice and expertise is of such immense value to the organisation. On a personal note, I found both my time as Chairperson, and as an Authority member prior to that, to be a hugely enjoyable and professionally rewarding experience. It has been a privilege and an honour to serve in such an expert organisation that fulfils such a crucial role on behalf of the Irish public.

Ms Ann Horan
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 2020 were:

Ms Ann Horan (Chairperson)
Term ended 31 December 2020

Mr Joe Collins
Appointed 28 September 2020

Prof David Kerins
Term ended 31 December 2020

Mr David Holohan

Prof Caitriona O'Driscoll
Term ended 31 December 2020

Mr Brian Jones

Prof Richard Reilly
Appointed 1 January 2020

Prof Elizabeth Keane

Dr Diarmuid Quinlan

Management Committee

The members of the Management Committee in 2020 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

Dr Caitríona Fisher
Director of Quality, Scientific Affairs and Communications

Mr John Lynch
Director of Compliance

Dr Niall MacAleenan
Director of Medical Devices

Ms Lynsey Perdisatt
Director of Human Resources and Change

Ms Grainne Power
Director of Human Products Authorisation and Registration

Chief Executive's Report

As always, it is a great pleasure to give my foreword to the HPRA's annual report and to highlight the achievements of the year that has past.

COVID-19 Pandemic Response

The COVID-19 pandemic has affected almost every facet of life in 2020. Unfortunately, we have all seen harrowing stories of the devastating effects of COVID-19, but we have seen equally extraordinary and inspirational efforts of frontline healthcare workers – both here at home and across the world – to care for those suffering from this terrible disease. Just as extraordinary has been the global scientific response by biomedical researchers to develop therapeutics and vaccines to treat and prevent this disease, and ultimately control the pandemic. We have witnessed incredible scientific achievements, possibly the most remarkable of which in 2020 was the first phase one clinical trial of a COVID-19 vaccine commencing less than two months after the genetic sequence of SARS-CoV-2 was first published. It has been an incredible year for biomedical research, and indeed the global medicines regulatory community.

Protection of public health is foundational to every aspect of our work, and I am extremely proud of the HPRA and the role we have played in the national COVID-19 response. For several years, we have emphasised the importance of collaboration in carrying out our role to ensure better outcomes for public and animal health protection. Throughout 2020, the HPRA has provided expert regulatory support to colleagues from across multiple levels of government responsible for health service delivery, in addition to sustained engagement with healthcare professionals and patients. Because of our engagement and partnership with colleagues from across the broader national health care system, I believe there is now a greater understanding and appreciation of the HPRA's role as it relates to medicines, medical devices and other health products in protecting and enhancing public health.

In addition to our role in the national COVID-19 pandemic response, the HPRA has also contributed to a range of activities at European level, not least of all through the provision of strategic direction and leadership within the European Medicines Regulatory Network (EMRN). Moreover, representatives from across the organisation have expertly contributed to various pandemic preparedness activities through European Medicines Agency (EMA) scientific committees, task forces and working groups, in addition to our involvement in EMA scientific assessment of COVID-19 therapeutics and vaccines. We have also worked steadfastly with other health stakeholders throughout the year at both national and European level to support the availability of critical medical devices such as ventilators, diagnostics and personal protective equipment.

The impacts of COVID-19 will remain with us for some time and as part of this, we will continue to closely monitor the safety of vaccines to ensure the benefits of vaccination continue to outweigh any risks. Following the introduction of an extraordinary suite of adapted regulatory procedures, the HPRA and the broader global regulatory community are committed to a period of reflection to consider the learnings from this. What is interesting is that as regulators we are not just considering the success of these adapted regulatory procedures on a national or even European basis, but on a global level through the work of the International Coalition of Medicines Regulatory Authorities (ICMRA). There is a real opportunity not only for more agile value-add regulatory approaches, but also greater harmonisation and convergence across global regions. Positioning patient safety and wellbeing at the heart of all decision-making will ultimately facilitate robust, effective and sustainable regulation.

Success of the Shortages Framework

Over the last number of years, we have invested resources to develop a framework to ensure enhanced management of medicines shortages nationally. This work is progressed through close cooperation with the Department of Health and the HSE in addition to our engagement with a range of stakeholders, including manufacturers, marketing authorisation holders, wholesale distributors, healthcare professionals, patients and representative groups. The return on investment and success of the framework has been clear, particularly in the context of both Brexit and COVID-19. Through our engagement with key stakeholders, Ireland has been able to manage the supply of critical medicines to meet healthcare demands and avoid any shortage of critical medicines despite the significant difficulties presented by Brexit and COVID-19, respectively.

Brexit

The work of our internal cross-departmental task force, which was established to inform HPRA Brexit planning, continued throughout 2020. This was in addition to considerable engagement with key stakeholders including the Department of Health, the HSE, the European Commission, European National Competent Authorities (NCAs), marketing authorisation holders and distributors. As a result of the tireless efforts of all involved, the potential risk to the supply of critical medicines and medical devices was essentially avoided. Apart from a very small number of cases, for which alternatives were available, supply was preserved. That said, the long-term risk posed by Brexit may only become apparent in the coming years. As a result, we will continue to monitor the situation closely and engage with key stakeholders to ensure the supply of medicines and medical devices.

Looking Ahead to 2021 and Beyond

We have seen how an integrated public health system can achieve incredible progress to protect public health in response to one of the most devastating global pandemics in over a century, in addition to mitigating the very significant potential disruption to the supply of medicines resulting from Brexit. Now more than ever, stakeholders from across the health system, in addition to the biopharma and medtech industries, must continue to work collaboratively, to ensure continued access to safe and effective medicines, medical devices and other health products.

As we embark on the implementation of the next iteration of the HPRA's new strategic plan, I am excited to build and sustain new and existing partnerships with colleagues from across the national public health system, in addition to maintaining positive working relations with researchers to support innovation. We have set ambitious goals and objectives, and from a personal perspective, I have truly enjoyed working with our Authority in shaping the next stages of the HPRA's development. Thanks to their vision and strategic oversight, I believe the HPRA will continue to excel in health product regulation through science, collaboration and innovation.

Acknowledgements

I wish to thank and acknowledge the Ministers and staff of the Department of Health and of the Department of Agriculture, Food and the Marine for the support, co-operation and collaboration with the HPRA on a range of activities during what has been a challenging year.

On behalf of the Management Committee and all our colleagues, I want to sincerely thank the outgoing members of the Authority and advisory committees for their valuable contribution and commitment to the HPRA over a number of years. Their independent expertise and advice has been of immense value to the workings of our organisation. In particular, I wish to acknowledge the strategic input and leadership provided by the outgoing Authority Chairperson, Ann Horan, and thank her for the considerable time and energy she has devoted to her role as Chair, which followed an initial period as a member of the Authority. I would also like to take this opportunity to welcome our new Authority Chairperson, Mr. Michael Donnelly. I very much look forward to working together with Michael and all the Authority members to ensure the HPRA continues to achieve its strategic goals and objectives, and continues to protect and enhance public and animal health into the future.

Finally, I would like to thank all my HPRA colleagues, and emphasise again how incredibly proud I am of everyone within the organisation. We have made, and will continue to make, a real difference in peoples' lives through the work we do every day. Despite the difficult circumstance presented by the pandemic, we have all come together as a team to protect and enhance public and animal health. The level of commitment shown by everyone in the HPRA is what makes me so proud of our organisation.

Dr Lorraine Nolan

Chief Executive

COVID-19 Response

Background

On 31 December 2019, the WHO Country Office in China was notified of a cluster of viral pneumonia cases in Wuhan, the capital of Central China's Hubei province. By late January 2020, the zoonotic SARS-CoV-2 virus had already been identified as the cause of this viral pneumonia, with the respiratory disease becoming known as COVID-19. The WHO ultimately declared COVID-19 a pandemic on 11 March, having already spread to 114 countries, resulting in more than four thousand deaths. With that announcement, SARS-CoV-2 became the first coronavirus to cause a global pandemic.

While COVID-19 has spread rapidly both within and between countries, the volume of published scientific research investigating almost every aspect of this disease was equally as rapid. By the end of 2020, there was approximately 100,000 COVID-19 related scientific publications, representing the greatest surge in biomedical research on a single topic in documented history. Within weeks of identifying the first cases of viral pneumonia, clinical trials were already underway investigating the safety and efficacy of experimental vaccines to protect individuals against COVID-19 disease.

HPRA Regulatory Response

In an effort to ensure the availability of safe and effective COVID-19 therapeutics and vaccines, in addition to supporting the rate at which biomedical research was progressing throughout 2020, medicines regulators, including the HPRA, implemented a range of adapted regulatory processes and procedures to meet healthcare demand for critical health products. There are many examples of the application of adapted regulatory agilities to

ensure access and availability of medicines, medical devices and other products to protect public health. Of particular note, there has been:

- Accelerated assessments for therapeutics and vaccines required in the context of the pandemic including the provision of rapid scientific advice and the implementation of rolling reviews and expedited assessment of conditional market authorisation (CMA) applications to safely accelerate the access to safe and effective products;
- The use of the exceptional change management processes for post-approval changes for medicines and vaccines required for the treatment and prevention of COVID-19;
- Greater use of technology to disseminate product information to healthcare professionals and patients;
- Adaptation of various regulatory compliance requirements to take account of the switch in the working environment for manufacturing facilities, specifically, the transition from on-site to remote inspections.

To ensure continued access to critical medicines and medical devices, and to support the broader national pandemic response from a regulatory perspective, there has been a range of cross-functional activities and work-related agilities introduced across the HPRA. Significant engagement and collaboration with colleagues from the wider public health system further complemented these adapted regulatory procedures introduced to ensure the continued supply of critical health products. HPRA specific COVID-19 related activities and significant engagements with external health system partners undertaken by the HPRA include the following:

Medicines Availability and Authorisation

- Participated in COVID-19 planning with the Department of Health, the HSE and the National Immunisation Office (NIO) through participation in the National Public Health Emergency Team (NPHET).
- Worked in partnership with the Department of Health and the HSE to minimise and proactively address any risks posed to the ongoing supply of medicines to Irish patients. This work involved liaising closely with industry stakeholders (including representative bodies, manufacturers and wholesalers) and healthcare professionals, with the objective of mitigating and, where possible, preventing shortages so that there remained continued access to medicines for patients with COVID-19.
- Worked with the Department of Health and Health Research Board Clinical Research Coordination Ireland (HRB CRCI) to facilitate the establishment of the WHO SOLIDARITY Trial.
- Collaborated with the Department of Health and the Office of National Research Ethics Committee to support expedited regulatory review for COVID-19 related health research.
- Contributed to multiple ad hoc meetings of working parties and committees to support rolling reviews and expedited timelines associated with conditional marketing authorisation (CMA) assessments for COVID-19 vaccines and therapeutics.
- Co-operated with the drafting and development of HSE clinical anti-viral guidance for therapeutics used in the treatment of COVID-19 disease.
- Active engagement in the assessment of COVID-19 vaccines and therapeutics at the EMA's committee for human medicines (CHMP) and its COVID-19 EMA pandemic task force (COVID-ETF).

Medicines Safety Monitoring

- Published regular COVID-19 specific safety updates detailing the national reporting experience, in addition to communication of the latest safety information to healthcare professionals via dedicated Drug Safety Newsletters (DSN) and direct healthcare professional communications (DHPC).
- Provided rapid scientific assessments and communication of emerging safety issues to support HPRA colleagues at NPHET, as well as the HSE and Department of Health.
- Actively contributed to newly established COVID-19 safety monitoring activities, at both national and European level, including:
  - Assessment of safety issues associated with repurposed therapeutics, including, for example, non-steroidal anti-inflammatory drugs (NSAIDs), angiotensin receptor blockers (ARBs), angiotensin converting enzyme (ACE) and hydroxychloroquine;
  - Participation in working groups aimed at vaccine pharmacovigilance and safety monitoring preparedness;
  - Significant involvement in the EMA's Pharmacovigilance Risk Assessment Committee (PRAC).
- Conducted accelerated assessment of the marketing authorisation applications for both therapeutics and vaccines.
- Provided regulatory support concerning COVID-19 vaccines to the National Immunisation Advisory Committee (NIAC).

Compliance

- Adopted a suite of extraordinary risk-based flexibilities to ensure the continued availability of medicinal products, including:
  - Manufacturing requirements;
  - Importation of finished products and active ingredients;
  - Variations requests;
  - Changes to good practice (GxP) inspections, transitioning from on-site to fully remote or combined inspections.
- Led on the development of an EMA guideline on remote inspections and distant assessments.
- Worked together with colleagues from An Garda Síochána and Revenue's Customs Service to proactively monitor the supply chain for unauthorised or falsified COVID-19 health products. Additionally, monitored and responded to the advertising and promotion of unauthorised/non-compliant treatments and medical devices purported to be for the detection, cure or prevention of COVID-19.

Medical Devices

- Worked as part of the medical devices criticality assessment group, a subgroup of NPHET to provide regulatory advice and input on relevant medical devices. The HPRA was also a member of the NPHET subgroup on diagnostic testing approaches.
- Developed a specific process for COVID-19 regulatory derogations for critical non-CE marked devices where there is an identified urgent public health need.
- Worked closely with the Health Information and Quality Authority (HIQA) to support rapid health technology assessment of alternative diagnostic testing for SARS-CoV-2, as well as working with the Health and Safety Authority (HSA), the Competition and Consumer Protection Commission (CCPC) and the National Standards Authority of Ireland (NSAI), in relation to products such as facemasks, gowns and gloves.
- Provided regulatory support to the Department of Health regarding the use of antigen diagnostic tests (ADTs) and rapid antigen diagnostic tests (RADTs).

Future Pandemic Response

Continued Regulatory Support and Interaction with Public Health Partners

While significant progress has been made in the authorisation of safe and effective therapeutics and vaccines in response to the COVID-19 pandemic, the HPRA's regulatory responsibilities will continue throughout the coming year. Importantly, the HPRA will continue to provide regulatory support in respect of medicines and medical devices to, or as part of, a range of public health partners, including the Department of Health, NIO, NPHET, NIAC and the High-Level Task Force on COVID-19 Vaccination. As vaccines and indeed therapeutics progress through their life cycle, the timely communication to health system partners of any post-authorisation changes affecting the optimal use of these products will be critically important. Of significance, the HPRA will also continue feeding into the general Government and Department of Health communications strategy to ensure alignment of key messaging from a regulatory perspective.

Safety Monitoring of COVID-19 Vaccines

In addition to future assessment of new vaccines and therapeutic candidates, combined with inspection activities to ensure regulatory compliance of authorised COVID-19 related products, extensive safety monitoring will continue throughout 2021 to ensure authorised vaccines remain safe and effective. Following a request to healthcare professionals and members of the public to submit reports of suspected side effects following vaccination, there has been a significant increase in the number of reports received, which allows regulators to monitor vaccine safety and take the most appropriate action required should new or re-emerging safety issues arise.

Planning for Brexit – Annual Update on Progress

The UK left the European Union on 31 January 2020, which commenced a transition period to 31 December 2020 to allow for negotiation of the new relationship between the UK and EU. In June, the UK formally rejected any extension to this period and therefore provided a definitive timeline to prepare for Brexit, with or without a trade agreement. During the transition period, the UK remained subject to EU law and while it could not act as a lead Member State nor participate in the EU institutions, it remained within the economic union and subject to medicines and medical devices legislation.

After some months of negotiations and with all parties preparing for a 'no-deal' on 31 December, the Trade and Cooperation Agreement (TCA) was signed by the EU and UK on 24 December. The TCA came into effect from 1 January 2021 alongside the Northern Ireland Protocol. Late December also saw the EU Commission agreeing to provide four derogations to Ireland (IE), Malta (MT), Cyprus (CY) and Northern Ireland (NI). These exemptions, of one year, were focused on the special characteristics of these markets for medicines and their greater dependency on the UK market. They also reflect the particular needs of Northern Ireland arising out of the NI protocol.

Year-End Emergency Planning

After four years of planning, the end of the transition period would mark a fundamental change to the EU and Ireland's relationship with the UK. With limited progress in negotiations, the HPRA continued its 'no-deal' preparations throughout the year. In this context, the HPRA continued to provide guidance and direction to industry stakeholders based on a requirement for them to carry out all their regulatory changes in advance of the 31 December deadline. This involved confirming that their supply routes were capable of continuing supply to Ireland and reviewing stock levels to ensure that they had sufficient product available in the event of issues affecting entry points to Ireland as well as those in the UK and Europe. This planning included significant engagement with the Department of Health and, through the department, onwards to the 'whole of Government' Brexit monitoring team. Stringent planning was in place to cover all expected and unexpected events as the transition period came to an end.

As with previous years, the HPRA had contingency planning in place covering the following areas:

- Regulatory compliance of medicines and clinical trials authorised on the Irish market;
- Supply chain management and stock levels;
- Exempt medicinal products;
- Shortages protocol;
- Development of a list of essential medicines;
- Communications with stakeholders;
- Medical devices with UK CE marks;
- Veterinary medicines and engagement with the Department of Agriculture, Food and the Marine;
- Engagement within the European regulatory network.

The Trade and Cooperation Agreement

The trade and cooperation agreement (TCA), which was signed on Christmas Eve, provides for no tariffs and no quotas for trade originating in the UK/EU and between these two jurisdictions, provided there are equivalent standards in both jurisdictions. However, no tariffs/quotas does not equate to free trade and all imports/exports are subject to full customs declarations and border inspections. The TCA reflects one positive agreement in an appendix related to medicines whereby UK and EU GMP certificates will be recognised in each other's territories unless a particular issue is identified. Both parties can also choose to recognise each other's third country inspections. This is a positive development and enables a more streamlined and efficient approach to inspection. The TCA also allows for the sharing of information on regulatory initiatives between the UK and the EU and perhaps paves the way for an enhanced relationship in the future.

Northern Ireland Protocol

The Protocol on Ireland/Northern Ireland ('IE/NI Protocol') has been in place since the end of the transition period on 31 December 2020. The IE/NI Protocol provides that the EU pharmaceutical acquis applies to and in the United Kingdom in respect of Northern Ireland and thus a medicinal product placed on the market in Northern Ireland has to comply with the EU acquis for medicinal products. Marketing authorisation applicants who wish to obtain a marketing authorisation for the United Kingdom in respect of Northern Ireland have to meet the requirements of EU medicines law subject to the exemptions that were agreed for 2021. The HPRA has provided guidance on the practical application of these rules.

Key Brexit Pillars – Activities carried out in 2020

The key strategic objective across all areas of Brexit planning remained the protection of supply of medicines and medical devices to patients and animals.

Building on progress achieved during 2019, the following details the main activities and work streams delivered during 2020 in respect of our five Brexit pillars:

1. Stakeholder Engagement and Communications

- There was extensive communications and outreach with all stakeholders. The HPRA contacted all marketing authorisation holders for human and veterinary medicines seeking confirmation of their plans for regulatory compliance, stock levels and supply chains pre year-end.
- All HPRA communication platforms and guidance documents were updated to reflect the impact of the transition period and the Northern Ireland Protocol as well as all emerging information from the European Commission, the EMA and the Heads of Medicines Agencies (HMA).

2. Existing Portfolio of medicines and medical devices

- All medicines, medical devices and clinical trials, which still had an exposure to the UK from a regulatory perspective, were reviewed in detail, particularly during quarter three of 2020. The HPRA had significant engagement with companies, requesting them to transfer all regulatory functions to the EU before 31 December. Regulatory guidance and support was provided to ensure regulatory compliance.

3. Future Work

- The HPRA continued its objective of increasing its contribution to the EU network following the departure of the UK. Second only to Germany in terms of numbers, the HPRA took on the role of reference member state (RMS) for marketing authorisation holders who had previously used the UK as RMS. As outlined elsewhere in the report, the HPRA continues to develop its contribution to the centralised procedures including scientific advice. The HPRA is also increasing its outgoing decentralised work.

4. Leadership/Public Health/Advocacy

- We participated in extensive planning with the Department of Health, the HSE and the Food Safety Authority of Ireland (FSAI) for Brexit particularly at year-end in the lead up to 31 December. In addition, we participated in all Commission and other EU meetings to advocate and promote greater understanding of the potential unique impact of Brexit for Ireland. In particular, the HPRA engaged with the Commission on issues specific to the Irish market such as dual-labelled medicines and the Falsified Medicines Directive.

5. Internal Capability

- Throughout 2020, we devoted expert staff resources to this important area to ensure the availability of sufficient staff levels to manage the implications of Brexit.

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 a number of 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 424. The 2020 figure incorporates:

  – 61 new national applications including 45 parallel import applications;

  – 39 applications made under the MRP and 147 applications made under DCP. The HPRA acted as reference (lead) Member State for the assessment of 23 of these DCP applications;

  – 12 rapporteurships and six co-rapporteurships under the centralised route;

  – An additional 155 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 medicines under the simplified/ national rules schemes.

- 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 2020, the HPRA acted as co-ordinator for 119 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 11 requests under this procedure.

- Participation in clinical trials can enable patients to benefit from new and promising therapies. During 2020, we issued 73 new clinical trial applications, including seven COVID-19 related trials, three of which were voluntary harmonisation procedures with the HPRA acting as lead Member State responsible co-ordinating work-sharing assessments of multinational clinical trials.

- 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. Of note in 2020, a medicine for the treatment of erectile dysfunction was 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 102 active substances or combinations of active substances.

- The Medicines Shortages Framework brings together key players in the health sector with the aim of developing strategies to mitigate the effect of shortages in Ireland. The effectiveness of this multi-stakeholder approach is reflected in an 11% reduction in the number of shortages notified in 2020 compared to 2019.

  This reduction was achieved in spite of significant challenges to medicines' supply and distribution arising from the COVID-19 pandemic. The HPRA worked closely with the Department of Health, the HSE and supply chain stakeholders to quickly address and resolve these issues and ensure continuity of treatment for patients.

  The HPRA is also taking a prominent role in European and international initiatives that have been put in place in recognition of the need to address medicines shortages, which continues to be an ongoing global concern.

- As the use of multilingual labelling continues to be considered as an important means of minimising the impact of Brexit and supporting the availability of medicines in Ireland, the HPRA remains actively involved in progressing this initiative at the HMA level through its Coordination group for Mutual recognition and Decentralised procedures – human (CMDh).

  Significant progress was achieved in 2020, including:

  – The HPRA leading a working group of member states supporting a pilot exercise for the preparation of EU reduced harmonised labelling text for new medicine applications being processed through the mutual recognition/ decentralised procedures and presented this topic at the Interested Parties meetings.

  – Taking a leading role in updating the 'CMDh Best Practice Guide on Multilingual Packaging' to ensure that information on the pilot, and responses to feedback from member states and interested parties on approaches to multilingual packaging, was readily available to marketing authorisation holders.

  – Updating our 'Guide to Labels and Leaflets of Human Medicines' to ensure current advice on development of multilingual labelling was actively available to national stakeholders.

  – Continuing 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 continuity of supply to the market place in the event of a medicine shortage following Brexit, the HPRA has also granted 181 temporary 'batch-specific request' authorisations.

- We continued to monitor the numbers of unauthorised products notified to us through the exempt medicinal product scheme. One aspect of our approach to reducing the risks to patients is to actively seek new marketing authorisation applications for high-volume products currently being imported through this scheme. Two such authorisations were marketed in 2020 with significant assistance from the HPRA.

Authorisation and registration: Key figures	2018	2019	2020
Classification queries/reviews	93	76	88
Scientific advice			
Lead in EMA scientific advice:	78	102	119
National scientific advice	10	20	11
Clinical trial applications	100	88	73
Voluntary Harmonisation Procedures (multinational clinical trials)			
Lead	1	2	4
Participating member state	22	8	7
New medicines applications for marketing authorisations			
National (including new parallel imports)	66	49	61
Mutual recognition and decentralised RMS	25	20	23
Mutual recognition and decentralised CMS	178	229	163
Centralised Rapp/Co-Rapp/Peer reviewer	19	17	18
Traditional herbal medicinal products under the simplified registration scheme	4	2	2
Homeopathic medicines under the simplified/national rules schemes	3	3	2
Variations to marketing authorisations (Type IA, IB, II)	10,077	14,957	12,026
Articles 45 and 46 - Variations to Update Product Information	1	0	1
Renewals of marketing authorisations	597	291	390
Transfer of marketing authorisation holder	801	1,583	202
Manufacturers	127	135	138
Manufacturers of investigational medicinal products	63	69	76
Wholesalers	358	385	379
Registrations for active pharmaceuticals ingredients			
Manufacturers	29	30	29
Importers	67	68	75
Distributors	87	92	102
Brokers	8	8	9
Export certificates	1,319	1,367	1,019
Exempt medicines programme for notification of unauthorised medicine import	3,209,365 packs	2,586,120 packs	2,789,340 packs

Safety and Quality

- Adverse reactions reporting assists the HPRA, in co-operation with pharmacovigilance professionals in Europe and further afield, to look for new types of reactions or changing trends in reports. 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 also include known adverse reactions, such as those described in the product information.

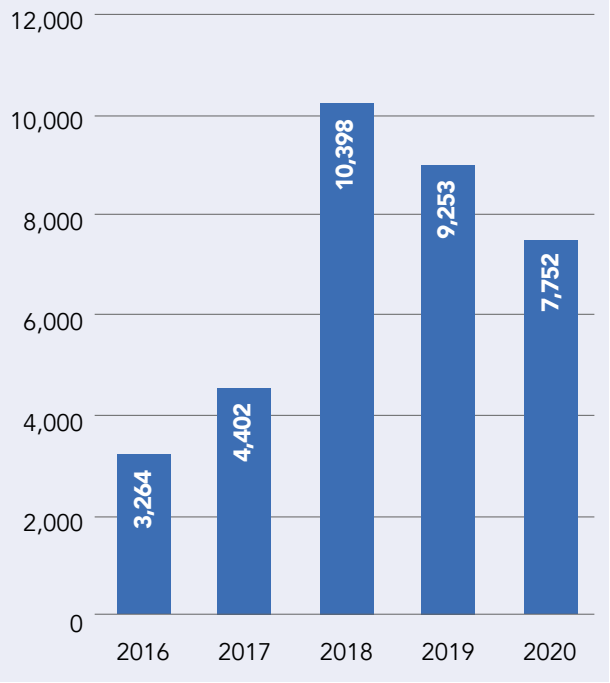
This year:

– 7,752 suspected adverse reaction reports were received associated with the use of human medicines, which represents a 16% decrease in the total number of reports received as compared with 2019.

– This decrease was solely related to cases received from marketing authorisation holders via the Eudravigilance database managed by the EMA, and can be attributed to increased stability in the operation of the pharmacovigilance system in 2019 after changes to the reporting rules across the EU were introduced in November 2017.

– In relation to reports to the HPRA receives from healthcare professionals and members of the public, there was a 19% increase in the total number of reports received as compared with 2019.

Adverse Reaction Reports



– Of the adverse reaction reports received by the HPRA in 2020, 87.6% were reported by marketing authorisation holders, with a further 0.6% 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 18% of the reports submitted.

– The breakdown of reports submitted directly by members of the public and healthcare professionals was as follows:

Sources of Suspected New Adverse Reaction Reports	%
Doctor	16
Patient/Consumer	32
Nurse	29
Pharmacist	19
Healthcare professional - Other	4

– The medicines most frequently included in reports to the HPRA accounted for approximately 80% of the adverse reaction reports received in 2020 (see 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	3,423
Psycholeptic medicines	578
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	525
Vaccines	427
Medicines for the treatment of Diabetes Mellitus	261
Medicines for the treatment of Parkinson's Disease	257
Other nervous system medicines	246
Cardiovascular medicines, including anti-hypertensive, anti-arrhythmic, and lipid lowering medicines	244
Analgesics, including medicines for prevention and treatment of migraine	208
Pituitary and hypothalamic hormones and analogues	199

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

– Of the new adverse reaction reports received by the HPRA in 2020, 137 patients were reported to have died while on treatment. The following table outlines the medicines or class of medicines associated with the highest number of reports. In many of these cases, the patients concerned had significant underlying illness and were treated with multiple medicines and/or surgery, which may also have contributed to the outcome. In addition, many of these cases were influenced by disease progression or other complications unrelated to the medicine. The majority were associated with medicines used in the context of products subject to close monitoring, those used in the management of severe underlying medical conditions, in patient support programmes and special patient monitoring programmes.

Suspect Medicine(s)/ Class of Medicines	Number of Reports*
Antineoplastic medicines, including immune-modulating medicines, monoclonal antibodies and endocrine medicines	55
Psycholeptic medicines	42
Antithrombotic medicines including anti-coagulant and anti-platelet medicines	8
Anti-infective medicines, including antibacterials, antimycotics, antivirals and immunoglobulins	6
Cardiovascular medicines, including anti-hypertensive, anti-arrhythmic, and lipid lowering medicines	4
Pituitary and hypothalamic hormones and analogues	4
Medicines for the treatment of Parkinson's Disease	3
Medicines for the treatment of Epilepsy	3
Medicines used for the treatment of addictive disorders	3
Analgesic medicines	3

* 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 PRAC at the EMA. During 2020, 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 70 nationally-authorised active substances. Serving as PRAC rapporteur, we were also responsible for the further management of any signals detected in relation to 56 centrally authorised medicines (containing 40 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 691 PSURs and leading the single EU assessment for 38 procedures;
  - Participated as a concerned Member State in six ongoing safety referrals, five of which reached a conclusion during the year;
  - Contributed to the review of 408 risk management plans (newly approved or updated) submitted via national, mutual recognition, decentralised and centralised procedures. We also provided assessment input to 557 post-authorisation safety procedures (including safety study protocols, reports and other post authorisation safety-related measures).
- The HPRA continues to engage with multi-stakeholder groups, including patient and clinical practice representatives, to facilitate clinical readiness at national level for new recommendations on the safe and rational use of medicines following major EU benefit-risk reviews.
- Also during 2020, the HPRA progressed a research project, in collaboration with researchers from the Royal College of Surgeons in Ireland (RCSI), to assess the effectiveness of risk minimisation measures to prevent harms from teratogenic medicines. The project was funded through a Health Research Board Applied Partnership Award, bringing together the HPRA as knowledge user and the RCSI as academic researcher.
- The HPRA's inspections programme focuses on ensuring compliance with relevant standards and legislation. This year, there were:
  - 63 good manufacturing practice (GMP) inspections at sites that produce human medicines or active substances;
  - 40 good distribution practice (GDP) inspections at wholesalers and distributors;
  - Six good clinical practice inspections at investigator or sponsor sites;
  - Five pharmacovigilance inspections;
  - One regulatory compliance inspection 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 our monitoring of the quality and safety of medicines on the Irish market and those which are manufactured in Ireland for export. It involves the analytical testing of products and the examination of their packaging and labelling. In 2020, 433 cases were opened under the programme. These included:
  - Examination of the packaging and labelling of 224 medicines. Fifty-eight non-compliances were identified. These included the absence of safety-

related information in package leaflets and summary of product characteristics (SmPCs), a number of braille-related issues on outer cartons, and other packaging and labelling issues. In addition, a number of non-compliances with the Falsified Medicines Directive were identified. Appropriate follow-up actions were taken in each case.

- Analytical testing of 205 medicines and other samples of products. With respect to non-enforcement samples, the majority were found to be compliant with their specifications. However, a number of out-of-specification results were obtained. While the most frequent of these were appearance or reconstitution related, tablet disintegration and tablet subdivision out-of-specification results were also obtained. Appropriate follow-up actions were taken in each case, including the recall of a batch of an unauthorised medicine used to treat COVID-19 patients.
- Usability checks on four medicines were performed, in response to earlier quality defects reports having been received on those medicines. Three of the samples were found to be non-compliant and appropriate follow-up actions were taken.

- 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. Quality defects pertaining to 1,408 medicines for human use were reported or identified in 2020. This represented a 49% increase over the 2019 figure (948). The risk classifications assigned, along with the corresponding figures for the previous years, are outlined in the following table:

Classification	2018	2019	2020
Critical quality defects	325	259	312
Major quality defects	280	291	701
Minor quality defects	308	375	378
Number of reports not justified	12	23	17
Total Number Quality Defects	**925**	**948**	**1,408**

The majority of reports (40%) were submitted by pharmaceutical companies, including manufacturers, distributors and/or marketing authorisation holders, and other competent authorities (37%). Significantly, in 2020, an increased number of reports were also submitted by community pharmacists (20% of the total) through the HPRA online reporting portal.

- In certain cases, it is necessary to withdraw, or recall, medicines from the Irish market in order to protect public health. During the year, 72 human medicines were recalled, for reasons outlined in the table below. This was a significant decrease over 2019, when 125 medicines were recalled. However, in many cases in 2020, Caution in Use Notifications (CIUNs) and Dear Healthcare Professional Communications (DHPCs) were issued for medicines with a quality defect, where a recall action was not initiated or where an out-of-stock situation for a medicine might arise as a result of a quality defect issue. Fifty-two such communications occurred during 2020.

Cause of Recall	Number of Products
Non-compliance with specifications	18
Lack of Sterility Assurance issues	10
Marketing Authorisation Non-compliance issues	8
Non-compliances with GMP	7
Erroneous distribution issues	5
Cold chain/temperature excursions	4
Contamination issues	4
Other causes	16

- The HPRA monitors the sale of certain consumer health products in outlets such as grocery shops, health food shops and, where necessary, pharmacies. During 2020, 22 cases were investigated, some of which involved multiple products. Of these:
  - Twenty one cases related to the sale of medicines that did not carry a valid registration number or authorisation number for the Irish market, resulting in 32 medicines being removed from sale and necessary follow-up actions being taken;
  - One case related to an investigation into a non-compliance with the paracetamol regulations as established by the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

  In addition, 66 queries linked to the sale of health products in Ireland were addressed.

- Under our enforcement programme:
  - The HPRA detained 1,610,295 dosage units (including tablets, capsules and vials) of falsified and other illegal medicines in 2020, compared to 1,018,678 dosage units in 2019. The products detained included sedatives (36%), erectile dysfunction medicines (30%), analgesics (9%) and anabolic steroids (6%). 8,043 enforcement cases were initiated, compared to 6,167 in the previous year;
  - Several HPRA operations took place in conjunction with An Garda Síochána and Revenue's Customs Service. These operations resulted in several large detentions, including, in one case, the detention of over 370,000 erectile dysfunction tablets;
  - We initiated three prosecution cases and issued eleven 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. All three prosecutions 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 XIII 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 2020.
  - In addition, the monitoring of websites, online marketplace advertisements and social media sites throughout the year resulted in the amendment or shutdown of 482 websites, e-commerce listings and/or social media pages.

Legislation and Regulation

- The implementation of new Clinical Trial Legislation, Regulation EU No 536/2014, is provisionally planned for 2022, subject to the development of the Clinical Trial Information System (CTIS) by the EMA.

  The following national activities were progressed during 2020 to support clinical research:
  - We continued to engage with the Department of Health and the National Office for Research Ethics regarding the implementation of the Regulation and the development of national legislation;
  - We continued to offer a pilot project for simultaneous submission of applications to both the HPRA and ethics committee, which enables preparation for implementation of the Regulation. Guidance and templates for sponsors are available on our website;
  - We actively participated in the European voluntary harmonisation project, which is similar to the approval process for clinical trials under the planned new legislation.

- 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 2020:
  - Work on the national implementation and introduction of these measures intensified. We worked with the Irish Medicines Verification Organisation (IMVO), which was responsible for establishing and managing the repository and software systems;
  - We contributed to a national oversight steering group of stakeholders which met regularly to monitor progress on implementation both nationally and across the EU;
  - We contributed to the EU Expert Group on Safety Features and led one of its working groups to develop guidance on supervision of the national repositories of unique identifiers;
  - Notwithstanding these efforts, the drive for full implementation was considerably hampered by the COVID-19 pandemic and the process remained in a 'use and learn' phase at year-end.

Stakeholders and Partners

- There has been significant engagement with a range of partners from across multiple levels of government, including key public health stakeholders responsible for health care delivery in response to Brexit and the COVID-19 pandemic. Please refer to dedicated earlier sections of this report for further detail.

- 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 2020 relevant to human medicines is provided in Appendix 2. As a result of the public health measures introduced in response to the COVID-19 pandemic, presentations were delivered remotely from March onwards.

- Publications and Information
  - The Drug Safety Newsletter provides important safety information to healthcare professionals with hyperlinks to product information and other relevant documents on the HPRA and EMA websites. Five issues of the newsletter were published and distributed to registered healthcare professionals, all of which are accessible from the HPRA website. A full index of topics covered during the past year is included in Appendix 3.
  - Risk communications:
    - During 2020, 113 new or updated educational materials were approved by the HPRA in addition to 22 direct healthcare professional communications.
    - The PRAC monthly agendas, minutes, meeting highlights, notifications of safety reviews and signals were also made available via our website.
  - There were 21 articles provided 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.
  - The Medicinal Products Newsletter provides regulatory news and updates for those working in the pharmaceutical industry. Three editions were published on our website in 2020 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. A number of existing guidance documents were updated during 2020 and are available to download from our website. This includes a number of documents which were the subject of significant revision, including:
    - Brexit guidance - human and veterinary medicines;
    - Guide to biosimilars for healthcare professionals;
    - Guide to new applications and variations to manufacturer's authorisations.

Medical Devices

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

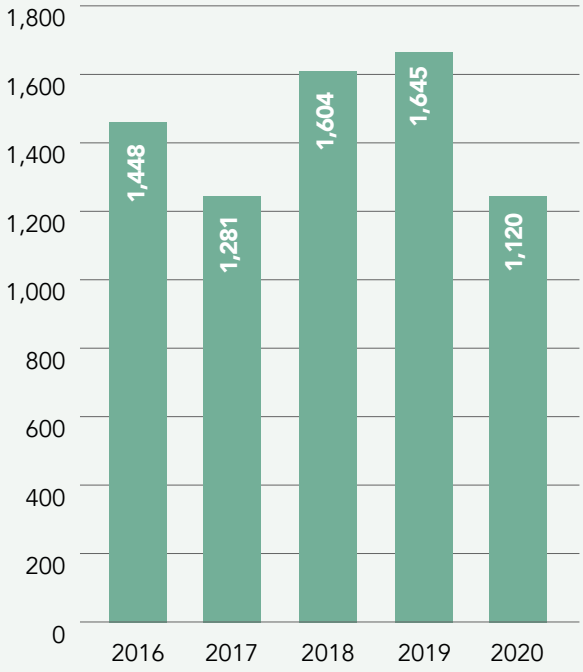
Authorisation and Registration

- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at national and European level. In 2020, we:
  - Designated a notified body in Ireland under the new EU Medical Device Regulation (MDR);
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits;
  - Continued to support development of EU coordination of notified body designation and oversight through participation in the EU Notified Body Operations Group (NBOG) and the Medical Device Coordination Group (MDCG);
  - Worked along 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.
- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2020, this involved:
  - The review of applications to conduct clinical investigations of medical devices in Ireland. The number of clinical investigations increased with nine new applications and six amendments to ongoing investigations. The HPRA anticipates that these numbers will increase further when the new EU Regulations are implemented;
  - 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 met with 11 groups of innovators to discuss potential clinical investigation applications in 2020;
  - The provision of technical, clinical and regulatory support to the work of the HPRA Innovation Office on medical devices queries received.
- Manufacturers of certain medical devices and in-vitro diagnostics (IVDs) are required to register with the HPRA. In 2020, the HPRA registered 183 new medical device economic operators (for example manufacturers, authorised representatives) in Ireland. A total of 20,757 medical devices were also registered. This represented a significant increase in registrations when compared to previous years, some of which is attributable to the UK's exit from the European Union. During 2020, the HPRA estimates that 52 of the 183 economic operators registering in Ireland were as a consequence of Brexit.

Safety and Quality

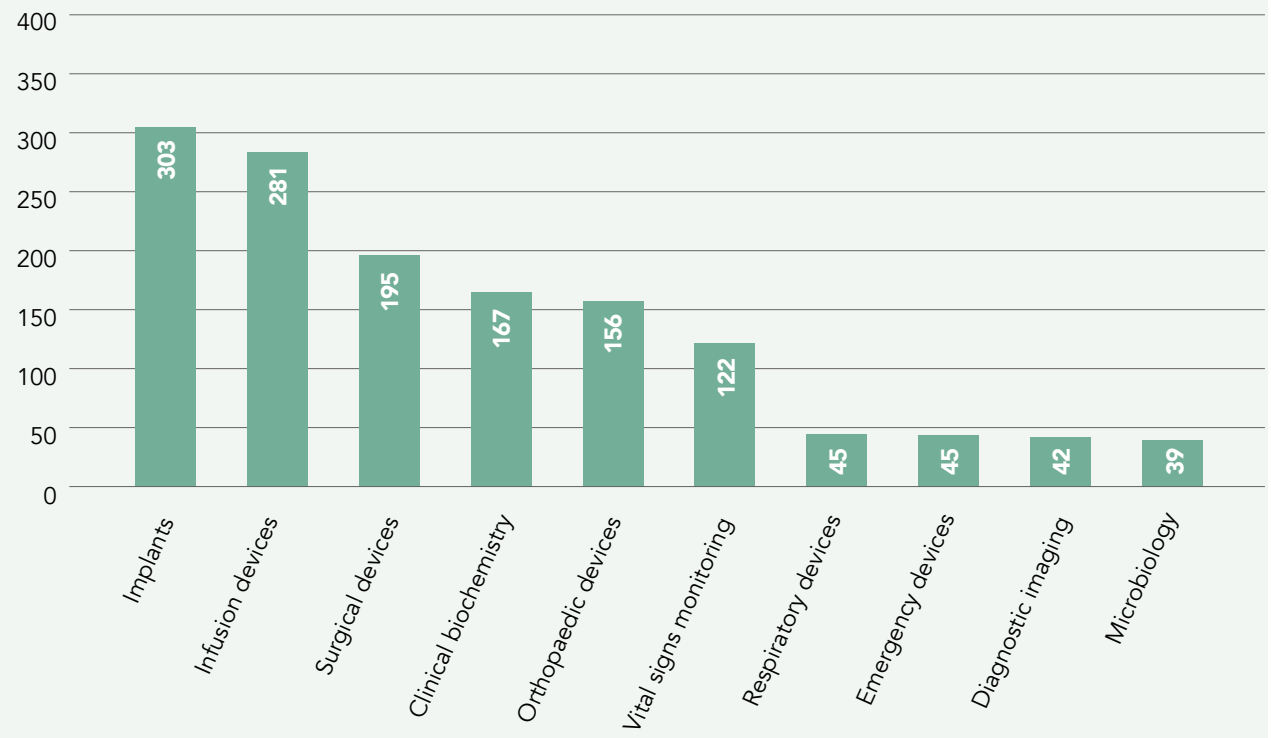
- We continue to develop and reinforce our market surveillance activities, with particular emphasis on proactive rather than reactive actions. Of note in 2020:
  - We further developed our lifecycle market surveillance strategy and planning mechanism to allow for more effective management and reporting of these activities;
  - We concluded work in leading the EU Joint Action on Market Surveillance (JAMS) of a medical devices initiative, funded by the European Health Programme, which aims to develop market surveillance activities at European level. The work programme was completed over a three-year plan and was presented at a European stakeholder conference attended by 15 organisations representing patients, clinicians and other stakeholders, along with 23 national competent authorities and the EU Commission;
  - A total of 18 COEN notices were sent by HPRA to the European network relating to medical device compliance concerns;
  - There were 1,120 market surveillance cases undertaken in 2020, a decrease compared to 2019 due to a significant reduction in the number of certificate notifications from notified bodies. The number of complex assessment and proactive market surveillance activities substantially increased overall in 2020;
  - Significant market surveillance activities were undertaken in the area of medical devices and IVDs used in response to the COVID-19 pandemic. This included work related to thermometers, ventilators, surgical/medical facemasks and surgical gowns in addition to IVDs utilising PCR (polymerase chain reaction), antibody and antigen based diagnostic technologies;
  - A number of information notices were published in relation to IVDs such as falsified tests for COVID-19. Information notices were also published to provide advice to the public about devices such as thermometers and COVID tests;
  - An information notice was also published on cybersecurity vulnerabilities for certain medical devices;
  - We conducted reviews of IVD devices for COVID-19 diagnosis registered with HPRA.

Market Surveillance Cases



- We continued to focus our vigilance activities during 2020 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:
  - The receipt and assessment of 1,668 medical device vigilance cases, a decrease compared to 2019. Of the reports received in 2020, manufacturers accounted for 76%, 17% came from other competent authorities and 6% were received from users. Of the 956 incident reports notified directly to the HPRA, 11% came from users of medical devices;
  - There were 301 field safety corrective actions (FSCA) associated with the national market including 77 product removals conducted in Ireland during 2020;
  - We issued 106 national competent authority reports, four notified body forms and one vigilance enquiry form;
  - We also issued 14 safety notices in relation to medical device issues and 17 direct to healthcare professional communications;
  - Implants, infusion devices, surgical devices and orthopaedic devices accounted for 56% of the total vigilance reports. Reports continue to be received relating to in-vitro diagnostic devices in the area of clinical biochemistry (10% of reports) and medical devices in the areas of vital signs monitoring (7% of reports) and respiratory devices (3% of reports);
  - During the year, we also continued development work on signal detection of medical device issues.

Vigilance Reports Received – Top 10 Product Types



- As part of its market surveillance activities, the HPRA undertakes proactive and 'for-cause' audits of manufacturers, notified bodies and authorised representatives with the objective of monitoring compliance of devices emanating from Irish based organisations. During 2020, ten audits were performed at notified bodies, medical device manufacturers and authorised representative facilities, of which:
  - One was a for cause audit;
  - Nine were based on proactive market surveillance projects and notified body surveillance/ assessment.

Legislation and Regulation

- The Medical Device Regulation (Regulation (EU) 2017/745) was due to become fully applicable in May 2020. Due to the impact of COVID-19, and the unprecedented pressure on the health services and the medtech sector, the date of application of this regulation was deferred to May 2021. We continued our work during 2020 to help ensure an effective and timely implementation of these EU Device Regulations (EUDR) at national and European level. This included:
  - Continued work on the HPRA programme plan for continued development of appropriate resources, processes and systems to meet our obligations under the new regulations;
  - Engagement with key stakeholders in the sector to ensure awareness to the impact of the regulations and the development of guidance and communication initiatives;
  - Working with the Department of Health and key 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 involving implementing and delegating acts;

  - Participating in the EU Medical Device Coordination Group (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 2020, this included:
  - Continued participation in to the Executive Group of the CAMD network;
  - Participation in the CAMD's Operations Working Group (OWG) which aims to improve co-ordination and consistency of implementation of the new EU Regulations and prioritise implementation activities in the short, medium and long term;
  - Continuing to lead the work of the clinical investigation and evaluation working group (CIEWG), acting as the co-chair along with the EU Commission.

- In early 2020, the HPRA led calls in Europe for a readiness check for implementation of the MDR, which resulted in the Commission's Joint Implementation Plan agreed in March 2020. Throughout the year, our focus remained on identifying and promoting discussions on practical measures for implementation of the system to ensure the system operates effectively in practice.

- At national level, we further developed our national fee-based funding model for medical devices to recover costs associated with our medical device activities. The model was revised in 2020 to streamline the approach and to ensure that new activities under the MDR are accounted for when MDR becomes fully applicable in May 2021.

- 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, France and Germany);
  - Continuing to act as the IMDRF secretariat for the National Competent Authority Report (NCAR) Exchange programme;
  - Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review.

Stakeholders and Partners

- The advent of the COVID-19 pandemic had an unprecedented and significant impact on all stakeholders – patients, health services, industry, notified bodies and on government departments and agencies. The HPRA worked with key stakeholder groupings to provide guidance on the regulatory framework for devices and IVDs in the context of COVID-19. Interagency processes were developed to ensure CE marked critical medical devices were available to Irish health services and available to Irish patients. A specific medical devices COVID-19 webpage was launched and updated regularly with guidance and information on key aspects of medical device regulation linked to managing the treatment of patients with COVID-19.

- In January 2020, Brexit was formalised with the UK departure from the EU. Our work to ensure preparedness for the end of the withdrawal agreement between the EU and the UK continued throughout the year. A number of stakeholder briefings and guidance materials were developed specific to the medical devices sector as well as participating in relevant EU taskforces on the certification capacity of notified bodies following the withdrawal of UK notified bodies.

- Our work to encourage the direct reporting of incidents and medical devices issues by device users and members of the public continued throughout 2020. 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 EUDR. During 2020, we:
  - Hosted a webinar series on medical devices and *in vitro* diagnostic medical devices for manufacturers, authorised representatives, distributors and importers. The series, which ran over the course of a week, had a daily average attendance of between 350 – 450 participants;
  - Continued to update the HPRA website and social media channels to provide information and guidance regarding EUDR;
  - Provided information releases on the HPRA website and social media platforms relating to both COVID-19 and the new EU Regulations resulting in some of the most frequently visited pages during 2020.
  - Delivered briefings, advice and workshops on the new Regulations to a range of different stakeholders including notified bodies and distributors.

- 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 those 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 full list of all presentations related to the regulation of medical devices that were delivered during 2020 is provided in Appendix 2.

Medical devices: Key figures	2018	2019	2020
Lead Competent Authority role on specific vigilance issues	74	84	106
NCARs and vigilance related communications	111	118	142
Vigilance cases received/ opened	2,358	2,295	1,668
Field safety notices uploaded	475	461	362
Medical device safety notices	39	33	14
Medical device targeted healthcare professional communications	37	63	17
NCARs managed as IMDRF NCAR secretariat	8	8	10
COEN reports (market surveillance and vigilance) to EU network	38	9	18
Medical device information notices	2	1	4
Market surveillance cases (unadjusted)	353	263	469
Notifications relating to notified body certificates	1,174	1,305	561
Classification requests	37	45	38
Compassionate use applications	8	24	34
Medical device free sale certificates	2,581	2,710	2,520
Medical device queries received	547	857	1,928

Blood, Tissues and Organs

The HPRA is responsible for monitoring the safety and quality of blood and blood components, and of tissues and cells. 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	2016	2017	2018	2019	2020
Blood establishments	3	3	3	3	3
Tissue establishments	25	25	26	27	25
Organ procurement/ transplantation	4	4	4	4	4

Safety and Quality

- Following collaboration with the National Haemovigilance Office (NHO), we submitted an annual report of serious adverse reactions and events to the EU Commission during 2020. The report reflected information received by the NHO in 2019 and included information on 55 serious adverse reactions and 119 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 2020. The report reflected information received in 2019 and consisted of some 41 reports, 33 of which met the legislative reporting requirements, including two serious adverse reactions and 31 serious adverse events.
- Updates to the common approach for defining reportable serious adverse reactions and events and other vigilance activities in Europe are continuing under the SoHO Vigilance Expert Sub-Group (VES) at which the HPRA is actively participating.
- 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 2020, the HPRA received 17 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 inspect relevant establishments, organisations and centres to monitor compliance with applicable national and EU legislation and guidelines on the quality and safety of blood, blood products, tissues and cells, and human organs intended for transplantation. Our inspection programme in 2020 included:
  - Five tissue establishment inspections, all of which were routine; and
  - Four routine inspections of blood establishments.
  - Two routine inspections at organ procurement organisations/transplant centres.

Legislation and Regulation

- In relation to assisted human reproduction, we engaged with the Department of Health on development of related legislation and engaged in respect of the commencement of parts 2 and 3 of the Children and Family Relationships Act 2015. A related Commencement Order came into effect on 4 May 2020.

Stakeholders and Partners

- As the UK became a third country following Brexit, we published three new guides on our website in November to provide further information to our stakeholders in relation to Brexit and tissues and cells:
  - Brexit Guide for Stakeholders - Tissue Establishments;
  - Brexit Guide for Stakeholders - Organisations Responsible for Human Application for Tissues and Cells - Dentists ;
  - Brexit Guide for Stakeholders - Organisations Responsible for Human Application of Tissues and Cells - Hospitals.

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 the products concerned 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 following applications were issued by the HPRA during 2020:
  - Five new national applications;
  - 41 new applications made under the DCP;
  - Eleven new applications made under the MRP.

  We acted as reference (lead) Member State for the assessment of three MRPs and seven of the DCPs. We also led a further 14 applications as RMS under the repeat use procedure.

  The centralised route administered by the EMA is another mechanism whereby veterinary medicines can be authorised for supply in Ireland. HPRA experts acted as rapporteur or co-rapporteur in respect of three new veterinary medicines.

  Based on the figures presented above, the HPRA was the third leading national competent authority in the EU for outgoing work during 2020.

  Additionally, by year-end, there was a record total of more than 1,880 veterinary medicines authorised in Ireland.

- During 2020, HPRA experts acted as co-ordinator or joint co-ordinator for six EMA scientific advice procedures.

- Concerning Brexit planning and preparation, 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;
  - Recruitment and training of additional staff in response to anticipated increase in workload;
  - Discussion with the UK's Veterinary Medicines Directorate regarding maintenance of common labelling for medicines post Brexit.

- Medicine shortages continue to be a challenge for many veterinary practitioners tasked with treating different species and conditions. Non-availability can arise for a number of reasons and different solutions are needed depending on the issues involved. In 2020:
  - We conducted planned quarterly reviews of AR18 and AR16 lists which provide details of veterinary medicines that have been granted special import licences by the Department of Agriculture, Food and the Marine. The HPRA strategy is to review

the lists to identify required medicines and to encourage an applicant to seek a standard marketing authorisation where practicable;

– Carried out gap analysis and prioritised applications linked to shortages;

– Meetings were held with the Department of Agriculture, Food and the Marine to discuss shortages related issues including the need to develop an inter-departmental process in respect of potential shortages arising from Brexit;

– Communicated and met with applicants regarding transfer of RMS to Ireland;

– We worked closely with EU competent authorities to enable the use of common packs.

Authorisation and registration: Key figures	2018	2019	2020
Classification enquiries	26	12	11
Clinical trials	10	4	5
New centralised as (co-)rapporteur	3	24	3
New MR/DCP as RMS	34	38	10
New MR/DCP as CMS	57	48	34
New homeopathic applications	0	3	0
New national applications	11	6	5
Renewals, national and MR	148	87	71
Variations, national and MR	1,820	2,153	789
Manufacturers of veterinary medicines	23	24	23
Export certificates	109	125	106

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. The companies, in turn, must relay the data to the HPRA.

  Over the course of 2020, we received 391 national reports of suspected adverse events to veterinary medicines with the vast majority of reports, as in previous years, received from pharmaceutical companies.

	2016	2017	2018	2019	2020
Adverse events reported	337	397	394	347	391

- We processed 565 periodic safety update reports (PSURs) which 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.

- Containment of 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. The data show that, due to a variety of factors, there are significant fluctuations in sales annually and, consequently, a clear trend is not identifiable.

Veterinary antibiotic use	2015	2016	2017	2018	2019
Tonnes sold	96.9	103.4	99.7	99.4	88.8

- The analytical testing and examination of veterinary medicines is a key component of our risk-based sampling and analysis programme. Twelve veterinary medicines were sampled for surveillance work in 2020, one of which was included in the EDQM's surveillance programme for centrally

authorised products. One sample was out-of-specification when tested for average tablet weight. Another sample contained a package leaflet that was not in line with the approved leaflet text. Appropriate follow-up actions were taken in each case.

- Quality defects pertaining to 78 veterinary medicines were reported or identified in 2020. This represented a 15% increase over the 2019 figure (68). The risk classifications assigned, along with the corresponding figures for the previous two years, are outlined in the following table:

Year	2018	2019	2020
Critical quality defects	26	10	12
Major quality defects	43	19	36
Minor quality defects	56	38	29
Number of reports not justified	0	1	1
Total Number Quality Defects	125	68	78

  The majority of the reports (55%) were submitted by pharmaceutical companies, which included manufacturers, distributors and marketing authorisation holders. 44% 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.
  - Thirteen such recalls occurred during 2020, a substantial increase from the seven recalls that occurred in 2019.
  - Three of the recalls related to stability issues, three to non-compliances with specifications, two to contamination issues and two to artwork/SmPC non-compliance issues.
  - Two Caution-in-Use Notifications were also issued for veterinary medicines to mitigate the risks presented by quality defect issues.

- Our inspections programme focuses on ensuring compliance with relevant standards and legislation. In 2020, there were 16 good manufacturing practice (GMP) inspections of sites that manufacture/test veterinary medicines.

Legislation and Regulation

- The new veterinary regulation came into effect on 28 January 2019 and will be applied from 2022. During 2020, we continued to meet and engage with the Department of Agriculture, Food and the Marine in respect of the preparations needed to support the new Regulation (Regulation 2019/6). Planning in respect of the implications of the legislation on HPRA procedures is ongoing.

- We continued to monitor developments regarding the judicial review proceedings that contended that the labelling and packaging of veterinary medicines should be in both the Irish and English languages. A final judgment is awaited at time of writing.

Stakeholders and Partners

- As part of our ongoing stakeholder engagement, in 2020 we:
  - Completed a consultation with stakeholders regarding the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals, and produced a report on this topic;
  - Met with key interested parties (veterinary and farming organisations) to discuss availability issues and possible solutions.

- Throughout 2020, we continued our involvement across the EU regulatory network, which includes active participation at the EMA and the HMA.

- As in recent years, we continued to deliver a programme of presentations to veterinarian students and veterinary nursing students on the role of the HPRA and the promotion of veterinary pharmacovigilance. We also presented at a number of industry stakeholder events. A full list of presentations for 2020, 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 on our website in 2020 and are available to download from the 'Publications' section of the HPRA 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 2020 figures
Individual authorisations	190
Individual renewals	38
Project authorisation	110
Individual amendments	32
Project amendments	90
Establishment renewals	16

As outlined in the accompanying graph, there was a decrease in the number of new individual authorisations issued in 2020 versus 2019. This was possibly due to the impact of COVID-19 public health restrictions on research activities within authorised establishments.

Authorisations

- In December, we published the seventh 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 2020, there were 17 inspections completed to monitor animal welfare standards and compliance with legislation. This total incorporated 16 breeder, supplier, or user establishment renewal inspections (announced), and one compliance inspection (unannounced). Announced inspections are typically carried out as part of the authorisation renewal process as they allow for a comprehensive review of every aspect of the establishment's activities and operations under the scientific animal protection legislation.

- Of the 29 non-compliances recorded under the annual inspections and compliance programme, 38% were self-reported to the HPRA by personnel at the authorised establishment with the remainder detected on inspection or during other HPRA activities. 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. In 2020, of the non-compliance reports:

  – 14% were Type 1

  – 55% were Type 2

  – 31% were Type 3

  The most common non-compliances recorded related to (i) breaches of project authorisations, (ii) breaches of individual authorisations and (iii) failure to comply with the requirements of Annex III to Directive 2010/63/EU in relation to the care and accommodation of animals. In relation to the third issue, a common example would be failure to maintain relative humidity in animal holding rooms within the required specifications.

Legislation and Regulation

- Commission Implementing Decision 2020/569/EU (replacing Decision 2012/707/EU) sets out a common format for submitting information to the European Commission, including non-technical (or lay-person) summaries of project proposals granted authorisation by the HPRA. During 2020, we led a European Commission expert working group to develop guidance for project applicants on drafting non-technical project summaries.

Stakeholders and Partners

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

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

- Throughout 2020, 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.

Controlled Drugs Licensing Activity

- The following table shows the licensing activity for precursor chemicals since 2018.

Precursor Chemicals Licensing Activity	2018	2019	2020
Total	23	13	14

- We process, on behalf of the Department of Health, applications for licences to cultivate hemp. 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	2018	2019	2020
Total	24	74	94

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 2020, eight inspections were conducted linked 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 2020, the HPRA provided support to the Department of Health in the development of the Medical Cannabis Access Programme. The HPRA continued to receive a small number of applications from potential suppliers seeking to have their products included in the programme. From these applications, one additional cannabis product was considered to meet the specified requirements and was added to the programme. In total, four cannabis products have been accepted for use.

  When the programme is fully operational, consultants on the specialist medical register will be able to prescribe a cannabis-based treatment for patients with any of three specified conditions:

  – Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions;

  - Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes;

  - Severe, refractory epilepsy that has failed to respond to standard anticonvulsant medications.

  Further information is available on the Department of Health website.

Stakeholders and Partners

- In April 2020, in conjunction with the Department of Health, a process was initiated to issue emergency electronic e-licences to ensure continued processing of import and export licences for controlled substances. This e-licence can be issued within a short timeframe and allows for monitoring and tracking of the legitimate movement of controlled substances. Hard copy licences for controlled substances continued to be issued where possible.

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

Safety and Quality

- As part of proactive market surveillance activities, we conducted three inspections of cosmetic distributors. Those distributors were informed of any non-compliances identified and requested to implement corrective actions. One Product Information File (PIF) review, to assess compliance with the Cosmetics Regulation, was also initiated.

- Our reactive market surveillance includes investigation of quality-related complaints (compliance cases), reports of adverse events relating to the use of cosmetics (vigilance cases) and serious risk alerts received from other countries (Safety Gate RAPEX).

  During 2020, 300 market surveillance cases were initiated, including both proactive and reactive surveillance of cosmetic products.

Stakeholders and Partners

- We were invited to present at the Irish Cosmetics, Detergent and Allied Products Association (ICDA) workshop 'Regulatory Briefing with Irish Authorities on Brexit, Biocides, and Cosmetics Regulations'. Irish and UK cosmetics and detergent responsible persons, manufacturers and distributors attended the workshop.

Other Regulatory Programmes

Inspections, Audits and Market Compliance

- Throughout 2020, HPRA contributions to the EU included participation in/leading on:
  - the drafting group for the new EU GMP Guide Annex 21 on importation;
  - 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 tool-kit for the Official Medicines Control Laboratory (OMCL) Network; and
  - development of a procedure for remote assessment/distant inspection of manufacturers and distributors. This was in order to permit continued oversight of those authorisation holders during the COVID-19 pandemic.

Innovation Support

- The HPRA continues to focus on supporting innovation as one of our five strategic goals. This reflects our role not just to protect but also to enhance public and animal health. 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 to support innovation in 2020 included the following:
  - The HPRA's Innovation Office continues to offer regulatory support and advice to anyone developing an innovative health product or technology. Over 65% of the queries to Innovation Office originate from academia or small and medium enterprises who may have limited access to specialist regulatory advice. Medical devices was the most frequent area addressed through Innovation Office queries followed closely by medicines;
  - In 2020, the HPRA was appointed as co-chair of the EU Innovation Network reflecting the prominent role that the HPRA had played within this group since it was formed in 2016. We also continued to take a lead role in the development of horizon scanning processes at a European level (within the EU Innovation Network) and

at international level (within the International Coalition of Medicines Regulatory Authorities). Horizon scanning is intended to identify novel health products at an early stage and inform the development of appropriate regulatory tools and approaches. This facilitates both effective regulation of such products and patient access;

- Throughout 2020, our 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 is part of a consortium of European medicines regulatory agencies who are undertaking a Horizon 2020 funded project entitled 'Strengthening regulatory sciences and supporting regulatory scientific advice' (STARS). 2020 was the second year of this project and one of the key achievements during the year was an EU stakeholder workshop which brought together representative from regulatory agencies, clinical research centres , funding agencies and other interested parties to discuss how best to facilitate the translation of academic medical research into approved health products. A number of Irish research centres participated in this workshop during which the HPRA gave a presentation on regulatory supports for innovation and chaired a break-out session.

STARS: Project Aims

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 innovation developments in Ireland:
  - The HPRA continued to meet and interact with a number of other state agencies and organisations who seek to support innovation in Ireland as well as representatives from third level institutions. We also 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.
  - As a result of our prominent role within the European network, the HPRA was invited to present on supports for innovation available from national competent authorities at the DIA Europe meeting, TOPRA symposium and an EMA event to mark the 15th anniversary of their SME Regulation.
  - The HPRA continues to contribute to education programmes at both undergraduate and postgraduate levels. During 2020, we developed and began implementing a new policy related to our involvement in third level educational programmes. We also provided training placements to a 4th year pharmacy student as part of the five-year integrated pharmacist training programme.
- Stakeholder communications and engagement:
  - We continued our public information campaign: Zero Gains. The campaign is focused on building awareness of the many and often serious side effects associated with the non-medical use of anabolic steroids. The rollout of the 2020 media plan was initially impacted due to COVID-19 but commenced in November for a period of approximately four weeks. The highly targeted campaign incorporated a mix of social media, website and in-app advertising in addition to digital audio advertising, which was included for the first time. This involved an audio advert featuring key campaign messages airing via podcasts and streaming music services. In respect of social media, the reach was extended to include TikTok, which has emerged as a platform of particular significance to our main target audience. The website - zerogains.ie - continued to be an important element of the campaign providing reliable and trustworthy information on the real risks of anabolic steroid use. Overall, the various channels continued to perform in line with expectations with strong engagement levels across most platforms.
  - 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 a range of 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 addition, we responded to more than 220 initial and follow-up queries from national, local and specialist media during the year.

– The HPRA is committed to widening its engagement with patients and patient organisations, to enable a deeper understanding of patient perspectives and experiences in relation to the regulation of health products. To this end, following extensive preparatory work, we established our first ever patient forum on a pilot basis with the inaugural meeting held remotely in September. Participants, who had responded to a call for expressions of interest from potential members in 2019, included both patients and representatives of patient organisations. Our Chief Executive and members of our senior management team represented the HPRA. A second meeting was subsequently held in December. Initial topics considered by the forum, which is independently chaired, included:
  - The goals and expectations of participants;
  - Development of a forum mandate, terms of reference and procedures;
  - Initial consideration of a work programme including proposals around potential areas and topics of discussion and development;
  - The HPRA's new five year Strategic Plan 2021-2025.

  The establishment of the forum represents an important and exciting new approach to patient-centred regulation. As an organisation, our primary focus is to ensure enhanced outcomes for patients through access to safe and effective health products. Consequently, it is imperative we listen to and work with patients to ensure their voice is heard and their perspective is incorporated into regulatory decision-making. While initially developed as a pilot, it is anticipated the forum will become an integral means of engaging with patients on key regulatory issues. Once the forum is fully established with an agreed mandate, procedures and work programme, it is intended that membership will be opened to other patients and patient groups.

– The HPRA website – www.hpra.ie – is a key communications channel and we continuously monitor and analyse key visitor and usage statistics. The key findings from 2020 included:
  - More than 620,000 users of our website during the past twelve months;
  - There were in excess of 4.4 million page views in total throughout the year;
  - Of those who accessed the site, more than 35% were mobile phone users.

– 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 2020 and by year-end we had grown our number of followers to in excess of 3,000, an increase of more than 25%. Among the highlights was our continued participation in an international social media campaign to promote the reporting of suspected side effects from medicines. The #MedSafetyWeek campaign was supported by a range of patient organisations and other national health agencies. We also published a large volume of posts to highlight key regulatory messages linked to COVID-19 and Brexit.

– Our LinkedIn account continues to support the growth of our employer brand. In addition, it facilities the dissemination of important regulatory and safety information to health and industry professionals. By end 2020, our total number of followers had grown to more than 12,000.

– Also during 2020, we continued to utilise our corporate Instagram account to highlight and promote certain activities and events. The use of Instagram stories was again a key component of our Zero Gains anabolic steroids information campaign.

- European and international contribution:

  – Details of the extensive Brexit preparatory work carried out by the HPRA during 2020 are outlined earlier in this report. As part of crisis preparedness in respect of Brexit, there were many additional meetings hosted by the EMA and the Commission, which included the EU Executive Steering Group on Shortages of Medicines caused by Major Events and ad hoc meetings on preparedness activities and shortages.

- We continued our participation in all HMA and all EMA management board meetings. These were held virtually from March due to the COVID-19 pandemic:
  - The coordination of the regulatory response to COVID-19 was a key issue for the EMA Management Board throughout 2020. 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).
  - We continued our role as a member of the European HMA Management Group, which contributes to the direction and oversight of the HMA. In addition to attending the quarterly HMA meetings, we also participated as part of the secretariat for the monthly meetings of the HMA Brexit Task Force.
- Additionally, as part of our ongoing contribution to the European regulatory system, HPRA scientific and technical staff participated in a broad range of committees and working parties at the European Commission, EMA, HMA, CAMD and other fora (see Appendix 4).
- The HPRA was re-elected as a member of the International Coalition of Medicines Regulatory Authorities (ICMRA) Executive Committee in April. Following the ICMRA Summit in September, the HPRA has worked alongside the FDA in establishing a new working group to establish a Pharmaceutical Quality Knowledge Management System. We continued to co-ordinate the Governance project, which involved a review of ICMRA's membership structure and initiated a review of the terms of reference. COVID-19 became a dominant topic for the group in 2020 and we actively participated in ICMRA COVID-19 Policy and Working Group teleconferences as well as the COVID-19 Vaccine Pharmacovigilance Network and the working group on remote inspections.
- In 2019, the EU Commission commenced its work in developing the new Pharmaceutical strategy for the EU, and the HPRA continues to participate in the development of that strategy.

Key outreach and engagement figures	**2020**
Public consultations held: - Proposed regulatory fees for human products - Proposed regulatory fees for veterinary medicines - Public consultation on HPRA Strategic Plan 2021-2025	3
Public consultations responded to: - Included Department of Health; Department of Business, Enterprise and Innovation; EMA; and PSI	4
Events managed by HPRA events teams	1
Freedom of information requests	26
Requests received in accordance with the Data Protection Acts	5
Parliamentary questions	16
Queries from Government departments or members of the Oireachtas	90
Protected disclosures received by external persons under section 7(2) of the protected Disclosures Act, of which investigation is:	
- Concluded	3
- Ongoing	7
Complaints	4
Customer service queries	2,636

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

During 2020, we continued to deliver a number of items under the HR and Change (HR&C) Strategy including:

- Developing management and leadership capability;
- Provision of change management support;
- Progressing cross organisational group activities;
- Rollout of the Health & Wellbeing plan for 2020.

From March 2020 onwards, the focus of the HR&C team was redirected to provide support to all employees during the unplanned remote working environment resulting from the COVID-19 pandemic. As a result, for Q1 and Q2, both the HR and the learning and development teams were largely focused on operational activities and managing queries and issues within departments. From June onwards, the department progressed a number of key activities under each of the following strategic themes:

- Retention and Engagement
  - Design and implementation of two staff surveys with the purpose of understanding how employees were managing while working remotely and identification of areas where more focused supports would be beneficial.
  - The HPRA recognition programme completed its first full annual cycle, which included the KUDOS awards, the Accolade award and length of services certificates.
  - 2020 saw the continuation of our diversity and inclusion activities including a focus on educational materials and a virtual meeting with the external group, 'Shout Out'. Preparatory activities for progression in the Investors in Diversity framework were initiated.
  - The health and wellbeing agenda continued as a key focus with a number of initiatives adapted to the remote environment. The HPRA successfully achieved reaccreditation with the IBEC Keep Well Mark in October, which included the completion of a large body of preparatory work by the team prior to the associated audit.
- Career Development
  - Outputs from the cross-organisational working group achieved consensus of approach from the Management Committee.
  - The third iteration of the graduate programme commenced in September 2020. Recruitment for the fourth iteration was also completed with graduate resources confirmed to commence in September 2021.

- HR and Change:
  - The HR Business Partner model played a key role in delivering on the department specific HR business needs during the pandemic.
  - Coordination of COVID-19 contact tracing volunteers including the selection, training and scheduling of volunteers, and acting as main point of contact with the Department of Health and HSE.
  - HR&C held a lead role in the Business Continuity group and sub group, which focused on ensuring the health and safety of employees were safeguarded and relevant information and documents implemented.
- Organisation Design:
  - To ensure the HPRA can respond accordingly to future needs, a 'Future of Work' project commenced to analyse what the impact of more flexible working models might be on the organisation.
  - An operational excellence project was supported in its initial stage through the procurement of services and the provision of training.
- Talent Management:
  - An agile recruitment process was adopted to support remote working and remote recruitment.
  - The recruitment and appointment of a number of key senior appointments was supported.
  - Consultation on the MDP (management development programme) was undertaken with directors and managers.
  - A virtualised version of our iLM-accredited train the trainer (TTT) programme was developed.
- Change Management:
  - Tools and supports were provided to managers to aid their ability to manage remotely and ensure any people related issues or concerns were managed appropriately.
  - Ongoing change management support was delivered to various projects across the organisation. This included, for example, the EU medical device Regulations, EOLAS and the rollout of Skype for Business.

IT Developments

- Enhancements continued to Eolas, the HPRA's workflow and data management system, which is a central platform to support its regulatory activities. The functionality of Eolas will continue to be enhanced and its footprint expanded to integrate other HPRA processes and procedures.
- A number of significant upgrades to additional systems were completed during the year giving added capability to users in support of their activities.
- Upgrades were made to the office and collaboration infrastructure including the introduction of Skype for Business and enhancements to the technology available in meeting rooms.
- There were 562,397 regulatory submissions made through the Common Electronic Submission Portal (CESP), which is managed by the HPRA on behalf of the wider EU regulatory community. By year-end, there were 6,943 organisations availing of CESP with over 31,612 individual users.

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 five data subject requests received in 2020. All requests were managed within the required timelines.
- In the HPRA's continued commitment to the quality management system, 10 internal audits were completed in 2020 throughout various departments.
- Various 'Lean' projects were carried out in 2020, supporting the culture of continuous improvement within the HPRA.

Finance

- The HPRA is committed to the highest standards of corporate governance. During 2020, 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 2019 Annual Report. All financial transactions during the period were reflected and reported upon in these statements.
- The annual review of regulatory fees for 2021, incorporating a public consultation, was completed followed by the publication of the updated fees.
- Two internal audit reviews took place and reports were issued on payroll, travel and subsistence, and on human resources.

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 2020, the HPRA consumed 589.5 MWh of energy consisting of:

  – 339.7 MWh of electricity;

  – 249.8 MWh of fossil fuels;

  – 0 MWh of renewable fuels.

  Total energy reduction at year-end was 44.9%*, exceeding the goal of 33% by 2020 as calculated and published by the Sustainable Energy Authority of Ireland (SEAI).

  * published by the SEAI

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 Medical Devices and the Advisory Committee for Veterinary Medicines.

- The Authority of the HPRA met seven times in 2020 and considered a number of strategic matters including the response to COVID-19, preparations for Brexit, strategic planning and financial matters. The latter included monthly management accounts, annual budgets and the financial statements for 2019. The Authority also reviewed update reports from the Statutory Advisory Committees and the Audit and Risk Committee. In addition, it reviewed the licences for all medicinal healthcare products as approved by the Management Committee.

  The number of meetings attended by each Authority member during 2020 was as follows:

  – The Audit and Risk Committee, a subcommittee to the Authority, met four times in 2020. Further details are provided in the HPRA's Financial Statements.

  – The Advisory Committee for Human Medicines met on two occasions in 2020. 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 Advisory Committee for Veterinary Medicines met once.

  – The Advisory Committee for Medical Devices met twice.

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
Ms. Ann Horan (Chairperson)	7	7
Dr. Joe Collins	2	2
Mr. David Holohan	7	7
Mr. Brian Jones	7	5
Prof. Elizabeth Keane	7	7
Prof. David Kerins	7	7
Prof. Caitriona O'Driscoll	7	7
Dr. Diarmuid Quinlan	7	6
Prof. Richard Reilly	7	7

– The National Committee for the Protection of Animals Used for Scientific Purposes, a statutory committee to provide guidance to the regulator and those working in this area, met once in 2020.

- 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 2020

Authority Members and Other Information

Authority:	*Most recent appointment date*	*Expiry date*
Ms. Ann Horan (Chairperson)	01/01/2016	31/12/2020
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
Prof. Elizabeth Keane	22/05/2019	21/05/2022
Prof. David Kerins	22/03/2019	31/12/2020
Prof. Caitriona O'Driscoll	01/01/2016	31/12/2020
Prof. Richard Reilly	01/01/2020	31/12/2024
Dr. Diarmuid Quinlan	22/05/2019	21/05/2024

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

Solicitors:

Eugene F. Collins
Temple Chambers
3 Burlington Road
Dublin 4

Eversheds
1 Earlsfort Centre
Earlsfort Terrace
Dublin 2

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 2020.

Audit and Risk Committee

The HPRA has an audit and risk committee comprising three Authority members, which met on 4 occasions during 2020. 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 2020 the internal auditor carried out internal audit reviews on the areas of payroll, travel & subsistence and human resources. The audit and risk committee has also been involved with the review of the quality systems as described below.

Quality Systems

During 2020, 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 54 to 55.

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 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 2020.

Performance Review

The Authority were subject to an external evaluation of their own performance during the year ended 31 December 2020.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 24 June 2021

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 and Reform, has been in place in the HPRA for the year ended 31 December 2020 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 2020.

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 2020 two internal audit reviews were conducted.

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

Risk and Control Framework

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

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

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

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

Ongoing Monitoring and Review

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

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

Procurement

I confirm that the HPRA has procedures in place to ensure compliance with current procurement rules and guidelines, and that during 2020 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 2020. This review was carried out at its meeting on 29 April 2021. Prior to this meeting, a document outlining the effectiveness of the internal controls in the HPRA for 2020 was circulated to the Authority members by e-mail. This document was circulated on 30 March 2021.

Internal Control Issues

No weaknesses in internal control were identified in relation to 2020 that require disclosure in the financial statements.

During 2019, four supplier contracts were identified as not being in compliance with current procurement rules. A full tender process was completed during 2020 for one of these contracts, and the other three contracts are expected to be tendered for in Q3/Q4 2021.

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.

All staff are predominately working off site, with many resources diverted to managing implications of the pandemic. This has had little or no effect on internal controls already in place, many of which were not dependant on physically being in the office.

Mr. Michael Donnelly
Chairperson to the Authority

Date: 24 June 2021

Comptroller and Auditor General

Report for presentation to the Houses of the Oireachtas

Qualified opinion on financial statements

I have audited the financial statements of the Health Products Regulatory Authority (the Authority) for the year ended 31 December 2020 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 2020 and of its income and expenditure for 2020 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 2020 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 Ins``titutions. 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.

Andrew Harkness

For and on behalf of the Comptroller and Auditor General

29 June 2021

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

Responsibilities of the Comptroller and Auditor General

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

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

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

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

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

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.

I also 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.

Statement of Income and Expenditure and Retained Revenue Reserves
For the year ended 31 December 2020

	Note	2020 €	2019 €
Fee Income	3	**29,712,923**	27,932,876
Department of Health Funding	3	**4,975,000**	4,964,255
Other Income	4	**803,196**	805,824
		35,491,119	33,702,955
Salaries and Wages	5	**25,436,125**	23,862,438
Other Operating Costs	6	**5,059,018**	7,639,373
Depreciation	2	**1,080,820**	1,274,848
		31,575,963	32,776,659
Surplus for the year before write back of Superannuation contributions		**3,915,156**	926,296
Staff Superannuation Contributions		**637,287**	691,855
Surplus for the year		**4,552,443**	1,618,151
Balance brought forward		**31,106,264**	29,488,113
Balance carried forward	12	**35,658,707**	31,106,264

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 62 to 72 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 24 June 2021

Statement of Financial Position
As at 31 December 2020

	Note	2020 €	2019 €
Fixed Assets			
Property, Plant and Equipment	2	**24,665,841**	24,896,454
Current Assets			
Debtors and Prepayments	7	**2,846,261**	2,514,984
Inventory of Stationery		**4,936**	5,533
Cash and Cash Equivalents	9	**22,629,442**	2,290,820
Short Term Deposits	10	**-**	17,658,240
		25,480,639	22,469,577
Current Liabilities - Amounts falling due within one year			
Creditors and Accruals	8	**13,814,425**	12,293,087
Mortgage	13	**168,337**	793,332
		13,982,762	13,086,419
Net Current Assets		**11,497,877**	9,383,158
Long Term Liabilities - Amounts falling due after more than one year			
Mortgage	13	**505,011**	3,173,348
NET ASSETS		**35,658,707**	31,106,264
Reserves			
Retained Revenue Reserves	12	**21,053,422**	19,138,266
Superannuation Reserve	12	**14,605,285**	11,967,998
		35,658,707	31,106,264

The Statement of Cash Flows and the notes on pages 62 to 72 form part of the financial statements.

On behalf of the Authority

Mr. Michael Donnelly
Chairperson

Mr. David Holohan
Authority Member

Date: 24 June 2021

Statement of Cash Flows
For the year ended 31 December 2020

	Note	2020	2019
		€	€
Cash flows from Operating Activities			
Surplus for financial year		4,552,443	1,618,151
Depreciation of property, plant and equipment		1,080,820	1,274,848
(Profit)/Loss on Disposal of property, plant and equipment		0	(49)
(Increase) in Debtors		(331,277)	(316,644)
(Increase)/Decrease in Stock		597	(2,035)
Increase in Creditors - amounts falling due within one year		1,521,338	1,532,175
Deposit Interest		(5,508)	(16,737)
Bank Interest		349,040	174,075
Cash from Operations		7,167,453	4,263,784
Bank Interest Paid		(349,040)	(174,075)
Net Cash generated from Operating Activities		6,818,413	4,089,709
Cash flows from Investing Activities			
Deposit Interest Received		5,508	16,737
(Increase)/Decrease in Bank Deposits		17,658,240	(9,441,426)
Payments to acquire property, plant and equipment		(850,207)	(1,744,103)
Receipts fom sales of property, plant and equipment		0	680
Net cash from Investing Activities		16,813,541	(11,168,112)
Cash flows from Financing Activities			
Repayment of Borrowings		(3,293,332)	(793,332)
Net cash used in Financing Activities		(3,293,332)	(793,332)
Net increase/(decrease) in Cash and Cash Equivalents		20,338,622	(7,871,735)
Cash and Cash Equivalents at beginning of year		2,290,820	10,162,555
Cash and Cash Equivalents at end of year	9	22,629,442	2,290,820

Notes to the Financial Statements
For the year ended 31 December 2020

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. The HPRA is availing of the reduced disclosures allowed by FRS 102 in relation to legal provisions, in instances where full disclosure 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.

Notes to the Financial Statements
For the year ended 31 December 2020

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.

Notes to the Financial Statements
For the year ended 31 December 2020

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 employes who are members of the scheme are credited to the statement of income and expenditure when received. The surplus/(deficit) 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 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.

Notes to the Financial Statements
For the year ended 31 December 2020

2. Property, plant and equipment	Fixtures and Fittings €	Computer Equipment €	Leasehold Improvements €	Improvements To Premises €	Premises €	Total €
Cost						
Balance as at 1 January 2020	1,323,908	17,713,306	773,461	4,374,608	23,156,037	47,341,320
Additions for the year	32,139	725,474	92,594	-	-	850,207
Disposals for the year	(35,899)	(1,336,989)	-	-	-	(1,372,888)
As at 31 December 2020	1,320,148	17,101,791	866,055	4,374,608	23,156,037	46,818,639
Depreciation						
Balance as at 1 January 2020	1,234,795	16,565,772	529,547	4,114,752	-	22,444,866
Charge for the year	34,196	926,951	36,360	83,313	-	1,080,820
Disposals for the year	(35,899)	(1,336,989)	-	-	-	(1,372,888)
As at 31 December 2020	1,233,092	16,155,734	565,907	4,198,065	-	22,152,798
Net Book value at 31 December 2020	87,056	946,057	300,148	176,543	23,156,037	24,665,841
Net Book value at 1 January 2020	89,113	1,147,534	243,914	259,856	23,156,037	24,896,454

3. Income	2020 €	2019 €
Fee Income		
Clinical Trials	339,738	389,916
Human Medicine - National Fees	6,907,352	7,034,900
Human Medicine - European Fees	10,469,002	9,197,663
Veterinary Medicine - National Fees	1,930,987	1,988,373
Veterinary Medicine - European Fees	2,098,606	1,691,326
Compliance Department	5,878,330	5,845,249
Medical Devices	1,989,240	1,715,249
	29,613,255	27,862,676
Movement in deferred revenue	99,668	70,200
	29,712,923	27,932,876
Dept Of Health Funding (Vote 38 Subhead E1)	4,975,000	4,964,255
Other Income (Note 4)	803,196	805,824
Total Income	35,491,119	33,702,955

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 €21,128,900 in 2020, shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure and Reform directs.

Notes to the Financial Statements
For the year ended 31 December 2020

4. Other Income

	2020	2019
	€	€
Conference Fee Income	-	12,860
Deposit Interest	5,508	16,737
(Loss)/Gain on Disposal of Fixed Assets	-	49
IT Income	797,688	714,875
Zambia Project Income	-	61,303
	803,196	805,824

5. Salaries and Wages

Basic Pay	20,785,092	19,622,110
Overtime	9,270	10,956
Allowances	190,173	178,300
Staff Short Term Benefits	20,984,535	19,811,366
Retirement Benefit Costs	1,044,800	1,153,648
Employer's Contribution to Social Welfare	2,123,813	1,986,755
Employer's Contribution to Single Scheme Pension	1,282,977	910,669
	25,436,125	23,862,438

The average number of staff employed during the year was 353 (2019 - 348).
Payroll numbers at 31 December 2020 can be analysed across the following departments:

Chief Executive	4	3
Compliance	71	63
Finance, Corporate & International	26	26
Human Products Authorisation & Registration	105	101
Human Products Monitoring	35	34
Human Resources & Change	10	10
IT & Business Services	17	18
Medical Devices	43	44
Quality, Scientific Affairs & Communications	11	12
Veterinary Sciences	39	35
Staff	361	346
Authority Members	5	7
Pensioners	47	46
	413	399

No termination or severance payments were made during the year.

Additional superannuation contributions for Public Servants of €644,813 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 €432,857 were deducted from staff during the year and paid over to the Department of Public Expenditure and Reform. In agreement with our parent department and DPER, the HPRA have also paid over Single Scheme employer contributions since January 2019 for employees not employed in exchequer funded areas.

Notes to the Financial Statements
For the year ended 31 December 2020

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

Salary Band	2020	2019
€0 to €60,000	206	214
€60,001 to €70,000	74	54
€70,001 to €80,000	19	20
€80,001 to €90,000	15	16
€90,001 to €100,000	21	20
€100,001 to €110,000	15	15
€110,001 to €120,000	6	4
€120,001 to €130,000	4	2
€130,001 to €140,000	-	-
€140,001 to €150,000	-	-
€150,001 to €160,000	-	1
€160,001 to €170,000	1	-
	361	346
Average Salary	€55K	€54.9K

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

	2020 €	2019 €
Accommodation Costs	1,498,976	1,291,822
Travel, Representation and Training	365,503	973,179
Bank Charges and Interest	353,621	179,047
Legal Fees	147,150	2,344,387
Audit Fees (External and Internal)	34,323	34,305
Stationery, Publications, Postage and Communications	336,144	464,148
Consultancy	332,980	499,038
Sampling and Analysis	240,179	243,132
IT Costs	1,591,951	1,342,133
Document Storage	124,379	152,279
Telephone and Telecommunications	107,972	97,616
Movement on Bad Debt Provision	(74,160)	18,287
	5,059,018	7,639,373

Travel costs include an amount of €23,792 related to staff hospitality, and an amount of €80,697 related to travel and subsistence, of which €69,854 is national and €10,843 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 €173,142 related to public relations/marketing, €125,735 related to human resources/ pensions and €34,103 related to other.

Notes to the Financial Statements
For the year ended 31 December 2020

7. Debtors (all due within one year)

	2020	2019
	€	€
Trade Debtors	2,505,431	2,018,140
Prepayments	244,562	309,093
Other Debtors	96,268	187,751
	2,846,261	2,514,984

Trade debtors are shown net of the bad debt provision.

8. Creditors (amounts falling due within one year)

Trade Creditors	402,819	1,174,870
Credit Balances on Debtor Accounts	5,570,223	3,180,518
Accruals	5,506,511	5,512,384
Deferred Revenue	1,638,629	1,738,297
Revenue Commissioners	696,243	687,018
	13,814,425	12,293,087

9. Cash and Cash Equivalents

Cash at Bank and in Hand	10,472,026	772,549
Demand Deposits (Convertible to Cash on Demand)	12,157,416	1,518,271
	22,629,442	2,290,820

10. Short Term Deposits

Short Term Deposits (not immediately convertible to cash)	-	17,658,240
	-	17,658,240

11. Administration Expenses

Surplus for the year was calculated having charged:		
Auditor's Remuneration	20,000	20,000

Notes to the Financial Statements
For the year ended 31 December 2020

12. Movement on Income and Expenditure Reserves

	As At 01/01/2020 €	Income & Expenditure €	Transfer to Superann Reserve €	As At 31/12/2020 €
Retained Reserves	19,138,266	3,915,156	(2,000,000)	21,053,422
Superannuation Reserve	11,967,998	637,287	2,000,000	14,605,285
	31,106,264	4,552,443	0	35,658,707

Our Audit and Risk Committee recommended the transfer of a further €2,000,000 in 2020 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:

	2020 €	2019 €
- within one year	168,337	793,332
- between one and five years	505,011	3,173,328
- after five years	-	20
	673,348	3,966,680

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 4 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.

Notes to the Financial Statements
For the year ended 31 December 2020

15. Financial Commitments

Accommodation Costs (Note 6) includes expenditure of €645,106 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. At 31 December 2020 this lease had 1 year and 4 months remaining.

	2020 €	2019 €
The amounts due under this lease are as follows:		
- within one year	**285,984**	285,984
- between one and five years	**95,328**	381,312
- after five years	**-**	-
	381,312	667,296

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 2020 this lease had 13 years and 5.5 months remaining.

The amounts due under this lease are as follows:		
- within one year	**365,246**	360,735
- between one and five years	**1,460,983**	1,485,683
- after five years	**3,089,372**	3,508,230
	4,915,601	5,354,648

16. Capital Commitments

Contracted For (Contract Signed)	**20,963**	26,779
Contracted For (Contract Not Signed)	**93,436**	-
	114,399	26,779

Notes to the Financial Statements
For the year ended 31 December 2020

17. Authority Remuneration

	Fees	Expenses
	€	€
Ann Horan (Chairperson)	11,970	-
Joe Collins	2,012	-
David Holohan	7,695	450
Brian Jones	7,695	989
Elizabeth Keane	7,695	171
David Kerins	-	164
Caitriona O'Driscoll	-	264
Diarmuid Quinlan	7,695	-
Richard Reilly	-	-
	44,762	2,038

Up to the 15th February 2017, other than the Chairperson, no other Authority Member received a salary. On 16th February 2017, the Health (Miscellaneous Provisions) Act was enacted, which made provision for payment of fees to other Authority members, provided that they were in compliance with the 'one person one salary' principle. Three Authority members do not receive a fee under this principle.

Authority expenses comprise €1,049 domestic and €989 foreign.

18. Key Management Personnel Remuneration

	2020	2019
	€	€
Chief Executive	160,524	157,031
Senior Management	940,884	812,419
	1,101,408	969,450

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 and Reform (DPER) covering the personal interests of Authority members. A register of such interests is maintained. In addition to the DPER 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.

Notes to the Financial Statements
For the year ended 31 December 2020

21. Exchange Rates

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

2020	€1 = STG £0.90453
2019	€1 = STG £0.85369

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. The Authority is availing of the reduced disclosures allowed by FRS 102 in instances where full disclosure might prejudice seriously its position in a dispute 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 and resources diverted to managing implications of the pandemic. The Authority assesses this event to be a non-adjusting post balance sheet event in relation to the 2020 financial results. No impact is expected in relation to the 2020 financial statements and currently we are not predicting a significant financial impact for 2021, although due to the nature of the pandemic, the final impact cannot be estimated at this point. HPRA's income is derived from the pharmaceutical, medical devices and related industries, which continue to operate throughout the pandemic and therefore are financially less impacted than those industries which have closed or have limited output.

24. Approval of Financial Statements

The financial statements were approved by the Authority of the HPRA on 24 June 2021.

Appendix 1

2020 Committee Members

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

Dr. Caitríona Fisher
Director of Quality, Scientific Affairs and Communications

Mr. John Lynch
Director of Compliance

Dr. Niall MacAleenan
Director of Medical Devices

Ms. Lynsey Perdisatt
Director Human Resources and Change

Ms. Grainne Power
Director of Human Products Authorisation and Registration

Authority (Board)

Ms. Ann Horan – Chairperson
(Term ended December 2020)

Dr Joe Collins
(Appointed September 2020)

Mr. David Holohan

Mr. Brian Jones

Prof. Elizabeth Keane

Prof. David Kerins
(Term ended December 2020)

Prof. Caitriona O'Driscoll
(Term ended December 2020)

Dr. Diarmuid Quinlan

Prof. Richard Reilly
(Appointed January 2020)

Audit and Risk Committee

Prof. Elizabeth Keane – Chair

Mr. David Holohan

Prof. Caitriona O'Driscoll

Advisory Committee for Human Medicines

Prof David Kerins – Chair

Dr Kevin Connolly

Prof Desmond Corrigan

Ms Maria Egan

Prof Tom Fahey

Dr Paul Gallagher
(Appointed August 2020)

Ms Fionnuala King

Prof Patrick Murray

Dr Fionnuala Ní Ainle

Dr Brian O'Connell

Mr Ronan Quirke

Dr Patrick Sullivan

Advisory Committee for Veterinary Medicines

Dr. Ruadhrí Breathnach

Ms. Eugenie Canavan

Dr. Robert Doyle

Dr. Helena Kelly

Dr. Nola Leonard

Dr. Edward Malone

Dr. Bryan Markey

Dr. Ciaran Mellett

Dr. Warren Schofield

Dr. Robert Shiel

Dr. Christina Tlustos

Advisory Committee for Medical Devices

Prof. Richard Reilly – Chair
Dr. Vivion Crowley
Mr. Ger Flynn
Dr. Fergal McCaffrey
Ms. Margaret O'Donnell
Prof. Martin O'Donnell
Prof. Mary Sharp
Mr. Sean-Paul Teeling
Prof. Sean Tierney

Clinical Trial Sub-Committee of Advisory Committee for Human Medicines

Dr. Patrick Sullivan – Chair
Dr. Liam Bannan
Dr. Patrick Morris
Dr. Thomas Peirce
Prof. Catherine McHugh
Dr. Amjad Hayat

Experts Sub-Committee of the Advisory Committee for Human Medicines

Prof. David Kerins – Chair
Dr. Fionnuala Breathnach
Dr. Linda Coate
Dr. Peter Coakley *(Appointed August 2020)*
Dr. Kevin Connolly
Mr. James Colville
Dr. Noreen Dowd
Dr. Stephen Eustace
Prof. Stephen Flint
Dr. Tim Fulcher
Dr. Joseph Galvin
Dr. Sheila Galvin
Dr. Patrick Gavin
Dr. Paul Gallagher
Dr. Kevin Kelleher
Dr. Catherine Kelly
Dr. Mary Keogan
Dr. Mark Ledwidge
Dr. Frank Murray
Dr. Yvonne O'Meara
Dr. Cormac Owens
Dr. Jogin Thakore
Dr. Gerry Wilson

Advisory Sub-Committee for Herbal Medicines

Prof. Des Corrigan – Chair
Dr. James Barlow
Dr. Kevin Connolly
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 2020

Educational/Professional Development Presentations and Training

Institution	Course	Presentation Title
DCU	Bioprocess Engineering	Regulation of Biologicals
DCU	Bioprocess Engineering	Regulation of Medicines
DCU	Chemistry	Regulatory Affairs and Risk Management
Irish Defence Forces	Training Workshop	The Role of the HPRA and Safety Monitoring of Medicines
LAST Ireland	Training Workshop	Implementation of Directive 2010/63/EU in Ireland
Letterkenny IT	Seminar	Regulation of Veterinary Medicinal Products in Ireland
Maynooth University	Immunology and Global Health	Regulation of Medicines
RCSI	Pharmacy	Regulation of Medicines, From Discovery to Commercial Product; Non-Clinical Pharmacology and Toxicology
RCSI	Nurse/Midwife Prescribing	The Role of the HPRA and Pharmacovigilance
RCSI	Pharmacy	Overview of Pharmacovigilance
St Johns College, Cork	Seminar	Regulation of vmps in Ireland
TCD	Pharmaceutical Medicine	Early Access to Medicines
TCD	Pharmaceutical Medicine	The Centralised Procedure & Overview of CHMP
TCD	Pharmaceutical Medicine	The Work of EMA's Scientific Advice Working Party
TCD	Pharmaceutical Medicine	Nonclinical drug development
TCD	Pharmaceutical Medicine	Committee for Orphan Medicinal Products (COMP)
TCD	Pharmaceutical Medicine	Communication of Drug Safety Data & Overview of the WHO Programme for International Drug Monitoring

TCD	Pharmaceutical Medicine	Collection and reporting of adverse events/reaction reports arising from Clinical Trials
TCD	Immunotherapeutics	Regulation of Biologicals
TCD	Immunotherapeutics	Biological Medicinal Products
TCD	Immunotherapeutics	Regulation of Medicines
TCD	Pharmaceutical Medicine	The role of the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)
TCD	Immunology	Regulation of Medicines
TCD	Pharmaceutical Medicine	Medicines Regulation: International Quality Standards and Pharmacopoeias
TCD	Pharmaceutical Manufacturing Technology	The HPRA and the Role of the Pharmacopoeia in the regulation of medicines
TCD	Pharmacy	Overview of Pharmacovigilance
TOPRA	Training Workshop	The SmPC - A Regulator's Perspective
UCC	Medicine/Pharmacy	Notification of Adverse Reactions
UCD	Biotechnology	Regulation of Clinical Trials
UCD	Biotechnology	Regulation of Biological Medicines
UL	Regulatory Affairs (Bio) Pharmaceuticals	Compiling a Successful Clinical Trial Application - The Agency Viewpoint
UL	Regulatory Affairs (Bio) Pharmaceuticals	Fundamentals of Pharmaceutical Development
UL	Regulatory Affairs (Bio) Pharmaceuticals	The Future of Regulation and Lessons Learned during COVID-19

Regulatory Presentations

Event/Organiser	Presentation Title
5th EFSPI Workshop on Regulatory Statistics	Regulatory Update on Estimands
EMA Workshop	Article 117 - The Notified Body Opinion - An Assessor's View
EMA Workshop	Implementation of MDR on drug-device combinations
EMA Workshop	Update on the DDC guideline
PDA	Regulatory advances - new technologies and Industry 4.0
CASSS CMC Forum Europe 2020	ICH Q13 - Short Update
Biopharma Ambition	ATMPs - the Regulatory Perspective
TOPRA Conference	Module 3: An Agency Perspective
PMI	The HPRA and COVID
EMeRGE conference	Optimising safe and effective use of medicines
Klifovet AG	Safety requirements for veterinary medicinal products
17th Munich Workshop on VICH Good Clinical Practice and efficacy studies in animals	The regulatory view in the assessment of clinical efficacy of Veterinary Medicinal Products
17th Munich Workshop on VICH Good Clinical Practice and efficacy studies in animals	Benefit-risk balance: the assessment of authorities
European Commission - DG Environment -	Development of NTS Guidance
HPRA Webinar Series	HPRA November Webinar Series: Implementation of MDR and IVDR
EMA/DIA	ICSR Data Quality and Impact on Data Analysis and Safety Monitoring
EMeRGE Conference	Health Products Regulation - Optimising safe and effective use of medicines
DIA Europe	Experience of HPRA in European Medicines Regulatory Network
HCRI	Regulatory Support for COVID-19 Vaccine Development and PPI
MedTech Ireland	Changing Times & Approach For Progressive Regulation

Appendix 3

Publications and Articles 2020

Drug Safety Newsletters

Edition	Topics
April 96th Edition	– Ulipristal acetate 5mg (Esmya) for uterine fibroids – suspension of marketing authorisation during ongoing review of liver injury risk – Paracetamol – reminder to prescribers on risk of hepatotoxicity in patients with risk factors – Durvalumab (Imfinzi▼) – risk of myasthenia gravis – Rivaroxaban (Xarelto) – not for use as thromboprophylaxis in patients who have recently undergone transcatheter aortic valve replacement – Selective Serotonin Reuptake Inhibitors (SSRI) and Serotonin-norepinephrine reuptake inhibitors (SNRI) – persistent sexual dysfunction after drug withdrawal – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter – DHPC appended due to limitations resultant from the COVID-19 pandemic: Direct Healthcare Professional Communication: Restrictions in use of cyproterone acetate due to risk of meningioma
May 97th Edition	– Teratogenicity of valproate-containing medicines (Epilim▼) – Reminder of important restrictions for use in women and girls
May 98th Edition	– Adverse reaction reporting during the COVID-19 pandemic – reminder – Picato (ingenol mebutate) – EMA review concludes negative benefit risk balance due to risk of skin malignancy – Levetiracetam – risk of abnormal and aggressive behaviours – Cyproterone acetate – restrictions in use due to risk of meningioma – Carbimazole and propylthiouracil – use in pregnancy and in women of childbearing potential – Carbimazole – risk of acute pancreatitis – Testosterone-containing medicinal products: caution in patients with thrombophilia or risk factors for venous thromboembolism (VTE) – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter

September 99th Edition	– Erythromycin – Updated warnings regarding cardiovascular risks and infantile hypertrophic pyloric stenosis – Vascular Endothelial Growth Factor (VEGF) pathway inhibitors – Risk of aneurysm and artery dissection – Implanon NXT (etonogestrel implant) – Updated insertion and removal instructions due to risk of neurovascular injury and implant migration – Insulin-containing medicines – Risk of cutaneous amyloidosis and potential for associated changes in glycaemic control – Leuprorelin-containing depot medicines – Risk of lack of efficacy due to incorrect reconstitution and administration – Xeljanz▼(tofacitinib) – Updated recommendations due to increased risk of venous thromboembolism and serious and fatal infections – Risk of respiratory depression and sedation associated with Epaclob 1mg/ml and 2mg/ml oral suspension (clobazam) – Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter
November 100th Edition	– Introductory article written by the Pharmacovigilance Manager, Ms Niamh Arthur, on the occasion of the 100th edition of the DSN – Optimising safe and effective use of medicines in clinical practice through proactive risk management – Adverse reaction reporting – Product information for medicines – Registering with the HPRA for safety alerts and updates

Veterinary Medicines Articles – External Publications

Month	Publication	Topic
March	Veterinary Ireland Journal	Why is the HPRA changing the method of supply of antiparasitic veterinary medicinal products?
July	Veterinary Ireland Journal	Veterinary Antibiotics – Future European Developments
January	It's Your Field	HPRA review of antiparasitic veterinary medicinal products used in food-producing animals
March	It's Your Field	Classification of borderline products by the HPRA
July	It's Your Field	How the HPRA regulates veterinary medicines
September	It's Your Field	Implementation of the HPRA report on the change to prescription control in respect of antiparasitic veterinary medicinal products

Appendix 4

European and National Committee/Working Group Participation

Committee/Working Group	Organisation	Meetings in 2020
Counterfeiting of Medical Products (CMED)	Council of Europe	2
EU Veterinary Medicines Regulation	Department of Agriculture, Food and the Marine	3
iNAP (Ireland's National Action Plan on AMR) Animal Health Implementation Committee	Department of Agriculture, Food and the Marine	4
Blood & Organ Transplant and Acute Hospital Service Planning Policy Unit	Department of Health	1
Children and Family Relationships Act	Department of Health	3
Connecting for Life Strategy	Department of Health	1
Controlled Drugs Cross Border Group	Department of Health	2
Early Warning and Emerging Trends Group	Department of Health	3
National Public Health Emergency Team – COVID-19	Department of Health	63
Committee for Cosmetics and Consumer Health	EDQM	1
Committee for Cosmetics and Consumer Health and European Network of OCCLs – Joint meeting	EDQM	2
EDQM Committee Meetings	EDQM	8
European Pharmacopoeia Commission	EDQM	3
National Pharmacopoeia Authorities – Annual Meeting	EDQM	2
OMCL Network Active Pharmaceutical Ingredient (API) Working Group	EDQM	2
OMCL Network Advisory Group	EDQM	5
OMCL Network Centrally Authorised Products (CAP) Working Group	EDQM	1
OMCL Network Communications Working Group	EDQM	1
OMCL Network Mutual Recognition and Decentralised procedures (MRP/DCP) Working Group	EDQM	1
Biological Working Party	EMA	11
Biosimilar Medicines Working Party (BMWP)	EMA	5

Committee/Working Group	Organisation	Meetings in 2020
Committee for Advanced Therapies (CAT)	EMA	11
Committee for Herbal Medicinal Products (HMPC)	EMA	6
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	11
COVID-19 EMA Pandemic Task Force	EMA	2 meetings per week
Good Clinical Practice (GCP) Inspectors' Working Group (including training seminar)	EMA	13
Good Manufacturing and Distribution Practice (GMDP) Inspectors' Working Group	EMA	4
Management Board	EMA	4
Paediatric Committee (PDCO)	EMA	11
Pharmacovigilance (PV) Inspectors' Working Group (human & veterinary)	EMA	4
Pharmacovigilance Risk Assessment Committee (PRAC)	EMA	11
Pharmacovigilance Working Party - Veterinary	EMA	6
Quality Defects and Rapid Alert Working Group	EMA	4
Quality Review of Documents Working Groups	EMA	3
Quality Working Party	EMA	4
Rapid Alert Network re Nitrosamines	EMA	4
Safety Working Party - Human	EMA	13
Safety Working Party – Veterinary	EMA	1
Sartans Lessons Learned Group	EMA	2
Scientific Advice Working Party - Human	EMA	11
Signal Management Review Technical Working Group (Methods) – PRAC	EMA	4
Signal Management Review Technical Working Group (SMART) Processes – PRAC	EMA	5
Veterinary Medicines Regulation – Drafting of implementing acts	EMA	8
Working Group on Revision of ICH Q9 Guideline	EMA & ICH	19
Competent Authorities for Organ Donation and Transplantation	European Commission	1
Competent Authorities for Tissues and Cells	European Commission	3
Competent Authorities on Blood and Blood Components	European Commission	2
Expert Group on Clinical Trials	European Commission	4
Expert Sub-Group on Vigilance for Blood, Tissues and Cells, and Organs (VES)	European Commission	1
Expert Working Group on Safety Features (including meetings, telecons & workshop with EMVO)	European Commission	3

Committee/Working Group	Organisation	Meetings in 2020
Expert Working Group on Safety Features (including meetings, telecons & workshop with European Medicines Verification Organisation)	European Commission	3
Joint Action Market Surveillance of Medical Devices	European Commission	3
Medical Device Coordination Group (MDCG) (MDR/IVDR)	European Commission	8
MDCG - Notified Body Oversight (NBO)	European Commission	2
MDCG - International matters	European Commission	2
MDCG - *In Vitro* Diagnostic (IVD)	European Commission	1
MDCG - Nomenclature	European Commission	1
MDCG - Annex XVI	European Commission	2
MDCG - Standards	European Commission	1
MDCG - Clinical Investigation and Evaluation (CIE) - Including Monthly Teleconference	European Commission	10
MDCG - Market Surveillance and Vigilance (PMSV)	European Commission	2
MDCG - Borderline and Classification	European Commission	1
MDCG - Unique Device Identification (UDI)	European Commission	1
MDCG - New Technologies (NT)	European Commission	1
MDCG - EUDAMED by videoconference	European Commission	2
MDCG - Unique Device Identification (UDI)	European Commission	2
National Contact Points for the Implementation of Directive 2010/63/EU	European Commission	1
Pharmaceutical Committee	European Commission	7
Platform of European Market Surveillance Activities in Cosmetics (PEMSAC) – Market Surveillance	European Commission	1
Standing Committee on Cosmetic Products	European Commission	3
Standing Committee on Veterinary Medicinal Products	European Commission	4
Sub-group on borderline issues relating to cosmetics	European Commission	2
Working Group on Cosmetic Products	European Commission	5
Working Group on Good Distribution Practice for Active Pharmaceutical Ingredients and Veterinary Medicinal Products	European Commission	1
Working Group on Guidance for the Completion of Non-technical Project Summaries	European Commission	3
Interpretation Guide for Harmonised Assessment Checklist for Audits of GMP Inspectorates	European Commission / EMA / HMA / PIC/S	1
Authorisation of Preparation Process for blood, tissues and cells (GAPP Work Package Five, Six and Seven)	European Commission / National Competent Authorities	14
Inspections Expert Subgroup (IES) Work Cluster IV (Blood, Tissues and Organs)	European Commission / National Competent Authorities	2

Committee/Working Group	Organisation	Meetings in 2020
Operational/Liaison meeting	Europol	10
Food Fraud Task Force	Food Safety Authority of Ireland (FSAI)	1
Clinical Trials Facilitation Group (CTFG)	HMA	7
CMDh/GCP Inspectors Sub-Group	HMA	2
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 Innovation Network	HMA	7
Heads of Agency Meeting	HMA	4
Homeopathic Medicinal Products Working Group	HMA	1
Pharmacovigilance Worksharing Procedures Working Party	HMA	11
Risk Assessment tool for surveillance testing	HMA	1
Risk-based Surveillance Testing – Drafting Group (including telecons)	HMA	1
Working Group of Communications Professionals	HMA	2
Working Group of Enforcement Officers (WGEO) (including management committee)	HMA	7
Working Group of Quality Managers	HMA	2
ICMRA Plenary Meeting	ICMRA	50
International Coalition of Medicines Regulatory Authorities (ICMRA) – Pharmacovigilance group	ICMRA	3
International Coalition of Medicines Regulatory Authorities (ICMRA) - Vaccine Confidence Working Group	ICMRA	3
International Medical Device Regulators Forum (IMDRF) Management Committee	IMDRF	2
Next Generation Biologics Forum	National Institute for Bioprocessing, Research and Training (NIBRT)	3
Permanent forum on International Pharmaceutical Crime (PFIPC)	PFIPC	2
Pharmaceutical Inspection Co-Operation Scheme (PIC/S) Executive Bureau	PIC/S	1
PIC/S Executive Bureau	PIC/S	1
PIC/S Expert Circle on Quality Risk Management (QRM)	PIC/S	20
PIC/S Strategic Roadmap Working Group	PIC/S	1
PIC/S Sub-Committee on Harmonisation	PIC/S	4
PIC/S sub-committee on Training	PIC/S	2
National Immunisation Advisory Committee (NIAC)	Royal College of Physicians of Ireland (RCPI)	7

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin
D02 XP77
Ireland

Tel: +353 (1) 676 4971
E-mail: info@hpra.ie
www.hpra.ie