

**Public Consultation on  
Annual Review and Proposal for Fees –  
Financial Year 2023**

**Human Medicines, Compliance Activities,  
Blood, Tissue Establishments and Organs  
and Medical Devices**

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## 1 INTRODUCTION

The Health Products Regulatory Authority (HPRA), since its establishment in 1996, has successfully run its regulation of human medicines authorisation, manufacturer and wholesaler operations without recourse to exchequer funding, and has established sufficient reserves to allow it to fund capital and IT expenditure and deal with unexpected costs as these arise. This is both a requirement under the Irish Medicines Board Act and a stated objective of the Authority<sup>1</sup> of the HPRA. Since 2004, the HPRA has implemented a policy of annual fee reviews following consultation with industry.

As stated in previous consultations, it is a priority for the HPRA to match resources from fee income, with current work volumes and to plan for future activity. The second aim, in respect of fee income, is to provide predictability, stable timelines and ability to fund the cost of the regulatory system that we operate.

To ensure that we manage the business properly, we have agreed to review our fees on an annual basis to reflect changes to our cost base and service levels. This document summarises the outcome of our review of fees and it sets out the current operating environment, the service levels and activities and expected changes in service levels and activities for 2023.

## 2 THE OPERATING ENVIRONMENT

2022 has been another challenging year for both the HPRA and the industry. As with all companies, the COVID-19 pandemic continues to require the HPRA to work in a different way. In May 2022 the HPRA returned to the office under a hybrid working model. Enabling 350 staff to return to the office while continuing to facilitate homeworking has brought its own challenges.

As a health agency with responsibility for medicines and medical devices, 2022 continued to be impacted by the authorisation and the roll out of the COVID-19 vaccines, vaccine boosters and therapeutics. While the COVID-19 related activity scaled down from 2021, the development of new vaccines and therapies with continued vaccination programmes has continued to be a significant focus nationally, in Europe and internationally. In relation to Brexit, the HPRA worked with Government and the Commission in the development of an EU legislative proposal to implement the Brexit exemptions (initially provided for by way of a Commission communication) until December 2024 which helps to protect human medicine access to the Irish market. Overall, we have seen a decrease in human medicine income while other income categories remain at expected levels.

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<sup>1</sup> The term 'Authority' is used to refer to the persons appointed under section 7 of the Irish Medicines Board Act, 1995, and previously referred to as the 'Board' of the IMB.

In 2023 overall authorisation and inspection volumes are expected to be equal or less than the previous year and costs are expected to increase. Payroll costs were less than planned in 2022 as full employment in the market and resource constraints meant that positions were unfilled for part of the year. In 2023 we expect significant increases in the cost of payroll from both increases in staff numbers and significant pay increases being negotiated by Government across the State sector with a gross increase in cost of between approximately 5% -6%. The increase in staff numbers is due mainly to delays in recruiting in 2022 and greater staff turnover. The additional staff were/are being recruited to manage COVID-19 therapeutics and vaccines, implementation of the Medical Devices regulations (MDR, IVDR) and the Clinical Trial Regulation (CTR), implementation of new legislation in assisted reproduction, cosmetics and the pharmaceutical strategy review at Europe. Other costs in 2022 were still below pre COVID-19 levels as the HPRA offices were closed for the early part of the year and travel and other events have not recovered to pre pandemic levels. However, the indications for the latter part of the year show a significant increase in activity and related costs and we expect this increase to be maintained into 2023. General inflation is high and is expected to impact costs for 2023. Additionally, it is expected that fuel costs will increase in 2023 with a knock-on impact for other costs.

Due to the increased complexity of regulation and enhanced regulatory and public health offerings, staff numbers continue to increase.

As noted previously, since 2019, the HPRA makes an employer contribution in respect of staff employed since 2013, under the single service scheme. This contribution is up to 17% of the payroll cost of those employees. By its nature, it will increase exponentially as all new staff are covered by this obligation and this means that as longer serving employees leave, they are replaced by a more expensive resource. It is appropriate, in common with all pension schemes that the employer makes a contribution and we have flagged in previous fee consultations the long-term impact of an unfunded pension scheme. This pension liability continues to impact on fees.

A particular area of concern is increased litigation, in the areas of both personal injury and judicial review. This unfortunately results in increased costs and resources dedicated solely to work which delivers nothing under our public health remit.

Public scrutiny and the role of the regulator in relation to medicines has increased in the areas of global supply and shortages, vaccines and vaccine hesitancy, and availability and access to innovative therapies.

### **3 STRATEGIC DIRECTION OF THE HPRA**

During 2020-2021, the HPRA developed a new strategic plan for the period 2021-2025. Following extensive consultations and a detailed review of the environment within which we operate, we have identified the themes and activities which we believe are relevant to the

development of our regulatory activities over the next five years. The high-level strategic goals under the current plan are as follows:

- **Health system partnerships** (strengthening our collaborations across all areas of the health system)
- **Progressive regulation** (increasing our use of proportionate and adaptive approaches for better patient outcomes)
- **Communication and engagement** (improving our models of engagement to strengthen public trust and confidence)
- **Enabling innovation** (enhancing our supports for innovation from discovery through to regulatory approval)
- **Great people, great processes** (developing our organisation and people to successfully achieve our goals)

The key projects for 2023 will include:

- Building on relationships with key stakeholders within the health system. The HPRA will continue to develop relationships with health service providers and policy makers in order to discuss significant issues relating to health products and related risk mitigations.
- Managing the continued review of COVID-19 vaccines and therapeutics and maintaining the post-authorisation systems as further booster campaigns are rolled out.
- Replacing the existing HPRA website with a new website with greater functionality. This is a major development project with a cross organisational team and external service supplier.
- Developing plans (including capital investment) to deliver on the Government sustainability plans for 2030
- Engaging with clinical researchers to support innovative research in Ireland
- Implementation of the IT strategy to ensure longevity and resilience in the system, including facilitating new ways of working resulting from the COVID-19 pandemic
- Contributing to the planned inquiry into sodium valproate
- Participating in a number of workstreams under the EU Health4Europe initiatives.
- Assessing and managing the impact of hybrid working.
- Participating in European and international projects in pharmacovigilance, crisis management and GMP
- Feeding into the review of pharmaceutical legislation in Europe
- Increasing our regulatory offering both centrally and in the decentralised system
- Continued implementation of the Clinical Trials Directive, Medical Devices and IVD regulations

All the above initiatives will provide real and tangible benefits to our stakeholders.

## 4 THE OUTLOOK FOR 2023

### *Operating environment for 2022*

The operating environment is challenging in 2023. Significant cost of living inflation combined with full employment on the Irish market has made recruitment challenging. Further increases in costs Q4 2022 and in 2023 will impact on the ability to match income with costs. Hybrid working and changes to standard working hours also provide challenges in the working environment which must be managed.

### *New legislation*

In 2022 the HPRA implemented three new regulations: veterinary (NVR), clinical trials (CTR) and medical devices (IVDR). The HPRA will continue to implement these regulations in 2023 as the transition provisions expire. Further legislation is expected in the areas of substances of human origin and following the outcome of the review of the pharmaceutical legislation which should be published in 2023. Legislation in the area of orphan and paediatric medicines will also be published.

The workload of the medical device department has increased significantly. The significance of the role that medical devices play in healthcare delivery and the related challenges in their regulation was highlighted in recent years by the COVID-19 pandemic. The Medical Device Regulation (MDR) and the *In vitro* Diagnostic Medical Device Regulation (IVDR) are both applicable. Significant work remains in providing support to stakeholders to aid their understanding and support their implementation of the regulations.

The new regulations place very explicit obligations on regulatory authorities in relation to their activities, resources and capabilities. In addition, growth in specific technological areas, such as digital health products and *in-vitro* diagnostics will necessitate reallocation, re-purposing and development of our staff. This means that staff increases in 2022/2023 are required to manage this increased workload. This will impact on the funding model, which is currently subvented by the Department of Health.

Implementation of new legislation does not just impact the departments concerned, their impact is felt across the organisation as management, legal, HR, IT and financial support is necessary for the successful delivery of the new legislation

### *Financial implications for 2023*

While income was lower than expected in 2022, costs including payroll numbers were also below normal, which helped the HPRA absorb some of the increases in payroll costs that have occurred in 2022, however the current negotiations in respect of pay which may be backdated to February 2022 will impact the final outturn for 2022. In 2023, it is expected that costs will increase significantly due to pay awards, the energy crisis and related inflation, increased onsite activity, the return of staff to the office on a hybrid basis for a full year. Implementing the hybrid model will continue to bring additional costs to both IT and facilities.

### *Payroll*

Payroll will increase in 2023 due to:

- The impact of the new pay deal, which has yet to be finalised will result in pay awards in 2022 and 2023 as follows:

#### **Year 2022**

- o 1% backdated to February 2022
- o 3% to be paid October/November backdated to February 2022 (proposed in current negotiations)
- o 1% in October 2022

#### **Year 2023**

- o 2% in March 2023 (proposed in current negotiations)
- o 1.5% in October 2023 (proposed in current negotiations)

The 3% in October 2022 was not included in costings for 2022 and the other 2022 increases will be in place for a full year in 2023. The net impact of these increases is a 6% uplift from the costs budgeted for in 2022.

- A significant number of payroll vacancies are being filled in Q4 which will lead to increased costs in 2023.
- The HPRA receives no funding for pensioners under the local government superannuation scheme (LGSS). Previously as a 'young' agency, this did not affect the HPRA significantly, but we have seen significant increases in pension costs in the last two years and it now accounts for 4% of payroll.
- COVID-19: Increased staff numbers brought on board 2022 will be kept on in 2023. Although it is hoped that the pandemic will become an epidemic, it is still a novel disease and it is expected that there will still be considerable activity related to it in 2023. From a regulatory perspective, in 2023 more therapeutics are expected and the issue of boosters/new vaccines and updated vaccines will also form part of the regulatory landscape.
- Continued implementation of new legislation; CTR, NVR, MDR and IVDR
- The EU pharmaceutical strategy and the revision of the pharmaceutical legislation
- Projects under the new strategy.

### *Other Costs*

While other costs have been below average during the lock down, we are seeing significant increases in Q4 2022 and these are expected to continue into 2023. The current energy crisis will significantly increase costs in 2023 and the impact on the economy while uncertain will result in increased costs. While inflation (which has been running as high as 9% in 2022), is expected to steady in 2023, there is a lag in terms of the impact of inflation on a business like the HPRA where most costs are either service based or related to the office. All contracts that are being renewed for 2023 have increases built into them ranging from 5-15% and energy costs may double or triple this winter and on into 2023.

The HPRA expects that 2023 will be very challenging for the reasons outlined above.

## **4.1 Risks and uncertainties in relation to the fee model**

The fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2022. The nature of regulatory income is that it is dictated by industry activity, which can change significantly over a period of time. In addition, the uncertainty from COVID-19 means that forecasting is extremely difficult and subject to change.

As with previous years, the HPRA commits to review the proposed fees during the planning cycle in 2023 and further amend the fees and fee structure, if required, for 2024.

## **5 PROPOSED FEES**

A general fee increase of 9% is proposed. The general increase will not be applied to the clinical trials (to support the implementation of the CTR) and the dormant fee for marketing authorisations. Medical device fees increased overall in 2022 due to the implementation of the MDR and the IVDR and it is proposed that the general increase will not be applied to the annual medical device fees but will be subject to a review in 2023 as the full impact of the new legislation is understood.

## **6 DETAILED CHANGES TO FEES**

### **6.1 General change to fees**

It is proposed that there will be a general increase of 9% in fees for the year 2023.



## 6.2 Other Proposed adjustments to fees – Clinical Trials

### 6.2.1 Clinical Trial fees under the Clinical Trials Regulation (CTR) – the HPRA fee and NREC fee

A single fee is charged by Ireland (the HPRA and the NREC Office) for each clinical trial application (CTA) or substantial modification (previously known as substantial amendment). The sponsor pays the total fee to the HPRA at the time of application to the CTIS and following validation the HPRA will transfer the corresponding portion to the NREC Office.

The HPRA is not proposing to increase the current CTR fees, however NREC intends to review their fees and conduct an independent consultation on clinical trial fees that may impact the total single fee for CTR clinical trials. Following the NREC consultation, the HPRA will publish any changes to the single fee for CTR clinical trials in our fee documents. For information on NREC fees, see <https://www.nrecoffice.ie/about/national-office/>.

Please note for clinical trials authorised under the Clinical Trials Directive (CTD), fees charged by both the HPRA and NREC are not linked and therefore payment of fees is made to each organisation based on each organisation's set of fees. The HPRA is not proposing to increase fees in 2023 for CTD trials. For information on NREC fees, see <https://www.nrecoffice.ie/about/national-office/>.

### 6.2.2 Request for authorisation under Regulation No: 536/2014 (fee codes 1003 and 1009)

It is proposed to clarify that requests for authorisation with or without an IMPD where IE is the concerned member state includes applications where IE is added as an additional MSC to a new trial or a transitioning trial.

Fee code	New Description
1003	Application with IMPD – IE Concerned Member State, <i>initial, transitional or additional applications</i>
1009	Application with no IMPD or with simplified IMPD or a low intervention trial – IE Concerned Member State, <i>initial, transitional or additional applications</i>

### 6.2.3 Request for authorisation under Regulation 14

The fees relating to requests for authorisation under Regulation 14 (fee codes 338 and 339) will not be operational and will not apply to any application received after 31 January 2023.

#### 6.2.4 Safety Assessment – DSUR/AR/SUSAR

The fee (fee code 348) relating to drug safety update reports where HPRA is the lead member state under a work sharing procedure also applies to a safety assessment member state role.

Fee code	New Description
348	Drug Safety Update Report where HPRA is the lead member state under a work-sharing procedure or <i>Safety Assessment Member State (saMS)</i>

### 6.3 Other Proposed adjustments to fees – Medical Devices

#### 6.3.1 Certificates of free sale or letter confirming the location of a manufacturing facility

It is proposed to introduce a fee of €120 for the generation of a letter that confirms that devices are registered with the HPRA.

	Current fee	Proposed fee
Certificates of free sale/letter confirming the location of a manufacturing facility in Ireland (four certificates per request)	255	255
Each additional certificate of free sale/letter confirming the location of a manufacturing facility in Ireland (available at the time of the initial request)	25	25
Letter confirming that a device or a list of devices are registered with the HPRA		120

#### 6.3.2 Registration of devices

The fee for the registration of devices will only be charged for initial national registrations. Where an economic operator is already registered with the HPRA in the context of the Directives, they will not be charged a second administrative fee when they register in the context of the Regulation or when additional roles are added.

#### 6.3.3 Annual fees for Distributors and Importers

It is proposed to remove the fee for the additional supplement for entities that are acting as both a distributor and importer where the company's turnover is less than €500,000.

It was also proposed to amend the additional supplement fee for entities that are acting as both a distributor and importer where the company's turnover is more than €500,000 to apply only to companies whose turnover is over €3 million.

	Current fee	Proposed fee
Additional supplement – Entities acting as both a distributor and importer (turnover less than €500,000)	250	0
Additional supplement – Entities acting as both a distributor and importer (turnover between €500,000 and €3m)	1,000	0
Additional supplement – Entities acting as both a distributor and importer (turnover more than €3m)	1,000	1,000

#### 6.3.4 Clinical Investigations and Performance Studies

It is proposed:

- to remove fees relating to AIMD clinical investigations (fee code 453) as this activity, under the MDR is now included in the fee for Class III and Class IIb devices, including relevant MDR Annex XVI clinical investigations (fee code 451)
- to include notifications under IVDR Article 70(1) and substantial modifications to notification (Art 74(1), Art 82, Art 58(2) under the fee code 450 - notifications associated with MDR article 74(1), Article 82 and IVDR Article 58(2).
- to include applications for authorisations of *in vitro* diagnostic medical device (IVDR) performance studies under IVDR Article 70(2) under fee code 449.
- to remove the fee for non-substantial amendments to a previously approved clinical investigation/performance study as the notification of these amendments are not required.

Fee Code	Clinical Investigations and IVDR Performance Studies	Current fee	Proposed fee
453	Active implantable medical devices clinical investigations	4,300	0
451	Class III and Class IIb medical devices, including relevant MDR Annex XVI clinical investigations	4,300	4,300
452	Class IIa and Class I medical devices, including relevant MDR Annex XVI clinical investigations	1,900	1,900
450	Notifications and <b>substantial modifications</b> to notifications in accordance with MDR article 74(1) & Article 82, IVDR Article 58(2) and <b>IVDR Article 70(1)</b>	200	200

449	Application for authorisation of <i>in vitro</i> diagnostic medical device (IVD) performance study under IVDR Article 58(1) (first submission) and PMPF study under IVDR Article 70(2)	2,500	2,500
448	Notification of Performance study involving Companion Diagnostic IVD using left over samples (IVDR Article 58(2))	265	265
447	PMPF study under IVDR Article 70	2,500	Covered under fee code 449
454	Substantial modifications and technical amendment to a previously approved clinical investigation / performance study	1,240	1,240
455	Non-Substantial amendment to a previously approved clinical investigation/performance study	200	0
456	Resubmission of a clinical investigation/performance study following a withdrawal or objection or if the application has lapsed	1,900	1,900
457	Resubmission of a clinical investigation/performance study – Academic Sponsor	510	510

### 6.3.5 Designation fee for a Notified Body

It is proposed that the fee for a designation of a notified body (fee code 484) is applied to both the initial designation and to the re-assessment of the notified body under the new Device Regulations 745 and 746 of 2017.

The re-assessment of the notified body is a new activity under the new Device Regulations 745 and 746 of 2017.

Fee Code	Designation fee for a Notified Body	Fee
484	Initial designation of a notified body and to the re-assessment of the notified body under the new Device Regulations 745 and 746 of 2017.	10,200
485	Extensions to the scope (per extension)	5,100

### 6.3.6 Assessment under Article 59 of the MDR and Article 54 of the IVDR

It is proposed to remove the current three fees which are based on the class of device and apply a fee of €4,000 to these assessments regardless of the class of medical device as the assessment process is very similar for all classes. No fee will be charged for single patient

applications however a fee will be charged in the case of applications relating to multiple patients.

These fees will apply to Article 54 of the IVDR and Article 9.12 of the IVDD will be removed.

Fee Code	Assessments under Article 59 of the MDR and Article 65 of the IVDR	Fee
417	Assessment relating to Article 59 of the MDR and Article 54 of the IVDR	4,000

### 6.3.7 European Union Reference Laboratories (EURLs)

It is proposed to charge a fee for the verification that the HPRA will conduct on any European Union Reference Laboratories (EURLs) designation applications that are prepared for submission to the European Commission.

Description	Fee
European Union Reference Laboratories (EURLs)	2,700

## 6.4 Other Proposed adjustments to fees – Compliance

### 6.4.1 Clinical Trials Regulation – Register of Exemptions (Article 61(5))

It is proposed to introduce the following fees for IMP manufacturing processes that are exempt from requiring manufacturers' authorisations.

Description	Fee
Initial application	280
Amendments to the registered details	155
Inspection fees	HPRA inspection fees apply to these registrations

## 7 CONSULTATION

The HPRA welcomes comments on these proposals and invites respondents to comment.

**Contributions to the consultation** on these proposals may be provided to the HPRA by 29 October 2022. Contributions should be sent by email to [feesconsultation@hpra.ie](mailto:feesconsultation@hpra.ie).

## **APPENDIX I SERVICE LEVELS - HUMAN PRODUCTS AUTHORISATION, REGISTRATION AND SAFETY MONITORING**

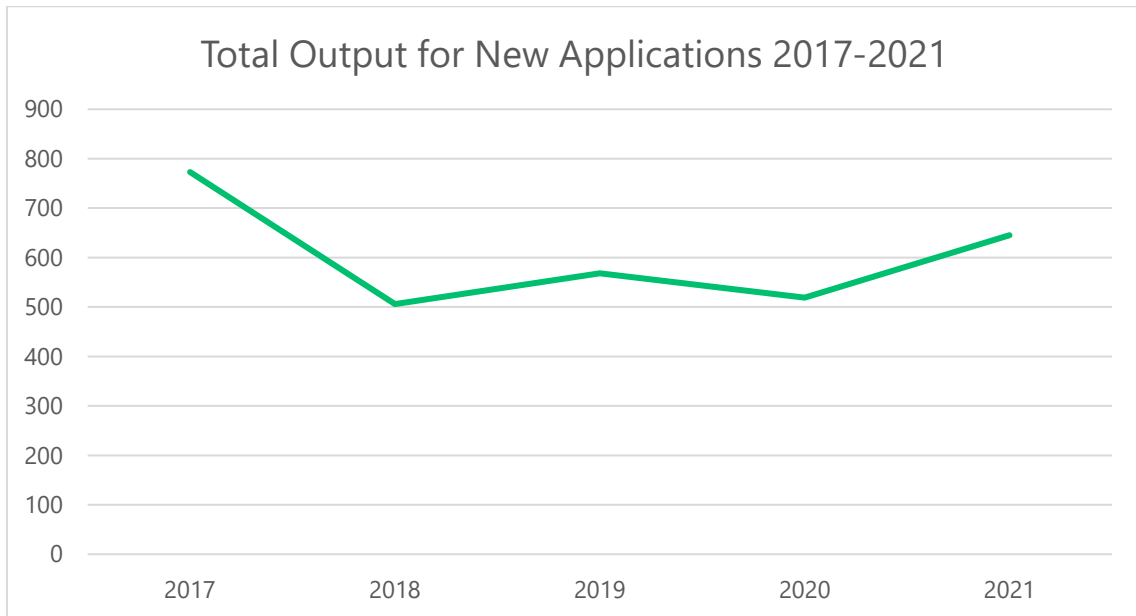
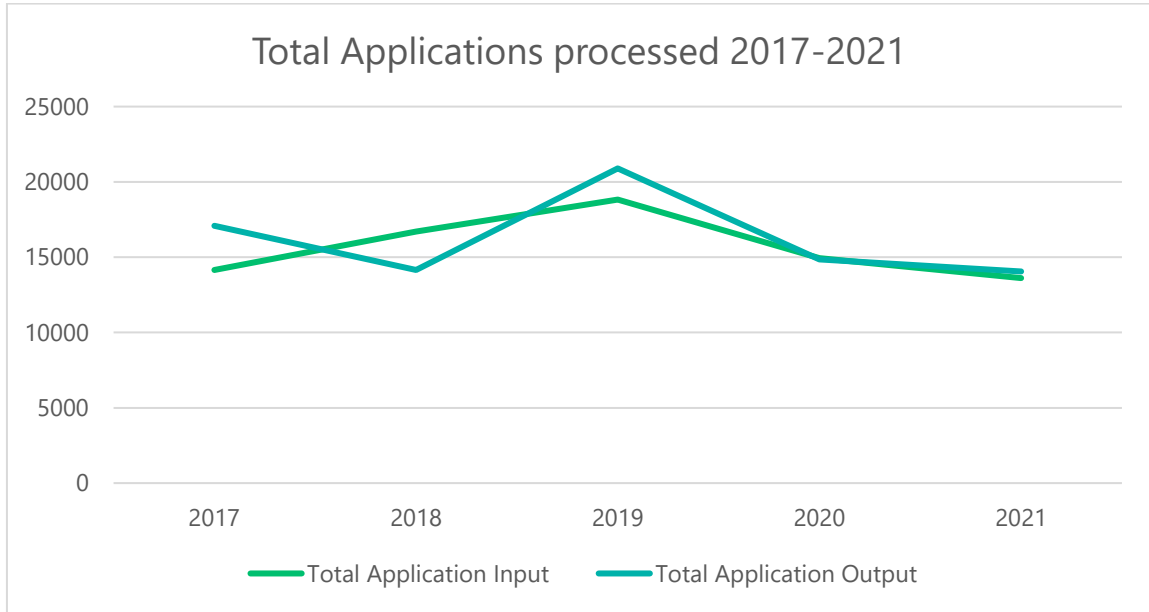
The most significant projects undertaken by the HPRA in the last number of years were driven by the requirement to maintain and further improve patient safety, protect access to medicines and service levels to industry.

These projects include in summary:

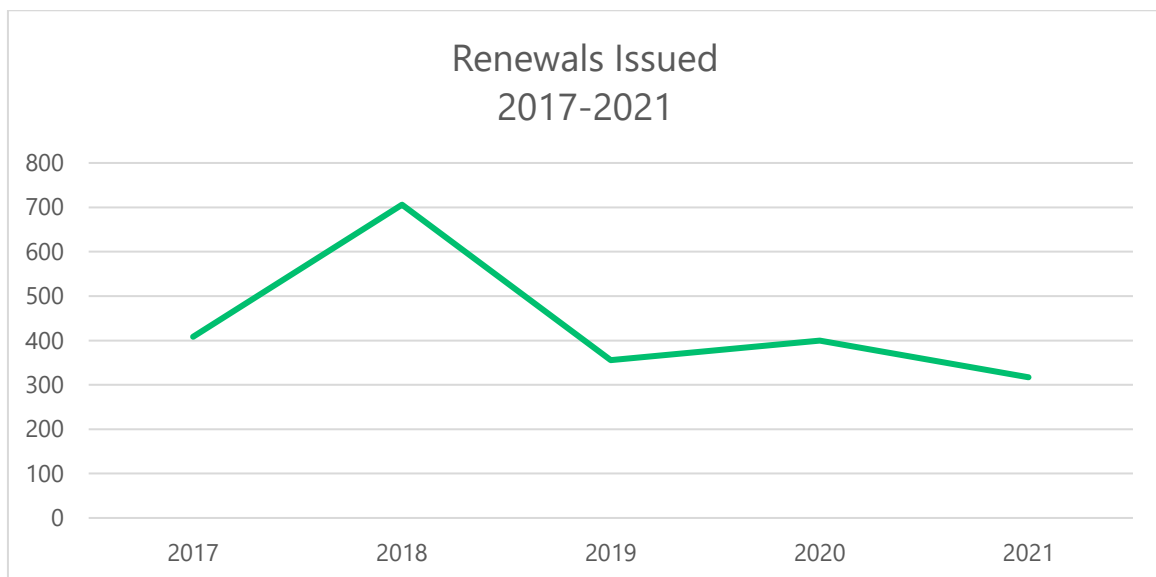
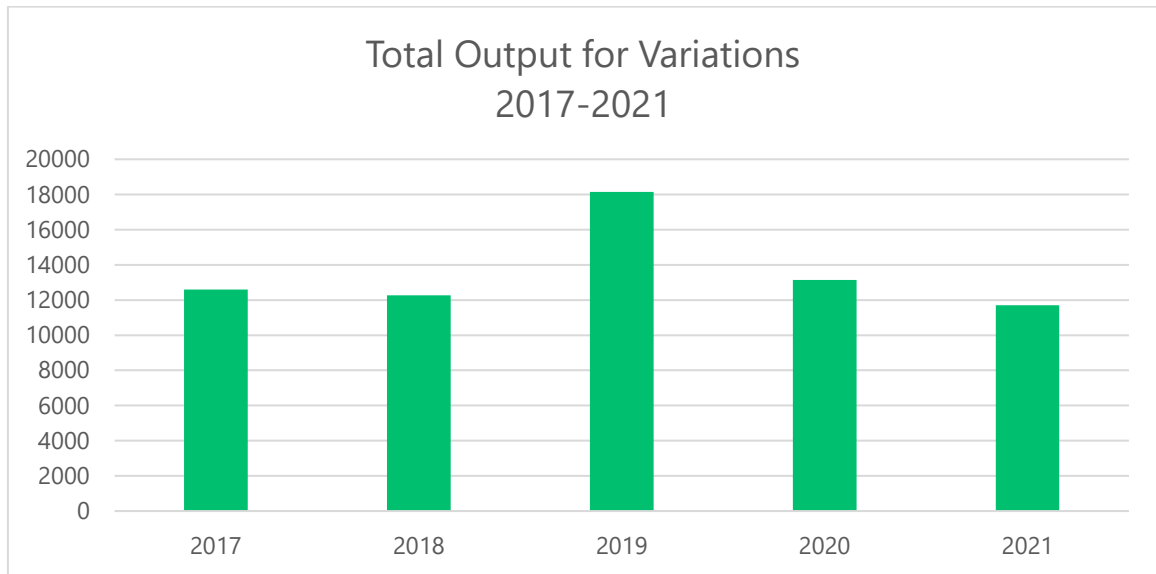
- Readiness to operate as Reference Member State for both MR and DCP new procedures.
- A national scientific advice procedure was introduced in 2016. This assists applicants in the development of new or existing human medicinal products by taking into account the current knowledge of a given condition, targeted patient population, existing treatment modalities and specificities of the product being developed.
- Progress has been made in the development of a new HPRA workflow system. Our focus is now on further optimisation of this workflow technology to ensure ongoing delivery of continued benefits to the organisation and stakeholders in the tracking and managing of workloads. Further development of capabilities in using key performance indicators to allow for more effective monitoring of timelines will improve utilisation of resources and drive further efficiencies.
- Integration of the online reporting system for adverse reactions with the HPRA adverse reaction database which is accessible to patients and health care professionals in tandem with further streamlining of current adverse reaction processing procedures to allow for improved case processing efficiencies. This work supported the significant increase in adverse reaction reports submitted directly to the HPRA arising from the COVID-19 pandemic, including vaccines and therapeutics.
- Continued customer-focused approach.
- Work on the list of interchangeable medicines to support generic substitution by pharmacists in line with the Health (Pricing and Supply of Medical Goods) Act 2013 continues, and is a routine component of our assessment work. We review substances as requested by the Minister for Health or the HSE. In addition, we review applications made by industry to have their products incorporated on to the list.
- Focus on the continued provision of guidance and support to industry stakeholders in areas undergoing evolving regulatory development, including:
  - o the new requirements of the Clinical Trials Regulation
  - o the new requirements of the Medical Devices Regulations

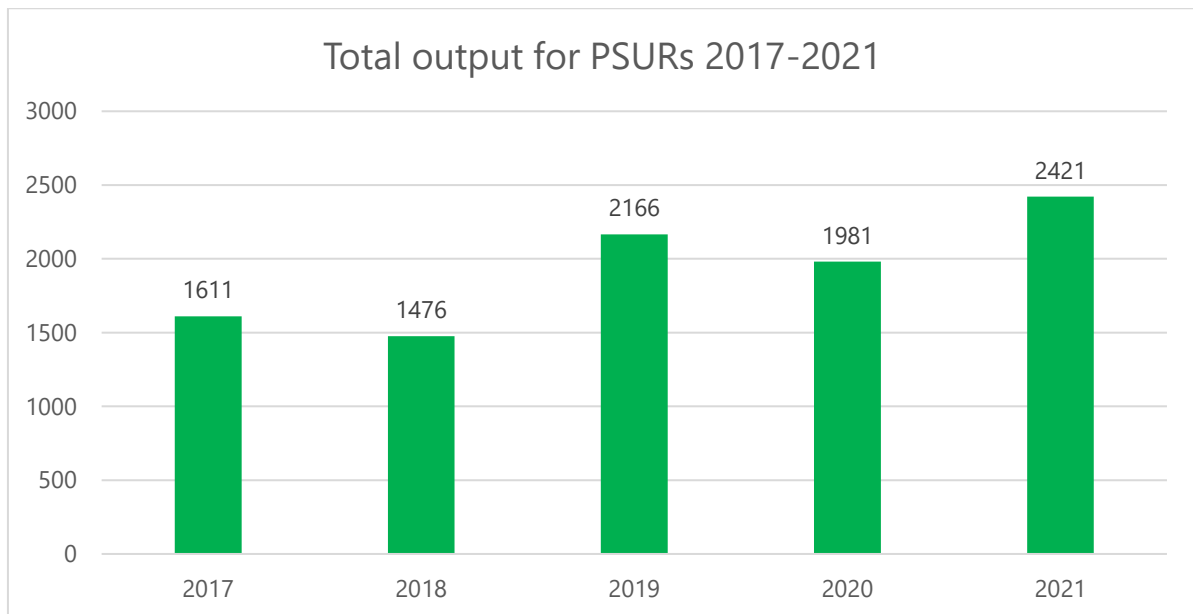
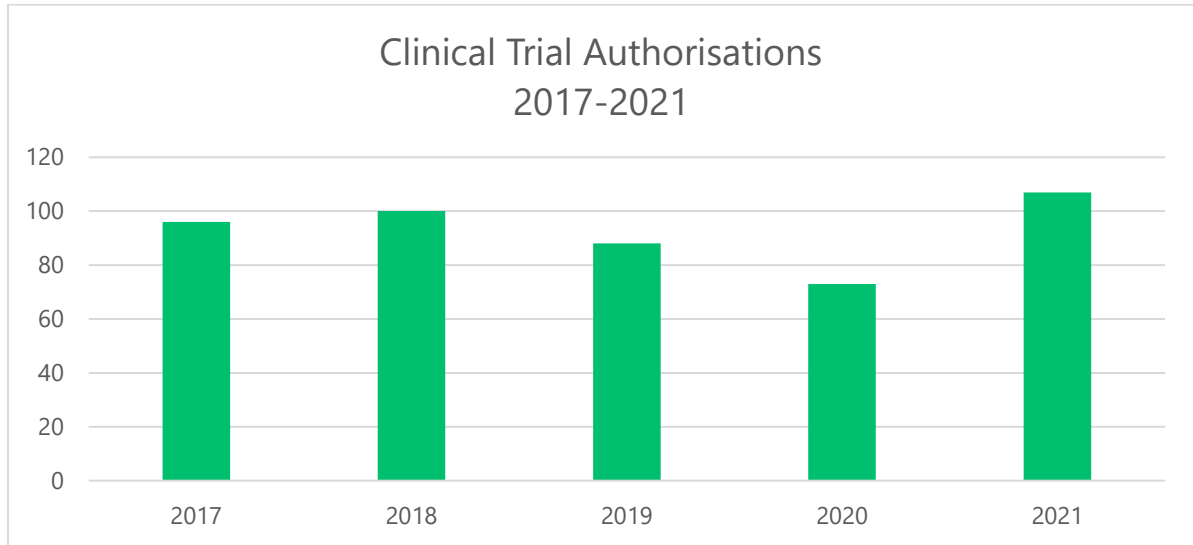
- A proactive approach to reclassification of the legal status of medicines (switching) continues. The HPRA is open to discussing innovative switches.
- Raising awareness of the regulation of medicines and important safety considerations via publications and contributions to undergraduate programmes in the medical and paramedical fields.
- Enhanced patient engagement through the Patient Forum which facilitates dialogue and exchange on topics relevant to patients regarding the regulation of medicines and medical devices.
- Enhanced monitoring of vaccines and therapeutics related to COVID-19. The substantial increase in the number of direct reports to the HPRA continue to be made available to MAHs via Eudravigilance.

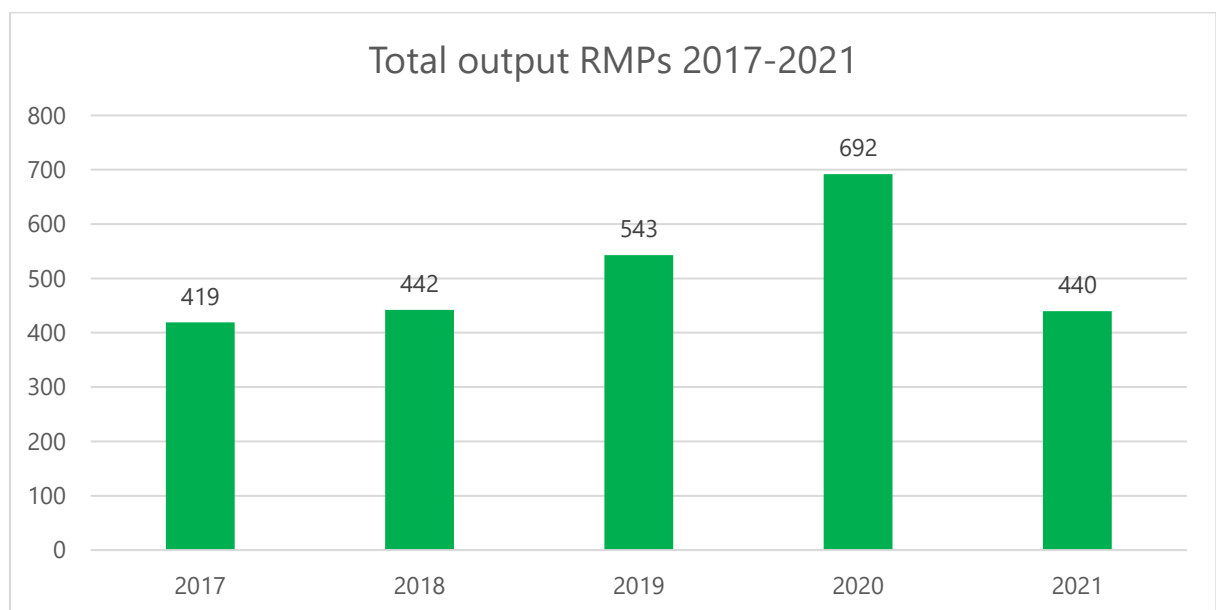
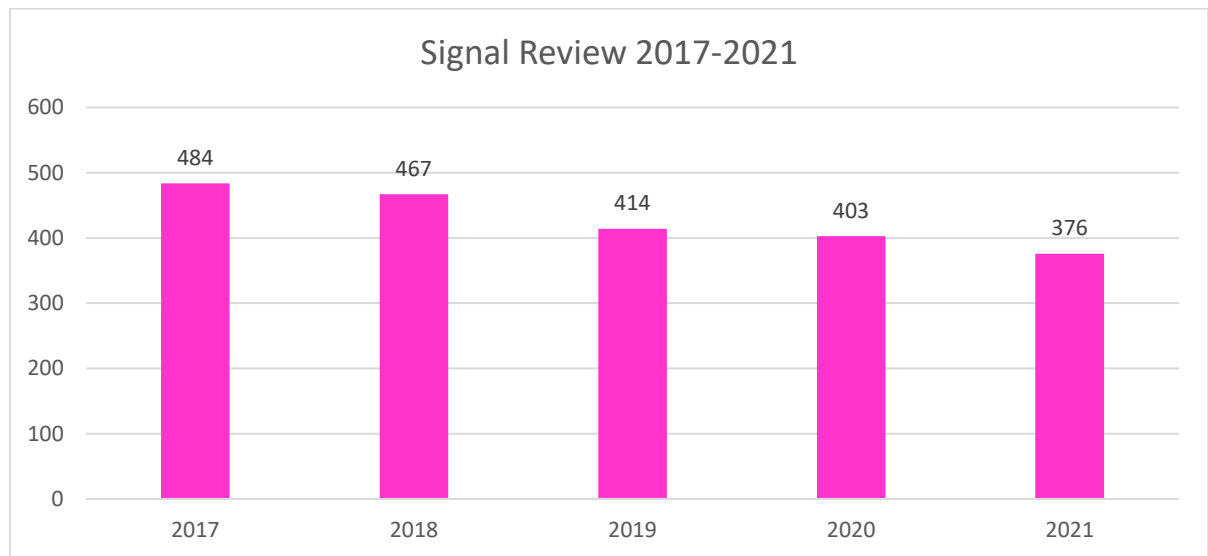
The following graphs outline the output across all application types up to the end of 2021.

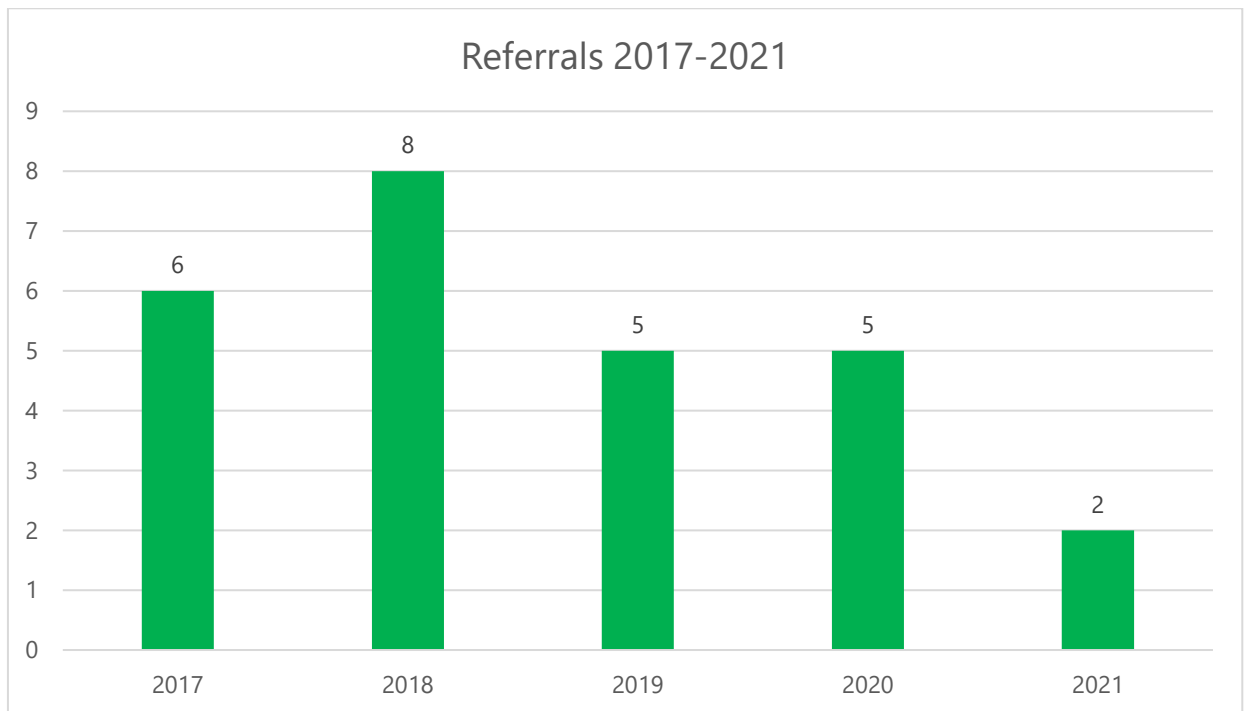
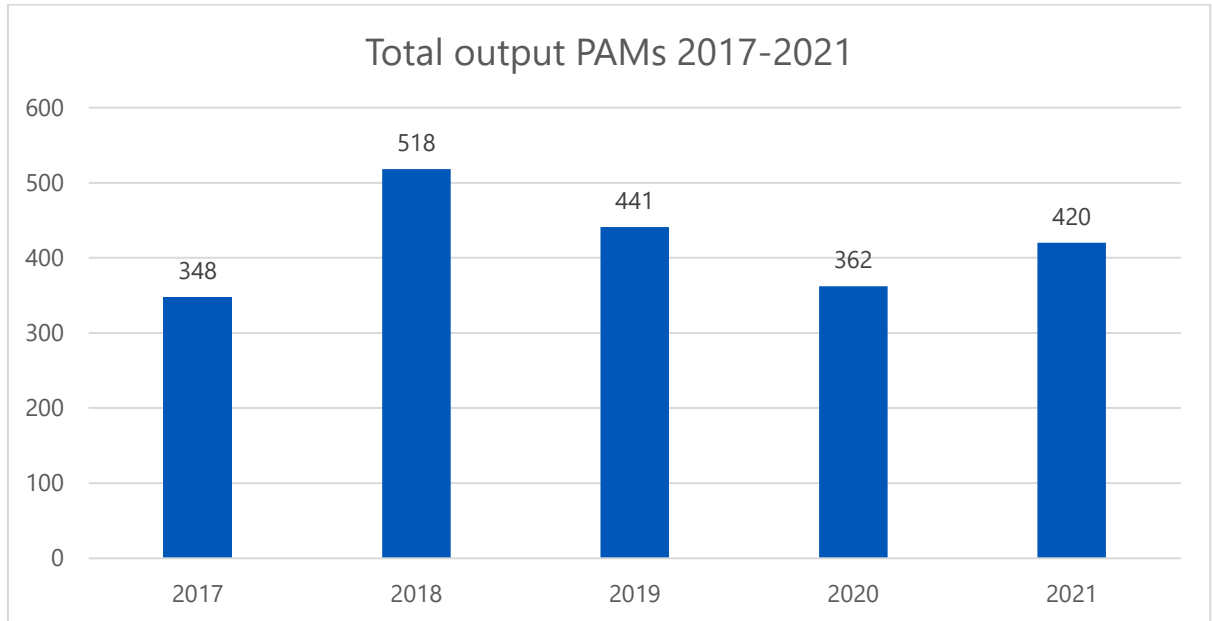


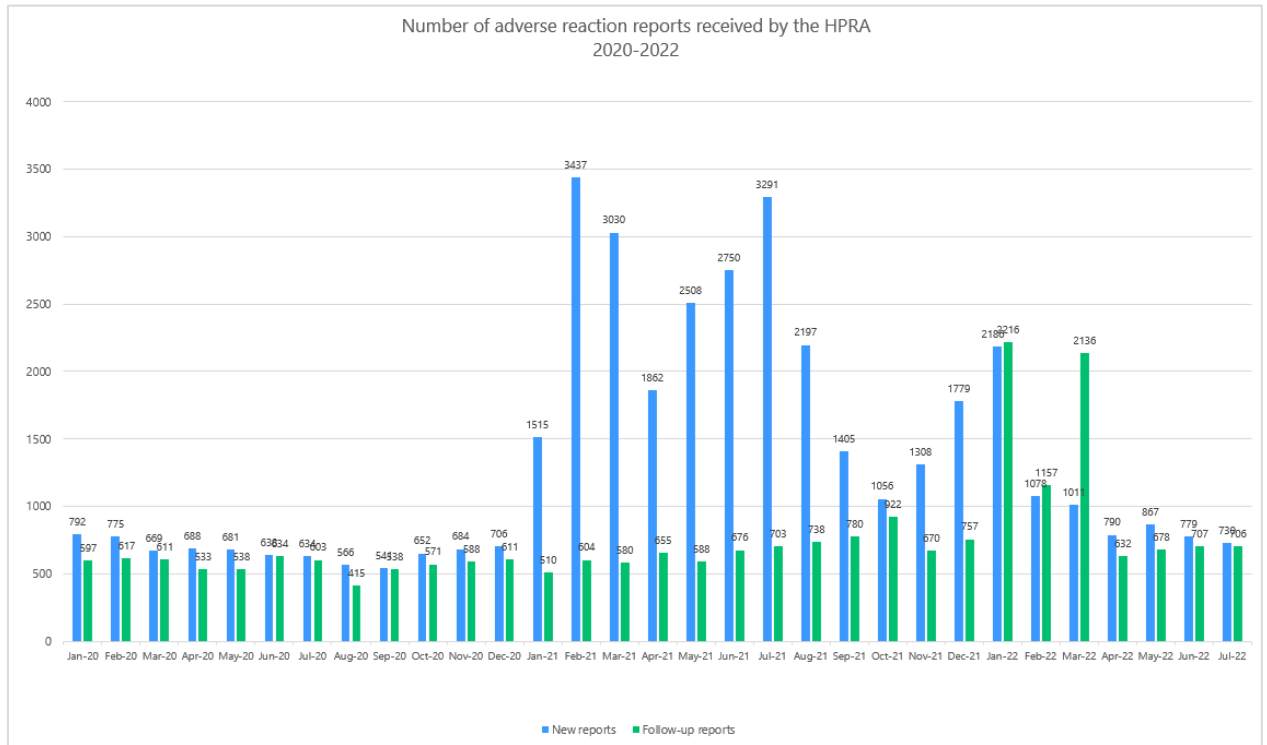












## APPENDIX II SERVICE LEVELS – COMPLIANCE DEPARTMENT

Initiatives undertaken/further developed in 2021/2022 included:

- Preparations for Brexit, in conjunction with other departments across the organisation, have included:
  - o Continued engagement with stakeholders with the primary purpose of maintaining supplies of health products through and beyond Brexit.
  - o Meetings continued with stakeholder companies in order to discuss their Brexit related plans and to clarify issues arising. Such meetings and liaison will continue to be an important focus.
  - o Regular liaison with key wholesalers to clarify ongoing stock levels of medicines, plans for replenishment, identify any particular difficulties in the supply chain and, if necessary, to assist in remediating those.
  - o Meetings with industry representative bodies, and attendance at workshops organised by some of those bodies, in order to consider and clarify Brexit related questions.
  - o Advising potential applicants for authorisations and licences of the requirements and processing of a number of new applications.
  - o Provision of support to the Departments of Health and Agriculture, Food and the Marine, including participation in regular meetings of the Brexit Operations Group and the Brexit Medicines Review Group, both convened by the Department of Health.
  - o Liaison with other agencies, including the Health Service Executive and Revenue's Customs Service, on issues of mutual interest.
- Since July 2019 when the EU-US mutual recognition agreement (MRA) on GMP inspection became fully operational, the HPRA has responded to a significant number of requests from the US Food and Drug Administration (FDA) for inspection reports relating to manufacturing sites in Ireland that are supplying human medicines into the US. This has led to a considerable reduction in the number of FDA inspections of Irish manufacturing facilities. In relation to importation of human medicines manufactured in the USA, the requirement for retesting of each batch on importation to the European Economic Area has been removed by virtue of the MRA becoming operational.
- Continued provision of support to the Department of Health on the implementation of national legislation aimed at preventing the entry of falsified medicines into the legal supply chain – implementation of Directive 2011/62/EU ('Falsified Medicines Directive' (FMD)).
- Under the FMD, annual updates to registrations of manufacturers, importers and distributors of active substances and brokers of medicines for human use were processed during 2020 and 2021.
- Also under the FMD, staff in the HPRA continued to participate in an expert group on safety features convened by the European Commission. A Commission Delegated Regulation, which sets out the requirements around safety features on the majority of

prescription medicines for human use, was implemented by relevant marketing authorisation holders (MAHs) and manufacturers on 9 February 2019. In relation to this, the HPRA has liaised closely with MAHs, manufacturers, wholesale and retail stakeholders which have come together as the Irish Medicines Verification Organisation (IMVO) to implement the so called 'stakeholder model'. This has included the development of a national database (repository) for batches of human medicines bearing safety features that are placed on the Irish market and a system for authentication of packs at various points in the supply chain, principally at point of dispensing. The purpose is to guard against falsified medicines reaching patients.

While not part of the governance structure of the IMVO, we continue to liaise closely with it. We have an oversight role in relation to the repository and have taken on the role of lead of the EU working group on supervision of the repositories. We also participate in a National Oversight Group made up of key stakeholders and convened by the IMVO. Implementation of authentication was not straightforward and, accordingly, was approached in a 'use and learn' mode. Gradual transition to full implementation, as per the Delegated Regulation, had commenced during the first quarter of 2020 but had to be postponed due to the advent of the COVID-19 pandemic. The 'use and learn' phase officially concluded on the 30 May 2022.

- Continued upload of post-inspection good distribution practice (GDP) certificates to the EudraGMDP database. All existing Wholesale Distribution Authorisations (WDAs) had already been uploaded to the database and upload of new or varied WDAs continued.
- Continued upload of Manufacturers'/Importers' Authorisations (MIAs) and post inspection good manufacturing practice (GMP) certificates to the EudraGMDP database.
- The Veterinary Regulation, 2019/6 was implemented in January 2022. Work is ongoing with colleagues from the Veterinary Sciences department, the legal section and the Department of Agriculture, Food and the Marine to ensure smooth implementation of the new regulation.
- Provision of support to the Department of Health on the implementation of national legislation relating to the Children and Family Relationships Act, Human Tissue Bill and Health (Assisted Human Reproduction) Bill which overlaps with the human tissues and cells legislation for which HPRA are the designated competent authority.
- Continued support to the Department of Health on the implementation of national legislation regarding quality and safety of human organs intended for transplantation – Directive 2010/53/EC. This included monitoring of authorised procurement and transplant centres, via inspections and other follow up measures. The framework for quality and safety of organs for human transplantation, developed in conjunction with Organ Donation and Transplant Ireland (ODTI), is used in evaluating these centres. Review and updating of this framework, in conjunction with ODTI, continued in 2019/20.
- A system for reporting and assessment of serious adverse events/reactions relating to organs for human transplantation remains in place.

- Continued support to the Department of Health on the development and implementation of national legislation regarding controlled drugs. An upgraded system for processing of licence applications and collation of statistics became fully operational in Q1 2021 and has provided a much improved service to stakeholders.
- Continued provision of support to the Department of Health in the development and implementation of an access programme for cannabis for medical use. The HPRA continue to receive and review applications for inclusion of products under the programme. A number of products have been recommended to the Department for inclusion under the programme. This work is ongoing.
- Monitoring, via inspections, of the implementation of Good Manufacturing Practice requirements, Good Distribution Practice, Good Clinical Practice, and Good Pharmacovigilance Practice standards, and of the required controls relating to controlled drugs and precursors.
- Provision of support to the Department of Health in implementing two European regulations relating to precursor chemicals.
- Monitoring, via inspections, of the activities of Marketing Authorisation Holder companies with respect to their obligations under the Medicinal Products (Control of Placing on the Market) Regulations, 2007 to 2019.
- Active participation in harmonisation of standards and inspection practices through EMA working groups and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Committee and its Expert Circle meetings. The HPRA's Inspection Manager assumed the Chair of the PIC/S for 2020-2021. PIC/S has 54 member regulatory authorities, drawn from all continents.
- Active participation in the work of the Official Medicines Control Laboratories (OMCL) network to promote risk-based approaches to surveillance programmes and effective work-sharing programmes. The HPRA also led on an initiative within the Heads of Medicines Agencies Group on developing a new risk-based approach to the sampling and analysis of mutual recognition, decentralised and centralised medicines which was finalised during 2018 and implemented during 2019. Work on extending this initiative to the post marketing phase began in 2020.
- The HPRA continues to participate in optimisation of the processes used by EEA medicines competent authorities for the management of quality defects, recalls and rapid alerts. This has included implementation of revised (more risk-based) versions of the relevant EEA procedures during 2020 and 2021.
- Continued development of the advertising compliance programme which includes regular liaison with industry to outline HPRA requirements and to clarify our interpretation of the legislation.
- Further development of the monitoring of the availability of medicines in non-pharmacy retail outlets with appropriate follow up where unauthorised or pharmacy confined/prescription only medicines are identified.
- Continued development of our role as competent authority for cosmetics. This includes maintenance of effective working relationships with the Department of Health, HSE and



the Competition and Consumer Protection Commission, and the implementation of a coordinated national approach to market surveillance and testing of cosmetics.

- The National Cosmetics Safety Forum was continued by the HPRA and the HSE for the purpose of reviewing the safety of cosmetic products available within the Irish market place. The forum develops the market surveillance programme in line with risk based principles and takes account of new legislative and technical progress.

COVID-19 pandemic:

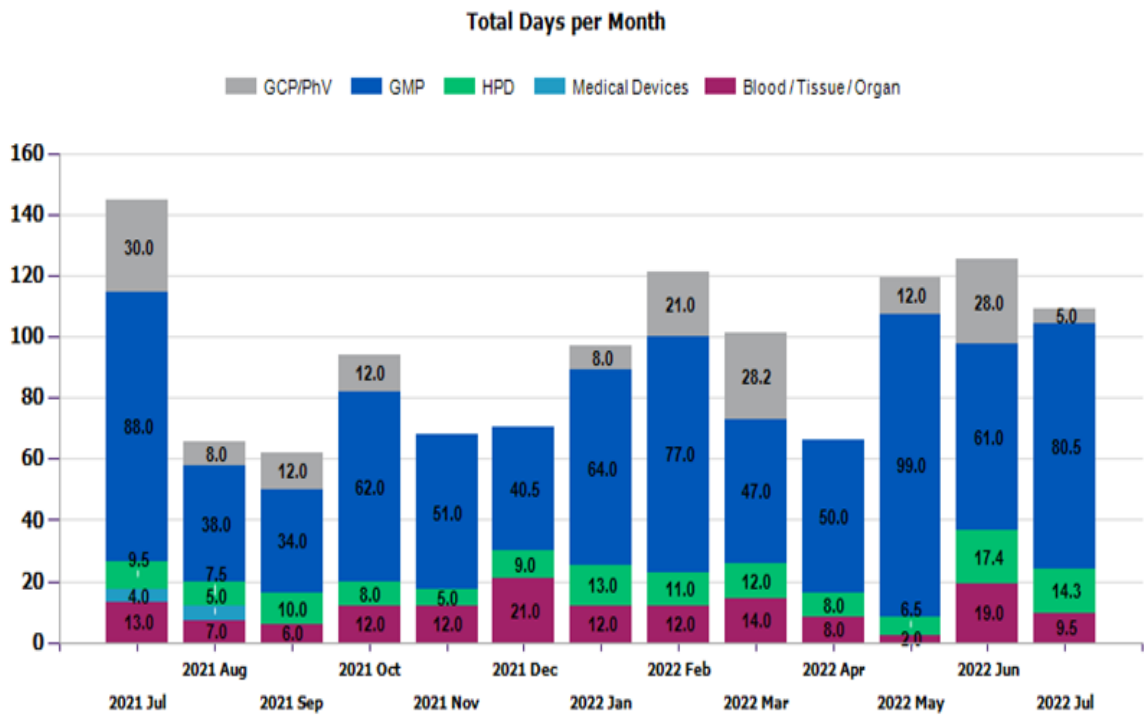
- Processing of controlled drugs licences, export certificates and the various authorisations continued throughout.
- The pandemic meant that all inspection activities had to be suspended during March 2020. Since then the HPRA has led in the development of EU guidance on remote inspections/distant assessments. A programme of remote inspections is in place across the GxP inspection activities in the organisation
- Guidance was drawn up for safe return of inspectors to regulated sites and training was completed. A hybrid inspection model, comprised of remote and focused onsite elements was used, where necessary, during Q3 2020.
- All other activities of the Compliance department continued as normal throughout the pandemic.
- In conjunction with colleagues from the Medical Devices department, the Enforcement section monitored for illegal supplies of test kits for diagnosis of COVID-19 and treatments for the virus. Monitoring for illegal supplies of medicines continues. Co-operation from Revenue's Customs Service and An Garda Síochána was of great assistance in this monitoring and, where necessary, in the investigation of suspected illegal activities.

Other activities included:

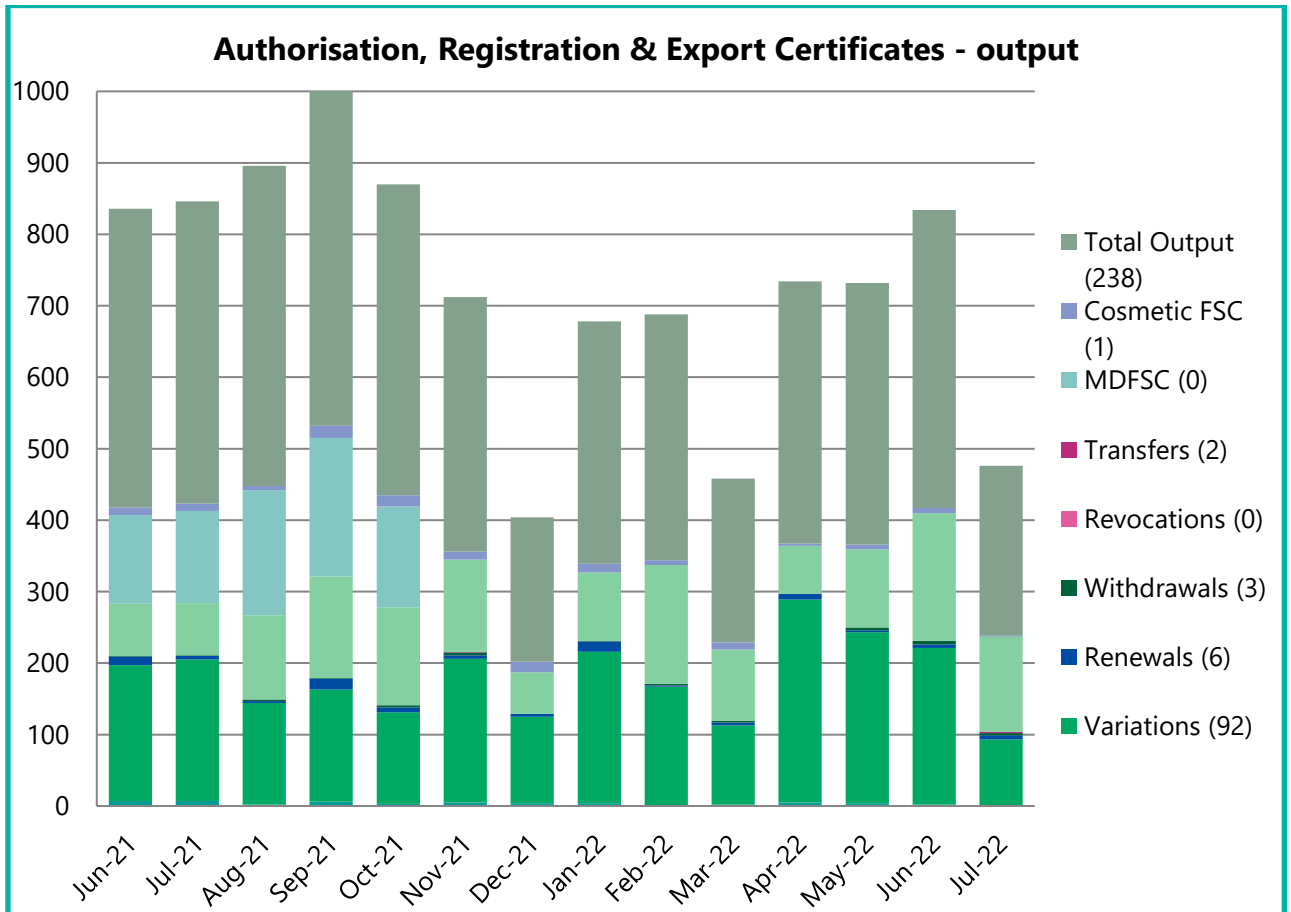
- Continued interaction and communication with stakeholders, including industry and other representative groups. These included meetings (virtual) with industry representative bodies and individual companies.
- Continued management of the controlled drugs function on behalf of the Department of Health.
- Continued management and use of the exempt medicinal products importation/supply data that are notified to the HPRA by wholesalers sourcing exempt products. These data continue to serve as a source of relevant information for the quality defect and recalls programme.
- Efficient turnaround of applications for variations to manufacturers' and wholesalers' authorisations, and for export certificates (medicines, medical devices and cosmetics) and controlled drugs licences.
- Further development of good clinical practice, bioequivalence and pharmacovigilance inspections.
- Full programme of good practice inspections of blood, tissue and organ establishments.

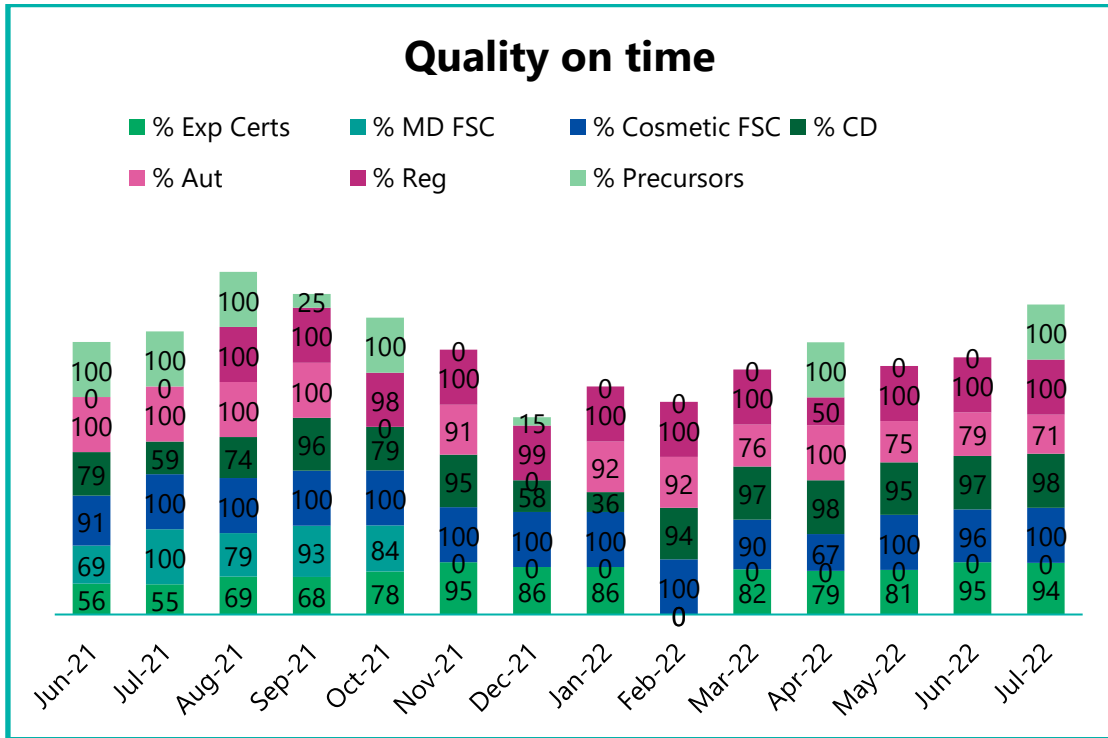
- Continued strong focus, through good distribution practice inspections and enforcement activities, on the legitimate supply chain to prevent infiltration of falsified products.
- Continued monitoring of the parallel trading of medicines by wholesalers based in Ireland, particularly relative to ensuring that the needs of Irish patients are met.
- The particular focus on the illegal trade in anabolic steroids and associated products has continued.
- In co-operation with Revenue's Customs Service, ongoing detection and detention of illegal supply, including mail-order importations of prescription-only medicines.
- Co-operation with Revenue's Customs Service, An Garda Síochána, Sport Ireland, and the Food Safety Authority of Ireland (FSAI) to identify and disrupt medicinal products/food supplements supply among sport and leisure participants that are, in particular, considered to present a risk to human health.
- Co-operation with An Garda Síochána and the Pharmaceutical Society of Ireland to detect and stem the flow of unauthorised medicinal products and leakage of authorised medicinal products from the legitimate supply chain for illicit supply and use.
- Enhanced level of intelligence-led enforcement operations with An Garda Síochána, Revenue's Customs Service and enforcement agencies worldwide on Operation Pangea XIII, an Interpol-coordinated international operation against illegal supplies, including trafficking, of unauthorised prescription medicines and medical devices via online and social media activities.

The graph below shows the level of inspection activity for the period July 2021 to July 2022 inclusive.

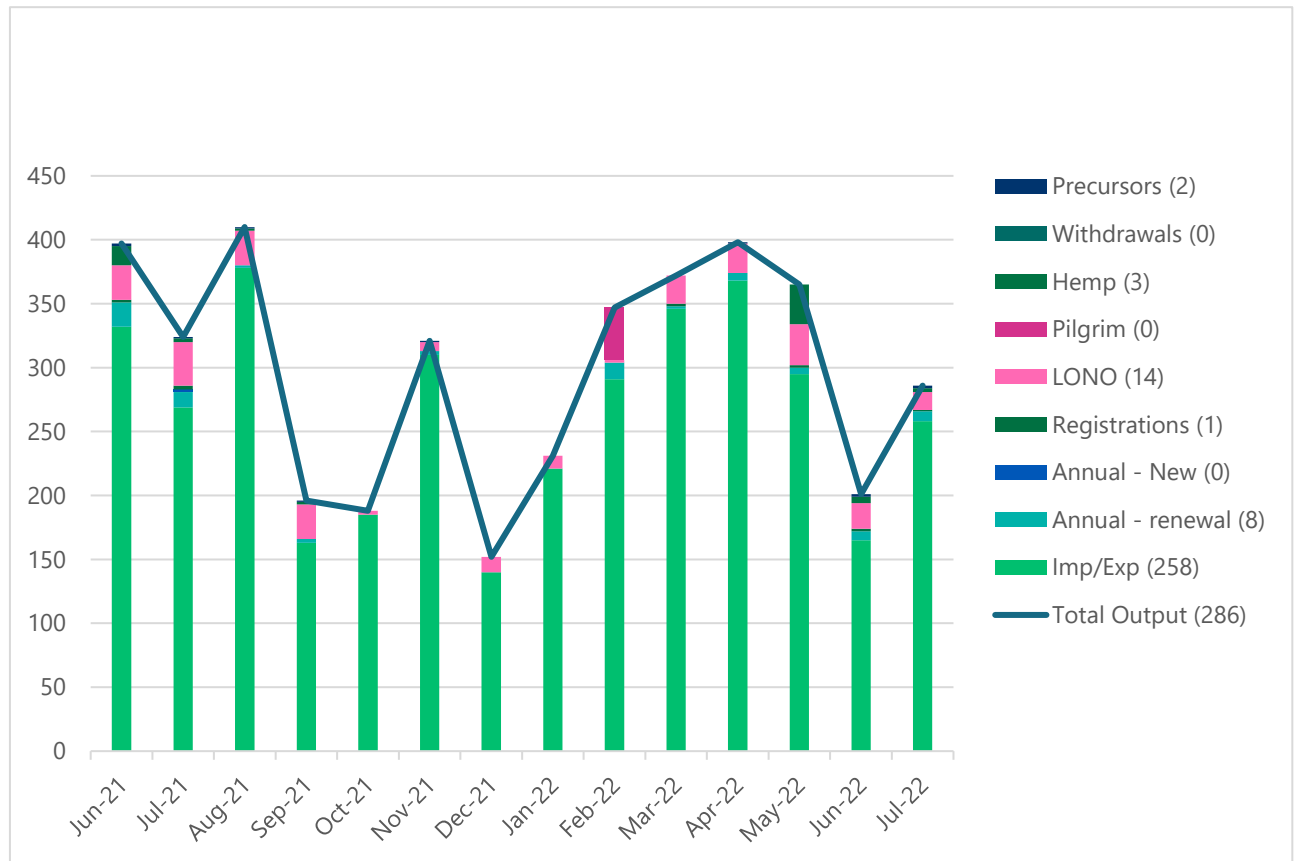


The following graphs show the numbers issued and the percentages issued on time, for export certificates, controlled drugs licences and GDP, GMP and IMP licences, over the period July 2021 to July 2022, inclusive.

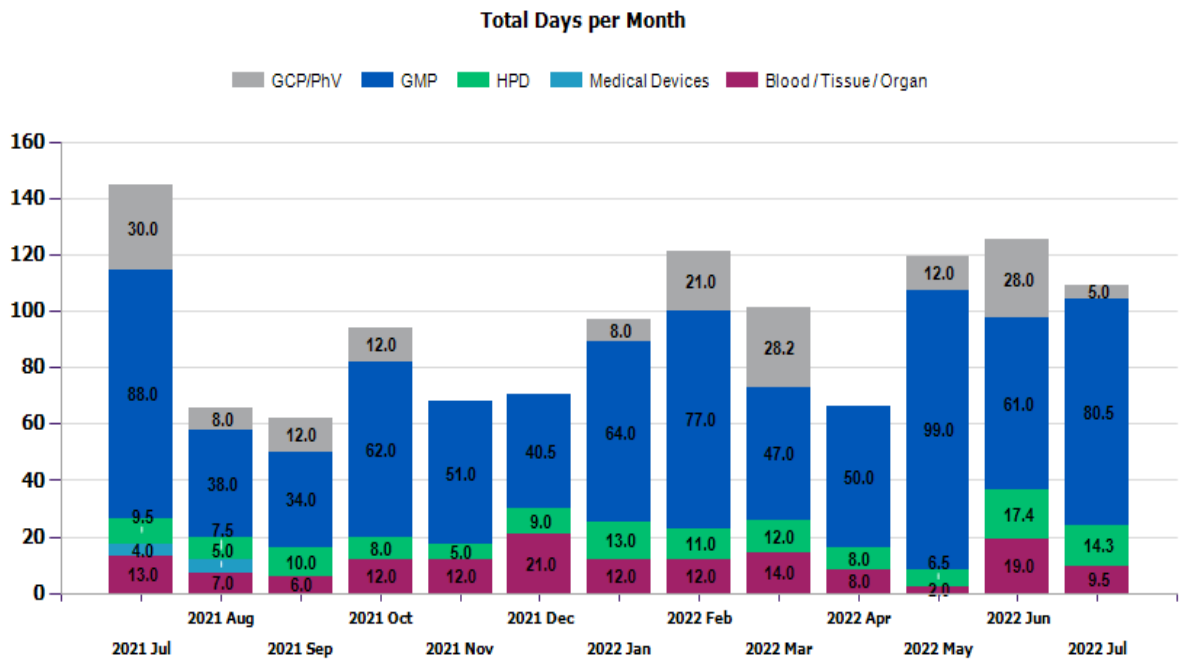




The graph below shows the output of licensing of controlled drugs, by category of licence.



The graph below shows the number of enforcement cases for the period July 2021 – July 2022 inclusive. The majority of these relate to attempts to illegally import prescription-only medicines, an amount of which are falsified. The remainder involve the supply by wholesale and retail sale of prescription only medicinal products which are authentic, but diverted and falsified medicines.



### Blood, tissues and cells

During 2021 and 2022 to date, a full inspection programme for blood establishments (i.e., involved in the collection, testing, processing, storage and distribution of blood) was carried out. Annual reports from all blood banks were received and reviewed during both years.

The HPRA also continued its interaction with the National Haemovigilance Office (NHO) in relation to haemovigilance reporting requirements and updates.

The tissues and cells legislation requires all sites involved in the procurement, testing, processing, storage and distribution of tissues and cells to be authorised. A programme of inspections of tissue establishments has been carried out.

The HPRA also continued to operate the tissues and cells vigilance system, participating at EU activities and training to support development of further harmonisation initiatives across the EU.

### **Human organs for transplantation**

Directive 2010/53/EC was transposed into Irish legislation via Statutory Instrument No. 325 of 2012. Under this legislation, the HPRA is the competent authority responsible for the inspection and authorisation of organ procurement and transplant centres and for serious adverse event and reaction reporting. The HSE (via Organ Donation and Transplant Ireland (ODTI)) also has competent authority functions in the areas of standards and traceability/registries.

The organs legislation applies to the donation, procurement, testing, characterisation, transport and transplantation of organs. A programme of inspections of procurement and transplant centres was carried out with follow up, as appropriate. The HPRA continued to liaise with the HSE lead and ODTI colleagues in relation to the vigilance system in place for reporting of suspected serious adverse reactions and events, in accordance with the legislative provisions in place.

### **Controlled drugs**

The HPRA continues to be responsible for management of the application and issuing processes for all controlled drugs licences, with the Department of Health retaining a signatory role for all official documentation. In 2019, the HPRA took on responsibility for managing applications for products to be included within the Medical Cannabis Access Programme (MCAP), on behalf of the Minister of Health. The Minister retains the final decision to include a product within the MCAP as this requires the schedule to a statutory instrument to be amended. Inspections related to import, export and holding of controlled drugs and drug precursors have been implemented and continue to be developed. The significant increase in applications for licences to cultivate hemp, first seen in 2019, has continued in 2021 and 2022.

### **Exempt medicinal products**

The number of packs of exempt (unauthorised) medicines notified to the HPRA maintained relatively consistent through 2020 and 2021, with a slight reduction in 2021. The HPRA has an electronic notification system and continues to work closely with companies to ensure data has been uploaded correctly. The notifications are an important source of information, particularly when checking on whether products recalled in other countries have been supplied as exempt medicines in Ireland.



### **APPENDIX III SERVICE LEVELS – MEDICAL DEVICES**

As the national competent authority for medical devices, the HPRA is the authority responsible for notified bodies and the market surveillance authority for medical devices in Ireland. The HPRA carries out a range of classification, registration, surveillance, assessment and compliance activities. We also review clinical investigations, inspect manufacturing sites and authorised representative facilities, designate and oversee notified bodies, and investigate activities associated with non-compliant supply and manufacture of medical devices. 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.

Caseload volume continued in line with recent trends observed since 2015 in medical devices. There continues to be a focus on vigilance cases and field actions (recalls, device modifications, etc.) relating to devices on the Irish market. These cases are increasing in complexity and significance in terms of assessing the impact on public health. In addition, the HPRA has engaged significantly and developed its activities relating to medical device market surveillance, notified body oversight and technical and clinical assessment. Another key area of focus during the past year has been our contribution to ongoing legislative and policy initiatives aimed at developing the regulatory framework as well as our involvement in supporting the Department of Health, the HSE and industry in managing medical device related aspects of the COVID-19 pandemic. Further details on these issues are outlined below.

#### **AUTHORISATION AND REGISTRATION**

- The HPRA is focused on ensuring effective and consistent designation and oversight of notified bodies at national and European level. In 2021, we:
  - Assessed an application for designation under Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) which included completion of a preliminary assessment report, an on-site assessment and review of follow-up CAPA responses. This process will continue into 2022.
  - Continued our schedule of oversight of the notified body in Ireland based on ongoing assessment, surveillance and observed audits. We completed the first surveillance assessment under Regulation (EU) 2017/745 on medical devices (MDR).
  - Contributed national experts as part of a European Joint Assessment Team (JAT) for a designation application under the IVDR for an Italian conformity assessment body
  - Continued to support development of EU coordination of notified body designation and oversight through participation in the EU Notified Bodies Oversight group (NBO) and the Medical Device Coordination Group (MDCG)
  - Worked with the European Commission and the competent authorities for medical devices on initiatives to gather data on notified body capacity and certification workload associated with MDR and IVDR.

- Supporting innovation and research of new technologies is a key strategic priority for the HPRA medical devices team. In 2021, this support included:
  - The review of applications to conduct clinical investigations of medical devices in Ireland. The number of clinical investigations increased with nine new applications for clinical investigations and seven amendments to ongoing investigations. The HPRA anticipates that these numbers will increase.
  - A continued focus on this area to ensure 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 held pre-submission meetings with innovators to discuss potential clinical investigation applications in 2021.
  - Provided technical, clinical and regulatory support to the work of the HPRA Innovation Office on medical devices queries.
- Manufacturers of certain medical devices and *in vitro* diagnostics are required to register with the HPRA. In 2021, the HPRA registered 294 new medical device economic operators (for example manufacturers and authorised representatives) on the national database. 586 economic operators were validated on the European medical device database (Eudamed) by the HPRA. A total of 7,299 medical devices were also registered. This represented a significant increase in economic operator registrations when compared to previous years, some of which is attributable to the UK's exit from the European Union. During 2021, the HPRA estimated that around 35% of economic operators that registered in Ireland did so 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 2021:
  - We further developed our lifecycle market surveillance strategy and planning mechanism to allow for more effective management and reporting of these activities.
  - The HPRA actively participates in EU market surveillance activities which includes submission of CEF notifications and review of CEFs circulated by other member states. These are evaluated for relevance to the Irish market with action taken accordingly.
  - The HPRA supported the European network of authorities via the Market Surveillance Working Group to further develop coordination practices for market surveillance. The HPRA also participated in the newly formed joint inspector's group. There were 882 market surveillance cases undertaken in 2021, a decrease compared to 2020 due to a significant decrease in the number of certificate notifications from notified bodies. The number of complex assessment and proactive market surveillance activities increased overall in 2021.
- We continued to focus our vigilance activities during 2021 on the areas of user reporting and dissemination of HPRA medical device safety communications. This included:

- The receipt and assessment of 1,855 medical device vigilance cases, an increase compared to 2020. Of the reports received in 2021, manufacturers accounted for 77% of all reports received in 2020 while 15% came from other competent authorities and 13% from users of medical devices.
- There were 359 field safety corrective actions (FSCA) associated with the national market including 113 product removals conducted in Ireland during 2021.
- We issued 141 national competent authority reports, while also contributing to vigilance enquiry forms and notified body forms circulated within the network.
- We issued eight safety notices in relation to medical device issues and 22 direct to healthcare professional communications.
- Infusion devices, implants and surgical devices accounted for 48% of total vigilance reports. Reports continue to be received relating to *in-vitro* diagnostic devices in the area of clinical biochemistry (8% of reports) and medical devices in the areas of orthopaedic devices (7% of reports) and respiratory devices (5% of reports).

During the year, we also continued development work on signal detection of medical device issues.

Product types (Top 10)	Number of reports
INFU - Infusion devices	426
IMPL - Implants	252
SURG - Surgical devices	212
IVD - Clinical biochemistry	153
ORTH - Orthopaedic devices	131
RESP - Respiratory devices	94
EMCY - Emergency devices	82
VSM - Vital signs monitoring	57
IVD - Microbiology	56
OPTH - Ophthalmic devices	50

## LEGISLATION AND REGULATION

- The Medical Device Regulation (EU) 2017/745 became fully applicable in May 2021. Our work during 2021 continued to help ensure an effective and timely implementation of these EU Device Regulations (EUDR) at national and European level. Work also included preparation for the implementation of Regulation (EU) 2017/746 on *In-vitro* Diagnostic Medical Devices. This included:

- Continued work on the HPRA programme for continued development of appropriate resources, processes and systems to meet our obligations under the new regulations
  - Engagement and information to 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 relevant stakeholders on national policy and national provisions to ensure transposition of the national requirements into Irish law
  - Working with the Commission and EU authorities identifying both key challenges with regulatory system readiness and potential solutions for the notified body bottleneck
  - Contributing to the European Commission's development of the secondary legislation relating to MDR and IVDR
  - 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.
  - Identification and proposed resolution to issues posed by the collapse of the Swiss MRA for medical devices.
- The HPRA continues to play a significant role in the development of EU regulatory systems and mechanisms to promote co-ordination, co-operation and consistency. In 2021, this included:
    - Continued participation in the Executive Group of the CAMD network
    - Participation in MDCG discussions on improving the coordination and consistency of the implementation of the new EU Regulations and prioritising implementation activities in the short, medium and long term
    - Continuing to take a leading role in the work of the clinical investigation and evaluation working group (CIEWG).
  - Throughout the year, our focus remained on identifying and promoting discussions and development of practical measures for application of the system to ensure the system operates effectively in practice. Our core priority is development of European coordination of medical device safety issues. To this end, we participated in a number of competent authority workshops identifying key aspects to give effect to a coordinated approach to EU wide issues.
  - 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 2021, however fees were not increased during 2021 reflecting the impact of the COVID-19 pandemic on the sector.
  - We continued to participate actively in initiatives to promote regulatory convergence and harmonisation of medical devices globally through the International Medical Device Regulators Forum (IMDRF). This involved:

- Participation in the IMDRF Management Committee as part of the European delegation (along with the EU Commission and Germany)
- Continuing to act as the IMDRF secretariat for the National Competent Authority Report (NCAR) Exchange programme
- Participation in the clinical evaluation working group of the IMDRF
- Contributing to discussions and development of the Medical Device Single Review Programme, which relates to product review.

## **STAKEHOLDERS AND PARTNERS**

- Our work to encourage the direct reporting of incidents and medical devices issues by device users and members of the public continued throughout 2021. 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. In 2021, we initiated a specific project in this area to increase engagement and information on medical device issues to members of the public and healthcare professionals.
- The HPRA undertook a number of communication initiatives to raise awareness of the impact and requirements arising from the new EUDR. During 2021 and in Q1 2022, we:
  - Hosted a training and education workshop for patients through collaboration with the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), to raise awareness to the value and importance of patient engagement on the regulatory system and to encourage user reporting.
  - 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
  - Delivered briefings, advice and workshops on the new Regulations to a range of different stakeholders including the HSE, notified bodies and distributors
  - Held a webinar for key industry stakeholders on the practical aspects of IVDR implementation and expectations of the HPRA.
- 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.

- The HPRA contributed to a Horizon 2020 funded project (Co-ordination of Research and Evaluation of Medical Devices) CORE-MD. The HPRA are leading a work package and are part of the project board.

### **Case Workloads**

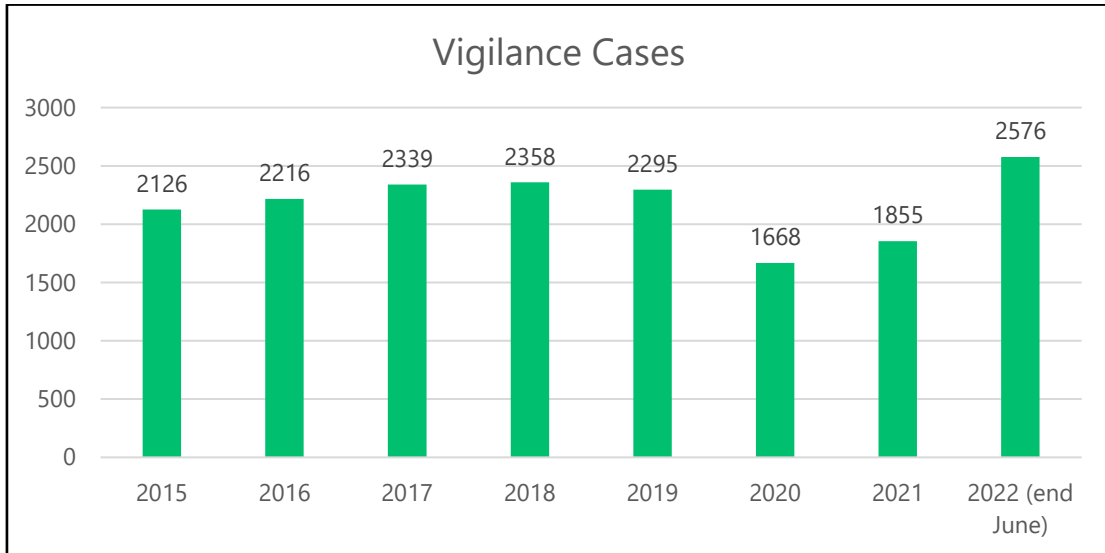
#### Vigilance and Compliance

There has been ongoing work with the HSE in various National Incident Management Teams during 2019- 2021 and case work continues to lead to the identification of significant issues that require increased monitoring and oversight by HPRA.

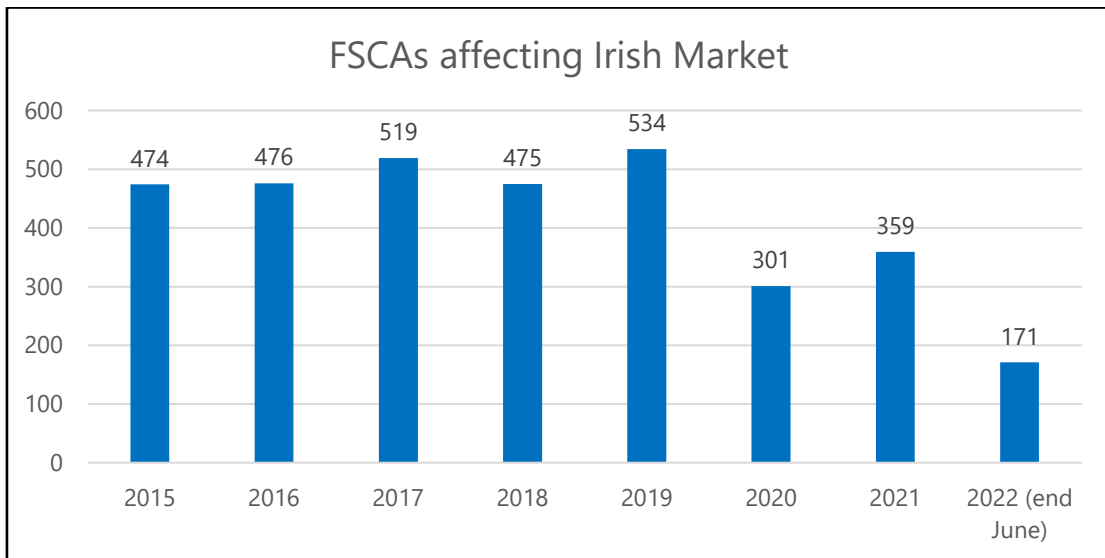
Our vigilance workload continues at consistent levels, with an increase in complexity in relation to vigilance cases, where in 2022 to date (January to end June) 2576 vigilance cases were opened and reviewed. Also in this period, among other communications, two HPRA safety notices and 48 NCAR's were issued nationally, across Europe and internationally. The HPRA continues to be very active at a European level in the area of vigilance.

Work has continued to enhance the vigilance function through the introduction of a signal detection and trend analysis system on medical device vigilance data. The aim of this system is to analyse the data on all vigilance reports received to identify trends, patterns or signals relating to medical devices at an earlier stage and to further enhance the contribution of the vigilance function to the overall regulatory system for medical devices.

See charts showing activity levels below.



**Graph 1: Number of vigilance reports received (2015 to end of June 2022)**

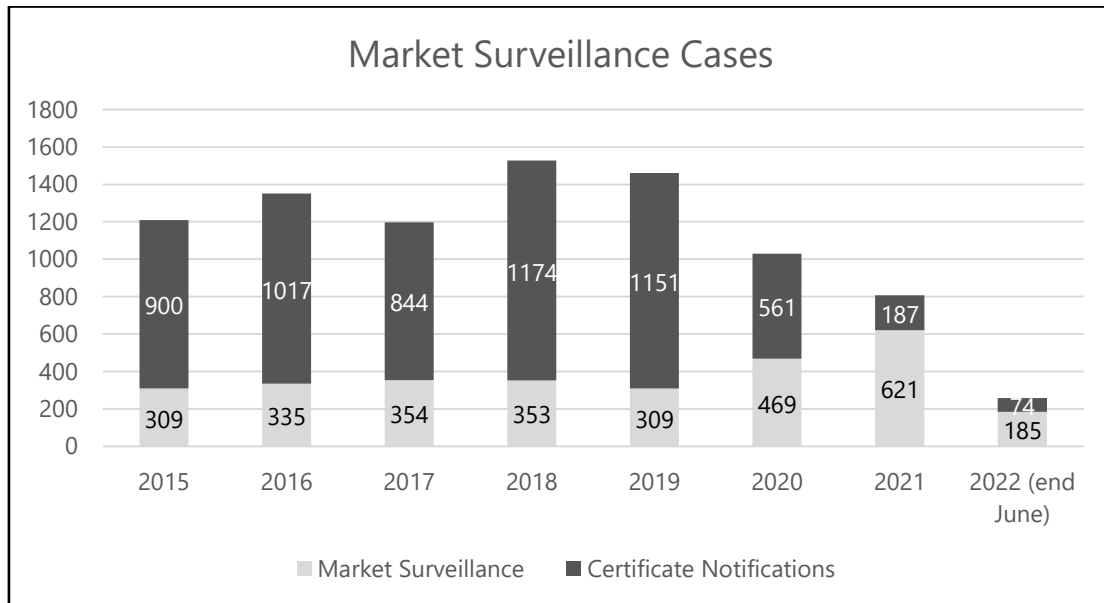


**Graph 2: Number of field actions affecting the Irish market (2015 to end of June 2022)**

## Designation and monitoring of notified bodies

### Surveillance Cases

During 2021, the HPRA continued to develop its lifecycle approach to market surveillance and investigated 469 market surveillance cases and received 561 certificate notifications from notified bodies.



**Graph 3: Number of market surveillance cases (2015 to end of June 2022)**

The HPRA has increased its level of proactive market surveillance activities to check conformance of marketed medical devices with the essential requirements defined in the legislation to help ensure performance and safety and to protect public health. In addition to documentation and labelling checks, this has also included an increased emphasis on sampling and analysis of products from the marketplace and detailed reviews of technical and clinical documentation. These proactive activities include assessment of specific devices, groups of devices or issues identified through the review of scientific data and literature.

The HPRA intends to continue to increase its level of proactive market surveillance activity for medical devices to help ensure that all medical devices placed on the Irish and European market are safe and meet the requirements of the legislation and to help prepare and provide guidance on new legislative requirements arising from the new EU Regulations.

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 2021, inspections were performed at notified bodies, medical device manufacturers and authorised representative facilities, all of which were based on proactive market surveillance projects and notified body surveillance/assessment.

#### Clinical evaluation review

The HPRA has increased its activities further in the assessment of clinical data presented by manufacturers to support the safety and performance of their device. The work was undertaken both reactively in response to a number of specific device issues over time and proactively as part of our ongoing market surveillance activities. This work also formed a significant part of our notified body designation and oversight activities both at national and European levels as part of EU joint assessment activities.

#### Product registrations

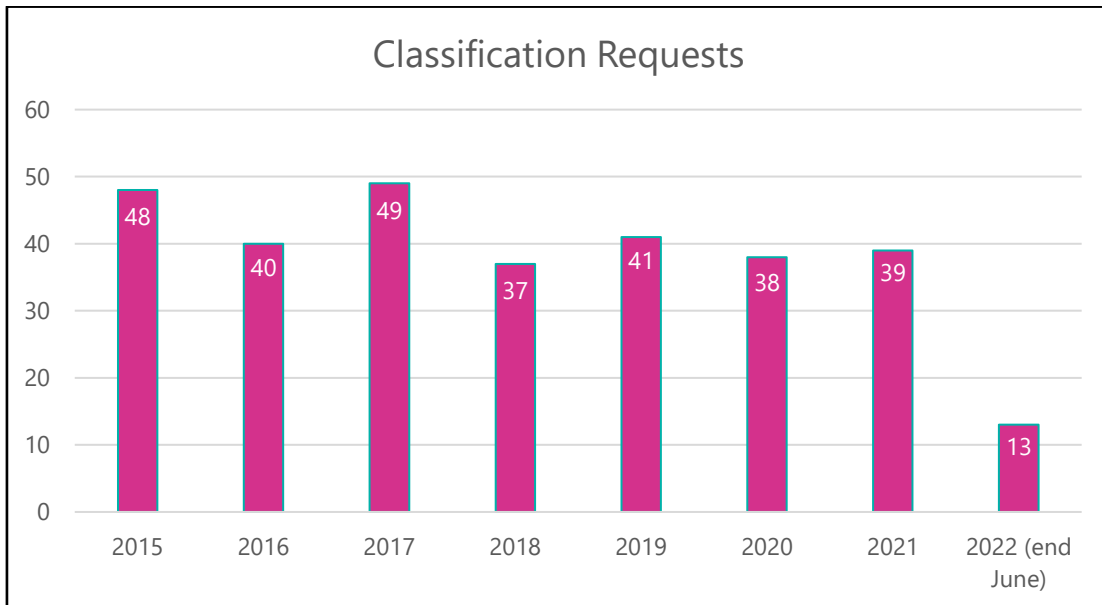
In 2021, a total of 7,299 medical devices were registered. In addition, 294 new organisations as Irish-based manufacturers or authorised representatives for class I, custom-made, *in-vitro* diagnostic medical devices, as manufacturers of system or procedure packs, or as sterilisers of medical devices, have been notified.

This increase in new organisations registering has already impacted on the number of market surveillance activities undertaken with regard to the register and it is expected that it will continue to be an ongoing focus of the market surveillance activity. In the first six months of 2022, 234 medical device economic operators have registered with the HPRA. 179 economic operators have been validated on Eudamed.

#### Classification requests

The HPRA received 39 applications for classification of medical devices or products queried as medical devices in 2021. This included many complex queries relating to borderline or combination products. The queries emanated from other medical device competent authorities in Europe, from medical device manufacturers, distributors and legal firms.

On foot of a number of these enquiries and as a result of HPRA investigations, a number of products were up-classified to a higher device classification.



**Graph 4: Classification requests (2015 to end of June 2022)**

Clinical investigation applications

The HPRA received nine applications for clinical investigations and seven amendments to a clinical investigation of a medical device to be conducted in Ireland in 2021. In addition, 23 compassionate use procedures were completed in this period.

Queries

During 2021, the HPAR medical devices team received 1397 queries relating to medical devices.

Certificates of free sale

During 2021, the HPRA issued 4482 certificates of free sale compared with 2520 in 2021.